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Article

Changes brought by Theme 1234 to Health Judicialization and Role of Public Defenders

Modificações trazidas pelo Tema 1234 à Judicialização em Saúde e Atuação das Defensorias Públicas

Modificaciones introducidas por el Tema 1234 en la Judicialización en Salud y Actuación de las Defensorías Públicas

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Abstract

Objective: To evaluate the changes resulting from the judgment of Theme of General Repercussion No. 1234 by the Federal Supreme Court in the judicialization of health and its impact on the performance of Public Defender's Offices for the access to health justice by the underprivileged population. **Methodology:** critical analysis of the jurisprudential change represented by the decision in question, especially in view of the paradigm of federative solidarity in health matters. The study was developed in a descriptive way, through jurisprudential, bibliographic and institutional database research, based on the historical evolution that supported the ruling and on the comparison with other cases decided by the Court. It culminates in an exploratory evaluation of the repercussions of the decision on the provision of legal assistance by the defender's bodies, in the context of the right to health. **Results and discussion:** From the analysis of the ruling, in comparison with the conduct in force until then in the judicial phasis, the following were observed, as main changes: the definition of cases of federal and state jurisdiction for pharmacological assistance, the emphasis on calculating the value of the claim according to official and non-market parameters, the orientation about the way of compliance, the creation of a national platform. The new discipline also highlighted the need for the Federal Public Defender's Office to be internalized in order to take on federalized demands, which, however, clashes with the structural reality of the agency. **Conclusion:** in spite of the intention of systematizing and rationalizing the matter, the decision of Topic 1234 seems, at first, to pose serious practical difficulties to the realization of the right to health through the courts, notably, in federalized cases, for the underprivileged population, largely dependent on the Unified Health System and on the public defense assistance.

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Keywords: Right do Health; Health's Judicialization; Jurisprudence.

Resumo

Objetivo: avaliar as modificações decorrentes do julgamento do Tema de Repercussão Geral nº 1234 pelo Supremo Tribunal Federal na judicialização da saúde e seu impacto na atuação das Defensorias Públicas e no acesso à justiça sanitária pela população hipossuficiente. **Metodologia:** análise crítica da mudança jurisprudencial representada pela decisão em exame, sobretudo em face do paradigma da solidariedade federativa em matéria de saúde. O estudo foi desenvolvido de forma descritiva, mediante pesquisa jurisprudencial, bibliográfica e em bancos de dados institucionais, partindo da evolução histórica que embasou o acórdão e do cotejo com outros posicionamentos judiciais. Culmina em avaliação exploratória acerca de como o decisum repercute na prestação da assistência jurídica pelos órgãos defensoriais, no âmbito do direito à saúde. **Resultados e discussão:** da análise do acórdão, em comparação com a condução até então vigente, observaram-se, como principais alterações: a definição dos casos de competência federal e estadual para a assistência farmacológica, a ênfase no cálculo do valor da causa segundo parâmetros oficiais e não mercadológicos, a orientação do modo de cumprimento, a criação de plataforma nacional. A nova disciplina evidenciou, ainda, a necessidade de interiorização da Defensoria Pública Federal para assunção das demandas federalizadas, o que, todavia, choca-se com a realidade estrutural do órgão. **Conclusão:** em que pese a intenção de sistematização e racionalização da matéria, a decisão do Tema 1234 parece, de início, importar sérias dificuldades práticas à efetivação do direito à saúde pela via judicial, notadamente, nos casos federalizados, para a população hipossuficiente, amplamente dependente do Sistema Único de Saúde e da assistência defensorial.

Palavras-chave: Direito à Saúde; Judicialização da Saúde; Jurisprudência.

Resumen

Objetivo: Evaluar los cambios resultantes de la sentencia del Tema de Repercusión General Nº 1234 del Supremo Tribunal Federal en la judicialización de la salud y su impacto en el desempeño de las Defensorías Públicas y en el acceso a la justicia en salud de la población desfavorecida. **Metodología:** Análisis crítico del cambio jurisprudencial que representa la decisión en cuestión, especialmente a la luz del paradigma de la solidaridad federativa en materia de salud. El estudio se desarrolló de manera descriptiva, a través de investigaciones jurisprudenciales, bibliográficas y de bases de datos institucionales, a partir de la evolución histórica que sustentó la sentencia y a partir de la comparación con otras decisiones judiciales. Culmina con una evaluación exploratoria de cómo la decisión repercute en la prestación de asistencia jurídica por los órganos de la defensoría, en el contexto del derecho a la salud. **Resultados y discusión:** Del análisis de la sentencia, en comparación con las conductas vigentes hasta entonces en la fase judicial, se observaron, como principales cambios, los siguientes: la definición de los casos de jurisdicción federal y estatal para la asistencia farmacológica, el énfasis en el cálculo del valor del crédito de acuerdo con parámetros oficiales y no de mercado, la orientación del modo de cumplimiento, la creación de una plataforma nacional. La nueva disciplina pone de manifiesto la necesidad de internalizar la Defensoría Pública Federal para asumir las demandas federalizadas, lo que, sin embargo, se choca con la realidad estructural del órgano. **Conclusión:** a pesar de la intención de sistematizar y racionalizar la cuestión, la decisión del Tema 1234 parece, en un primer momento, plantear serias dificultades prácticas para la realización del derecho a la salud por la vía judicial, en particular, en los casos federalizados, para la población desfavorecida, en gran medida dependiente del Sistema Único de Salud y de la asistencia a la defensa pública.

Palabras clave: Derecho a la Salud; Judicialización de la Salud; Jurisprudencia.

Introduction: Theme 1234, in the historical course of health judicialization in Brazil

On September 19, 2024, the Federal Supreme Court published a ruling by Justice Gilmar Mendes in Extraordinary Appeal Nº. 1.366.243/SC, deciding General Repercussion Topic Nº. 1234(1) and promoting intense changes in the way public health is judicialized in the country. It should be noted that, since the new formulations of jurisdiction were the result of an inter-institutional agreement, there is no question of usurping legislative or even constitutional powers in this case. The *decision* was also the basis for the proposal for Binding Precedent No. 60(2), which established that:

> The administrative request and analysis of drugs in the public health network, the judicialization of the case, as well as its consequences (administrative and jurisdictional), must comply with the terms of the 3 (three) inter-federative agreements (and their flows) ratified by the Federal Supreme Court, in collaborative judicial governance, in theme 1.234 of the general repercussion system (RE 1.366.243).(2)

The Federal Public Defender's Office[3], in its capacity as *Amicus Curiae*[4] , has filed a Motion to Set Aside the Judgment, notably in view of the modulation of effects provided for in the supplementary role of the State Public Defender's Offices in federalized cases, while the federal body is not equipped to take them on throughout the country. The content of the ruling, however, has already been in force since the date of its publication, giving rise to a number of questions, even from those who work on the matter on a daily basis.

The leading vote in the leading case[5] results from a historical construction that has been developed through the Judiciary's(3) decisive role in ensuring the social right to health, especially highlighted since STA 175(4), published on April 30, 2010. Since then, other Issues of General Repercussion have also held significant importance, starting with Issue Nº. 06 (RE 566471)(5), which addressed whether there is a state obligation to provide high-cost medications, published on December 7, 2007. In the present case, the final decision outcome resulted from the evolution of three inter-federative agreements drafted throughout the process and now endorsed as a whole in the vote and referenced summative statement.

The issue of judicialization in health has been a very frequent concern in Brazil. On the one hand, it is an important mechanism for making the fundamental social right in question effective, in both its individual and collective subjective spheres, including the right to the rules and measures necessary for its proper implementation(6). On the other hand, the growth in health demands has taken on sometimes worrying proportions, with significant repercussions on public budgets. There are cases in which they can compromise more than 80% of the annual resources allocated to health, as seen in the state of Bahia which, in 2023, had a cost resulting from judicialization in pharmaceutical assistance of around R$371,489.131.38, appearing as the sole defendant in 54.9% of the lawsuits, not always with the corresponding federal reimbursement(7).

Of these amounts, more than 30 million were blocked by the courts(7), a measure that has often been necessary to ensure compliance with court orders(8). It should also be noted that 58.2% of the

[3] Motion for Clarification: a type of appeal made to the judge himself, seeking clarification of a decision (Art. 1022 of the Code of Civil Procedure/2015).

[4] *Amicus curiae*: Latin expression meaning "Friend of the Court". This is a person or organization that is interested in the issue and/or can contribute to it, but is not a direct party (plaintiff or defendant) to the action (Art. 138, CPC/2015).

[5] Leading case: an English expression that indicates a leading case, i.e. cases that are representative of a controversy of greater importance, whose first judgment on the subject becomes a reference for other similar situations. In the case under analysis, this was a situation of general repercussion, as provided for in art. 1032 c/c art. 1036 of the CPC/2015.

lawsuits were sponsored by one of the Public Defenders' Offices, especially the state one (50.2%)[7], a total percentage equivalent to that found in Rio Grande do Sul the previous year, debunking the belief of "judicialization by the elites"[9], at least in the area of public health. It is no coincidence, therefore, that the role of the Public Defender's Office featured prominently in the discussions that preceded the Theme's decision.

Concern about the budgets of the federal entities and the aim of standardizing the conduct of these actions also permeated and motivated the recognition of the current general repercussion, which promoted the revision of the understanding espoused in Theme Nº. 793[10]. The latter endorsed cooperative or neoclassical federalism[11] in health matters, based on the recognition of joint and several liability between public entities, as cumulative and/or alternative defendants in these demands[12]. Until then, the position had been widely recognized for medicines, other inputs, products and procedures that had not been incorporated[13], with the exception of cases without national registration - of exceptional deferral and necessary federal competence, according to Theme No. 500[14] and with the exception of the equivalence to registration, in the case of import admission, provided for in Theme 1.161[15]

Solidarity has played an important role in access to health justice, especially for the most vulnerable population. This is because it is noteworthy how often the preliminary question of passive illegitimacy used to be at the top of the defense manifestations of the three entities simultaneously, even after Theme 793, demonstrating a tendency towards difficulty in accessing health resources, even through the courts. Any change in jurisdiction, in these cases, or even the difficulty for poor citizens to know which body to go to for assistance, would result in an especially serious delay when it comes to risks to life and limb. Particular caution is needed, therefore, so that the uncertainty of identifying the person responsible, which has repercussions on the legal route to be taken, does not lead the claim to fall "into vagueness and emptiness, with great chances of serious damage to the health of those affected, until the jurisdiction was defined"[16].

The proposal for compulsory federalization of part of these claims, in turn, was motivated not only by the federal government's increased financial and budgetary capacity (the claim for reimbursement by the federal government was an objective already being pursued by the states and municipalities), but also by the competences legally provided for pharmacological discipline and the aim of reducing judicialization and rationalizing analyses.

To this end, a Special Commission with representation from the three federal spheres and the participation of various observer bodies (Defender's Offices, Public Prosecutor's Office, TCU, OAB, etc.) met numerous times, starting in September 2023, resulting in the three agreements approved by the Court. The aim was to balance the proposals for the federalization of demands for non-incorporated drugs (the main objects of the decision) with the identification of the smallest practical federal structure (including the Federal Public Defender's Office) for monitoring these disputes.

Given this brief history, the aim of this study was to assess the changes resulting from the Supreme Court's ruling on General Repercussion Topic Nº. 1234 in the judicialization of health and its impact on the work of the Public Defender's Offices and on access to health justice, especially for the poor.

Methodology

This is a critical analysis of the change in jurisprudence represented by the decision in General Repercussion Topic Nº. 1234[1], ruled by the Federal Supreme Court in September 2024, which reconfigured the paradigm of federal solidarity in health matters, in the provision of pharmacological assistance.

The study was carried out in a descriptive manner[17,18], by means of jurisprudential and bibliographical research and consultation of institutional databases, starting from the historical evolution that underpinned the ruling in question and its comparison with adjunct rulings and other General Repercussion precedents already decided by the Court, notably Themes Nº. 06[5], 500[14], 793[10] and 1161[15], and Theme Nº. 106[19], decided by the Superior Court of Justice.

Finally, we carried out an exploratory assessment[17,18] of how the decisive part of the ruling and its modulation of effects will have repercussions on the provision of legal assistance by the federal and state defense agencies, within the scope of the right to health. We then discussed more specifically the practical impact of the regulatory discipline established, in terms of the federalization of the matter, given the structural limitations, especially of the Federal Public Defender's Office, in exercising its constitutional competence to defend the socially vulnerable.

The main changes in competence, costing, instruction and execution

The analysis of the ruling, in comparison with the conduct that had been in force until then during the judicial phase, revealed the following main changes: a) the definition of cases of federal and state competence for pharmacological assistance (modifying, with regard to medicines in the strict sense, the understanding of joint and several liability and the defendant's option exercised by the plaintiff in the action, in force in Theme 793 of the STF[10] and in IAC Nº. 14, STJ[13] , now superseded); b) the emphasis on calculating the value of the cause according to official parameters and not market ones; c) the uniform orientation regarding the method of compliance, which is now more focused on the Judiciary, in the event of non-compliance by the defendants, instead of blockages and transfers for direct acquisition by the private individual. Furthermore, although it did not constitute a change on such a significant scale, the requirements to be analyzed in the case are reflected in the brief, with an even more specific focus on Evidence-Based Medicine, so as to also direct the activity of the prescribing doctor more closely.

Another important change concerns the provision of a national data platform:

> The Federative Entities, in collaborative governance with the Judiciary, will implement a national platform that centralizes all information relating to administrative and judicial demands for access to pharmaceuticals, which will be easy to consult and inform citizens, containing basic data to enable analysis and possible administrative resolution, as well as subsequent judicial control.[1]

The gateway to this platform will be based on electronic prescriptions fed in by medical professionals, with the aim of facilitating access to health legalization information and favoring, as much as possible, the administrative solution of claims, in order to reduce judicialization. According to the vote,

> 5.2) The national platform aims to guide all the players involved in the public health system, making it possible for the public authorities to carry out an efficient analysis and share information with the judiciary, by creating differentiated service flows, depending on whether or not the request is included in the SUS public pharmaceutical assistance policy and in accordance with the administrative flows approved by the federal entities themselves in self-composition.
> 5.3) The platform, among other measures, should identify who is responsible for the administrative costs and supplies between the Federative Entities, based on the responsibilities and flows defined in self-composition between all the Federative Entities, in addition to making it possible to monitor patients who benefit from court decisions, with permission for virtual consultation of nationally centralized data, by simply consulting the CPF, drug name, ICD, among others, in compliance with the General Data Protection Law and other legislation on the processing of sensitive personal data.[1]

In its discussion, Theme 1234 was based, according to its own wording, on the following points:

> 1) Responsibility, costing and reimbursement for the supply of medicines incorporated or not incorporated by the SUS;
> 2) Extrajudicial methods of resolving disputes, including in the administrative sphere of the SUS, in order to prevent and resolve conflicts involving the implementation of public health policy, both in relation to users and system managers;
> 3) Monitoring of SUS users, from the administrative request to the conclusion of the treatment granted through judicial intervention, with a view to assessing the quality and relevance of judicial intervention in public policy, by means of the mechanisms, protocols and flowcharts necessary to ensure the population's effective access to a fundamental right, without financial imbalance and budgetary deprogramming.[1]

It is worth highlighting the great importance of item 3, as a necessary mechanism for control, transparency and economy in the spending of public resources, including monitoring the efficacy, efficiency and effectiveness of the drugs provided by the patients themselves. This is a responsible and sensible measure, in order to prevent fraud and even favor the adoption of administrative policies for incorporation, based on the data thus obtained and the direct assessment of the usefulness of the concessions obtained with public funds[16].

With regard to jurisdiction, the most visible change in the new discipline, federal or state jurisdiction was established for pharmacological claims, expressly overriding the solidarity option of Theme 793[10]. Among these cases (and it should be reiterated that the current Theme has only been applied to medicines, with the optional solidarity of Theme 793 still in force for other products and procedures), it is important to first highlight the distinction between incorporated and non-incorporated drugs, and, among those incorporated, those actually made available and those still in the process of being made available.

In the words of Theme 1234, drugs that are provided "in a protocol or essential or complementary list of drugs, including off-label drugs as long as they are provided for in a Ministry of Health protocol (after a favorable opinion on incorporation from Conitec) or a basic component of Rename"[1], and which already have an administrative supply flow, are considered to have been incorporated (an expression that was preferred in the decision to the previous "standardized"[16]).

The incorporated drugs that have not yet actually been made available are referred to by the vote as incorporated drugs in the process of being made available, understood as "the situation of the drug after the publication of the incorporation ordinance by the Ministry of Health referred to in art. 19-R of Law 8.080/1990 and before it is made available in the public network"[1], that is to say: those that,

although already admitted for supply by the public system, have not yet had the administrative flow organized to enable the effective supply.

In the first case (incorporated and made available), any shortage will be challenged in court, according to the jurisdiction provided for in Theme 1234, before the Union, in the Federal Court, only in the case of drugs:

a) of Appendix B, Annex II of RENAME - National List of Medicines of the Strategic Component of Pharmaceutical Assistance (CESAF)[20],
b) of group 1A of Appendix B, Annex III of RENAME - National List of Medicines of the Specialized Component of Pharmaceutical Assistance (CEAF)[20],
c) of the CEAF components in general (1A, 1B, 2 and 3), when they are to be provided for indigenous health care[1,20] , under the terms of GM/MS Consolidation Ordinance No. 4/2017;
d) of high-cost cancer treatments (over 210 minimum wages per year)[1].

The other medicines incorporated and officially made available, including the entire CBAF (Basic Component of Pharmaceutical Assistance), from Annex I of the RENAME, if not adequately supplied, must be claimed, on a residual basis, from the States and Municipalities, before the State Courts.

In the case of those incorporated in the process of being made available, they will be treated, as long as financial responsibility has not been agreed by the Tripatite Inter-Management Commission, as not incorporated[1,22] , thus obeying the criterion of the value of the cause to define its competence.

Medicines that have not been incorporated ("those that are not included in the SUS public policy; medicines provided for in PCDTs for other purposes; medicines not registered with ANVISA; and *off-label* medicines without a PCDT or that are not part of the basic component lists"[1,21]), will follow the rule of the value of the cause (federal jurisdiction for annual costs of 210 minimum wages or more), provided for in the Judgment of this Theme, as long as they have been registered with ANVISA:

> 1) For the purposes of establishing jurisdiction, claims relating to medicines not incorporated into the public policy of the SUS, but registered with ANVISA, will be brought before the Federal Court, under the terms of art. 109, I, of the Federal Constitution, when the value of the specific annual treatment of the drug or active ingredient, based on the Government's Maximum Selling Price (PMVG - located at the zero rate), published by the Medicines Market Regulation Chamber (CMED - Law 10.742/2003), is equal to or greater than the value of 210 minimum wages, in the form of art. 292 of the CPC.[1]

This rule will also apply to oncology drugs, whether incorporated or not, as long as they are registered with Anvisa[1,22].

Drugs not registered with Anvisa, on the other hand, which are still considered to be experimental and to be granted exceptionally, are governed by Theme 500[14], which already provided for a claim against the Federal Government, with the following requirements:

> 1. The state cannot be forced to supply experimental medicines.
> 2. The absence of registration with ANVISA prevents, as a general rule, the supply of medication by court order.
> 3. It is possible, exceptionally, to grant a drug without health registration, in the event of an unreasonable delay by ANVISA in assessing the request (a period longer than that provided for in Law Nº. 13,411/2016), when three requirements are met: (i) the existence of an application for registration of the drug in Brazil (except in the case of orphan drugs for rare and ultra-rare diseases); (ii) the existence of registration of the drug with renowned regulatory agencies abroad; and (iii) the lack of a therapeutic substitute with registration in Brazil.

> 4. Actions demanding the supply of medicines not registered with ANVISA must necessarily be brought against the Federal Government.[14]

It is important to reiterate that *off-label* use (outside the package leaflet's indication as to the purposes, conditions, ages or doses registered with Anvisa) does not equate to experimental drugs for this purpose[1,23] and will correspond to those not incorporated with registration, for the purpose of establishing jurisdiction, and will therefore be based on the value of the case. Similarly, requests for inputs that fall within the hypothesis of Theme 1161[8,15,22] will also be treated as non-incorporated registered, since the aforementioned *decision* considers that authorization to import corresponds to Anvisa registration for these cases (Chart 1). Finally, non-pharmacological claims (products, procedures, etc.), whether incorporated or not, remain under the aegis of Theme 793[10], with joint and several liability, at the plaintiff's choice.

Table 1. Federal jurisdiction in health (Theme 1234), as of September 19, 2024

Drugs incorporated: Strategic Components of Pharmaceutical Assistance (CESAF) - Appendix B, Annex II, RENAME
Drugs incorporated: Group 1A of the Specialized Components of Pharmaceutical Services (CEAF) - Appendix B, Annex III, RENAME
Drugs incorporated: CEAF in general (1A, 1B, 2 and 3), when intended for indigenous health
Oncology drugs (incorporated or not) with an annual value of 210 minimum wages or more
Drugs not registered with ANVISA or equivalent (Theme 1161, STF) and off-label uses*, with an annual value of 210 minimum wages or more
Drugs not incorporated without registration with ANVISA (Theme 500, STF)

* "intentional use in situations that differ from the package leaflet of medicines registered with Anvisa, for therapeutic purposes and under prescription", which may "include differences in indication, age group/weight, dose, frequency, presentation or route of administration", as provided for in art. 2, XXXI, of Anvisa Collegiate Board Resolution RDC 406/2020, without PCDT (Clinical Protocols and Therapeutic Guidelines) or outside the PCDT for the ICD (International Classification of Diseases).

Source: author's summary, based on the rapporteur's vote.

With regard to the calculation of the value of the case, which will be made under art. 292 of the Code of Civil Procedure, it is worth noting that it will no longer be done by means of market estimates, but by using the list of the Medicines Market Regulation Chamber (CMED)[24], according to the Maximum Government Sales Price (PMVG) and a zero ICMS rate. This means a reduction in the market cost of these actions, also reducing the number of federal lawsuits. The judgment on Theme 1234 also provided that:

> 1.1) If there is more than one drug of the same active ingredient and no specific drug is requested, the one listed at the lowest value on the CMED list (PMVG, situated at zero rate) is considered for the purpose of competence.
> 1.2) If there is no value fixed on the CMED list, the value of the annual treatment of the medicine requested in the claim will be considered, and the magistrate may, in the event of a challenge by the defendant, request assistance from CMED, in accordance with art. 7 of Law 10.742/2003.
> 1.3) If there is no timely response from CMED, the judge will analyze the budget submitted by the plaintiff.
> 1.4) In the event of a combination of claims, for the purposes of jurisdiction, only the value of the unincorporated medicine(s) will be taken into account and added together, regardless of whether there is an alternative combination of other claims involving an obligation to do, pay or deliver a certain thing.[1]

Funding and reimbursement were points that were much sought after by the member states, which often found themselves burdened with high-cost condemnations, in the name of solidarity, exceeding their health budgets and not always spontaneously reimbursed by the federal entity, thus prolonging the judicialization process in order to find a solution. In the current provision, there was a clear statement that actions for the supply of "incorporated or non-incorporated medicines, which fall within the jurisdiction of the Federal Court, will be fully funded by the Federal Government"[1], even if there is another entity in the liability position.

In this case too, even if the conviction is against another entity, the federal government will have to reimburse the full amount, via a Fund-to-Fund transfer (FNS to FES). This can happen because, as is also foreseen, even if the Federal Government is alone on the liability side,

> it is up to the magistrate, if necessary, to promote the inclusion of the State or Municipality in order to enable effective compliance with the decision, which will not entail financial responsibility, nor a burden of succumbence, and compensation should be made by the means indicated above in the event of any financial cost being borne by the aforementioned entities.[1]

Reimbursement for non-incorporated drugs and oncological medications will also be made with federal funds, even in cases where the Federal Government is not a party to the lawsuit and, therefore, the state is, respecting the limits set out in the agreements reached in the Theme. These were the subject of the second and third agreements reached during the course of the trial, and reimbursement will be made at a rate of 65% for drugs that have not been incorporated, in convictions between seven and 210 minimum wages, via fund-to-fund transfers[1,21,22], resulting in the following summary:

a) Non-incorporated drugs and oncology in general, with an annual cost equal to or greater than 210 minimum wages: federal competence and full funding by the Union.
b) non-incorporated drugs with an annual cost between 7 (seven) and 210 minimum wages: state competence and 65% federal reimbursement, except oncology (incorporated or not), whose reimbursement is of the order of 80%, funded by the Union, for actions filed until June 10, 2024, and in a percentage to be defined by the Tripartite Interagency Commission, as of that date[21][25].
c) Non-incorporated drugs with an annual cost of less than 7 (seven) minimum wages: state competence and costing ("although the thesis is not explicit about the exclusion of municipalities"[21], suggesting the possibility of an agreement regarding reimbursement to this entity by that entity[25]).

Finally, it established the duty of the Federal Government to reimburse past expenses incurred by states and municipalities as a result of the judicialization of health, retroactive to 2018,

> This will reduce the budget and financial deficit of these federal entities, as well as preventing a 'judicialization of judicialization', which is the collection and judicial execution against the Union of credits from the States and Municipalities, resulting from the forced supply of medicines that fall under federal and/or joint competence.[26]

The changes triggered by the Theme in question have also called into question traditional statements from Health Conferences, such as FONAJUS/CNJ and even from the recent First Health Conference of the Federal Justice Council (CJF), which took place in June/2024. Others, however, remain consistent with the current discipline, or may evoke new discussions, such as CJF Statement Nº. 01, given the new rules on reimbursement:

> In the event of joint and several liability of federal entities in public health, the award of attorney's fees will, as a rule, fall only on the entity that has administrative competence in the health policy that is the subject of the dispute, by virtue of the principle of causality.[27]

In view of the content of the ruling, some details must also be observed with regard to the instruction of the lawsuit, from the initial request, as well as for the preliminary injunction or anticipatory analysis of the claim. As a rule, in addition to personal documents (identification; proof of residence, to define territorial jurisdiction, and income, to characterize the plaintiff's lack of resources - despite Enunciation No. 31, CJF[27], according to which: “The right of the public health user (SUS) to access medicines and/or procedures incorporated into public policies does not require proof of hyposufficiency or financial incapacity” -; SUS card, when it is the public sector being sued), with: dated medical prescription, informing the intended request, preferably in generic composition and at the lowest cost, presentation/formulation; medical report also dated, indicating the pathological condition, the treatments available through the Health System that have already been carried out or the reason why they cannot be used, the justification for any extra-framework option, with the scientific backing for the choice of the requested therapy, the urgency of the supply, if applicable, and the risks of delay; registration of the input with Anvisa, import authorization or indication of an excess of time in its appreciation by the Agency; administrative denial, despite registration with the Health System, if applicable; tests that corroborate the condition and indication, in order to be analyzed by NAT-JUS; budgets that support the information on the value of the cause[16].

These requirements had already been outlined in Theme 6 of the STF[5], which recently advanced in relation to Theme 106 of the STJ[19]. In a similar vein, CJF Statement Nº. 35[27] recently provided for the following:

> In health claims, it is recommended that the initial petition be accompanied by all documents related to the patient's diagnosis and treatment, such as: disease with ICD, medical history, essential tests, medication or treatment prescribed, dosage, contraindication, active ingredient, duration of treatment, previous use of public or supplementary health programs, indication of generic drugs, therapeutic plans, among others, as well as the record of the request to the operator and/or respective denial.[27]

In the current context, the judgment of this Theme specifies, in addition to the more specific budget, according to CMED/PMVG, that

> (iii) in the case of a drug that has not been incorporated, the onus is on the plaintiff to demonstrate, on the basis of Evidence-Based Medicine, the safety and efficacy of the drug, as well as the lack of a therapeutic substitute incorporated by the SUS, and to attach a reasoned and detailed report describing the treatment carried out (including each drug used, dosage and time of use).
> (iv) according to the decision of STA 175-AgR, the mere allegation of the need for the drug 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 scientific evidence, based solely on randomized clinical trials, systematic review or meta-analysis.[1]

The greater emphasis on the burden of proof for the plaintiff[21] can be a hindrance, especially for SUS patients, who don't always find it easy to book appointments. Prescribing professionals will also be more demanding with regard to medical documents, both in terms of feeding the national platform and in terms of monitoring the condition, especially in the case of drugs that have not been incorporated:

> (5.4) The health service whose professional prescribes a drug not incorporated into the SUS must assume continuous responsibility for the patient's clinical follow-up, periodically submitting an updated report on the patient's clinical condition, with detailed information on the progress of treatment, including improvements, stabilizations or deteriorations in the patient's state of health, as well as any relevant changes in the therapeutic plan[1].

In this last regard - a relevant precaution, no doubt, even to assess the usefulness and safety of any extra-schedule concessions - it is worth remembering the convenience of reasonableness in setting deadlines for such reports, considering the scheduling difficulties mentioned above, with, *for* example, a six-monthly deadline being more reasonable than a quarterly one[16].

When dealing with the national platform, it was pointed out that the ethical and social control of prescriptions is the responsibility of the Professional Councils, which will have to analyze the motivation for repeated prescriptions outside of SUS policy. The excerpt from the vote referred in this regard to the Code of Medical Ethics[28], which, however, also recognizes the autonomy of the professional in their prescriptions, as they see fit for the patient, respecting the legal prohibitions - which is not the specific case of the drugs that have not been incorporated. But society as a whole benefits from greater care in prescribing, avoiding heroic attempts; disorderly choices, to the detriment of standardized ones, without reasonable justification; and, of course, fraud, which puts at risk not only the physical and/or psychological integrity of the patient and the health of the system, but also the reliability of the professional class itself. Special responsibility is required when prescribing hope[29] . In this sense, the electronic prescription system and the emphasis on periodic monitoring will, in effect, allow for greater control in pharmaceutical care[21].

Ethical zeal has also already challenged the concern of judicial bodies, which may indicate extra documentation, as can be seen in the recent CJF Statement 5[27], which reads: "In lawsuits involving medicines, OPMEs, supplies or procedures that have not been incorporated, the detailed medical report or report issued outside the Unified Health System must be accompanied by a declaration that the prescribing doctor has no conflict of interest". Along the same lines of treatment *follow up*, Statement 30, of the same origin, had already been issued:

> In lawsuits for the continuous supply of cancer drugs, for *off-label* use or that have not yet been incorporated into the SUS, the party will submit a report on their clinical evolution with any benefits obtained, signed by the attending physician, at intervals to be determined by the court, for the purposes of assessing whether the court decision should be upheld.[27]

In a similar vein, including with regard to the aforementioned appeal to the reasonableness of the deadline, is Statement no. 41 of the same body[27].

With regard to judicial analysis, it should be noted that one of the aims of the Theme seems to have been to limit even more clearly the replacement of administrative discretion by that of the judge. It was made clear, for example, that “the judge must analyze the act of non-incorporation by Conitec and the denial of administrative supply. This means that the judge cannot simply ignore administrative decisions and must consider them in his analysis”[21]. This emphasis does not mean a discussion of the merits of the technical body's refusal, whose contrary opinion may even be a matter of collective cost-effectiveness, but it does aim to make concessionary decisions in situations where there is a recommendation not to incorporate more rare. Furthermore, with regard to administrative denials of supply in specific cases, it was established that:

> (ii) judicial review of the administrative act that refuses to supply a drug that has not been incorporated is restricted to examining the regularity of the procedure and the legality of the act of non-incorporation and of the administrative act being questioned, in the light of the control of legality and the theory of determining motives; it is not possible to delve into the administrative merits, with the exception of the cognition of the discretionary administrative act, which is linked to the existence, veracity and legitimacy of the reasons given as grounds for its adoption, subjecting the public entity to its terms.[1]

In terms of legality, the judge can check "whether the administrative act is in conformity with the Constitution, current legislation and SUS public policy"[21]. In this case, it is worth questioning whether the indication/possibility indicated in Statement nº. 37 of the DJF[27] is still relevant:

> If there is a recommendation from the National Commission for the Incorporation of Technologies into the SUS (Conitec) not to incorporate a technology that has been judicialized, the decision to grant it, disregarding these technical grounds, must be preceded by an analysis by the Judiciary's Technical Support Center (NatJus), or a substitute, which points to scientific evidence of a significant outcome in light of the patient's specific condition.[27]

Still with regard to Conitec's decision, the Vote states that "collective administrative processes to request the incorporation of medicines with Conitec through the intermediation of the Federal Public Defender's Office or the Federal Public Prosecutor's Office" will be possible at the administrative level, with Conitec being obliged to "meet with these bodies to verify the technical possibilities and implementation requirements"[1]. In this respect, it should be added that:

> In the case of medicines that have not yet been evaluated by Conitec, with the aim of national standardization and for the purposes of item I of § 1 of art. 19-R of Law 8.080/1990, the national coordination bodies of the MPF, DPU and other national technical bodies may submit a request for analysis of the incorporation of medicines into the SUS that have not yet been evaluated by Conitec, respecting the technical analysis of the bodies involved in the usual administrative procedure for incorporation, when the existence of repeated demands is observed.[1]

Pre-judicial action is therefore emphasized, with the aim of making it less likely that a drug that has not been incorporated will be granted judicial approval. In June 2024, the priority validation of the technical body's opinion on non-incorporation had already motivated CFJ Statement 22[27], which reads: "If there is a recommendation from the National Commission for the Incorporation of Technologies into the SUS (Conitec) for the non-incorporation of judicialized technology, it is recommended that the plaintiff be summoned to expressly comment on this issue, if it has not done so in the initial petition". If, on the one hand, the right to hope[29] cannot override all technical considerations, it is also a fact that administrative decisions can be subject to some judicial analysis. On the other hand, the prior hearing of NAT-JUS for an injunction or when "substituting or adding input(s)/medication(s) in the course of the claim", although not expressly required in the agreements in question, has ample support in the Health Law Statements, as can be seen in the most recent Statements Nº. 45 and 46 of the CJF[27].

This position triggered a new trend in the historical evolution of health judicialization in the country, which, according to Cunha and Ferranha[31], was marked by an initial phase associated with non-activism (1988-1996), in which no case involving the right to health was judged by the STF[31]; followed by an absolutization of the issue (1997-2003), in which the mere mention of the right to health

was almost certain to be granted, with little critical analysis, but, at the time, not many demands[16]; a third phase, characterized by the discussion of the costs of rights and the clash between the reserve of the possible and the existential minimum (2004-2009)[16], and a fourth phase, based on Evidence-Based Medicine (2009 until then)[16,22,31]. Leite, Almeida and Pereira[22], in the course triggered by the Theme under analysis, saw the emergence of a fifth and current phase, qualified by deference to Conitec and the criteria of justification and - it is added and hoped - by the encouragement of the out-of-court settlement of health conflicts.

Along the same lines of recognizing Conitec's decisions[32], the STF's Theme 6[5] was established, which gave rise to the even more recent Binding Precedent No. 61[33], which determined that the theses established in the judgment of the aforementioned Theme 6 must be observed for the judicial granting of medicines registered with Anvisa, but not incorporated into the SUS dispensing lists.

Enforcement, on the other hand, has undergone significant changes and is also the subject of concern as to its feasibility and operationalization in light of the new provisions, since reports of non-compliance to the defense agency were already frequent[8]. The current provision was undoubtedly aimed at security and economy for public entities, but there is a fear that it will overload the Judiciary, leading to even more delays in compliance, with serious consequences for the health of those in court.

In this respect, the most important changes are: the direct purchase from the supplier/distributor (instead of the relatively frequent mediation by the patient/author, after blocking or sequestration and transfer of public funds), in the event of non-compliance; and the price limitation, according to the CMED table, with a zero ICMS rate and limited to the PMVG, exceptionally allowing the purchase at market value. Let's see:

> 3.2) In the judicial order to supply the drug, the magistrate must establish that the sale price of the drug is limited to the discounted price proposed in the Conitec incorporation process (if applicable, considering *venire contra factum proprium/tu quoque* and observing the annual drug price adjustment index defined by CMED), or the value already practiced by the entity in public purchase, whichever is identified as the lowest value, as provided for in the final part of art. 9 in CNJ Recommendation 146, of 28.11.2023. Under no circumstances may there be a judicial payment to the individuals/legal entities described above in an amount higher than the PMVG ceiling, which must be made by the judicial servant's office to the manufacturer or distributor.[1]

Purchasing directly from the supplier was already preferred by the courts (in this regard, see also CJF Statement Nº. 4[27], which states: "The transfer of public funds deposited in court in order to guarantee compliance with the obligation to do something for health protection should, as a rule, take place in favor of the service provider/supplier indicated in the court case file, upon presentation of the invoice."), but it was not uncommon for the amounts to be transferred to the plaintiff's own account, upon later presentation of the invoice and return of any financial residue, when it was not possible to obtain the acquisition/fulfilment by the defendants.[8]

It is to be feared that the current system, in addition to burdening the judiciary, will lead to even greater delays in complying with court orders of such delicate application[8]. In this case, Voted predict - it is not yet known how effectively - that:

> (v) in the event of operational difficulties in acquisition, the judge must order the supplier directly to deliver the drug to the federal entity that bore the burden of supply in the case, in accordance with art. 11, § 2, of CNJ Recommendation 146/2023[30] , with the possibility of

> imposing a fine in the event of non-compliance on the third party, without prejudice to any other measures that may be appropriate. In any case, any discussions about the price of the drug, which are the responsibility of distributors, suppliers, manufacturers and representatives, cannot serve as an obstacle to the supply of the drug to the court.[1]

We reiterate that,

> [With regard to products of interest to health that are not characterized as medicines, such as orthoses, prostheses and medical equipment, as well as therapeutic procedures, on a home, outpatient and hospital basis, it should be clarified that they were not debated in the Special Commission and are therefore not covered in this topic 1.234.[1]

In short, says the ruling, "the discussion has focused on tackling problems identified in three areas"[1]:

> (i) greater ethical control of the prescribing professional's actions, so that they can justify prescribing drugs that are not in line with or are not in line with SUS public policy;
> (ii) improving the form of administrative response, including a new tool for administrative requests for the supply of medicines, with national standardization of initial and final protocols, with agreements on the division of responsibility for medicines incorporated and not incorporated into SUS public policy; and (iii) altering judicial cognition and the phase of compliance with sentences, through clinical monitoring of the efficacy of the medicine.[1]

The proposals are laudable. The practical difficulties, however, go beyond mere knowledge of the new rules and impact, above all, the most socially and economically deprived population, who are largely dependent on the SUS and the assistance of the Public Defenders' Offices, as will be discussed below.

The repercussions on defense work and on making access to justice and health effective

The new discipline also highlighted the need to internalize the Federal Public Defender's Office to take on federalized demands, which, however, clashes with the structural reality of the body, which has so far failed to implement the command of art. 98 of the Transitional Constitutional Provisions Act of the 1988 Federal Constitution. This provision, instituted by Amendment 80/2014, stipulated an eight-year deadline for all jurisdictional units to have a Public Defender. However, in the first two years of the deadline, Constitutional Amendment No. 95 froze the ceiling on public spending, making it practically impossible to expand the body. As a result, ten years after the forecast of universalization, the Federal Public Defender's Office covers only around 30% of the country's Federal Judicial Sections [8,9,16].

The realization that it was impossible for the vast majority of the Judicial Sections to take on the lawsuits, even in the face of mandatory federal jurisdiction in the situations provided for in the ruling, imposed a modulation of effects[34], applying them to the new lawsuits filed, and a deadline for the body to be able to take them on, otherwise part of the population would be left without assistance in their judicial access to health. This would be even more likely, considering that, as the main criterion defining federal jurisdiction for non-incorporated drugs and oncology drugs was based on the high value of the case, the jurisdiction of the Special Federal Courts is immediately excluded, which should have their caseload relieved in this respect[21], but in the Common Courts, legal representation is required.

In the case of Bahia, the new discipline affects the inter-institutional agreement signed in 2018 between the Federal and State Public Defender's Offices, which, then based on federative solidarity,

and in order to try to systematize local demands, established that demands for drugs, supplies in general and incorporated procedures would be the responsibility of the state body, and those not incorporated would be the responsibility of the federal defense body[8,16].

With the current provision, the incorporated CESAF and part of the CEAF (notably those in group 1A), in cases of shortages, for example, and high-cost oncology drugs would be handled by the Federal Public Defender's Office. Non-incorporated products (including oncology, off-label and presentations or uses other than those included in the CEAF and CESAF, even if the drug itself is included in these lists), costing less than 210 minimum wages per year, will fall under state jurisdiction. Other procedures and products, until further defined, can continue to follow the previous agreement or the question of value can be agreed by analogy, since Theme 1234 does not apply to them.

Although this configuration seems to represent (there is still no total data, either from the Defender's Offices, the Judiciary or the Administration) an easing of the burden on the federal level, the issue is exacerbated in relation to the demands made in the interior of the state, since the DPU only has around 600 Public Defenders in the whole country[8,16], insufficient for the necessary interiorization. In the case of Bahia, there are only centers set up in Salvador, Feira de Santana, Vitória da Conquista and Juazeiro, and, as of this year, demands from Ilhéus, Itabuna and Jequié, which have no physical headquarters, will also be met. Considering that the state has sixteen federal judicial sub-sections, it is clear that there is insufficient coverage, which is multiplied throughout the country.

The ruling was therefore based on encouraging extrajudicial actions and better equipping the State Public Defender's Offices, until the federal institution is equipped, which, however, cannot mean a permanent deviation from the constitutional functions of these bodies. Thus, it was stipulated that:

> 9) In order to ensure access to justice for the population in need in health actions that fall under the jurisdiction of the federal courts, under the terms defined in this agreement, the Federal Government undertakes to strengthen the Federal Public Defender's Office, to guarantee free legal assistance to the underprivileged for these health actions (exclusively, in principle) in all the country's judicial sub-sections.
> 10) The Federal Government and the Federal Public Defender's Office undertake to enter into a cooperation agreement to adopt measures for the proper handling of demands in the health area, such as pre-procedural conciliation for medicines incorporated into the SUS for which the Federal Government is responsible, in accordance with the terms of this agreement, and the creation of a committee to monitor the judicialization of health.[1]

Such projects, however, would not immediately solve the lack of assistance in monitoring the immediate cases proposed. Thus, a palliative measure was devised until the federal agency adapted itself:

> Exceptionally, within a period of up to one (1) year from the publication of the minutes of the trial - in the event that the State Court declines to the Federal Court (only for new cases) and in the event that the DPU does not provide assistance, either because there is no institutional action in that Judicial Subsection, or because the income limit for assistance by the DPU is exceeded -, it is permissible for the State Public Defender's Office (DPE), which has filed the lawsuit in the state court, to continue sponsoring the plaintiff in the federal court, in co-sponsorship between the Public Defender's Offices, until the DPU organizes itself administratively and starts defending the interests of the citizen on its own, with the provisions of Art. 5, § 5, of Law 7.347/1985.[1]

In addition to the doubts surrounding “co-sponsorship" between different institutions, it should be noted, as also pointed out in the excerpt above, that the income parameter also becomes another

obstacle to the displacement of defense counsel as a result of the new distributions of jurisdiction agreed upon, given the difference in the criteria for granting free legal aid, which vary, in the cases analyzed in the vote, between 2,000 reais and more than 7,000 reais (five minimum wages). In fact, both the Federal Public Defender's Office, the Federal District Public Defender's Office and each State Public Defender's Office, in exercising their constitutional autonomy and local contexts, adopt different maximum income limits for granting assistance. This distinction could, in the case of shifts in jurisdiction, also lead to gaps in defense. On the other hand, the imposition of a single ceiling, by external means, would clash with the premises of the autonomy of the bodies.

The Motion for Clarification filed by the Federal Public Defender's Office argued, in this regard, that the provision for supplementary action by the State Public Defender's Offices, in areas where the Federal Public Defender's Office has constitutional authority, without the institution's participation in such an agreement, undermines the functional and administrative autonomy provided for in the Magna Carta. In this sense, it is contradictory to the proposal to expand and strengthen the Federal Defender's Office, contained in the vote itself, as well as giving rise to legal uncertainty about its implementation and operation in practice, contrary to Complementary Law 80/94. The appeal has not yet had its admissibility and content analyzed.

Finally, recognizing the practical difficulties in operationalizing the new rules, including the still insufficient structuring of the Federal Public Defender's Office in the country, there was a modulation of effects[34], in the sense that the new competences only apply to cases filed after the publication of the result of the judgment on the merits of the Theme, which happened on September 19, 2024, according to the terms: "ruling out its incidence on proceedings in progress until said milestone, without the possibility of raising a negative conflict of jurisdiction with respect to proceedings prior to said legal milestone"[1].

Conclusion: Final (or still initial?) considerations

Despite the intention to systematize and rationalize the matter, the decision on Theme 1234 seems, at first, to impose some practical difficulties in making the right to health effective through the courts, in federalized cases, especially for the poor population, who are largely dependent on the SUS and on legal assistance.

On the one hand, the aim was to solve the problem faced by states and municipalities, in terms of the difficulty of being reimbursed by the federal entity, in convictions received in solidarity, under the aegis of cooperative federalism, as well as to give greater security and economy to executive procedures.

On the other hand, however, a series of potential obstacles have arisen, *verbi gratia:* with the fall in solidarity, the risk that poor knowledge of the rules of competence (which require consultation of different categories of the RENAME and the specific CMED/PMVG budget) will lead to an inappropriate application, with a consequent serious delay to the health or even the life of the applicant; the need for medical reports that are so thoroughly instructed and substantiated that they will often involve multiple consultations, a demand that is quite difficult for the applicant who is dependent on the SUS; the greater burden on medical services, already overloaded in the public service, when, in addition to the exhaustive reasoning of the reports, the feeding of the prescription platform for vestibular instruction and follow-up is ordered; the judicial execution through exclusive government

purchase, when a large part of the non-compliances had only been resolved by blocking public funds and transferring them to direct purchase by the plaintiff, etc...

With regard to legal aid provided by the Public Defender's Office, the federalization of high-cost claims presupposes that the federal defender's office has been equipped in a way that is still far removed from the reality of the office and which, having not been achieved in the eight years defined by art. 98 of the ADCT/CF88, seems unlikely to be achieved within the one-year time limit set by the modulation of effects of this ruling. Such a gap could give rise to a legal assistance gap or a distortion of the actions of federal and state bodies, in their constitutionally established competencies.

It is hoped, however, that the first analysis of the difficulties will not be confirmed and that, on the contrary, better scenarios and prospects will emerge, leading to a reduction in judicialization, driven by better administrative health provision, with faster incorporation of more up-to-date resources and more frequent out-of-court resolutions; more conscientious prescriptions based on evidence-based medicine; the necessary expansion and structuring of ombudsmen's offices, especially at federal level; quick and well-founded judicial decisions; more efficient and economical compliance; better distribution of budget burdens; greater control of results, etc. In short, may the issue in question lead, in fact, to greater effectiveness of the fundamental social right to health and its wider and more equitable access by the population.

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

Authors' contribution
Villas-Bôas ME contributed to the conception/design of the article, data analysis and interpretation and writing. Cunha Júnior D contributed to the critical review of the content and approval of the final version of the article.

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