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The right to treatment for children with refractory epileptic syndromes: challenges and opportunities in access to cannabidiol

The right to treatment of children with refractory epileptic syndromes: challenges and opportunities in accessing Cannabidiol

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SUMMARY
The use of cannabidiol in children with refractory epileptic syndromes is a topic that has generated heated debates in the medical and legal communities. Although cannabidiol is a substance found in the marijuana plant, its use for medicinal purposes has been studied and approved in several countries, including Brazil. However, despite its proven effectiveness in treating some diseases, access to this treatment is still a challenge for many families, who face bureaucratic and legal barriers to obtaining the medication. Given this, the question arises as to the impact of bureaucratic and legal barriers on the use of cannabidiol in children with refractory epileptic syndromes, and how to guarantee the right to access this treatment in a safe and effective way. The primary hypothesis is that the use of cannabidiol in children with refractory epileptic syndromes is effective and can provide a significant improvement in the quality of life of these patients. The general objective of this article is to analyze the challenges and opportunities in accessing cannabidiol treatment in children with refractory epileptic syndromes. It was noticed that bureaucratic and legal barriers in the use of cannabidiol in children with refractory epileptic syndromes have a significant impact, making access to this treatment difficult. This can result in delays in starting treatment, deprivation of the therapeutic benefits of cannabidiol, and increased suffering for these children and their families. Furthermore, it is essential to promote awareness and training of healthcare professionals on the benefits and risks of cannabidiol, so that they can make informed and informed decisions when prescribing this treatment.

Key words:cannabidiol; refractory epileptic syndromes; access to treatment.

ABSTRACT
The use of cannabidiol in children with refractory epileptic syndromes is a subject that has generated heated debates in the medical and legal community. Although cannabidiol is a substance found in the marijuana plant, its use for medicinal purposes has been studied and approved in several countries, including Brazil. However, despite its proven effectiveness in treating some diseases, access to this treatment is still a challenge for many families, who face bureaucratic and legal barriers to obtaining medication. Given this, the question is what is the impact of bureaucratic and legal barriers on the use of cannabidiol in children with refractory epileptic syndromes, and how to guarantee the right of access to this treatment in a safe and effective way? The primary hypothesis is that the use of cannabidiol in children with refractory epileptic syndromes is effective and can provide a significant improvement in the quality of life of these patients. The general objective of this article is to analyze the challenges and opportunities in the right of access to cannabidiol treatment in children with refractory epileptic syndromes. It was noticed that bureaucratic and legal barriers in the use of cannabidiol in children with refractory epileptic syndromes have a significant impact, making access to this treatment difficult. This can result in delays in the initiation of treatment, deprivation of the therapeutic benefits of cannabidiol, and increased distress for these children and their families. In addition, it is essential to promote the awareness and training of health professionals about the benefits and risks of cannabidiol, so that they can make informed and informed decisions when prescribing this treatment.
Keywords: Cannabidiol; Refractory epileptic syndromes; Access to treatment.

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1. INTRODUCTION

The use of cannabidiol in children with refractory epileptic syndromes is a topic that has generated heated debates in the medical and legal communities. Although cannabidiol is a substance found in the marijuana plant, its use for medicinal purposes has been studied and approved in several countries, including Brazil. However, despite its proven effectiveness in treating some diseases, access to this treatment is still a challenge for many families, who face bureaucratic and legal barriers to obtaining the medication.

The theme addressed in this article is the use of cannabidiol in children with refractory epileptic syndromes, focusing on the challenges and opportunities in the right to access treatment. From a scientific and legal perspective, the evidence proving the effectiveness of cannabidiol in the treatment of refractory epileptic syndromes will be analyzed, as well as the difficulties that families face in accessing this medication. The central theme of this article is the use of cannabidiol in children with refractory epileptic syndromes and the challenges and opportunities in the right to access treatment.

The use of cannabidiol in children with refractory epileptic syndromes has generated heated debates in the medical and legal community, especially in relation to its use in children. Although cannabidiol is a substance proven to be effective in treating some diseases, its use is still surrounded by prejudices and taboos, which has made it difficult for families to access this treatment. Furthermore, the use of cannabidiol in children raises ethical and legal questions, which makes the issue even more complex.

The problem surrounding the use of cannabidiol in children with refractory epileptic syndromes is the difficulty that families face in accessing this medication, due to bureaucratic and legal barriers. Although there is scientific evidence that proves the effectiveness of cannabidiol in the treatment of refractory epileptic syndromes, many families are prevented from using this medication due to the lack of regulation and resistance from some health professionals and the judicial system. In view of this, the research question is: what is the impact of bureaucratic and legal barriers on the use of cannabidiol in children with refractory epileptic syndromes, and how to guarantee the right to access this treatment in a safe and effective way?

The primary hypothesis is that the use of cannabidiol in children with refractory epileptic syndromes is effective and can provide a significant improvement in the quality of life of these patients. Another hypothesis is that the lack of regulation and resistance from some health professionals and the judicial system are the main obstacles to access to treatment.

Some possible secondary premises are: cannabidiol has anti-inflammatory, neuroprotective and anticonvulsant properties that make it an effective option for the treatment of refractory epileptic syndromes; the lack of regulation of the use of cannabidiol can put the safety of patients, especially children, at risk; The resistance of some health professionals and the judicial system towards the use of cannabidiol may be influenced by prejudice and misinformation.

The general objective of this article is to analyze the challenges and opportunities in the right to access cannabidiol treatment in children with refractory epileptic syndromes, from a scientific and legal perspective. Specifically, Investigate existing public policies in different countries to guarantee the right of access to cannabidiol treatment in children with refractory epileptic syndromes and their respective effectiveness; describe national and international legislation and regulations that deal with the use of cannabidiol in children with refractory epileptic syndromes and verify whether they are adequate to guarantee the right of access to treatment; evaluate the availability and access to cannabidiol treatment in

different countries, taking into account factors such as costs, availability of suppliers, access to medicines, among others; and investigate how the right to access cannabidiol treatment is perceived by health professionals, patients and their families in different contexts and cultures.

To carry out the bibliographic research, the PubMed, Scopus and Lilacs databases were used. These databases were chosen because they present a wide coverage of scientific literature in the medical field, in addition to allowing the search for keywords related to the topic in question. The methodological procedures involved the selection of relevant keywords for the research, such as “cannabidiol”, “refractory epilepsy” and “children”. Furthermore, inclusion and exclusion criteria for studies to be selected for analysis were established, as well as criteria for evaluating the methodological quality of the studies.

The inclusion criteria adopted for the present study consider the selection of scientific articles, technical reports, theses, dissertations and other documents that deal with the use of cannabidiol in children with refractory epileptic syndromes and the right to access treatment. Furthermore, studies that present evidence on the efficacy and safety of cannabidiol treatment in these conditions will be included.

On the other hand, the exclusion criteria aim to eliminate documents that are not relevant to the analysis of the topic in question, such as studies that address the use of other substances or therapies in children with refractory epileptic syndromes or that do not present information relevant to the analysis of the right to access treatment with cannabidiol.

The technical justification for choosing the exploratory bibliographical research methodology with a qualitative approach and deductive method lies in the need to understand the complexity of the topic in question, as well as to explore the relationship between the use of cannabidiol and the right to access treatment. in children with refractory epileptic syndromes. Furthermore, this approach allows us to identify the main barriers and challenges faced in this context, contributing to the defense of these children's right to health.

Finally, the social relevance of the study is present because it addresses a public health issue that affects children with refractory epileptic syndromes and their families around the world. Understanding the obstacles faced in accessing cannabidiol treatment and defending these children's right to health are fundamental to ensuring that these individuals receive adequate treatment, improving their quality of life and reducing the suffering of their families.

2 REGULATION OF THE MEDICINAL USE OF CANNABIDIOL FOR THE TREATMENT OF REFRACTORY EPILEPTIC SYNDROMES IN CHILDREN

Cannabis is a plant that has been used for thousands of years by different cultures around the world, mainly for its psychoactive properties. The plant contains more than 100 chemical compounds known as cannabinoids, the main one being tetrahydrocannabinol (THC).

However, another important compound present in the plant is cannabidiol (CBD), which does not have psychoactive effects and has gained prominence in recent decades due to its therapeutic potential. CBD is one of the main components of cannabis used in medical treatments, especially to alleviate symptoms of various diseases, such as epilepsy, anxiety, schizophrenia and inflammatory diseases.

Cannabidiol has proven to be a promising option in the treatment of several diseases, especially especially those who do not respond well to conventional treatments. Several studies have been carried out to investigate its therapeutic effects, and the results have been quite positive.

Some studies have shown that CBD can help reduce symptoms of anxiety, chronic pain, epi-refractory lepsy, multiple sclerosis, among other diseases. Furthermore, CBD is relatively safe and does not

presents the psychoactive effects associated with THC. However, despite advances in CBD research, there are still many uncertainties regarding its efficacy and safety, and many countries still face regulatory challenges in allowing access to medicinal cannabis.

2.1 NATIONAL LEGAL STANDARDS ON THE MEDICINAL USE OF CANNABIDIOL

Regulating the medicinal use of cannabidiol for treatments is of great importance for patients suffering from various diseases. According to Oliveira et al. (2019), cannabis has been used for medical treatments for thousands of years, with cannabidiol being one of the most studied compounds today. Although its effectiveness in various health conditions has already been proven, its regulation is still uncertain in Brazil.

According to Alchieri et al. (2020), regulating its medicinal use is important to ensure the safety and quality of treatments. This is because, without adequate regulation, patients may be subject to risks associated with inappropriate use and lack of quality control of products. Furthermore, the regulation allows doctors to be more confident in prescribing cannabidiol, which is especially important for children with refractory epileptic syndromes.

Regulating medicinal use can also bring economic benefits to the country. According to Souza et al. (2018), the cannabis industry has grown significantly in several countries, with the potential to generate significant revenue. However, without adequate regulation, the country could be missing out on important economic opportunities.

Furthermore, regulation can help reduce the stigma associated with cannabis use. According to Silva and Andrade (2019), the use of cannabis is often seen in a prejudiced and stigmatized way, which can lead to a lack of access to effective treatments for various health conditions. Regulating the medicinal use of cannabidiol can help change this perception and promote a more objective and scientific approach to the subject.

Silva and Andrade (2019) point out that its use has become increasingly relevant in several countries, especially for treatments of neurological conditions, such as refractory epilepsy. In view of this, many countries have established specific regulations for medicinal use, which vary according to the legislation of each country.

Furthermore, there are international legal standards that address the medicinal use of the substance. In view of this, we present Table 01 below, which presents some of the international legal standards on the medicinal use of Cannabidiol and the regulation of the medicinal use of the substance in other countries.

Table 01 - International legal standards on the medicinal use of Cannabidiol and regulation of the medicinal use of the substance in other countries

COUNTRY	LAW	OBJECTIVE OF THE LAW
United States	Farm Bill 2018	Legalization of hemp cultivation, including Cannabidiol extract
European Union	Regulation (EU) no. 2015/2283	Regulation of placing new products on the market foods containing CBD
Canada	Cannabis Act Canada)	Regulation of the production, distribution and sale of cannabis, including CBD
Australia	Poisons Standard 2018 (Australian Health Agency)	Regulation of the medicinal use of CBD, which became be considered a prescription controlled substance

Uruguay	Law No. 19,172 (Law of marijuana regulation)	Regulation of the production, distribution and use of cannabis, including CBD

Source: Prepared by the Author (2023) adapted from Silva and Andrade (2019).

It is observed that some countries have specific regulations for the medicinal use of cannabidiol, such as Canada and Australia, which have laws that regulate the production and sale of the substance for medicinal purposes. Other countries, such as the United States and Uruguay, have laws that regulate the production, distribution and use of cannabis as a whole. Furthermore, the European Union has established specific regulations for the placing on the market of new foods containing CBD.

In general, Table 01 presents some of the international legal standards that deal with the medicinal use of cannabidiol and the regulation of the substance in other countries. It is important to highlight that regulation can vary greatly from country to country, and it is essential that specific laws and regulations be observed in each location.

According to Alchieri et al. (2020), regulating the medicinal use of cannabis is a challenge for many countries, as it involves ethical, political and legal issues. In Brazil, the regulation of the medicinal use of cannabis is a controversial topic, which has generated many debates and discussions, involving different sectors of society.

According to Araújo et al. (2019), access to medicinal cannabis in Brazil has been limited due to a lack of adequate regulation and a lack of knowledge about the medicinal properties of the plant. However, the legalization of the medicinal use of cannabis has been supported by several professional associations, including the Federal Council of Medicine (CFM) and the Brazilian Bar Association (OAB).

Oliveira et al. (2019) highlight that cannabidiol is one of the most studied compounds in cannabis and has demonstrated effectiveness in treating several health conditions, including epilepsy, chronic pain, anxiety and sleep disorders. However, the lack of adequate regulation has prevented many patients from accessing treatment with this substance.

Table 02 presents a list of 12 regulations related to the medicinal use of this substance in Brazil, including laws and ongoing projects. The regulation of the medicinal use of cannabis has been an increasingly discussed topic in Brazil, especially in recent years. This is due, in part, to the growing number of studies proving the effectiveness of cannabis in treating various health conditions.

Table 02: Regulation of the medicinal use of cannabidiol in Brazil

LAW/PROJECT	OBJECTIVE OF THE LAW/PROJECT
Law No. 11,343/2006	Defines trafficking crimes and measures to prevent and repress illicit drug trafficking
Resolution No. 327/2019 - ANVISA	Regulates the manufacturing, import, commercialization, prescription, dispensing, monitoring and inspection of Cannabis-derived products
Ordinance No. 344/1998 - Ministry of Health	Defines the list of substances under special control
Ordinance No. 1,096/2018 - Ministry of Health	Approves the Clinical Protocol and Therapeutic Guidelines for the medicinal use of Cannabis
Project in Law no. 399/2015	Provides for the planting, cultivation, harvesting and exploitation of Cannabis for medicinal and scientific purposes
Project in Law no. 399/2021	Regulates cultivation, production, manufacturing, storage, the commercialization, transportation, distribution, use, import, export, research and innovation of Cannabis-based products
Opinion No. 04/2019 - Federal Council of Medicine	Recommends that doctors have the freedom to prescribe Cannabis-based products for treating diseases

Opinion No. 3/2020 - Federal Pharmacy Council	Establishes standards for prescribing, dispensing and monitoring the use of Cannabis-based products for medicinal purposes
Technical Note nº 03/2015 - Justice ministry	Clarifies the Ministry of Justice's understanding of the medicinal use of Cannabis
Technical Note nº 07/2017 - Federal Attorney's Office for Citizens' Rights	Provides guidance to public bodies on the right of patients to use Cannabis-based products for medicinal purposes
Technical Note nº 07/2018 - Federal Public Ministry	Recommends measures to ensure patient access to treatment with cannabis-based products
Resolution No. 2,113/2014 - Federal Council of Medicine	Provides for off-label prescription of medications

Source: Prepared by the Author (2023).

In this context, Table 02 presents an overview of the main laws and projects related to regulation. lamentation of the medicinal use of cannabidiol in Brazil, contributing to a broader understanding of the topic and to the discussion on the need for adequate regulation for access to medicinal cannabis.

The comparative analysis of regulations on the medicinal use of has been the subject of study in several countries, including Brazil. According to Alchieri et al. (2020), the regulation of the medicinal use of Cannabis is a complex topic that involves not only medical aspects, but also legal and social aspects.

According to Araújo et al. (2019), the regulation of the medicinal use of Cannabis in Brazil is relatively recent and is still in the consolidation phase. Law No. 11,343/2006, known as the Drug Law, was the first to regulate the medicinal use of Cannabis in the country. Subsequently, several standards and resolutions were issued, such as Resolution No. 327/2019 National Health Surveillance Agency (ANVISA), which provides for procedures for the import of Cannabis-based products for medicinal purposes.

However, the regulation of the medicinal use of Cannabidiol in Brazil still faces challenges. According to Oliveira et al. (2019), the lack of standardization of Cannabis-based products and the lack of well-controlled clinical studies are some of the obstacles to consolidating regulation in the country. Furthermore, the interpretation of legislation by health authorities has generated controversy and uncertainty for patients and doctors who wish to use it as treatment.

In relation to other countries, the regulation of this substance presents significant differences. According to Koppel et al. (2019), in countries like Israel and Canada, for example, regulation is more advanced and allows the population access to Cannabis-based products more widely. In countries such as the United States and the United Kingdom, regulations are more restrictive and limit access to Cannabis-based products only in specific cases.

Therefore, the comparative analysis of regulations on the medicinal use of Cannabidiol highlights the complexity of the topic and the need for more in-depth studies on the medical, legal and social aspects involved. It is essential that health and medical authorities seek to improve regulation in order to guarantee the population's safe and effective access to this type of treatment.

2.2 CRITERIA ESTABLISHED BY COMPETENT AUTHORITIES FOR GRANTING ACCESS TO TREATMENT WITH CANNABIDIOL

The medicinal use of Cannabis has been the subject of discussion and regulation in several countries, including Brazil. ANVISA Resolution No. 327 of 2019, which establishes the procedures for granting authorization for the manufacture and registration of medicines derived from Cannabis spp. and its derivatives.

According to Alchieri et al. (2020), this resolution establishes strict criteria for granting access to treatment, including the need for a medical prescription, the conduct of clinical studies and the assessment of the safety and efficacy of the product.

The regulation of the medicinal use of Cannabis in Brazil is part of a broader context of controlling substances and medicines subject to special control. Ordinance No. 344/1998, from the Ministry of Health, establishes standards for the control and inspection of these substances and medicines in the country. This ordinance establishes that the prescription and dispensation of substances subject to special control must be made using a specific prescription form and that the patient must be registered on a specific control form (BRASIL, 1998).

The policy of comprehensive health care for people deprived of liberty also includes the regulation of the medicinal use of this substance in Brazil. Ordinance No. 1,096/2018, from the Ministry of Health, provides for the policy of comprehensive health care for people deprived of liberty within the scope of the Unified Health System (SUS). This ordinance establishes that health services must guarantee access to the medicines necessary to treat patients, including cannabis-based medicines (BRASIL, 2018).

The medicinal use of this substance is the subject of discussion in bills currently being processed in the National Congress. Bill No. 399/2015, for example, provides for the production, industrialization, research, cultivation, transportation, commercialization, use, import, export, control and inspection of Cannabis spp. and industrial hemp. This bill has been the subject of debate between those who support the regulation of the medicinal use of Cannabis and those who are against this regulation (BRASIL, 2015).

The Federal Council of Medicine and the Federal Council of Pharmacy also issued opinions on the medicinal use of Cannabis in Brazil. Opinion No. 04/2019 of the Federal Council of Medicine provides for the use of Cannabis for medicinal and scientific purposes. This opinion establishes that prescription and use for medicinal purposes must be based on scientific evidence and specific clinical protocols (BRASIL, 2019).

Access to medicinal cannabis in Brazil is a matter of the right to health, care and emancipation, according to Araújo et al. (2019). However, according to Alchieri et al. (2020), regulation is necessary to guarantee the quality and safety of medicines, in addition to ensuring control over the quantity of substance used.

The amount of substance used in treatment with this substance is restricted by Ordinance No. 344/1998 of the Ministry of Health. This ordinance establishes limits for the prescription and dispensing of controlled medications, including those derived from Cannabis spp. (BRAZIL, 1998). Oliveira et al. (2019) highlight that this measure is important to prevent the misuse of the substance and guarantee its therapeutic effectiveness.

The Technical Regulation on substances and medicines subject to special control, approved by Ordinance No. 344/1998 of the Ministry of Health, is another device that establishes limitations on access to treatment with medicinal Cannabis. Araújo et al. (2019) argue that the aforementioned regulation prevents patients in serious condition or with chronic illnesses from accessing adequate treatment.

In order to improve the criteria established by the competent authorities, Bill No. 399/2015 was proposed to regulate the production, cultivation, commercialization and use of Cannabis spp. and industrial hemp. Oliveira et al. (2019) emphasize that the approval of this project could contribute to expanding access to treatment in the country.

In May 2018, Ordinance No. 1,096/2018 of the Ministry of Health changed the National Policy for Comprehensive Health Care for People Deprived of Liberty in the SUS. According to opinion No. 04/2019 of the Federal Council of Medicine (CFM), the aforementioned ordinance included the use of medicinal Cannabis in the list of medicines that must be made available within the scope of the SUS.

However, Koppel et al. (2019) point out that there is still a lack of clarity and guidance for health professionals on how to prescribe and monitor the use of this substance. Opinion No. 3/2020 of the Federal Pharmacy Council (CFF) provides guidelines for the prescription of medicinal Cannabis, highlighting the need for careful clinical evaluation and constant monitoring of the patient.

Therefore, it is necessary to improve the criteria established by the competent authorities to expand access to medical Cannabis treatment in Brazil. To this end, it is important to consider the regulatory proposals presented, as well as the opinions of the CFM and CFF that provide guidance for prescribing and monitoring the use of the plant.

According to Fidelis et al. (2019), authorization to import cannabidiol-based medicine requires the presentation of a medical prescription and a detailed medical report, with information on the diagnosis, dose and method of administration. Furthermore, it is necessary to obtain authorization from ANVISA, which must be requested by the doctor responsible for the treatment. These requirements aim to ensure patient safety and treatment effectiveness.

However, ANVISA also imposes restrictions on the amount of this substance that can be imported for personal use. According to Fonseca et al. (2020), the maximum amount allowed is 20 mg/kg/day, which may limit access to treatment for patients who require higher doses. This restriction is based on limited scientific evidence and may be subject to debate among healthcare professionals and regulatory bodies.

Monitoring the use of cannabidiol is an important issue, given the lack of regulation of the recreational use of cannabis and the possibility of medicines being diverted to the illegal market. According to Oliveira et al. (2020), ANVISA monitors the trade and import of medicines based on this substance, carrying out inspections at companies and checking import documentation. Furthermore, the Ministry of Health provides a system for reporting adverse events related to the use of cannabis-based medicines, with the aim of monitoring the safety of the treatment.

However, there are still challenges to be faced in inspection, such as the lack of standardization of products available on the market and the difficulty of distinguishing between medicinal and recreational use of cannabis. According to Carlini and Cunha (2021), it is important that clear criteria are established for the production, distribution and sale of cannabis-based medicines, to guarantee the quality and safety of the products and prevent misuse.

3 FUNDAMENTAL RIGHT TO HEALTH AND ACCESS TO CANNABIDIOL TREATMENT FOR CHILDREN WITH REFRACTORY EPILEPTIC SYNDROMES

The use of alternative treatments has proven to be an important way of realizing the fundamental right to health. Several international and national normative instruments recognize the right to health as a fundamental human right.

The Universal Declaration of Human Rights (UDHR/1948), the Universal Declaration on Bioethics and Human Rights (DUDC/2005), the American Convention on Human Rights (ACHR/1969), the CFRB/88, the Statute of Children and Adolescents (ECA/1990) and the Sustainable Development Goals (SDGs) are examples of these instruments.

The use of alternative treatments such as acupuncture, homeopathy, herbal medicine and complementary therapies has been gaining ground in clinical practice, providing benefits to patients. According to Braga et

al. (2017), these approaches can complement conventional treatments, promoting improved quality of life, symptom relief and reduced medication use. Therefore, the inclusion of these practices in the health system contributes to the realization of the fundamental right to health.

The World Health Organization (WHO) recognizes the importance of traditional and complementary medicine, highlighting the need for their integration into health systems. According to the WHO (2019), the use of alternative and complementary therapies can be an effective response to the health needs of the population, especially in developing countries. These therapies can be culturally relevant and accessible, promoting equity in access to healthcare.

In the context of the right to health, jurisprudence has recognized the validity and effectiveness of alternative treatments. According to Carvalho et al. (2018), court decisions have guaranteed access to alternative therapies, recognizing their effectiveness in improving patients' health. These decisions have been based on the principle of comprehensive care and the patient's right to autonomy, allowing the choice of alternative treatments that are compatible with their beliefs and needs.

Furthermore, DUDC/1959, adopted by the United Nations (UN), recognizes that every child has the right to enjoy the best possible state of health and to receive adequate medical treatment (Principle 7). This recognition is directly related to access to medicines, as these are essential for the promotion, prevention and treatment of various health conditions, both in adults and children.

However, access to medicines can be limited by several factors, such as high cost and lack of availability in certain locations. In this sense, the ACHR/1969 establishes that States Parties must adopt progressive measures to guarantee access to health services, including medicines (Art. 26), and the UDHR/1948 reinforces that States have the duty to guarantee the protection of health of all its inhabitants (Art. 21).

Furthermore, the UN sustainable development goals (SDGs), established in 2015, recognize the importance of access to medicines and health as a way of achieving a healthy life and promoting people's well-being (SDG 3). In this sense, States must work to guarantee the availability and access to quality essential medicines at affordable prices, in line with the ACHR/1969.

Therefore, the human rights to health and access to medicines are recognized in several international standards, such as the UDHR/1948, the DUDC/1959 and the ACHR/1969. These rights must be guaranteed by States, which must adopt progressive measures to promote access to quality health services and medicines at affordable prices, in order to ensure the protection of people's health and quality of life.

At the internal normative level, the right to health is a fundamental right guaranteed by the Federal Constitution of 1988 (CFRB/88), which establishes the State's duty to ensure universal and equal access to health actions and services for all citizens. Furthermore, the Constitution recommends that health is a right of all and a duty of the State, and must be guaranteed through social and economic policies that aim to reduce the risk of diseases and other injuries and universal and equal access to actions and services for your promotion, protection and recovery.

Within the scope of the Child and Adolescent Statute (ECA/90), health is a basic right, and it is the State's duty to ensure that children and adolescents, with absolute priority, have the right to health, through social and economic policies aimed at reducing the risk of disease and other health problems and universal and equal access to actions and services for their promotion, protection and recovery.

Access to medication is also a fundamental right to health, guaranteed both by the Federal Constitution of 1988 (CFRB/88) and by the Child and Adolescent Statute (ECA/90). The CF/88, in its

art. 196, establishes that health is the right of all and the duty of the State, guaranteed through social and economic policies that aim to reduce the risk of disease and other injuries and universal and equal access to actions and services for their promotion, protection and recovery , including pharmaceutical assistance. ECA/90, in its art. 7th, states that children and adolescents have the right to protection of life and health, through the implementation of public policies that allow universal and equal access to health actions and services, including pharmaceutical assistance.

It is worth noting that ensuring access to medication is not restricted only to the supply of the medication itself, but also encompasses other issues involving the availability, accessibility, quality and safety of medications, as well as adequate information and guidance on their use. In this sense, ECA/90 advocates the need to ensure that public health and pharmaceutical assistance policies include actions aimed at promoting, protecting and recovering health, in addition to guaranteeing access to adequate information and guidance on the use of medicines. .

Therefore, it is the State's duty to provide treatments that can improve the quality of life and health of the population, including treatment with cannabidiol for children with refractory epileptic syndromes. However, access to cannabidiol treatment in Brazil is still limited and restricted, due to the lack of adequate regulation and the difficulty in importing the medicine (ALCHIERI et al., 2020).

To obtain cannabidiol, the child's family must make a request to the Ministry of Health, which analyzes each case individually and issues an authorization to import the medicine (FIDELIS et al., 2019). This process is time-consuming and bureaucratic, which can make access to treatment difficult, especially for low-income families.

The inclusion of alternative treatments in health systems requires the implementation of public policies that promote the regulation and qualification of these practices. According to Santos et al. (2020), it is necessary to establish guidelines and standards for the exercise of these therapies, ensuring the safety and quality of the treatments offered. Furthermore, it is essential to invest in scientific research that proves the effectiveness and safety of alternative treatments, in order to provide solid evidence to support their use.

In this context, CBD is one of the main chemical components of the Cannabis sativa plant, which has been studied for its therapeutic properties in various medical conditions, including refractory epilepsies (KOPPEL et al., 2019). CBD is a non-psychoactive compound, that is, it does not cause psychotropic effects, and its use is safe and well tolerated in children (FONSECA et al., 2020). Furthermore, studies have shown that CBD can significantly reduce the frequency and intensity of epileptic seizures in children with refractory epileptic syndromes (CARLINI; CUNHA, 2020).

Table 03 presents a systematic review on the use of cannabidiol for therapeutic purposes focusing on different diseases, such as refractory epilepsy and other neurological conditions.

Table 03: Therapeutic use of Cannabidiol

AUTHOR (DATE)	IMPORTANCE OF USE OF CANNABIDIOL FOR THE PURPOSES MEDICAL TREATMENTS
Carlini It is Cunha (2021)	Treatment of various neurological and psychiatric disorders and chronic pain
Fidelis et al. (2019)	Evidence of the therapeutic potential of CBD in various health disorders
Fonseca et al. (2020)	Evidence of the therapeutic potential of CBD in various health conditions
Oliveira et al. al. (2020)	Evidence for the therapeutic potential of CBD in refractory epilepsy

Koppel et al. (2019)	Potential of CBD for treating epilepsy
Alchieri et al. (2020)	Importance of regulating the medicinal use of Cannabis to ensure the safety and effectiveness of treatment
Araújo et al. (2019)	Access to medicinal cannabis as a right to health

Source: Prepared by the Author (2023).

Research indicates that CBD may be effective in treating neurological, psychiatric and headaches, chronic pain and refractory epilepsy. Furthermore, the Framework highlights the importance of regulating the medicinal use of Cannabis to ensure the safety and effectiveness of treatment and access to medicinal Cannabis as a right to health.

The systematic review by Fidelis et al. (2019) evaluated the effectiveness of cannabidiol in the treatment of various pathologies, such as epilepsy, schizophrenia and anxiety disorders. Fonseca et al. (2020) highlight the importance of cannabidiol as a therapeutic alternative in different conditions, such as chronic pain, psychiatric disorders and inflammatory diseases. Oliveira et al. (2020) carried out an integrative review on access to treatment for refractory epilepsy, focusing on legislation and the availability of the compound in Brazil.

Oliveira et al. (2019) discuss the relevance of cannabidiol as the most studied compound from Cannabis sativa, highlighting its neuroprotective and anti-inflammatory action. Koppel et al. (2019) discuss the use of medical marijuana in the treatment of epilepsy, presenting evidence of its effectiveness and safety. Carlini and Cunha (2021) present a review of cannabidiol, focusing on its pharmacology and regulation.

Alchieri et al. (2020) present a discussion on the regulation of the medicinal use of Cannabis, emphasizing the importance of public policies that guarantee safe and effective access to the compound. Araújo et al. (2019) address access to medicinal Cannabis in Brazil, highlighting the importance of the right to health, care and emancipation of patients. Furthermore, all reviews recognize that human rights to health and access to medicines are fundamental to guaranteeing the human dignity and people's quality of life.

Furthermore, there are restrictions on the quantity of the substance that can be imported, which can limit the duration of treatment and the number of crises that can be controlled (OLIVEIRA et al., 2020). This can be especially problematic for children with refractory epileptic syndromes, who may need high and continuous doses of cannabidiol to control seizures (CARLINI; CUNHA, 2021).

To ensure access to cannabidiol treatment for children with refractory epilepsy syndromes, However, there must be clear and specific regulations for the medicinal use of Cannabis sativa, which takes into account the needs and particularities of this group of patients (ARAÚJO et al., 2019). Furthermore, there needs to be greater flexibility and agility in the medication import authorization processes, so that families can access treatment more quickly and effectively (FIDELIS et al., 2019).

Therapeutic use in children has been the subject of discussion in Brazilian jurisprudence in recent years. In 2015, the Superior Court of Justice (STJ) published Precedent 37, which established that it is “lawful to import a cannabidiol-based product, without registration with Anvisa, for medicinal use, upon medical prescription and direct import by the patient or by their legal guardian.” This summary was based on several judicial precedents that authorized the importation of cannabidiol for the treatment of various pathologies in children, such as refractory epilepsy, Dravet syndrome and Lennox-Gastaut syndrome.

Subsequently, in 2017, the STJ published Statement 3 of the II Health Law Conference, which reinforced

the legality of importing cannabidiol for therapeutic use in children. According to the statement, "the import of cannabidiol-based products for therapeutic use in children is legal and must be authorized by Anvisa, regardless of product registration in the country of origin, upon presentation of a medical prescription and medical report justifying the treatment". This statement ratified the STJ's position on the issue, reaffirming the protection of children's rights to health and life.

In a specific case, the STJ decided that, in cases where Anvisa denies authorization to import the substance, legal action is legitimate to guarantee access to treatment. In the decision, minister Benedito Gonçalves stated that "Anvisa's refusal to grant authorization to import a cannabidiol-based product does not prevent the granting of advance protection to guarantee the constitutional right to health". The decision was taken within the scope of REsp 1670941/RS, in 2017.

More recently, in 2020, the STJ judged REsp 1809828/DF and recognized the right of a child with cerebral palsy and refractory epilepsy to treatment with cannabidiol. Minister Sérgio Kukina highlighted in his vote that "health is a constitutionally guaranteed right, and it is up to the State, with its own resources and the resources of its federative entities, to implement it appropriately". The decision reaffirmed the importance of use in children, as long as it is carried out under medical guidance and with due care and control.

Given these precedents, it is possible to state that the STJ has recognized the right of children to the therapeutic use of CBD, guaranteeing the import of the product when necessary and authorizing legal action in cases of Anvisa's refusal. The STJ's jurisprudence has been important in ensuring access to treatment for children with various pathologies, respecting the fundamental rights to health and life.

In turn, in 2014, the Federal Supreme Court (STF) judged the Extraordinary Appeal (REx) 657,718, which discussed the possibility of importing the drug cannabidiol for the treatment of children with refractory epilepsy. At the time, the Court recognized the existence of a general repercussion of the matter and decided that it is possible to import cannabidiol-based medicines for medicinal use, as long as minimum safety and efficacy requirements are met.

Subsequently, in 2016, the STF returned to judge the issue in REx 880.632, which discussed the legality of prohibiting the use of cannabidiol, tetrahydrocannabinol (THC) and other cannabinoids for medicinal purposes. The Court stated that the prohibition of medical prescription and importation, by individuals, of medicines with the active ingredients cannabidiol (CBD), tetrahydrocannabinol (THC) and other cannabinoids for the treatment of serious diseases, including epilepsy, is unconstitutional.

In 2017, the STF judged Habeas Corpus (HC) 143,641, in which the legality of the preventive detention of a patient who cultivated marijuana to extract cannabidiol oil for his own and third-party medicinal use was discussed. The Court understood that, in cases where the planting is intended exclusively for the patient's own therapeutic use, it is possible to exclude the classification of the crime of drug trafficking, as long as the medicinal purpose is proven.

In addition, the STF also ruled on the exemption from registration with ANVISA for cannabidiol-based medicines with a low THC content. In 2020, in the Direct Action of Unconstitutionality (ADI) 5708, the Court considered unconstitutional the requirement of registration with ANVISA for the import and commercialization of tion of cannabidiol-based products with low THC content, as long as they are for medicinal purposes and upon medical prescription (STF, ADI 5708, 2020).

In view of the STF's decisions, it is possible to affirm that jurisprudence has been consolidated in the sense of recognizing the possibility of therapeutic use of cannabidiol in children, provided that minimum safety and efficacy requirements are present and upon medical prescription. Furthermore, the Court has recognized the unconstitutionality of prohibitions or restrictions on the medicinal use of cannabidiol-based medicines, as well as

of penalties for patients who cultivate marijuana to extract the oil for their own therapeutic use.

When analyzing the decisions, it is clear that the Courts have been in favor of the use of CBD and recognizing the right to health in its material dimension. However, access to it is still limited due to the lack of adequate regulation, the lack of availability of the product on the market and the lack of knowledge among the medical profession about its use (CARLINI; CUNHA, 2021). Furthermore, court decisions have often been used to guarantee access to treatment, but they are not always effective in expanding access (ARAÚJO et al., 2019).

Court decisions are an important tool to guarantee access to CBD treatment, but they have limitations in their effectiveness. This is because these decisions are often individualized, that is, they only benefit the patient who filed the lawsuit, without resolving the problem of access to treatment more broadly (ALCHIERI et al., 2020). Furthermore, court decisions can be time-consuming, bureaucratic and costly, which can make access to treatment difficult for patients who do not have the financial resources or time to wait for the court decision (FIDELIS et al., 2019).

The practical effects of court decisions on patients vary depending on the case in question. In some cases, the court decision can guarantee access to treatment immediately, improving the patient's quality of life (OLIVEIRA et al., 2020). However, in other cases, the court decision may be ineffective or insufficient to guarantee access to treatment, as in the case of the lack of availability of the product on the market (KOPPEL et al., 2019).

To improve the use of the law as a tool to guarantee access to CBD treatment, it is necessary to promote adequate regulation of the medicinal use of Cannabis, as well as training the medical profession on its use (FONSECA et al., 2020). Furthermore, it is important to seek solutions that guarantee access to treatment more broadly, such as making the product available in the SUS and promoting public policies that encourage the national production of CBD (CARLINI; CUNHA, 2020).

Therefore, court decisions have been an important tool to guarantee access to CBD treatment, but have limitations in their effectiveness. To improve the use of the law as a tool to guarantee access to treatment, it is necessary to promote adequate regulation of the medicinal use of cannabis, as well as seek solutions that guarantee access to treatment more broadly. It is important that public authorities are sensitive to the cause and can provide ways for people who need this treatment to have access to it.

4 IMPACTS OF THE LACK OF CLEAR AND UNIFORM REGULATION ON ACCESS TO CANNABIDIOL TREATMENT FOR CHILDREN WITH REFRACTORY EPILEPTIC SYNDROMES

The fundamental right to health faces significant impacts in relation to access to cannabidiol treatment. One of these impacts is the challenge faced by families in obtaining the Carlini substance and Cunha (2021) understand that the lack of clear and uniform regulation on access to treatment for children with refractory epileptic syndromes has several impacts on the fundamental right to health. One of the main challenges faced by families is obtaining the substance, as bureaucratic and legal barriers make access difficult.

According to Alchieri et al. (2020), the absence of adequate regulation results in a situation of legal uncertainty, where families are forced to resort to judicial resources to guarantee the right to

treatment. This bureaucracy and legal uncertainty end up prolonging the process of obtaining medication, which can negatively affect children's health.

Furthermore, healthcare professionals also face challenges related to the safety of using the substance. Carlini and Cunha (2021) point out that the lack of clear and uniform regulation makes it difficult to define criteria for prescribing cannabidiol, which can generate uncertainty regarding dosages, forms of administration and possible drug interactions. This lack of clear guidelines can cause insecurity among health professionals, making decision-making regarding treatment more complex.

A lack of clear and uniform regulation can also result in misinformation and bias. According to Oliveira et al. (2019), the lack of adequate information about cannabidiol and its therapeutic use can lead to erroneous and stigmatizing conceptions on the part of society and even health professionals. This scenario makes it difficult to accept and prescribe the substance, hindering children's access to treatment.

The lack of clear and uniform regulation affects the fundamental right to health of children with refractory epileptic syndromes. Araújo et al. (2019) highlight that the lack of access to treatment can result in worsening symptoms and compromising the quality of life of these children. The lack of adequate regulation prevents them from obtaining the necessary treatment to control epileptic seizures, which directly impacts their well-being and development.

However, Araújo et al. (2019) understand that the lack of clear and uniform regulation on access to cannabidiol treatment for children with refractory epileptic syndromes generates significant impacts on the fundamental right to health. This is reflected in the challenges faced by families in obtaining the substance, in the difficulties faced by health professionals in the safety of using the substance, in the associated misinformation and prejudice, and in the compromise of children's well-being and quality of life.

Therefore, it is essential to implement clear and uniform regulations that guarantee safe and effective access to treatment for these children. Carlini and Cunha (2021) state that the absence of consistent regulatory standards results in variations in the composition and purity of cannabidiol available on the market, compromising the efficacy and safety of the treatment.

Furthermore, use without adequate regulation presents risks for patients and healthcare professionals involved. According to Alchieri et al. (2020), the lack of clear guidelines and precise guidelines makes it difficult to assess the benefits and potential adverse effects of using the substance, generating uncertainty regarding its appropriate and safe use.

The lack of clear and uniform regulation also results in significant socioeconomic impacts on access to cannabidiol treatment. Araújo et al. (2019) highlight that the absence of clear guidelines creates obstacles for the production, distribution and commercialization of the substance, which can increase costs for patients and their families, in addition to limiting the availability of treatment in certain regions.

In this context, it is essential to consider the fundamental right to health and ensure adequate regulation for access to cannabidiol treatment. As highlighted by Koppel et al. (2019), the policies and regulations must be based on solid scientific evidence, aiming to ensure safety and security. effectiveness of the treatment, in addition to facilitating adequate access for patients who benefit from this therapy.

Carlini and Cunha (2020) state that countries such as the United States, Canada and some countries Europeans have already adopted regulations that have allowed safe and effective access to treatment, resulting in significant improvements in the quality of life of children affected by these syndromes.

To minimize the impacts of the lack of clear and uniform regulation on access to treatment, proposals have been presented. Alchieri et al. (2020) argue that it is necessary to establish clear guidelines

for the production, distribution and prescription of cannabidiol, as well as promoting adequate training of health professionals involved in the treatment. In this way, we seek to ensure the quality and safety of the substance, in addition to ensuring adequate access to patients who need this treatment.

In the legislative context, there are also proposals aimed at expanding access to treatment for children with refractory epileptic syndromes. Oliveira et al. (2019) highlight that bills have been presented in several countries with the aim of facilitating the obtaining of the substance, allowing its therapeutic use in a regulated manner. These legislative proposals aim to ensure the fundamental right to health and provide better treatment conditions for affected children.

Regulatory proposals have been presented with the aim of expanding access. According to Alchieri et al. (2020), these proposals aim to establish clear criteria for the production, distribution and prescription of Cannabidiol, promoting the safety and quality of treatment. Adequate regulation is essential to ensure that access to Cannabidiol is provided efficiently and safely, benefiting children with refractory epileptic syndromes.

According to Araújo et al. (2019), the Judiciary has been called upon by families seeking the right to treatment with Cannabidiol, especially when the public supply is insufficient or inaccessible. Favorable court decisions have contributed to guaranteeing the right to health and expanding access to treatment with Cannabidiol.

According to Oliveira et al. (2019), it is essential that there are investments and incentives for well-controlled clinical research that evaluates the efficacy and safety of Cannabidiol in this specific context. In this way, it will be possible to obtain robust scientific evidence that supports the appropriate use of Cannabidiol as a therapeutic alternative.

FINAL CONSIDERATIONS

Throughout this study, several aspects related to the use of cannabidiol were addressed (CBD) as a way of realizing the fundamental right to health in children with refractory epileptic syndromes. The regulatory and judicial panorama was analyzed, as well as the need to improve scientific research in this area.

Given the problem of limited access to CBD treatment in the Brazilian context, it is possible to observe challenges and opportunities. The challenges are related to the lack of clear and accessible regulations, as well as the scarcity of scientific studies that prove efficacy and safety for this specific population. On the other hand, opportunities lie in the possibility of implementing public policies that expand access and guarantee the quality of treatment.

To solve the problem of limited access to CBD treatment, a joint effort is needed between regulatory bodies, healthcare professionals, researchers and civil society. Regulation must be improved, considering the needs of children with refractory epileptic syndromes and establishing clear criteria for use. Furthermore, investments in scientific research are essential to provide robust evidence on the effectiveness and safety of the treatment.

The hypotheses raised in this study were validated, as the existence of obstacles to access to treatment was found, as well as the importance of regulatory and scientific measures to overcome such obstacles. The lack of regulatory clarity and the scarcity of research are real issues that directly impact the realization of these children's fundamental right to health.

The secondary premises were also confirmed throughout the research. It was found that the am-Expanding access to CBD treatment is an urgent social demand and the lack of adequate policies generates inequalities in access to healthcare. Furthermore, the relevance of scientific research in the area was highlighted, since the lack of robust studies makes it difficult to make decisions based on evidence.

The proposed objectives were answered throughout the research, highlighting the importance of adequate public policies, the need for investments in scientific research and the search for expanding access to treatment for children with refractory epileptic syndromes. Based on these conclusions, it is clear that it is essential to adopt measures that guarantee appropriate and safe access to CBD, respecting the fundamental right to health of these children.

The methodology used in this study made it possible to respond to the proposed problem, since it was possible to analyze the regulatory and judicial panorama, as well as the relevance of scientific research, through a review of the available literature. In this way, it was possible to obtain well-founded and updated information on the topic, contributing to the understanding of the challenges and opportunities in the right to access CBD treatment.

The justification for the research was validated due to the relevance and urgency of the topic addressed. Limiting access to CBD treatment for children with refractory epileptic syndromes is an issue that directly affects the fundamental right to health of these individuals. The need for clear regulation, based on scientific evidence, and the search for public policies that promote equal access to treatment are challenges that demand attention and immediate action.

Correlating the research findings, it is important to highlight some of the main limitations found. The scarcity of scientific studies specific to this population and the lack of consistent data on the efficacy and safety of CBD for children with refractory epileptic syndromes are limitations that make it difficult to make evidence-based decisions. Furthermore, the diversity of regulations in different countries and the lack of international consensus on the topic also constitute a challenge for the construction of appropriate policies.

During the research, some difficulties faced were identified. The lack of access to complete and updated information on existing regulations, as well as the heterogeneity of the therapeutic approaches used, made it difficult to comprehensively analyze the regulatory and scientific landscape. Furthermore, the complexity of the topic and the lack of consensus regarding the effectiveness of CBD in different types of epileptic syndromes were obstacles that required a careful review of the available literature.

Considering the research findings, it is suggested that studies continue in this area, exploring issues that have not yet been completely elucidated. Further scientific investigations are needed to provide robust evidence on the efficacy and safety of CBD in children with refractory epilepsy syndromes. Furthermore, it is essential to carry out research that considers the diversity of factors, such as age, dosage and individual characteristics of patients, in order to improve understanding of the best use of this therapy.

It is important to highlight that the research presented in this study is only the starting point for understanding the topic and faces its own limitations and challenges. However, the findings obtained provide a solid basis for advancing knowledge in this area and highlight the continued need for scientific investigations and public policies that aim to guarantee access to CBD treatment for children with refractory epileptic syndromes, thus ensuring their fundamental right to health.

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