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Scientific consensus regarding judicial decisions on the provision of medicines not incorporated into the SUS

Scientific consensus in the face of court decisions on the granting of medicines not incorporated into the SUS

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SUMMARY

The right to health is one of the most sought-after rights in court, especially the provision of medications not covered by the SUS (Brazilian Unified Health System). As a result, legal instability exists, as judges do not always have the parameters to resolve such issues. On the other hand, social, technological, and informational advances are making people increasingly aware. With more information, they make demands on the State, requiring positive action from political and legal representatives. In this context, the Supreme Federal Court (STF) established parameters for granting medications and therapies not incorporated into the SUS (Unified Health System). It was decided that granting will be subject to high-level scientific evidence: randomized clinical trials, systematic reviews, or meta-analysis. Thus, it is understood that the STF established a *standard* of proof by establishing the types of evidence suitable for granting the right. The objective of this paper is to analyze the scientific studies required by the STF in the context of rare diseases and to question whether the applicant's requirement for high-level scientific evidence is reasonable. The method used was a qualitative approach, through a bibliographic review of national and international legal, medical literature, and an analysis of the STF's binding precedent and its impact on decisions regarding treatment for rare diseases. This approach is necessary, as judges are rarely aware of the production of this scientific evidence and the reasonableness of requiring it in all cases. Finally, we propose to shed light on the danger of a *standard* of evidence becoming a tariff-based test.

Keywords: evidentiary standard, information, health, evidence.

ABSTRACT

The right to health is one of the most sought-after rights in the courts, particularly the granting of medications not included in the SUS (Brazilian Unified Health System). As a result, there is legal instability, as judges do not always have the parameters to resolve such issues. On the other hand, social, technological, and informational advances make people increasingly aware. With more information, they make demands on the State, requiring positive action from political and legal representatives. In this context, the Supreme Federal Court (STF) established parameters for the granting of medications and therapies not included in the SUS (Brazilian Unified Health System). It was decided that granting of medications and therapies will be subject to high-level scientific evidence: randomized clinical trials, systematic reviews, or meta-analysis. Thus, it is understood that the STF established a standard of proof by establishing the types of evidence that are appropriate for granting the right. The objective of this paper is to analyze the scientific studies required by the Supreme Federal Court (STF) in the context of rare diseases and to question whether the requirement for high-level scientific evidence by the applicant is reasonable. The method used was a qualitative approach, through a literature review of national and international legal, medical literature, and an analysis of the binding precedent of the Supreme Federal Court (STF) and its impact on decisions regarding treatment in rare diseases. This approach is necessary because judges are rarely aware of the production of this scientific evidence and the reasonableness of requiring it in all cases. Finally, the aim is to shed light on the danger of a standard of proof becoming a tariff-based proof.

Keywords: evidentiary standard, information, health, evidence.

1. INTRODUCTION

The judicialization of health has increased over the years in the Brazilian justice system. There is a growing impasse between therapies coming to market (with protocols, treatments, medicines, etc.) and the possibility of the State providing them through the SUS. At the same time, people are increasingly aware and informed of their rights.

So that the goods of life are enjoyed by citizens, including the right to life and health, renowned authors of constitutional law, such as Paulo Bonavides, among others, affirm the importance of the right to information, as a fourth dimension right, to be guaranteed by democratic countries.

It is through the right to information that citizens can be informed and, in possession of this knowledge, take your demands to the state agents responsible for applying them in the public policies and in the provision of judicial decisions.

In this scenario, the information taken to the judiciary to grant the right to health is fundamental importance. After all, the breadth of information can be crucial for formulating the judge's value judgment on whether or not to grant the requested request.

Among the demands brought to court regarding the right to health, there are: requests for the provision of medicines not incorporated into the SUS by Conitec. They are medicines, often used in rare diseases that, due to their rarity, of the disease, may not have scientific studies with the same rigor as the others medicines for non-rare diseases.

However, the STF still established as *a standard* of evidence the understanding that for the granting of medicines for rare diseases, the existence of high-level evidence studies: randomized clinical trials, systematic reviews and meta-analysis.

The aim of the present study is to investigate these types of high-level evidence and question whether they are suitable to be used as *a standard* of evidence, or whether, at the same time, establish such strict standards of probative force, the STF would not be establishing a standard more focused on a fee-based test, removing the power of information produced by other means scientific and academic to influence the judge's decision.

It is expected that the analysis will bring legal operators closer together, especially magistrates, with the generation and discussion of scientific data and broaden the debate on the

requiring such strict standards in cases of rare diseases. This is an analysis of which scientific consensus is necessary to influence the judge's decision.

2. INFORMATION, PLURALITY AND DEMOCRACY: HOW FOURTH GENERATION RIGHTS CAN INFLUENCE JUDICIAL DECISIONS

Demands regarding the right to health, within the judiciary, are growing above the average of other demands. This is the conclusion presented by the National Council of Justice, in recent data release1 . This problem arises from a demand from society for one of the most basic fundamental rights of all: life in dignified conditions, the right to enjoy health.

In this sense, it is necessary to bring to light the doctrine of Paulo Bonavides2, according to which societies are moving towards a future model in which the universality of rights will have maximum dimension. Thus, in universal societies, it will be possible for fundamental rights already recognized – life, health, security, housing, property, freedom, among others – are effectively enjoyed by all citizens. For this future to happen, it is necessary that fourth-dimensional rights are respected. These are: the right to democracy, to information and pluralism.

The author informs that such rights can only be implemented thanks to the advances in communication technology. And no wonder, with decentralized information that individuals can have a voice and inform themselves and, in this way, can raise issues individual and social to State agents, so that these issues are addressed and resolved through inclusive public policies, which, in turn, only exist in societies democratic.

It is in this sense that the author argues that universal society will exist in an environment democratic, plural and with free circulation of ideas, as follows:

> Thus, it must also be a democracy free from the contamination of manipulative media, and from the exclusionary, autocratic, and unitarist hermeticism familiar to power monopolies. All this, of course, if information and pluralism prevail equally as parallel and supporting rights of democracy;

1 BRASILIA. National Council of Justice. Executive Summary. Judicialization of Health in Brazil: Profile of Demands, Causes, and Proposed Solutions. **Research Institute – INSPER.** 2019. 15 p. Available at: https://www.cnj.jus.br/wp-content/uploads/2018/01/f74c66d46cfea933bf22005ca50ec915.pdf. Accessed on August 27, 2025.

2 BONAVIDES, P. **Constitutional Law Course.** 15th ed. Bahia: Malheiros. 2010. 571-572 p.

It is possible to see that the author defends the three fourth generation rights intrinsically interconnected and capable of working in favor of the citizen. In this way, it is the individual which, inserted in a democratic society, monitors rights and exercises acts of control before legitimate institutions in order to protect them. Only then will a future in that the freedom of the people prevail. To this entire process of information, plurality and democracy, which works for the benefit of the citizen, the author calls political globalization.

According to another constitutionalist, author Marcelo Novelino3 , which also corroborates the rights of the fourth dimension along the lines of Paulo Bonavides, the fundamental right information is a corollary of the democratic system and the republican model, indispensable to government oversight and accountability.

Freedom of information encompasses three rights: 1. The right to inform; 2. The right to be informed and 3. To be informed. The first deals with a constitutional prerogative to transmit the information. The second, the right to seek information without disproportionate embarrassment and unfounded, while the third deals with the willingness of public bodies to offer information of particular interest.

Before proceeding, it is necessary to make a distinction. When talking about the right to information is referring to the citizen's right to access government data, mainly, the data that the government has about the person himself, in addition to the data about the government itself4 . This article is not about that topic. Here, it is about the right free circulation of ideas as an instrument for building knowledge and adapting the functioning of the State to the level of wisdom consolidated in society. It is this concept that is closer to the notion of pluralism, information and democracy, already conceptualized as fourth generation rights.

Thus, considering that information is an instrument for people to achieve the materialization of their rights, is what makes it so important to investigate how the information is available and active within the bodies of power responsible for implementing such rights directly into the lives of citizens, including the judiciary.

In this context, one of the most relevant national themes is the implementation of fundamental right to health. According to data released by the National Council of Justice, there was an increase of approximately 130% (one hundred and thirty percent) in the number of

3 NOVELINO, M. **Constitutional Law Course.** 11th ed. Bahia: Juspdvm. 2016. 365-367 p.
4 CEPIK, M. Right to information: legal situation and challenges. Available at: https://www.researchgate.net/profile/Marco_Cepik/publication/228601349_Direito_a_informacao_situacao_legal_e_desafios/links/54232fe90cf26120b7a6bd64.pdf. Accessed on 06/07/2025.

annual demands related to the right to health from 2008 to 2017. When comparing this growth with the other demands of the judiciary, it is clear that the demand related to health, in a general context, when considering the demands on health plans, insurance and health, medical and hospital treatment and supply of medicines, is much higher than the growth in general demands of the judiciary5 .

It was based on this problem that the Supreme Federal Court carried out the trial of RE 1366243/SC, which proposed to establish guidelines on a specific topic of judicialization of health, namely the granting of high-cost medicines, especially, in the case of those medicines not incorporated into the SUS. The Supreme Court tried to delimit the information necessary for the judge to be able to carry out the deliberation judgment by whether or not to grant the medicines, as will be demonstrated below.

3. SCIENTIFIC EVIDENCE AND THE SUBJECT OF GENERAL REPERCUSSION 1234 OF THE STF

The Supreme Federal Court, when judging RE 1366243/SC, expressed its opinion on the subject of general repercussion 1234, which deals with the granting of health treatment with medicines incorporated and not incorporated into the SUS. When addressing the issue, the STF reached a consensus on the jurisdiction to judge these cases as well as the possible treatments to be be made available and under what conditions.

This work deals with a specific aspect of this topic, which is the granting of medicines not incorporated into the SUS, whether recognized or not by ANVISA, because they are generally dealing with high-cost medications for rare diseases.

Initially, it is necessary to define the requirements necessary for a disease to is considered rare. According to the WHO, a rare disease is one that affects 65 people every 100,000 individuals. It is estimated that in Brazil there are 13,000 people who have some type of rare disease.6

5 BRASILIA. National Council of Justice. Executive Summary. Judicialization of Health in Brazil: Profile of Demands, Causes, and Proposed Solutions. **Research Institute – INSPER.** 2019. 15 p. Available at: https://www.cnj.jus.br/wp-content/uploads/2018/01/f74c66d46cfea933bf22005ca50ec915.pdf. Accessed on August 27, 2025.

6 Pfizer. News. Rare diseases – what are they and why are they called that? https://www.pfizer.com.br/noticias/ultimas-noticias/doencas-raras-quais-sao-e-porque-sao-chamadas-assim#:~:text=O%20conceito%20de%20Doen%C3%A7a%20Rara,de%20pessoas%20t%C3%AAm%20doe rare%20n%C3%A7as. Accessed on 08/24/2025.

Regarding non-incorporated medicines, according to the STF7 ruling itself , are those that are not included in the SUS policy; or medications provided for in the Protocols Clinical and Therapeutic Guidelines (PCDT) for other purposes; or even medications without registration with ANVISA; in addition to off-label medications – uses other than those prescribed in the package insert - without PCDT or that do not include lists of the basic component.

For these specific cases, the STF established some premises for the judicial analysis of the administrative acts of refusal of medicines. They are:

> 4) Under penalty of nullity of the jurisdictional act (art. 489, §1º, V and VI, combined with art. 927, III, §1º, both of the CPC), the judiciary, when assessing a request for the concession of non-incorporated medicines, must mandatorily analyze the administrative act of commission or omission of non-incorporation by Conitec and the refusal to supply in the administrative route, as agreed between the federative entities in self-composition at the Supreme Federal Court.
>
> 4.1) In exercising legality control, the judiciary cannot replace the will of the administrator, but only verify whether the specific administrative act of that specific case is in compliance with the guidelines present in the Federal Constitution, the governing legislation and the public policy in the SUS.
>
> 4.2) The jurisdictional analysis of the administrative act that rejects the supply of non-incorporated medicine is limited to examining the regularity of the procedure and the legality of the act of non-incorporation and the administrative act in question, in light of the legality control and the theory of determining reasons, and it is not possible to incur in the administrative merit, except for the cognition of the discretionary administrative act, which is linked to the existence, veracity and legitimacy of the reasons indicated as grounds for its adoption, to subject the public entity to its terms.
>
> 4.3) In the case of a non-incorporated drug, the burden of demonstrating, based on evidence-based medicine, the safety and efficacy of the drug, as well as the non-existence of a therapeutic substitute incorporated by the SUS, lies with the plaintiff.
>
> 4.4) According to the decision of STA 175-AgR, the simple allegation of need for the medication is not enough, even if accompanied by a medical report, and it is necessary to demonstrate that the professional's opinion is supported by high-level evidence, that is, only randomized clinical trials, systematic review or meta-analysis.

In view of the above, it is clear that the granting of non-incorporated medicines must fulfill the following assumptions: 1) analyze the administrative act of commission or omission of the non-incorporation by Conitec and the refusal to supply through the administrative route; 2) verify whether the administrative act that denied the incorporation of the drug is in compliance with

7 BRAZIL. Superior Federal Court. **Special Appeal No. 1366243 – SC. 2024.** Theme 1234 - Passive legitimacy of the Union and jurisdiction of the Federal Court, in lawsuits concerning the supply of medicines registered with the National Health Surveillance Agency - ANVISA, but not standardized in the Unified Health System - SUS. Appellant: State of Santa Catarina. Respondent: Union. Rapporteur: Min. Gilmar Mendes. 2024. Available in: https://portal.stf.jus.br/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=6335939&numeroProcesso=1366243&classeProcesso=RE&numeroTema=1234. Accessed on: August 27, 2025.

the guidelines of the Federal Constitution, governing legislation and public policy in the SUS; 3) analyze the regularity of the procedure and the legality of the act of non-incorporation and the act administrative questioned; 4) demonstrate, based on medicine based on evidence, safety and efficacy of the drug and 5) demonstrate that the granting of the drug is supported by high-level evidence, that is, only in clinical trials randomized, systematic review or meta-analysis.

Evidently, the judicial decision to grant medicines must be well substantiated in order to avoid the granting of supposed drugs that promise a cure or reduction of symptoms, but without real effectiveness. Furthermore, it should be considered that people who have rare or incurable diseases are more likely to seek alternative treatments, which do not have proven scientific efficacy. Even though we consider that health and life are central elements of human dignity, we cannot forget that the resources of the state to meet public and social needs are finite, therefore, they must be employed sparingly.

However, an important question must be raised about the guidelines set by the STF. Would the judges be prepared—provided with sufficient information—to declare null and void the refusals to incorporate medications made by Conitec? Is it possible? to the parties, especially those at a disadvantage, to bring such information to the records, especially when high-level scientific evidence is required, such as clinical trials randomized, systematic review or meta-analysis?

Such questions were raised in the context of the declaration of embargoes to the RE 1366243/SC by the Strategic Action Group of the State and District Public Defender's Offices in the Superior Courts – GAETS8 :

> Most users of the Unified Health System are in a situation of high social, economic and legal vulnerability, and even those with a moderate financial situation do not have access to technical bodies that can assist them in defending the fundamental right to health or carry out some type of analysis of the effectiveness, accuracy and cost-effectiveness of the medication for the purpose of contradicting CONITEC's opinions.
>
> The process of incorporating medicines involves complex analyses of technical studies, cost-effectiveness and budgetary impact, which, in addition to requiring

8 BRAZIL. Superior Federal Court. Special Appeal No. 1366243 – SC. 2024. Theme 1234 - Passive legitimacy of the Union and jurisdiction of the Federal Court, in lawsuits concerning the supply of medicines registered with the National Health Surveillance Agency - ANVISA, but not standardized in the Unified Health System - SUS. Appellant: State of Santa Catarina. Respondent: Union. Rapporteur: Min. Gilmar Mendes. 2024. Available in: https://portal.stf.jus.br/jurisprudenciaRepercussao/verAndamentoProcesso.asp?incidente=6335939&numeroProcesso=1366243&classeProcesso=RE&numeroTema=1234. Accessed on: August 27, 2025.

> specialized technical knowledge is hampered by the lack of access to detailed information, which is generally restricted to public administrators and CONITEC members themselves. We are also talking about a type of analysis that would require a very long timeframe.(…)
> The situation is especially dire when the plaintiff presents sufficient evidence of the indispensability and ineffectiveness of the drugs provided by the SUS for treating the disease. If the patient/jurisdictional entity only has access to the claimed treatment if they can prove that the CONITEC administrative process was improperly conducted or that the Commission's conclusions are tainted by illegality or misuse, access to treatment will be virtually impossible, even if the plaintiff has a detailed medical prescription and even a favorable technical note issued by a NATJUS. It is important to highlight that, in other universal health systems, such as the United Kingdom, there are ways for patients to gain access to treatments that are not incorporated as essential and cannot be replaced by the alternatives available to the general population. (eDOC 542, p. 22)

The appellant's argument is that such medicines for rare diseases, cancer treatments and new emerging therapies cannot be held to the same standards rigorous scientific proof that other common medications have, such as large controlled clinical trials and systematic scientific reviews with meta-analysis. While scientific standards are important, for this specific case of disease, the proof of sufficient evidence of quality, safety, efficiency and effectiveness registered with Anvisa and other reputable international health regulatory agencies how the *Food and Drug Administration* (FDA) and *European Medicines Agency* (EMA) could be sufficient.

Therefore, two problems have been identified. The first is related to medications. that do not have high-level evidence but have other scientific proof of quality, safety, efficiency and effectiveness. The second refers to the issue that even if such high-level scientific evidence exists, the lack of technical expertise of those in need of such medicines, to prove in the process that requires their concession, can make it impossible to grant the right to health.

4. SCIENTIFIC EVIDENCE: RANDOMIZED CLINICAL TRIALS, SYSTEMATIC REVIEW, AND META-ANALYSIS

According to the Brazin Journal of Videoendoscopic Surgery9 , clinical trials are studies formed with two groups of patients: one that uses the therapy, or experiment, and another that

9 OLIVEIRA, MAP; PARENTE, RC M; Understanding randomized clinical trials. **Brazilian Journal of** Clinical Trials **of Videoendoscopic Surgery.** p. 176. Available at: https://www.sobracil.org.br/revista/jv030304/bjvs030304_176.pdf. Accessed on August 27, 2025.

does not use it, called a control group. In this type of study, the researcher plans and intervenes activation in the factors that influence the sample, which has the consequence of minimizing the influence of factors that may confound the results. When the allocation of research participants is carried out randomly, there is a clinical trial randomized.

The author emphasizes that randomized clinical trials are the gold standard for determination of a therapeutic approach, but they are laborious and costly, which means that its development brings several practical challenges.

Regarding the systematic review, according to the Brazilian Journal of Physiotherapy10, This is research that uses literature on a given topic as a data source. In this research, a summary of the evidence regarding a specific strategy is made, that uses explicit and systematic methods of search, critical assessment and synthesis of information. The idea is that this systematized summary can incorporate a broad spectrum of relevant results, expanding the number of published studies.

However, the author emphasizes that this type of study is retrospective, secondary, for cases in which there are many experimental studies on a topic, which depends, above all, on the quality of the primary source. Therefore, it may not be possible to carry it out in some rare diseases.

Regarding meta-analysis, according to the Brazilian Society of Cardiology11, “it is a statistical method used in the systematic review to integrate the results of the groups included and increase the statistical power of primary research.” It is indicated for the analysis statistics from many individual studies to integrate the results.

In other words, we have the same problem, treatment with medication does not always work. incorporated into the SUS will have sufficient scientific literature available for this further analysis robust collection of data and cases.

In view of the above, it is clear that the STF, when imposing scientific evidence necessary for the granting of a certain medicine or therapy created a *standard* evidentiary. According to the literature on the subject12:

10 SAMPAIO, RF; MANCINI MC; Systematic review studies: a guide for careful synthesis of scientific evidence, **Brazilian Journal of Physiotherapy.** Vol. 11. 2007. p. 84. Available at: https://www.scielo.br/j/rbfis/a/79nG9Vk3syHhnSgY7VsB6jG/?lang=pt. Accessed on August 27, 2025.

11 SOUSA., MR RIBEIRO, ALP; Systematic review and meta-analysis of diagnostic and prognostic studies: a tutorial. **Brazilian Society of Cardiology.** 2009. p. 241. Available at: https://www.scielo.br/j/abc/a/fM7by9YHVXjb3GbdnnMcdJv/abstract/?lang=pt. Accessed on August 27, 2025.

12 MOURA, Clenio de Assis Manoel. Evidential standards and reasonable doubt applied to Brazilian criminal proceedings. Final Course Work. President Antônio Carlos University Center. Barbasena,

> Standards of *proof* are mechanisms that have their origins in the common law tradition, representing a degree of sufficiency that the factual hypothesis must overcome in order to be considered true. (…)
> We can define the evidentiary *standard* as the "amount" of evidence required to reach a decision. The *standard* is met when the level of confirmation meets the adopted standard. It is a benchmark that determines the minimum level of proof required to consider a fact proven.

It is, therefore, the establishment of an evidentiary *standard* that restricts the judge, in cases where it is possibly an impossible *standard* to achieve, since the subject matter under analysis – granting of medicines for rare diseases and without registration by the SUS – no involves such rigorous procedures.

5. WHO DECIDES: THE JUDGE, THE DOCTOR OR THE SCIENTIST?

The STF, when demanding robust scientific evidence for the granting of non-prescription drugs, acts in an unreasonable way. One of the greatest characteristics of science is, precisely, the reliability. For a new method, product, therapy, among others, to be declared reliable it is necessary that this enterprise be able to be approved by members of the scientific community.

Thus, several reapplication and reproduction tests are carried out, if the statements scientific – initially noted by the developers of the new venture - withstand several repeated tests, and show the same results, duly certified by the scientific community, then we are dealing with a reliable enterprise. Otherwise, it is not possible to distinguish the effectiveness of the product by simple randomness.

As a consequence of scientific activity itself, the question remains: if a medicine can only be granted in case of scientific consensus, which was generated through supported by high-level evidence, who will decide whether to grant it in the specific case: the judge, the doctor or scientist?

Minas Gerais. 2021. Available at: https://ri.unipac.br/repositorio/wp-content/uploads/tainacan-items/282/115531/Clenio-de-Assis-Manoel-e-Moura.pdf. Accessed on: August 27, 2025.

13 National Academies of Sciences, Engineering, and Medicine. (2019). Reproducibility and Replicability in Science. Washington, DC: **The National Academies Press.** Available at: https://doi.org/10.17226/25303. Accessed on June 7, 2025.

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A close approach to the topic was carried out by Dr. Murilo Avelino14, in the work:
The control of technical and scientific evidence, when dealing with the issue when the specific case depends of expert report.

> The judge is not bound by the report's attestation. It is possible that the expert evidence, when analyzed individually, may lead to a certain position not corroborated by the other evidence in the case file, or even that even after all prior instruments and controls have been passed, only after the report is presented will the unsuitability of the method or technique applied be determined.
> The fact is that an expert opinion cannot follow a judgment rule, following the expert's report without any critical judgment. In other words, the expert's statement alone is not sufficient to rule it (un)founded. Doing so would return us to a system of standardized evidence.

In this context, it is argued that technical and scientific evidence, despite being very important cannot, by themselves, determine the judgment of the case. For, in truth, the role of the evidence is to provide sufficient information to the judge so that a judgment can be made of value, well-founded, between granting or not the request for the action. As the author rightly says, if If this is not the objective, we fall into the error of returning to the priced tests – tests with value previously defined, regardless of the specific case - which are currently incompatible with the constitutionalized civil process.

There is currently a consensus in terms of process that achieving total truth within of the process is impossible, because even science, in its quest to understand reality, is failure. The rational knowledge that can be extracted is that within a given context, to what procedural scholars call possible truth, that is, the necessary and sufficient truth that serves as the basis for a fair sentence15.

In this sense, by requiring justification only for randomized clinical trials, systematic review or meta-analysis for the granting of new drugs, despite being well intended, the STF seems to be more focused on the assessment of tariff evidence than, properly, the reasoned conviction of the decision, which could come from other evidentiary elements other than those listed by the court, even though their importance is recognized.

CONCLUSION

Whether or not medication not incorporated into the SUS is granted depends on a series of factors: of factors that must be very carefully considered, after all, it is a fundamental right of

14 AVELINO, Murilo Teixeira. The control of technical and scientific evidence. Thesis (Master's in Law) – Recife Law School, Pernambuco Federal Unit. Recife, Pernambuco, 2016. 232 p.
15 DIDIER, F. **Course in civil procedural law.** 2nd ed. Bahia: Juspdvm. Vol. 2. 2016. p.

of utmost importance, namely people's health. As the judicialization on the subject is expressive and lack of uniformity in decisions, causing legal uncertainty, the STF decided establish guidelines for judges to deal with cases objectively.

In this context, we sought to delve deeper into the types of scientific evidence established by STF as able to grant the requested medication or treatment, to respond the following questions: is it reasonable to require high-level scientific evidence for granting of medicines not incorporated into the SUS, especially when it comes to rare diseases? Could this requirement prevent other information from influencing the judges' decision? Is it reasonable to require this type of evidence from disadvantaged individuals who do not have scientific technical knowledge?

To answer these questions, it was laid out in the previous topics on the law to information as an instrument for the acquisition of fundamental rights before the bodies public. In this sense, individuals equipped with information capable of guaranteeing their rights can take this knowledge to the state so that they can implement it through of the conviction of their point of view. With the state's judicial activity, it should not be different.

However, when deciding on the granting of medicines and treatments not registered with the SUS the STF set parameters that are difficult for the common man to achieve, because in addition needing analysis of the illegality of the administrative act that decided not to incorporation of the drug, it is also required to demonstrate scientific evidence of high level, solely through randomized clinical trials, systematic reviews and meta-analysis.

The problem is that establishing this evidentiary *standard ,* while difficult to the common man, especially in situations of insufficiency, assisted by the public defender's office public, it also hinders the party's power of influence, since other means of proof will not be taken into consideration by the judge. A *standard* of evidence should not be established of this level for cases in which there is no well-established scientific consensus.

It turns out that, in the field of medicine, each disease and clinical condition has its own particularities. Although the judge considers the cost and effectiveness of granting the treatment, should also consider possible alternatives, justifying the possible concession in other evidence, those that – despite not being of a high level – are registered with Anvisa and those with procedures adopted by other agencies health regulators in other countries, who may already have knowledge about the application of these treatments in more advanced stages.

The use of *off-label* medications itself may not have the robustness of data scientific requirements, but medical routine demonstrates the positive effects of the procedures, opening up possibilities so that, in the future, these data can be catalogued and studied in relevant scientific works. Therefore, in addition to scientific evidence, required by the STF, the judge must have the breadth to rely on other grounds, such as medical experience and technical advice, valuing all available data according to each specific case.

As a solution, the preparation of competent judges to decide this could be discussed. type of demand regarding scientific production and the different types of evidence available, so that the public authorities provide the necessary training to magistrates, with the purpose that they are more familiar with scientific production and its impact on medicine, as well as with the process of incorporating new procedures into the SUS, but in a way some control over what may or may not influence the judge's decision when the case concerns diseases in which medicine has not yet managed to find a cure.

Therefore, it is necessary that the parties have the right to inform themselves and the court, in order to influence the judge through the wide possibility of evidence provided to the process, so that the right to adversarial proceedings and full defense are respected. However, solution presented by the STF instead of expanding ends up restricting the power of influence of parties to the proceedings.

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