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The Brazilian Legal Position Regarding the Supply of Cannabidiol-Based Medicines: A Literature Review

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Abstract:
The screen research aimed to carry out a literature review on the constitutional protection of health and the supply of cannabidiol for medicinal use, in the light of the constitutional principle of Human Dignity, with the specific objectives of verifying in Brazilian jurisprudence the legal position, in the last 10 years, on the use and supply of Cannabidiol for therapeutic purposes, through scientific articles published between the years 2013 to 2023 and discuss the constitutionality of the requirements established by the legal system, for the concession of drugs not included in the list of medicines included in the Single Health System, in the perspective of article 196 of the Federal Constitution. For this purpose, a bibliographic research methodology was used, with data collected through an online database search on Google Scholar, establishing inclusion criteria such as the years of publication from 2013 to 2023, Portuguese language, with methodology recognized scientific, through descriptors: Cannabidiol, Right to Health, Human Dignity and Cannabis Sativa, excluding material that does not meet these criteria. The selected material was submitted to a survey and were analyzed Cannabidiol. Right to health. Human dignity. Cannabis Sativafrom the perspective of the effective Bibliographic Review the investigation of scientific productions. It resulted in 5 articles, which demonstrated that in the legal position Human Dignity has prevailed and remedied the failures of the public power regarding the issue of access to medicines derived from cannabis. Therefore, it is concluded that the objectives were achieved.

Key Word*:Cannabidiol. Right to health. Human dignity. Cannabis Sativa.*

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I. Introduction

The 1988 Federal Constitution enshrines in its article 196 the guarantee of the fundamental right to Health, which reflects the implementation of the principle of Human Dignity, one of the pillars of the Brazilian legal system.

The principle of Human Dignity is, therefore, the pillar that governs regulations and the entire Brazilian legal framework, directing legal provisions to its scope, and it is imperative that legal guidelines elect this principle as the final scope of any legal action.

Although it is stated that Health is a right of all and the State is given the duty to guarantee it, there are circumstances in which the advancement of scientific studies in relation to medicines is hampered by conflicts with other established norms, as occurs in the case of the use of substances derived from prohibited drugs, such as medicines derived from Cannabis sativa, popularly known as marijuana, prohibited by Federal Law 11343/2006.

It is well known that substances derived from Cannabis have been standing out in the scientific context as a promising pharmacological tool for therapeutic use in various pathologies such as cancer, anxiety, immunological diseases, cardiovascular diseases, standing out for having characteristics of tolerability, low toxicity, no effects psychoactive substances, also standing out for having anti-inflammatory, anti-epileptic, and antioxidant activities, as taught by Belém et al. al. (2017).

The conflict is since there is a legal provision in Brazilian legislation prohibiting the use of psychoactive substances such as Cannabis, reflecting the bureaucratization of access to medicines for individuals who need therapeutic treatment, since judicialization culminates in being the possible access route.

In addition to all the bureaucracy inherent in the procedure for accessing drugs derived from Cannabis, the high costs of medications present yet another obstacle.

In a study carried out in the III National Survey on Drug Use by the Brazilian Population promoted by the Oswaldo Cruz Foundation in 2017, Cannabis is the most consumed illicit substance, and criminally classified, with a prevalence of 3.1% of the total urban population, in a rate approximate to the world average of 3.8%, as stated by Rodrigues and Pereira (2022).

The survey also showed that 74.2% of Brazilians considered frequent use, that is, at least once or twice a week, representing a "serious health risk". And even though it is used moderately, that is, once a month, the health risk remains high, around 57.2%.

In this context, there is a negative situation regarding drug consumption that requires coercive measures and policies that can reduce and prevent drug consumption, avoiding the negative consequences of this behavior and others, the need for conduct that promotes access to medications derived from these substances, which promote an improvement in the health and Quality of Life of patients.

Therefore, the general objective of this review was to carry out a literature review on the constitutional protection of health and the supply of cannabidiol for medicinal use, in light of the constitutional principle of Human Dignity, with the specific objectives being to verify the legal position in Brazilian jurisprudence, in the last 10 years, on the use and supply of Cannabidiol for therapeutic purposes, through scientific articles published between the years 2013 and 2023 and discuss the constitutionality of the requirements established by the legal system, for the granting of drugs not included in the list of medicines members of the Unified Health System, in the perspective of article 196 of the Federal Constitution.

The relevance of the study in question becomes imperative both for the field of Public Health and Law and is situated in the need to understand the phenomenon of the judicialization of Health, specifically in the case of cannabidiol (CBD), as it allows to shed light to the problems arising from the criteria for preparing standardized lists of essential medicines of the Unified Health System, SUS, the bureaucratization of this process and the increase in costs for purchasing medicines. It is also important to discuss the way in which judges grant decisions on the forced supply of medicines without these being standardized, in addition to the slowness in incorporating new medicines into the lists of essential medicines from the perspective of the Principle of Human Dignity and of the 1988 Federal Constitution.

Therefore, the importance of the study in question is justified, as it can offer elements to legal practitioners, with the desire to investigate effective legal accountability regarding the right to Health in Brazil in light of the Principle of Human Dignity.

Therefore, the theme question can be listed as follows: "What is the current legal position of the Brazilian Justice regarding the supply of cannabidiol-based medicines, in light of the Principle of Human Dignity and the Constitutional Right to Health?"

II. Theoretic

The search for data on the chosen platform, using the descriptor cannabidiol, in the specific period from 2013 to 2022. The 1988 constitutional text expresses the Right to Life, in art. 5th as a fundamental, natural and, therefore, non-transferable, and inalienable precept just like human dignity, inaugurating a new system in the country's legal system, emerging during a situation that required a paradigm shift, exalting the protagonism of citizens.

The scholar Barroso (2020) argues that life is one of the most important protected rights and a driver of many others, since the life of a human being is what determines the maximum and minimum limits of a State's rights and, therefore, must be thought not only from the perspective of the individual, but before the State as guaranteed to life. In this way, the right to life must be guaranteed by the State in all its spheres and from all possible resources, with principles being established that aim to promote this guarantee, being a responsibility of the federative entities and which, to develop their activities, receive the financing established by law.

Thus, Human Dignity is, alongside life, a fundamental value, which entered the legal system in the form of a principle with constitutional status and must be analyzed from two perspectives: as a moral justification and as a normative foundation for fundamental rights.

Etymologically, the term dignity is related to a characteristic or particularity of someone who is worthy, a moral attribute that incites respect, authority or someone who is great, noble, decent and possesses decorum. That has respect for oneself, thus being related to the excellence and honorability of people and their behavior (Caetano, 2021).

Understanding what Human Dignity is considers that its concept needs to be operational, since the quality of being a human being is very personal and needs to be universally guaranteed. Barroso (2020) understands that, due to its specificity, its concept must have the characteristic of being secular, neutral, and universal, reserving the understanding that it is formed by three fundamental elements: an intrinsic character, autonomy, and community value. The intrinsic character refers to the fact that the human being is singular,

rational, with feelings and capabilities that differ from other beings, possessing an intrinsic value for being human, guaranteeing him rights.

Autonomy, in turn, is related to ethics and the ability to make decisions based on what human beings understand will be best for themselves, based on their religious, moral, cultural, and political beliefs. And third, community value refers to how individuals relate to other individuals, the external world, and everything around them.

Scarpeta and Orsi (2018), when analyzing the Principle of Human Dignity in relation to the Right to Health, allude that it is not a mere right to survival, and the jurist must always emphasize that the Brazilian legal system is based on Human Dignity. Thus, access to Health becomes a fundamental right and must aim to promote a dignified existence, guaranteeing the minimum necessary for a person to preserve their physical and mental integrity.

In this sense, inherent to the right to life is the right to health, which according to the World Health Organization (WHO) is the state of complete physical, mental and social well-being, that is, it is not merely the absence of illness, being recommended in several international documents that govern health protection, such as the Universal Declaration of Human Rights of 1948, in its article XI, determines universal support for human health, through the creation of sanitary and social actions concerning food , housing, medical care, among others.

Tavares (2020) also informs that the 1988 CF enshrines the right to health in several provisions, for example, in the Social Rights section, Title I, Fundamental Rights and Guarantees, expressing in its art. 6th establishes as social rights, among others, health, food, housing, security, social security, motherhood and childhood protection and assistance to the destitute. It is noteworthy that health actions and services are of public relevance, as expressly determined by the Federal Constitution, in its art. 197, corroborating that it is the State's duty to regulate, supervise and control these actions, in accordance with the legislation. The constituent's concern with health services is noted.

The legal apex of the right to health is in the Social Security chapter, which established the bases by which the Public Power will provide health services, through the creation of the Unified Health System (SUS), which is governed by Law No. 8080 of 1990, being the body responsible for creating policies and programs relating to public health, establishing the conditions for the promotion, protection and recovery of health, the organization and operation of services corresponding to health, throughout the national territory. In your art. 4th, Law No. 8080/90 in its caput legally defines the SUS as being responsible for materializing the form of health actions and services, which are provided by federal, state, and municipal public bodies and institutions, of direct, indirect, and foundational, maintained by the Public Power.

Thus, understanding public policies must be aimed at prioritizing actions that promote the exercise of the Right to Health effectively and when it is not possible for citizens to access these actions, Justice must be called so that public assistance can be applied. The Federal Supreme Court (STF) becomes a social support that will guarantee the fundamental right to Health, enabling the judiciary to be an intervener in this guarantee so that there is no conflict in the separation of powers, making the federative entities united in the promoting the provision of free medicines and treatments established by law, even if resources are scarce or non-existent.

In this area, the Judiciary is faced with several actions defending access to medicines derived from illicit substances, with scientifically proven efficacy, but which are prevented from being sold because they are described in legal provisions as prohibited, whether their use or planting. There is, however, a change in procedures, based on favorable decisions and the advancement of studies and confirmation of results, as is being addressed in this study, and it is important to verify the context of Cannabis and its pharmacology, as follows.

Scientifically, marijuana is known as Cannabis, originating in Asia, and belonging to the Cannabaceae family, whose most famous subspecies are Cannabis sativa subspecies sativa, Cannabis sativa subspecies indica and Cannabis sativa subspecies ruderalis, as written by Matos et. al. (2017), it is an herbaceous plant and contains around 400 chemical substances, highlighting its 60 alkaloids, known in the biomedical field as cannabinoids. Caetano (2021) describes that the best-known cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), the first being seen as responsible for the psychoactive effects and the second for its therapeutic use. Furthermore, CBD is found in small concentrations and only in certain plant species that age and become oxidized.

However, the consumption of this herb, due to its psychotropic effects, can reach the entire globe. In some countries there is legislation that authorizes its consumption without legal consequences or illicitness. In others, however, the discussion is far from a consensus as the Brazilian reality shows. As for cultivation, the differences between the types of this plant are related to its growth, amount of active ingredients and morphological characteristics, with the species most present in Brazil being Cannabis sativa staiva, as it adapts better to temperate and tropical climates, however, legislation prohibits the cultivation of this plant, without there being legal authorization, substantiated for medicinal use.

In Medicine, the substance cannabidiol (CBD) is used, which is extracted from Cannabis sativa, with the characteristic that it is not psychotropic, and which was identified in 1960, making it clear that Cannabis has interested scientists in terms of its therapeutic effects for some time, even in the face of its illicit aspects. According to Araújo (20215), the medicinal use of Cannabis was impacted on the scientific community in the 90s with the dissemination of the endocannabinoid system and its Cannabidiol-CB1 and Cannabidiol-CB2 receptors that could be activated or blocked by Cannabinoids (THC, CBD, among others, more than 70 Cannabinoids), producing some biological effects, including relief and control of diseases linked to the nervous system and immune system. The positive effects of using these substances aroused the interest of the scientific community focused on studying alternative treatments for serious neurological diseases that, until then, had no cure.

However, it is important to note that the discussion about the use of marijuana for medicinal purposes was already taking place well before this date, as there are writings by the Chinese emperor Shen Neng (2737 BC), who prescribed Cannabis to treat illnesses such as gout, rheumatism, malaria, and memory lapses. This procedure allowed the use of Cannabis to spread throughout Asia, the Middle East, and the eastern coast of Africa. Meanwhile, in Hindu sects it was used for religious purposes and to reduce anxiety symptoms, with its users observing the tranquilizing and relaxing effects caused after its use.

The use of Cannabis for medicinal purposes finds several records over time, well before what is currently known, as in Antiquity it is noted that doctors prescribed the plant to relieve pain, including childbirth, with the warning that its use excessive use generated side effects such as impotence, blindness and hallucinations, being highlighted in the work of the doctor PedâncioDioscórides, "De MatériaMédica" at the beginning of the 1st century. Over the years, several people used this substance for therapeutic purposes, without, however, have scientific proof. Which happened a long time later. Taking a leap to the present day, in Brazil, in 1988, the Ministry of Health published Ordinance 344, which approved the Technical Regulation on substances and medicines subject to special control, including marijuana and its derivatives, expressing in the items of narcotic and/or psychotropic substances substances prohibited for use in Brazil. This ordinance served as the basis for the following regulations, as occurred in 2015 when ANVISA approved RDC 17/2015, which defined parameters for the importation, exceptionally, of CBD-based products) for therapeutic purposes.

It is important to note that regarding ANVISA, Law 9,782/99, in article 8, § 1, item I, establishes that it must, respecting the legislation in force, regulate, control, and supervise products and services that involve a risk to public health, and must consider medicines for human use, their active substances and other inputs, processes and technology. Therefore, ANVISA is responsible for issues related to CBD medicines and their supply to patients, and must monitor this access, controlling and inspecting products and services, considering the relevant legislation. Therefore, medications with Cannabis derivatives must be subject to the responsibilities of ANVISA, being competent to regulate, control and supervise these medications, considering what is set out in the legal system.

In the Brazilian situation, in 2016, ANVISA authorized the prescription of products with Tetrahydrocannabinol (THC) and it was in this year that, in Rio de Janeiro, some families filed requests for the authorization of the cultivation of marijuana for medicinal purposes, being met by the court decision. and allowing precedents for other decisions that facilitated the use of marijuana-derived medications.

Since then, there has been the publication of several ANVISA resolutions that facilitated both the importation, prescription and registration of products derived from marijuana, with a relevant numerical leap, with 896 requests registered in 2015 and 19,074 in 2020. records and in the first 10 months of 2021, 22,028 requests were made, as taught by Rodrigo and Pereira (2022). These data could be even greater if they were analyzed by regions or legal bodies, but they already offer a parameter of the legal reality in terms of judicialization for requests for access to medicines derived from Cannabis. This does not mean, however, that other institutions do not also strive to promote the realization of fundamental rights, such as ANVISA.

In line with the reality of other countries, in 2019, ANVISA accepted its first proposal, in Resolution No. 327/2019, which registered the first national Cannabis-based medicine authorized by Anvisa at the beginning of 2020, an advance celebrated by patients and by their family members. However, discussions about planting have not yet reached consensus in Brazil, and the planting of marijuana is still prohibited, although some precedents are already registered in national jurisprudence. This prohibition ends with the fact that the use of marijuana is within a political legal discussion of legalization, which addresses the social and health issues associated with its consumption.

Resolution No. 327/2019 only came into force on March 10, 2020, establishing in its article 5 the possibility of prescribing products with CBD, provided that other therapeutic options have been exhausted and that all therapeutic options have been tried, establishing Furthermore, the composition has 0.2% THC content, as studies indicate that this is what is necessary to achieve the benefits of the medication. In this sense, ANVISA simplified the procedure for granting Health Authorization for the manufacture and import of Cannabis

products, based on a specific request filed by the interested company, prior to their manufacture, import or commercialization.

It is important to highlight article 19 of this resolution establishes the need for the company requesting health authorization for the Cannabis product to inform the content of all technical documentation on the quality of the final product or what is imported, also informing the list of manufactured or imported batches, what the exclusivity, manufacturing date, batch number and size, technical rationale for all changes occurring after authorized manipulation. Other information such as the latest version of documents containing tests, specification limits and analytical methods of product quality control, as approved by the company and stability study reports are also mandatory for the interested company to present with its request, as well as the technical and scientific rationale that justifies the formulation of the Cannabis product and the route of administration and the Periodic Benefit-Risk Assessment Report for the Cannabis product, according to Gurgela (2019)

Other legal requirements are required of the company that wishes to explore the field of medicinal use of marijuana and must have a Company Operating Authorization (AFE) issued by Anvisa with the activity of manufacturing or importing medicine. Also included in the list is the Special Authorization (AE) and the Certificate of Good Manufacturing Practices (CBPF) for Medicines for the company that manufactures the product. Good medicine distribution and storage practices; technical and scientific rationale that justifies the formulation of the Cannabis Product and the route of administration, technical documentation of product quality, operational conditions to carry out quality control analyzes in Brazilian territory, capacity to receive and treat notifications of adverse effects and Technical complaints about the product are other requirements for drug regulation.

It is necessary to disseminate knowledge of the concentration of the main cannabinoids present in the formulation, including, minimally, CBD and THC, and be able to justify the development of the Cannabis product, be it herbal medicine or phytopharmaceutical. Single paragraph. For the technical and scientific rationale, the company must consider the formulation, dose, duration of use and target population, as expressed in art. 21 of ANVISA Resolution No. 327/2019. It is important to consider that ANVISA also promoted administrative access to drugs derived from CBD. According to Caetano (2021), ANVISA, exceptionally and for personal use, granted access to CBD. The procedure included a written request addressed to the institution's Chief Executive Officer's Office. Such request should be accompanied by the original medical prescription and report proving the illness.

This access, however, was through import and must also be requested using a specific form, with the signatures of the doctor, patient, or their legal representative, essential for the initiation of an administrative process at ANVISA, on all documents. The need to use the medication began to be analyzed in the specific case, verifying the circumstances so that authorization could be granted to those interested.

III. Methodology

The research on screen is classified as bibliographic and qualitative and, as it is developed exclusively by consulting bibliographies, it is also exploratory, highlighting the use of safe sources, as it will use research carried out with scientific rigor and published in articles and journals with references in qualis. The study was carried out through a literature review, of a descriptive nature, which is characterized by the process of describing the state of the art of a specific subject, from a theoretical or contextual perspective, being a review of interpretation and personal critical analysis of the researcher, being able to promote the acquisition and updating of knowledge on a given topic, therefore consisting of the construction of a broad analysis of the literature, as taught by Gustin and Dias (2002).

To this end, six steps were followed, the first step (I) deals with the definition of the research question that has already been prepared previously and that will guide the search for the material to be analyzed. The second stage (II) was the search for the material on the platforms mentioned in the articles published according to the established criteria, using the descriptors, or key words, which will act as a filter for the articles. The next step (III) was to select the articles found in the search, including those that meet the selection criteria, and excluding those that did not correspond to the inclusion procedures. The fourth stage (IV) deals with extracting the data from reading the summaries and verifying the methodology used to carry out the data synthesis (V), that is, from the collected data the contents will be systematized in a table with author data, year of publication, journal and year of publication, objectives, types of research and conclusion. Finally, the results will be written and published (VI), presented with a summary of the considerations made.

Describing it in more detail, the data were collected through a search in an online database on Google Scholar (www.scholar.google.com) as it offers extensive research and makes it possible to establish inclusion criteria such as the years of publication of 2013 to 2023, Portuguese language, with recognized scientific methodology, through descriptors: Cannabidiol, Right to Health, Human Dignity and Cannabis Sativa, excluding material that does not meet these criteria. The selected material will be subjected to a survey to be analyzed from the perspective of Bibliographic Review, effective in investigating scientific productions.

IV. Result

The search for data on the chosen platform, using the descriptor cannabidiol, in the specific period from 2013 to 2023, in Portuguese, offered 403 results, excluding materials in the form of annals, course completion work, monograph, thesis and dissertation, a total of 5 (Oliveira, 2017; Silva &Lino, 2022; Silva &Teodoro, 2022; Gurgel, 2019) articles were selected and used in this review.

The included articles corresponded to the criteria and were therefore synthetically analyzed, supporting the scope of achieving the previously established goals. In this context, Oliveira (2017) shows in his article how the process of regulating cannabidiol in Brazil enabled the development of lay expertise with influence on institutions and public policies, offering guidance for those who venture into the topic proposed by this study. Thus, the issue of the Brazilian legal position regarding the use of substances derived from marijuana reaches a much larger scenario than the scientific or doctrinal community, thus prioritizing the Human Dignity of subjects affected by an illness that can be treated or even cured with the use of medicines derived from cannabidiol.

Silva and Teodoro (2022) showed, through their research, that the broad position of Brazilian jurisprudence is that the right to health has immediate applicability, being a provisional right that can be demanded by the citizen before the State, demonstrating the obligation to provide medicines which were sued in court. This research makes it clear that Human Dignity must always be considered when activating the Judiciary on issues relating to the realization of the right to services and medicines that the Brazilian Democratic State proposes to provide for subjects.

Therefore, the State must immediately devise possible means to ensure access to cannabidiol-based medicines for those who need them, going beyond any criminal classification. However, the authors emphasize that the issue of cannabis still generates great debate, however, the importance of this substance for people's health remains evident. From the same perspective Queiroz et. al (2019) concluded that, even with the entire evolutionary process and changes, there is a need for concrete actions by state power to realize the right to health. That said, due to the existing social demand, the immediate need of those who need the drug to extend their life expectancy and that this time be fully reached of human capacity, the state must create mechanisms to achieve these objectives.

Gurgel et. al (2019) reinforces this line of reasoning, reinforcing that in terms of implementing drug treatment with CBD, the action of the Judiciary is of great relevance and secondary, as it occurs after the actions of the Executive Branch, to correct the omission of this in achieving citizens' right to health. This makes it necessary for the Brazilian legal position to continue following the line of prevalence of life because of impediments to access to products derived from substances classified as illicit, since the Principle of Human Dignity underlies this position when the Public Power fails to provide your services.

Silva &Lino (2022) found that the legal uncertainty regarding the use of CBD-based medications was superficially mitigated by the incorporation of these drugs into the ANVISA list, seeking to remedy the breach and attack on the Human Dignity of those who need to resort to medications to treat their illnesses, highlighting their effectiveness.

In this context, it is clear that the authors studied converge on the understanding that Human Dignity prevails in the legal position when it comes to guaranteeing constitutional rights related to Health, and it is important to highlight that there is a positive view regarding legal action in the face of the failures that the Public Power presents or even places itself as legally prevented from acting, as occurs in the case of access to substances derived from cannabis. Although the research on screen has presented how the judiciary has behaved on the growing issue of the use of cannabis for therapeutic purposes, from the perspective of Human Dignity, it is clear that the topic is recent in the basis used, and efforts should be made to expand the possible study paths so that medicines are ensured more efficiently, in other words, that the judiciary does not need to be called when it is found that there is a need to use medicines derived from cannabis. There is a path to be followed to achieve the best results in realizing the right to health.

V. Conclusion

In view of the above, it can be understood that the scope of the study was achieved, since it was possible to carry out a literature review on the constitutional protection of health and the supply of cannabidiol for medicinal use, considering the constitutional principle of Human Dignity, finding foundations in studies and research that corroborated this theme.

Furthermore, it was possible to verify that in Brazilian jurisprudence the legal position, in the last 10 years, on the use and supply of Cannabidiol for therapeutic purposes is that constitutional principles prevail to the detriment of legalistic issues. Another point addressed was the constitutionality of the requirements established by the legal system, for the granting of drugs not included in the list of drugs included in the Unified Health System, from the perspective of article 196 of the Federal Constitution, which, although briefly, was addressed to corroborate with the objectives set.

From this perspective, understanding how the judicialization of Health is processed in the case of cannabidiol (CBD) allowed to shed light on the problems arising from the criteria for preparing standardized lists of essential medicines, demonstrating that there is a need to reduce bureaucracy in this process, as it tends to increase costs for ensure access to medication on screen. It is important to highlight that it was possible to realize that judicialization proved to be the best way to correct the failure of the public authorities in guaranteeing the resources necessary for treatment, but that this path could be avoided if the State updated itself regarding its legislation, following the changes arising from increasingly efficient scientific studies.

In general, the study of this review may contribute to new perspectives and new productions and may also promote developments to always seek to support beneficial understandings.

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