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Article

Health judicialization and the role of Public Defender's Office in a case of non-standardized input: the demand for Cannabidiol at the Federal Public Defender's Office in Salvador/Ba over the past decade

Judicialização em saúde e atuação defensorial em caso de insumo não incorporado: a demanda de Canabidiol na Defensoria Pública Federal de Salvador/BA durante a última década

Judicialización sanitaria y acción de la Defensoría Pública en un caso de insumo no incorporado: la demanda de Cannabidiol en la Defensoría Pública Federal de Salvador/Ba em la última década

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Abstract

Objective: To evaluate the performance of the Federal Public Defender's Office and the effectiveness of the juridification of health, as an instrument to guarantee access to the right, in the case of a non-standardized input (Cannabidiol), in the Salvador/Bahia unit. **Methodology:** a descriptive study with application of retrospective longitudinal method was carried out on the number of Cannabidiol claims that have reached the unit since the index case admitted in Brazil in 2014, its annual evolution and destination in the institution and in the court, until 2023. **Results and discussion:** there was a systematic growth in the number of cases, which doubled annually, especially from 2018 onwards, except in 2021. The percentage of judicialized lawsuits was about 59%, and, among those, more than half obtained a favorable decision in some instance, reaching 76% from the merit sentences. The time between the arrival of the applicant, the gathering of documents and the filing of the action was, on average, 2.4 months, and the average interval between the filing of the initial petition and the intimation of the anticipation decision, in the cases where it was granted, was 2 months. On the other hand, the interval between the intimation of the anticipatory decision and the effective compliance oscillated around 9.2 months, only being obtained through judicial blocking in almost 70% of the cases. **Conclusion:** it was found that the defense was swift, as soon as the necessary documents were gathered, as well as the injunctions granted. On the other hand, the time of compliance after the concession decision showed an alarmingly long interval, resulting in a new form of ineffectiveness of the social right to health, which the judicialization aimed precisely to combat.

Keywords
Health's Judicialization. Cannabidiol. Public Defender Legal Services.

Resumo

Objetivo: avaliar a atuação da Defensoria Pública Federal e a efetividade da juridificação da saúde, como instrumento para garantia de acesso ao direito, no caso de insumo não padronizado (Canabidiol), na unidade de Salvador/Bahia. **Metodologia:** estudo descritivo com aplicação de método longitudinal retrospectivo das demandas de Canabidiol que chegaram à unidade, desde o caso índice admitido no

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país em 2014, com evolução anual e destino, na instituição e na Justiça, até 2023. **Resultados:** houve crescimento sistemático dos pedidos, que dobraram anualmente, sobretudo a partir de 2018, exceto no ano de 2021, totalizando 88 casos. O percentual de pleitos judicializados foi de 59%, e, dentre eles, mais da metade obteve decisão liminar favorável em alguma instância, alcançando 76% nas sentenças de mérito. O tempo entre a chegada do requerente, reunião de documentos e propositura da ação foi, em média, de 2,4 meses, e o intervalo médio entre o protocolo da peça inicial e a intimação da antecipação de tutela, nos casos em que concedida, foi de 2 meses. O intervalo entre a intimação da decisão antecipatória e o efetivo cumprimento foi em torno de 9,2 meses, somente obtido mediante bloqueio judicial em quase 70% dos casos. **Conclusão:** a atuação defensorial se mostrou célere, tão logo reunidos os documentos necessários, bem como as liminares concedidas. O tempo de cumprimento após a decisão concessiva mostrou intervalo alargado, evidenciando uma nova forma de inefetividade do direito social à saúde, o que a judicialização visava exatamente a combater.
Palavras-chave
Judicialização da Saúde. Canabidiol. Defensoria Pública.

Resumen
Objetivo: Evaluar el desempeño de la Defensoría Pública Federal y la efectividad de la juridificación de la salud, como instrumento para garantizar el acceso al derecho, en caso de insumo no estandarizado (Cannabidiol), en la unidad de Salvador/Bahía. **Metodología:** se realizó un estudio descriptivo con aplicación del método longitudinal retrospectivo sobre los reclamos de Cannabidiol que han llegado a la unidad desde el caso índice admitido en el pays, en 2014, su evolución anual y destino, en la institución y en los tribunales, hasta 2023. **Resultados y discusión:** hubo un aumento sistemático en el número de solicitudes, que se duplicaron anualmente, especialmente a partir de 2018, a excepción de 2021. El porcentaje de demandas fue de alrededor del 59% y, entre los judicializados, más de la mitad obtuvo una decisión favorable en alguna instancia, llegando al 76% en las sentencias de mérito. El tiempo promedio entre la llegada del demandante, la recopilación de documentos y la presentación de la demanda fue de 2.4 meses, y el intervalo promedio entre la presentación de la petición inicial y la decisión de anticipación, en los casos en que fue concedida, fue de 2 meses. Por otro lado, el intervalo entre la intimación de la decisión anticipada y el cumplimiento efectivo osciló en torno a los 9,2 meses, obteniéndose únicamente a través del bloqueo judicial en casi 70% de los casos. **Conclusión:** se comprobó que la defensoría fue rápida, tan pronto como se reunieron los documentos necesarios, así como las medidas cautelares otorgadas, después de escuchado el órgano de soporte técnico. Por otro lado, el tiempo de cumplimiento posterior a la decisión de concesión mostró un intervalo alarmantemente largo, lo que resultó en una nueva forma de ineficacia del derecho social a la salud, que la judicialización pretendía precisamente combatir.
Palabras clave
Judicialización de la Salud. Cannabidiol. Defensoría Pública.

Introduction

The judiciary's relationship with the social right to health has been increasingly assiduous. According to data from the National Council of Justice, the number of lawsuits on the subject increased by 130% between 2008 and 2017, with a significant budgetary impact (1,2). In 2022, more than 295,000 new lawsuits were filed on the right to health, bringing the total to more than 800,000 cases underway in the country (3).

The impact has not only been quantitative, but also qualitative: the way in which the Judiciary has dealt with these issues has been refined over time and has played an important role in the interpretation and scope of the constitutional right under examination and the public policies relating to it, which is also the subject of the Supreme Court's General Repercussion Topic No. 698. The effort

to establish guiding parameters for decisions, given the increase in demands, translates into guidelines observed both in the decisions of the Higher Courts, in their General Repercussion Themes (such as Themes n. 500 and 793, of the Federal Supreme Court, relating to the supply of unregistered drugs and solidarity between public entities in the matter), and in the various enunciations of the National Council of Justice (CNJ) (4). These actions aim to balance the dilemmas between accessibility and sustainability, universality and integrality in the allocation of health resources, as well as providing a basis for greater legal certainty and equity in decisions (5).

Furthermore, although the issue of juridification in general and the judicialization of health in particular (6) has been frequently debated over the last decade (4,7), the participation of the Federal Public Defender's Office in this process has not been the subject of such assiduous analysis. It is a body with a still precarious structure and an insufficient number of people in the country, which in itself reveals rather than resolves the issue of social and health shortages, and challenges the constitutional project of eradicating poverty and promoting broad access to justice (8-13).

The defense agencies play an important role in guaranteeing access to the right to health for the underprivileged population, which is largely dependent on the Unified Health System (SUS) and state provision. The general growth in health claims seen in national courts naturally has repercussions for the institution. Statistics from the Federal Public Defender's Office (14) for the last five-year period show that health issues went from 20,496 new administrative requests in 2018 to 28,296 in 2022, representing an increase of almost 40% in five years and totaling 766,094 cases in the period, of which around 37,000 (around 5%) expressly involve medicines and supplies registered by ANVISA but not incorporated by the SUS.

In the same period, health was one of the three areas with the highest number of legal aid cases (PAJs) in Bahia, despite the alarming number of emergency aid cases in the pandemic period (10). Health claims accounted for 5,379 PAJs filed between January 2018 and December 2022 in the state, of which 3,887 were prosecuted, totaling 46,222 cases in the period (14), despite the scarce number of civil servants and federal public defenders in the state. In fact, the number of professionals in the area totals just 27 in the federative entity, distributed among the units in Salvador (21 defenders), Feira de Santana (three), Vitória da Conquista (two) and the shared unit in Juazeiro-BA/Petrolina-PE (one).

In 2022, Bahia was the fourth federal unit in terms of the number of cases involving non-standardized medicines, in the Federal Public Defender's Office's national survey, and the second among the units working with the Federal Regional Court of the 1st Region (TRF1). It was also the most prolific unit overall outside the South-Southeast (15). It should be noted that this position is particularly important for the population served, the target audience of which is mostly assisted by the SUS, without health insurance and is therefore entirely dependent on state provision (3).

At the Salvador unit, health claims went from just seven in 2006 to 30 times more in 2012, six years later (16). They have been growing exponentially since then, with more than 400 new lawsuits opened locally on the subject in 2022, not counting the accumulated from previous years, given that in many cases they are ongoing claims, with successive complaints of non-compliance.

In 2023, consulting the agency's internal system (SISDPU), it was found that a total of 5,453 new requests for assistance had been opened in this unit by the end of October, of which 2,197 dealt with civil matters, 469 of which were health-related, basically involving non-standardized supplies. Among these, around 6.4% of the requests involved the substance Cannabidiol.

This is a flourishing issue in the Higher Courts, especially in view of the resumption, in August 2023, of the trial of Extraordinary Appeal (RE) 635659/SP, with general repercussion declared (Theme 506), on the decriminalization of drug possession for personal use. On this discussion, Justices Alexandre de Moraes, Luís Roberto Barroso and Edson Fachin have already spoken out, in favor of establishing a national criterion, exclusively in relation to marijuana, to differentiate users from traffickers (17). Justice Gilmar Mendes, in turn, argued for the permissive to be extended to other illicit drugs as well, considering the impact of imprisonment for small amounts of psychotropic substances, which mainly affects poor and black people in the country. The appeal that triggered the repercussion was filed in the course of an action brought by the Public Defender's Office of São Paulo, in defense of a man convicted in 2009 for possession of 3g of the drug derived from Cannabis sativa.

Although this discussion does not involve a specific health issue, it has reinforced the long-standing debate about the need to review the legal approach to the production and use of cannabinoid derivatives for industrial (STJ, RE n. 2.024.250-PR) and/or medicinal (STJ, HC 783717) purposes in the country (18).

The history of these products in Brazil and around the world goes hand in hand with many aspects associated with poverty, ethnic and social prejudice and moral and behavioral discussions (19). Such resistance has also extended, in many cases, to the possibility of its medicinal use, despite the positive, although not miraculous, effects recorded, notably in the reduction of convulsive episodes in epileptic cases refractory to other treatments (20,21).

The fraction used in these cases is most often Cannabidiol (CBD), a derivative with no psychoactive effects from Cannabis sativa, a plant species native to tropical and temperate regions. Another fraction of the plant is Tetrahydrocannabinol (THC), which has psychoactive effects (22), aimed at recreational use of the substance, but which can also be of medical use in certain cases (22). In the middle of the 20th century, the isolation of the components made it possible to research the pharmacological effects of cannabinoids on the neurological system, among other organic systems, without altering consciousness (23).

In Brazil, although the planting and consumption of Cannabis sativa has been prohibited since the 1930s, by Getúlio Vargas' Decree-Law No. 891/38 (24), art. 2, paragraph 2 of the aforementioned law already provided for the possibility of authorizing cultivation for therapeutic purposes, if necessary. This provision was repeated in the current Law No. 11.343/2006:

> Art. 2 (...) Sole Paragraph. The Federal Government may authorize the planting, cultivation and harvesting of the plants referred to in the caput of this article, exclusively for medicinal or scientific purposes, in a predetermined location and timeframe, subject to inspection, respecting the aforementioned exceptions. (25)

The regulation of the provision, however, which would make the medicinal use in practice feasible, remained without due adaptation, with the discipline still subject to Ministry of Health Ordinance No. 344/98 (26), which lists Cannabis sativum (sic) among the plants that can produce narcotic and/or psychotropic substances, which had been interpreted as also prohibiting the production of its non-psychoactive derivative.

The situation changed substantially when, in April 2014, the Federal Supreme Court (STF) was asked to rule on an injunction granted in case no. 24632-22.2014.4.01.3400/DF, filed by the then minor Anny Bortoli Fischer, represented by her parents, against the National Health Surveillance Agency

(ANVISA). The action sought to ensure the importation of a drug whose active substance is Cannabidiol, the use of which, until then outside the country or illegally domestically, had been successful in drastically reducing the number of seizures suffered daily by the child, a result not achieved with other drugs (18).

The Supreme Court upheld the decision, according to which the prohibition in the Ordinance only applied to THC, since CBD did not produce the psychotropic effects that the rule sought to prevent. In the same year, the São Paulo Regional Council of Medicine and then the Federal Council of Medicine admitted the compassionate prescription of cannabidiol in cases of refractory epilepsy and, in the following year, ANVISA's Collegiate Board Resolutions (RDC n. 3 and 17/2015, the latter of which is now in force). 3 and 17/2015, the latter updated by RDC n. 128/16 and later revoked by the current RDC n. 335/20, updated by RDC n. 570/21) admitted the therapeutic effects and importation of products whose CBD content exceeded that of THC, a requirement no longer included in the current standard (27). Similarly, leveraged by other pioneering court rulings, RDC n. 327/19 approved the local manufacture and sale of cannabinoid medications, based on administrative parameters also outlined at the time, although domestic cultivation of the raw material was still not allowed. Such a measure could favor a more significant reduction in costs and easier access for people on low incomes (28).

It was these jurisprudential constructions that also paved the way for the authorization of local cultivation by associations, expanding the possibilities of national production (29), as well as clarifying the doubt about the application of the judicial positions themselves, whose General Repercussion Themes n. 106 and 990 (the latter relating to supplementary health plans) of the Superior Court of Justice (STJ) had established, among the requirements for the exceptional supply of non-incorporated drugs, the existence of registration with ANVISA. In this sense, General Repercussion Topic no. 1161, established by the Federal Supreme Court in October 2021, established that:

> It is up to the state to provide, on an exceptional basis, medication which, although not registered with ANVISA, has been authorized for import by the health surveillance agency, provided that the patient's economic incapacity, the clinical indispensability of the treatment, and the impossibility of replacing it with another similar medication on the official medication dispensation lists and SUS therapeutic intervention protocols are proven (30).

This understanding then became the basis for more frequent decisions granting concessions for the supply of cannabidiol-based medicines in the country.

More recently, in the state and municipal legislative spheres, there have been several initiatives to regulate the medicinal use of cannabinoids (19), since they are considered extra-criminal, in the light of the administrative rules and case law. At least in the municipality of Salvador, however, despite the recent Municipal Law no. 9.663/23 (31), the supply has yet to be regularized by the local Health Department, even in cases supported by the appropriate prescription and medical report. As a result, the number of claims continued to increase at the Public Defender's Office in question, with consequent judicialization, justifying the research under examination.

The objective was to evaluate the work of the Federal Public Defender's Office, through its unit in Salvador/Bahia, and the effectiveness of the juridification of health, as an instrument for guaranteeing access to the social right in question, when dependent on an input that is not standardized by the public administration, in this case, Cannabidiol.

Methodology

This is a descriptive study (32) carried out as part of a post-doctoral internship in the area of Social Policies and Citizenship, in the line of research into social rights and new rights. It is the empirical part of research into the judicialization of health and the role of the Federal Public Defender's Office in making the social right in question effective, and its evolution over the last decade. A retrospective longitudinal method was used with a qualitative-quantitative evaluation, which surveyed all the cannabidiol claims submitted to the Salvador unit of the Federal Public Defender's Office over the last decade, from the index case admitted by the Federal Supreme Court in 2014 (Anny Fischer case - case no. 24632-22.2014.4.01.3400/JFDF) until October 31, 2023. The annual number of requests and their fate in the institution and the courts until November 2023 were analyzed. In the discussion, some exploratory considerations are made about some of the most relevant data found.

The choice of drug to delineate the procedural sample that is the object of this research was due to the practical and temporal impossibility of analyzing all the health claims handled by the agency during the period, or even over a shorter interval, considering the scarcity of data available on the federal defense agency's website ("DPU in Numbers"). This source only indicates general figures for the health demands of the units in the last five years, without making it possible to search by drug or the destination of the requests, which requires a manual survey and evaluation on a case-by-case basis. Cannabidiol is a non-incorporated ingredient whose topical discussion gives rise to interest in the subject of judicialization and which showed a growing demand in the unit over the period studied, in a total number that would make analysis feasible within the time available to complete the research.

The study was authorized by the Research Ethics Committee of the Catholic University of Salvador on September 20, 2023, by means of opinion no. 6.313.667, and was carried out using the SISDPU System, appointments made by the Social Service of the Salvador unit and, in case of doubt, direct consultation of the Electronic Judicial Process System (PJE) of the Federal Regional Court of the 1st Region. The survey was carried out between September 20 and November 20, 2023, and the sensitive data that was accessed, including by professional practice, was pseudonymized in the collection, carried out entirely by the researcher, in order to protect the privacy of the applicants.

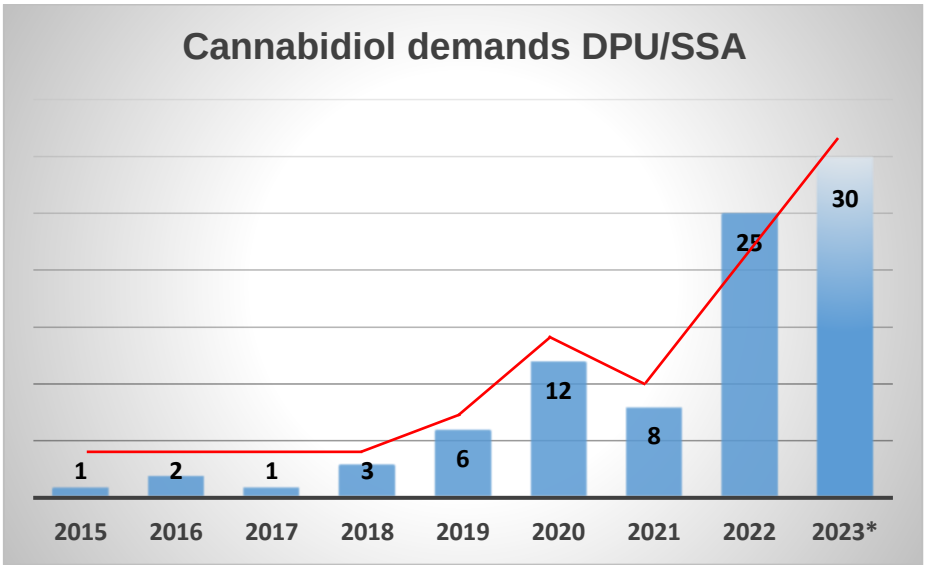
The following variables were assessed: the gender of those being assisted, whether they were an adult or a minor, the medical condition that prompted the search for the institution and the destination of the legal aid process (PAJ): whether it had been filed (with the respective reason), judicialized or awaiting documentation.

The average, mode, median and variability of the time between arrival at the institution and the filing of the initial petition were calculated. The same data was collected in relation to the time taken between the filing of the lawsuit and the notification of a favorable preliminary injunction decision, in cases in which a preliminary injunction was granted, and between the filing of the lawsuit and the first sentence (since there was a case of the sentence being annulled after an appeal, in which another decision had to be handed down), in cases that had already been sentenced. In the case of rejection, the reasons for this were examined qualitatively and whether there had been a judicial appeal by the body. In cases where the decision was granted, the time between the summons being issued and actual compliance by the defendants was assessed, as well as whether this was done through direct provision or through the need for a judicial blockade.

Results and discussions

Among the administrative processes investigated, it was found that in 2015, the Federal Public Defender's Office in Salvador received the first request similar to the Anny Fischer case, which had been decided favorably by the Supreme Court in April 2014, regarding the admissibility of importing cannabinoids for medicinal purposes, in favor of a child with refractory epilepsy. In the following three years, there were two, one and three requests a year respectively. As of 2018, when an agreement was signed with the Public Defender's Office of the State of Bahia, in order to concentrate requests for non-incorporated inputs from Salvador at the federal level, there was an almost geometric growth in demands for Cannabidiol at the unit (graph 1).

Graph 1 - Growth ib demands for canabidiol at the Federal Public Defender's Office in Salvador-Bahia (DPU/SSA) from 2015 to 2023.



Source: Own elaboration, data collected up to October 31, 2023.

The number of requests involving the substance doubled every year until 2023, except in 2021 - probably still as a result of the COVID-19 pandemic, with the interruption of some local care programs, such as the one carried out by the agency with the NGO Abraço a Microcefalia - totaling 88 PAJs referring to the substance opened until October 31, 2023. The product was among the drugs most requested by the unit in some months of 2022 and 2023.

Analyzing the data, it was observed that among the applicants there was a slight male prevalence (55%), except in 2020 and 2023, when there was no numerical difference in gender. In terms of age group, there was a higher number of underage applicants (65%), except in 2019, when there was an equal number of older and younger applicants, and 2023, when the number of older applicants exceeded that of children and adolescents, until the month of October surveyed. It is worth noting that 2019 and 2023 were also the years in which the rate of injunctions denied exceeded the number of successes the unit had in the matter.

In addition, the medical reasons for seeking help from the institution have undergone some changes over time, probably related to the age aspect mentioned above, also having repercussions on the panorama of administrative and judicial decisions. The most frequent medical causes throughout the period were difficult-to-control epileptic seizures, either in isolation or associated with other

underlying diagnoses (Dravet Syndrome, Tuberous Sclerosis, Congenital ZikaVirus, Perinatal Hypoxia, West Syndrome, Congenital Rubella Syndrome, Autism Spectrum Disorder - ASD). Some of these etiologies were expressly mentioned in Resolutions 2.113/14 ("Approves the compassionate use of cannabidiol for the treatment of epilepsy in children and adolescents refractory to conventional treatments" (33), revoked by Res. 2.324/22, but apparently reprised, given its suspension) and 2.324/22 ("Approves the compassionate use of cannabidiol for the treatment of epilepsy in children and adolescents refractory to conventional treatments"). 2.324/22 ("Approves the use of cannabidiol for the treatment of child and adolescent epilepsies refractory to conventional therapies in Dravet and Lennox-Gastaut Syndrome and Tuberous Sclerosis Complex") (34), suspended since October 2022 for public consultation by the Federal Council of Medicine (CFM). Seizures accounted for 52% of all PAJs on the subject and had the highest rates of success in judicialization.

Other medical causes reported, especially since 2019, when Anvisa's RDC 327 expanded the prospects for the medicinal use of cannabinoids, were: ASD conditions without seizure symptoms, whether or not associated with aggression or attention deficit hyperactivity disorder (ADHD) (22%), anxiety, depression, phobic disorders, Parkinson's syndrome, Alzheimer's syndrome and pain conditions (due to fibromyalgia, chronic migraine, cancer, shingles, Takayassu arteritis, chronic esophagitis and otalgia with tinnitus).

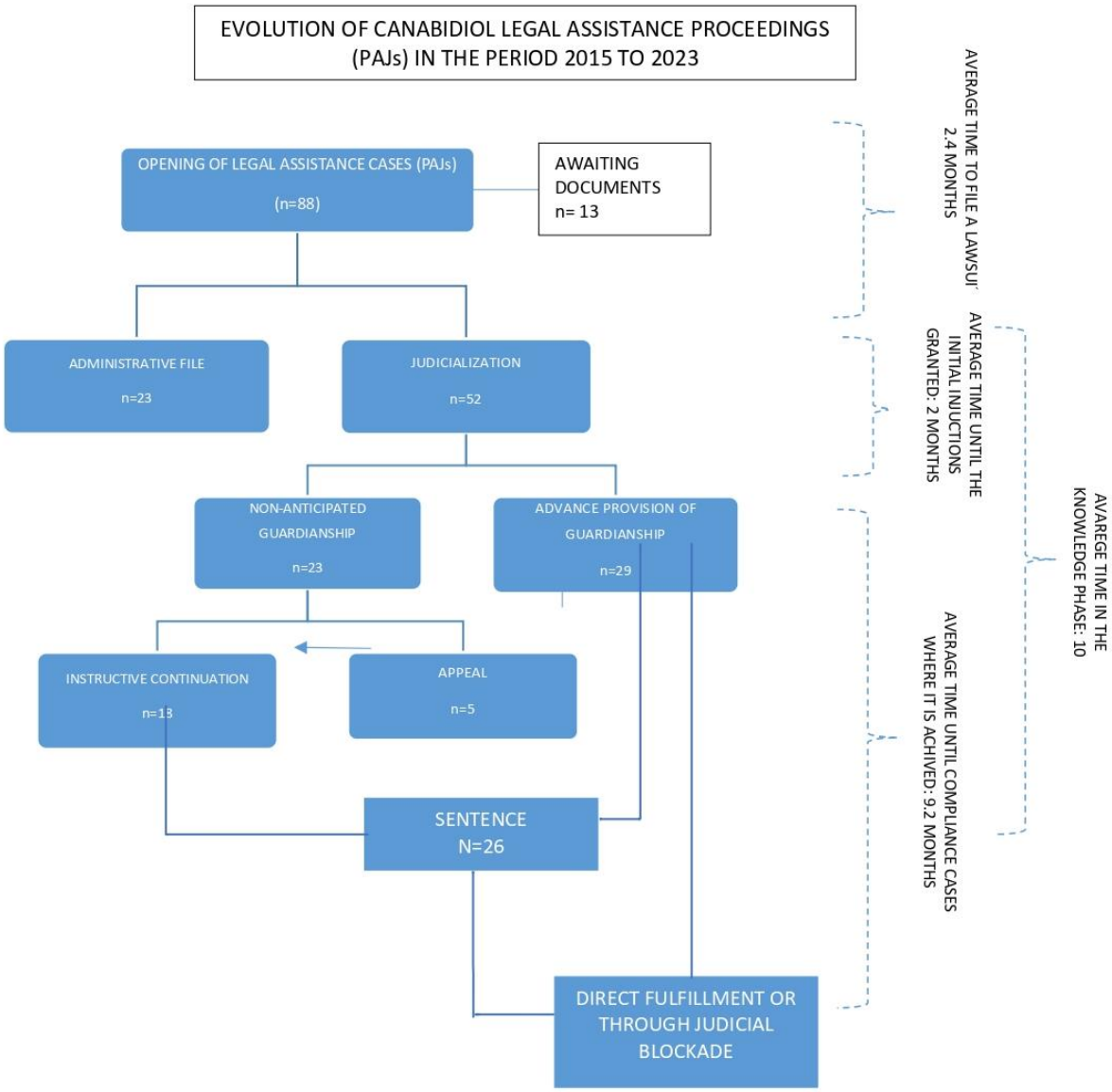
With the exception of ASD and ADHD, the other diagnostic causes were more frequent in older patients. These conditions not associated with seizures also had a higher rate of administrative filings due to lack of adequate supporting documentation or, in cases where they were judicialized, a higher number of dismissals or rejections due to lack of sufficient instruction or contrary technical opinions.

The qualitative description of the reasons for not going to court showed them to be more related to reasons for administrative filings (failure of the assisted person to return with the necessary documentation for more than six months, residence in a place that did not have a Federal Public Defender's Office office - which speaks against the compulsory federalization of demands for unincorporated inputs, an issue under discussion in the recent General Repercussion Theme Nº. 1.234/STF - and family income higher than the service ceiling of the public defender's office) or medical suspension. There were no cases of out-of-court settlements by administrative resolution, despite Salvador Municipal Law Nº. 9.663, of March 7, 2023, which:

> Provides for the Municipal Policy on the use of cannabis for medicinal purposes and the free distribution of prescribed medicines based on the plant, which contain in their formula the substances Cannabidiol (CBD) and/or Tetrahydrocannabinol (THC), in municipal and private public health units, or those affiliated with the Unified Health System - SUS, within the scope of the municipality of Salvador, and makes other provisions. (31)

Although it's not very common for the public to have access to private health insurance, there was also one request for closure due to obtaining the input from the supplementary health operator, obtained through the courts, but at the state level, which led to the PAJ being withdrawn. Finally, 43% (n=13) of the CBD requests opened in 2023, especially the most recent ones, have not yet been judicialized or filed, as they are awaiting pending documents needed to analyze judicial viability (Graph 2).

Graph 2- Course of the Cannabidiol legal aid cases (PAJs) studied and average times associated with the stages from administrative analysis to judicialization, preliminary injunction, knowledge phase and compliance.



Source: Author's illustrative graph, based on the data collected in the survey.

The percentage of total cannabidiol PAJs that were judicialized in the ten-year period from 2014 to 2023 was 59% (n=52) and, of those that were judicialized, approximately 56% (n=29) obtained a favorable preliminary injunction in some instance, and, as mentioned, in 2019 and 2023, the rate of denials exceeded that of preliminary injunctions in the first instance. The presence of the preliminary analysis by Nat-Jus Nacional has increased since the regulation of the center in 2019, with Bahia being the second state in the country that used the technical support the most in 2020, preceded only by Santa Catarina (35,36).

Only a minority (around 22%, with n=5) of the anticipatory denials were appealed. In the remaining cases, the decision was made to request further clarification from the prescribing doctor

about the points highlighted in court as the reason for the denial, in order to strengthen the instructional basis. The reasons for denial, although not quantified in isolation and alleged cumulatively in some decisions, consisted notably of: documentary deficits (such as more assertive medical reports and expired import authorizations during the course of the case); insufficient information about the use of the incorporated drugs available; lack of scientific evidence of safety or efficacy for the applicant's condition; non-specialist prescriber, although ANVISA Collegiate Board Resolution-RDC 327/19 does not require this (28), among others. Among the cases sentenced, there were ultimately more upheld sentences, representing 62% (n=16) of the total sentences handed down (n=26) and 76% of the sentences on the merits (n=21).

It should be noted that, in the period studied, only 50% of the lawsuits had a judgment issued by October/November 2023. It should also be noted, at this point, that because the value of the case, based on the annual cost of the prescribed drug, was less than 70 minimum wages, almost 85% of the lawsuits were filed with the Special Federal Courts (JEF) (n=44), which have speed as one of their guiding principles. Although the number of requests has gained momentum in the last five years, that is, since 2018, one would still expect a higher rate of sentenced cases.

With regard to concessions, the analysis was based on the date on which the summons was received by the body, and not the date on which the decision itself was issued. It was considered that only after publication does the decision take effect and that any time lapse between the decision being handed down and the parties being notified would also be a matter for the courts, not for the defense agency. On the other hand, the delay in compliance, from the date on which the preliminary injunction is served, whether in the form of an injunction, sentence or judgment, as well as the frequent need to order the sequestration of funds or a blockade in order to enforce the judicial command, indicate a failure, above all on the part of the defendants, who thus undermine judicial credibility and strength. The situation can only be attributed to the Judiciary when it takes too long to assess petitions reporting non-compliance and to demand compliance with its command, despite being informed of the delay. It should be noted that, even when provided for in the abstract, in none of the cases of non-compliance reported were astreintes (simply put, the daily fine set in the event of a delay in fulfilling the obligation by the party ordered to provide something judicially) applied.

Considering the specific analysis of compliance with the constitutional right to a reasonable duration of proceedings, both administrative and judicial, an aspect that contributes to the effectiveness of the social right under examination, four periods were evaluated. In the first, it was found that the time between the arrival of the assisted citizen at the defender's office and the filing of the lawsuit, after gathering the necessary documentation to support the initial petition, averaged 2.4 months, with a mode of “up to 1 month” and a median of 2 months. In other words: although there were some cases in which the party took a long time to present the necessary documentation (which generated the maximum variability of 11 months), once it was brought in, the lawsuit was drawn up and filed, most of the time, in a matter of days.

The average interval between the filing of the initial petition and the order for preliminary injunction, in the cases in which it was granted, was 2 months, with a mode of "up to 1 month" and a median of 1.5, even when it was analyzed by the Technical Support Centers. The variability found was 4 months in the cases in which the injunction was granted, i.e. there were judges who decided the injunction in less than a month, and others in just over four.

On the other hand, the interval between notification of the anticipatory decision and actual compliance fluctuated around 9.2 months, with extremes of more than two years and never less than 3 months, with a mode of 4, 9 and 10 months, a median of 8.5 months and variability of up to 24 months in cases where compliance has already taken place. It is worth noting that many are still waiting to be enforced and have therefore not been counted for this purpose. Two deaths were recorded during the wait, and no concession has yet been fulfilled in the processes started in 2023, with anticipation granted until November of the same year (n=3). In addition, compliance was only achieved after judicial blockage, sometimes repeated, in 69% (n=20) of the cases that had favorable decisions (n=29), including cases in which there had already been a final judgment.

The average time between the filing of the lawsuit and the sentence (knowledge phase) in cases that had already been sentenced was 10 months, with a mode of 6 and a median of 6.5. However, it should be remembered that half of the lawsuits surveyed had not yet been sentenced on November 20, 2023, at the time of the last consultation, and were therefore not counted. Furthermore, it should be noted that 19% of the sentences (n=5) were extinguished and handed down in the first few months of the proceedings, generally for failure to submit additional documentation deemed necessary to analyze the advance injunction. Considering only judgments on the merits, the average time taken to complete the knowledge phase was one year - 12 months - with a median of 11 months and a variability of 35 months.

Comparing the local data found with the national records published in 2020 by the National Council of Justice (CNJ) (37), it was observed that, with regard to procedural interregnums, the official data showed little difference when it came to State and Federal Justice, and recorded, with regard to procedural duration, "an average time of 9 months and 10 months, respectively, to judge the disputes, from the first movement to the first sentence of the case". When comparing the Ordinary Federal Court and its Special Courts, the Council identified that:

> With regard to the time it takes to become acquainted with the cases filed in the Federal Court, those received in the first degree had an average of 13 months from the first movement to the first sentence (...). The Special Courts of this segment of justice, following the pattern already mentioned, had an average time of 8 months until the first sentence. (37)

The purpose of this study was not to compare the results between state and federal courts, not least because, as of 2018, due to an inter-institutional agreement between the local State and Federal Public Defender's Offices, claims for drugs that had not been incorporated were directed entirely to the Federal Public Defender's Office. We also did not compare ordinary courts and Special Federal Courts (JEF), given the small number of lawsuits filed in the Ordinary Federal Court (eight) and, of these, those that had already been sentenced at the time of the research (only two).

With regard to preliminary injunctions, the local data identified greater speed in issuing preliminary injunctions, the average of which was two months in the period from 2015 to 2023 of the current study, while the national data indicated a longer period for the federal level:

> With regard to preliminary injunctions, between 2015 and 2020, (...) the State and Federal Justice segments recorded an average time of 1.4 months and 2.9 months, respectively, for the analysis of preliminary injunctions, whether granted or not, from the first movement of the case. (...)

> With regard to the time taken to analyze preliminary injunctions in cases filed in the Federal Court, (...) the first level of jurisdiction had an average of 3.9 months. The Special Courts in this segment of justice were not the fastest, contrary to what was identified in the State Courts. They had an average time of 3 months (37).

The national study did not analyze the issue of time taken to comply with decisions, an aspect that proved to be more relevant in the local research.

The local data is also close to what was found in a nationwide study, which analyzed 1,115 Natjus technical notes issued in cannabidiol lawsuits filed under the SUS between 2019 and 2022. This study found that 54.7% of patients were male, with an average age of 18.4 years, ranging from 0 to 90 years, and with epilepsy as the cause of the claim in 49.6% of cases (38). Regarding the content of the opinions, it was noted that:

> Of the 1,115 lawsuits submitted for evaluation in the period, 75.1% were based on scientific evidence - 35.2% of them had favorable opinions for access to CBD. Of the products sued, 43.4% were registered with Anvisa - 41.5% of them had favorable opinions. Only 29.8% of the therapeutic indications were in accordance with the product's registration with Anvisa - 53% of them received favorable opinions. Of the lawsuits, 29% sought products that had already been evaluated by Conitec, but 7.4% of them had been recommended for incorporation into the SUS. Of the lawsuits demanding products recommended by Conitec, 58.3% received favorable opinions (38).

On the other hand, the delay in implementing the court decision was also recorded in a case study carried out in the state of Pernambuco in 2019, which found lapses of four months to up to three years in the supply of the substance, in situations of successive non-compliance (39).

During the discussion of the data from the Salvador unit, it was suggested that this delay in compliance could be explained. It was questioned, for example, whether it could be caused by the social resistance that still exists in relation to the input under examination (19). Although no statistical comparison was made with another non-standardized drug in the same period, it doesn't seem to be a determining factor. In the day-to-day experience of working in health matters, there has been a notable delay in complying with injunctions for other drugs and procedures that have not been incorporated and which have been requested by the agency (in a quick underlying analysis, it was noted, for example, that there were seven reports of non-compliance in health in the last month surveyed (October 2023), out of the total number of procedures relating to health matters in the period (n=131), none of which dealt with the non-supply of cannabidiol. Seven new requests for the substance were opened at the unit that month). Furthermore, given the express judicial command, it would no longer be possible for any moral judgment by the defendants to affect compliance.

Nor does the price or difficulty of obtaining it seem to be sufficient justification for the delay. It should be borne in mind that this is not an exorbitant claim, and it was even made easier to obtain over the period studied, given that importation was waived in many of the cases, which already indicated a version available on the domestic market. It should be noted, however, at this point, that although the national product is simpler and easier to access, there has not been the substantial drop in cost that might have been expected (40). Even if these were the causes of the delay, since it was a substance outside the state's purchasing flow, it would be relevant, in any case, for this to be reported in the case file, with information on the measures taken and the timeframe for resolution. This care was not

observed in the cases examined, except for the first action brought in 2015, when the request still depended on complex import procedures, which were then communicated by the defendants.

The greater bureaucracy and expense of the individualized procedures for acquiring the unincorporated drug, in turn, while complicating matters for the Public Administration, would not justify such a lengthy delay. One wonders, by the way, if such obstacles shouldn't serve as a stimulus, at the state level, to broaden the discussion about the importance and need for more up-to-date lists for the incorporation of inputs that are in more frequent demand and whose scientific backing has already proven to be robust among specialists, in terms of safety and efficacy (not necessarily the case under examination here). Such a measure would favor the acquisition at a lower price and reduce the costs resulting from the frequent judicialization itself. It is inferred that this may even be the motivation for the multiplication of state and municipal regulations on the subject since 2020 (19), which, however, has not yet had a visible effect on reducing local defense demands for the drug.

Another hypothesis associated, this time, with the Judiciary's delay in enforcing its decisions, would point to judicial overload, but there is no way of ascertaining in this case whether the excess demand - numerical or of greater urgency - is due to the judicialization of health itself, since the lawsuits are filed in non-specialized courts: Special Federal Courts or Ordinary Civil Courts, and there are no exclusive health courts. In this sense, health claims would, a priori, be among those for priority analysis in those units. In addition, the majority of preliminary injunctions were granted with remarkable speed, as indicated by the averages calculated locally, which were even faster than the national data for the federal level (37). In this respect, it seems plausible to hypothesize that the fact that there is no immediate risk of death makes measures to ensure compliance or inhibit the defendants' delay less assiduous. Long waiting times, however, can end up causing severe damage, even in chronic cases (41), as well as undermining the very respectability of judicial decisions.

It is clear, therefore, that judicialization in health is a struggle that does not end, nor does it end with a favorable decision.

Conclusions

By way of concluding remarks - given that the issue of judicialization in health still seems far from its conclusion - it was found, in the light of the situation examined, that the work of the defense service proved to be conscientious in analyzing the demands and quick in filing them, as soon as the necessary documents were gathered to properly instruct the lawsuit. Similarly, the injunctions granted were prompt, even when they were reviewed by the Judiciary's Technical Support Centers, created by CNJ Resolution 238/2016. On the other hand, the time taken by the defendant state entities to comply with the decision has been alarmingly long, rendering the injunction vain in practice and for a long time.

It was thus found that the ineffectiveness of the social right in question migrated, to a certain extent, from the administrative to the judicial sphere, since even when non-compliance was reported, the Judiciary was unable to obtain compliance with its decision and the guarantee of the provision commanded within a reasonable time. In most cases, implementation was only achieved through repeated judicial blockades, and even then, with a significant delay in the transfer of resources. This fact was observed despite the fact that the indication was technically confirmed, the moderate value of the requests and the almost complete nationalization of the demand, which no longer requires

importing the input, and also the existence of a local law that would aim at the administrative supply of the input, which has been in force for almost a year.

The discussion about the judicialization of health covers multiple and inescapable challenges. The reality of scarcity and the dilemmas between accessibility and sustainability of the right, universality and equity of health provision are unlikely to find an easy or unique solution. Several advances have already been made over the last decade on the subject, such as, in judicial practice, the creation of Technical Support Centers, helping to make more informed preliminary injunction decisions, and the delineation of jurisdictional parameters by the Higher Courts, in order to favor legal certainty.

In the context of constitutional jurisdiction, the recognition of the judicialiability of the constitutional conformity of public policies and the affirmation of cooperative federalism in health matters and solidarity between entities are noteworthy, so as to avoid formal discussions ending up suppressing the right in practice. In the procedural sphere, the provision of *astreintes*, sequestration and blocking of funds and other mechanisms to ensure compliance with court decisions were important additions to enabling effective access to the health supplies claimed in court.

In medical practice, the adoption of Evidence-Based Medicine has led to more well-founded reports, although many still need to be studied in greater depth for the judicial purposes of prescribing drugs outside the framework, as seen in the causes of dismissal and rejection found. In the particular case of the substance under analysis, progress has been made in admitting domestic production, with quality criteria, and in gradually breaking down stigmas that discouraged discussion of the medicinal use of cannabinoid derivatives, among other aspects.

There is still a long way to go, however, to find mechanisms for access to health resources that do not overburden the state, the judiciary and the defense agencies so much. With regard to the latter, the need to better equip the institutions would be in line with the constitutional provisions on access to justice, and could help with this issue by, for example, providing a medical professional in the unit, given the difficulty for those assisted in obtaining timely appointments to seek the necessary reports and technical clarifications, as well as more specific filtering of demands.

Another possible idea would be to broaden the channels of administrative communication, with greater permeability to the defense agency by the Health Secretariats and even, nationally, with the Ministry of Health, in order to try to find out-of-court solutions to the demands, avoiding the need for individual or even collective actions for such discussions. For this to happen, however, it is still necessary to solve the problem of the structural shortage of the institution, which until now has been unable to fulfill the constitutional provision of reaching all the places where there is a federal court.

From the point of view of state entities, greater attention, speed and respect for court rulings are needed, especially considering that these demands are not too costly, which speaks in favor of a certain disorganization or even disregard for compliance. The very implementation of local rules on the specific subject could already prevent a large part of the current demands.

Finally, in the judicial sphere, the research carried out revealed the need for greater prioritization of health issues, even after the preliminary injunctions have been analyzed. The judiciary must pay close attention to reports of non-compliance in health matters, in order to ensure compliance with its own commands, through all procedurally available resources, as part of protecting the credibility of the judicial body itself, as well as guaranteeing the effective promotion of the right to health of the petitioning citizen.

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Conflict of interest
The author declares that there is no conflict of interest.

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