Judicialization of health: the theses of the STF

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ABSTRACT This article intends to systematize and analyze the legal theses signed by the Supreme Federal Court (STF) in relation to the judicialization of health. The STF has been pronouncing on the subject quite frequently, having in the set of its decisions, signed six theses of general repercussion, that is, which obliges all magistrates. The judicialization of health has been growing and controversial, both because of the decisions of the magistrates and because of its intensity, affecting the management of the Unified Health System (SUS) by its leaders, especially Brazilian municipalities. The present study aims to systematize the judges of the Supreme Court for a better understanding of public agents and the citizen regarding the constitutional legal understanding of the Superior Court for better guidance regarding the defenses of public entities and the demands of citizens who feel helpless in their health needs. This systematization is accompanied by critical analysis when the decisions that now hang the balance to one side or the other, when the best judgment is what keeps the balance. But not always, in the view of society and SUS managers, the balance is maintained in its desired balance. And the present work consists of these notes.

KEYWORDS Health’s judicialization. Unified Health System. Right to health.

RESUMO O presente artigo sistematiza e analisa teses firmadas pelo Supremo Tribunal Federal (STF) em relação à judicialização da saúde. O STF vem se pronunciando a respeito do tema, tendo firmado teses de repercussão geral, ou seja, que obriga a todos. A judicialização da saúde tem sido crescente e polêmica pelas decisões dos magistrados e pela intensidade, afetando a gestão do Sistema Único de Saúde (SUS), em especial os municípios. O presente estudo visa a sistematização dos julgados do STF para a melhor compreensão dos agentes públicos e do cidadão quanto ao entendimento jurídico-constitucional da Corte Superior para a melhor orientação quanto às defesas dos entes públicos e às demandas do cidadão que se sente ao desamparo em suas necessidades de saúde. Essa sistematização se faz acompanhar de análise crítica quando às decisões que ora pendem a balança para um ou outro lado, quando o melhor julgamento é o que mantém o fiel da balança. Mas nem sempre, na visão da sociedade e dos gestores do SUS, a balança é mantida em seu almejado equilíbrio. E o presente trabalho consiste nesses apontamentos.


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Introduction

This article intends to analyze the judicialization of health from the perspective of the legal theses signed by the Supreme Federal Court (STF) with general repercussion, systematizing them by isolated themes, since the same decision (ruling) may contain more than one thesis that deserves to be highlighted in specific comments. Every thesis highlighted comments will be made as to the correctness of the decision or possible ambiguities in the light of the organization and functioning of the Unified Health System (SUS), its principles, and constitutional and legal guidelines.

The judicialization of health is been booming and controversial, both because of the numerous decisions of judges granting injunctions, and of its intensity, affecting the SUS's management, especially for Brazilian municipalities, which find themselves pressed between the chronic underfunding of health and the demands of the Judiciary that often affect its budget and health planning.

The theses signed by the STF have the power to standardize the jurisprudence on certain aspects, such as the supply of medicines without registration with the National Health Surveillance Agency (Anvisa); experimental drugs; the solidarity regarding the responsibility of federative entities, among others.

The analysis of trials in the STF contribute to better understand the legal thinking of the Supreme Court on the right to health and to consolidate understandings of what comprises the completeness of health care — imprecise legal concept — which must have demarcations, legal outlines for its containment. An open rule demands outlines, a framework to specify its content and guide the necessary planning and financing. It is also important that the public manager has a precise understanding of the rulings of general repercussions to help their defense in legal actions, as well as to improve the health services within his competence, contributing still with citizens with knowledge about their health rights.

The systematization of the theses in this essay is accompanied by analyzes when decisions tip the scale more to the side, moving away from their desired balance. This work adopts a critical-analytic methodology on the Supreme Court’s jurisprudence in relation to the right to health in the light of health legislation and factual reality.

The legalization phenomena in the Country and the public hearings

The judicialization of health has been growing, with the number of lawsuits rising from two million (Justice in Numbers Report of the National Council of Justice – CNJ, 2019) in general — from medical error to the guarantee of medicines and other supplies, products and health technologies. Since its inception, in the 90s, and its increase, from 2003 on, judicialization has been the stage of countless debates, discussions, seminars, academic theses, publications, without its causes having been faced by the Executive and the Legislative, such as the low funding of health policies and aspects of public management. Meanwhile, the quality of court decisions has been the option, instead of their reduction, given that the confrontation of their causes has not taken place. Without taking care of the causes, there will be no improvement in these numbers due to the fact that the law continues to be ineffective, which leads the citizen to justice, excessively, causing all kinds of distortion, from the Judiciary in its sentences that often demonstrate lack of knowledge health law, the SUS, as well as that of its plaintiffs (author, lawyer, health professional, interested third parties, laboratories).

Due to this phenomenon, the STF has already called two public hearings to hear the society: the first in 2009, by Justice Gilmar Mendes, under the Suspension of Primary Injunction (STA) nº 1752, with a final decision in 2010; the second, in 2017, by Justice
Dias Toffoli, within the scope of Extraordinary Appeal (RE) No. 581488/20/2015, to discuss the possibility of a class difference in hospitalization in the SUS. In the first, the appeal filed by the Union was dismissed, establishing the understanding that, in health, the responsibility of federative entities is marked by solidarity and, in the second, the STF considered unconstitutional the possibility of a SUS patient paying to have superior accommodations or to be seen by a doctor of his choice (care class difference). The basis for denying the request in the RE is that this type of payment is contrary to article 196 of the Federal Constitution, which guarantees universal and equal access to health actions and services to all citizens.

The referred RE was filed by the Regional Council of Medicine of Rio Grande do Sul (Cremers) against a decision of the Federal Regional Court of the 4th Region (TRF-4), which upheld a sentence in a public civil action to prohibit this type of payment. The TRF-4 understood that, even at no cost to the State, making possible the difference in classes would represent giving differentiated treatment to patients within a system that provides universal and equal access to health actions and services, as established in the Federal Constitution.

The two hearings stated that: a) health actions and services are the joint responsibility of federative entities that must, in terms of the practical development of this type of responsibility, define a model of cooperation and coordination of joint actions; and b) SUS cannot have neither differentiated accommodations or choice of physician.

The joint liability thesis was re-discussed in RE 855178, conducted by Justice Luiz Fux, which confirmed the ruling, with divergent votes from Justice Luis Roberto Barroso and Alexandre de Moraes, in a judgment in 2019, that there is joint liability between the federative entities in the duty to provide health care:

Appropriate medical treatment for the needy is part of the State’s duties, as the joint responsibility of federated entities. The passive pole can be composed of any of them, alone or together.

Other issues were also the object of judgment in the STF in recent years, such as: a) there is or is not a state duty to supply medicine without registration with Anvisa; b) medicine not incorporated into the SUS obliges the State or not; c) high-cost medication not incorporated into the SUS, constitutes or does not constitute a state duty. We are reminded that medicine for rare diseases is still pending a decision, with a trial scheduled for 2020, but not yet carried out.

RE 566471 with judgment on March 11, 2020, decided that the State is not obliged to provide high-cost medications requested in court, when they are not provided for in the SUS list of the Exceptional Drug Dispensing Program. Exceptional situations will still be defined in the formulation of the thesis with general repercussion. Below, we systematize the decisions of the Supreme Court on these issues, commenting on the health legislation.

### Systematization of the STF theses, of general repercussion

1 - There is joint responsibility of federated entities for the duty to provide health care. Decision in STA No. 175, of 2009, reiterated in the judgment of RE 855178.

This decision, modulated by the STF, contains some complexities regarding its application. The decision, issued in 2009, predicted the need for ‘federative entities to define, together, in practice, a model of cooperation and coordination of joint actions’ which already existed, in reality, in the agreements arising from the inter-managerial committees at the national, state and regional levels and by the...
organizational contract for public health action, according to the Decree No. 7,508, 2011. It is important to bring brief comments about the contract for public health action. These contracts were signed in 2012, only in the states of Ceará and Mato Grosso do Sul, with a duration of 4 years, and have not been renewed. Even though Decree No. 7,508 of 2011 is in force, there is a disregard for its mandatory observance, which could be an improvement in the agreements signed in the inter-managerial committees, providing legal certainty to these consensual decisions. The agreements are signed in the commissions, but they are not always complied with or required administratively or judicially, as they lack greater legal support. These agreements must discipline the federative responsibilities, of a systemic nature, for the execution of health actions and services that each federative entity must assume before the population, individually or regionally shared. However, these agreements have rarely been respected in court decisions and contracts have not been signed within the Executive branch, which could guarantee greater legal certainty as to their compliance. By Law No. 12,466, of 2011, federative entities, as they have to integrate their health services in the form of article 198 of the Constitution, must agree on the federative responsibilities in the corresponding commissions, which are, the Tripartite Inter-manager Commission; the Bipartite Intermanagers Committee; and the Regional Inter-Management Commission.

In the 2019 RE, it was also established that it is incumbent upon the judicial authority, due to the decentralization and hierarchization guideline, to direct compliance in accordance with rules of competence and to determine the reimbursement to those who bore the financial burden. This brings great complexity to the judicial authority and will depend a lot on the defense made by the public entity regarding the demonstration of the defendant’s responsibilities, even without the execution of the public action contract, with the call to action in joinder.

The issue of compensation is also a problem because it presupposes that someone has shouldered the responsibility and will then have to obtain compensation from the other legal entity. The consequences are complex for the judicial authority as well as the defendant authority and will need to be very well argued and demonstrated by the defense. An excellent article is the one by federal judges Luciana Veiga and Ana Carolina Morozowski who well demonstrate its complexities. Not to mention that, when the Union is involved, the federal jurisdiction prevails, which does not exist in all counties, it should be said, bringing difficulties for the citizen when he sees the state’s duty to provide for his health not being complied with.

2 - Differential treatment as hospital accommodation or choosing a doctor in the SUS is prohibited. RE No. 581488.

Thesis established in the decision of the court that gave rise to the public hearing mentioned in item II of this work initiated by Justice Dias Toffoli. In the name of the principle of equality of care, as provided for in article 196 of the Constitution, there can be no differentiation in terms of comfort and choice of doctor within the scope of the SUS. Equality of care is a principle of the SUS, as well as its universal access. It was dismissed precisely because the SUS cannot have unequal treatment, as mentioned in item II of this work in more detail.

This decision is in absolute consonance with the constitutional principles of the right to health in article 196, namely, universality of access, equality of care and health security, as well as with the constitutional guidelines of the SUS, expressed in article 198. A correct ruling regarding SUS’ legislation.
However, we cannot help but comment that the judgment refers to the guarantee of the right to health for the ‘poor’ population. By making such an emphasis, the STF makes the mistake or ignores that access to SUS is universal and equal, and no distinction can be made between people, such as their economic condition, in order to receive care. This has been recurrent in court decisions.

3 - The State cannot be obliged to supply experimental medicines. RE 657718.

This decision does not require further comments because the Brazilian legal system does not admit a state obligation to supply experimental drugs, as it contravenes specific regulations, which only allow circulation of drugs registered with the competent body, that is, those that do not have an experimental nature. Experimental drugs depend on studies in their various phases and must, after their proven efficacy and safety, obtain registration with Anvisa, under the terms of Law No 6,3609, of 1976, and Law No 9,78210, of 1999. Drug registration aims at the necessary analysis of its safety, good manufacturing practices, effectiveness, efficacy, accuracy, under the terms of the law. Only a drug that was submitted to these analyzes at Anvisa, and that obtained its registration, is authorized to circulate freely in the country. It would not be admissible for a different understanding of the law enforcer.

4 - The absence of registration with Anvisa prevents, as a general rule, the supply of medication by court decision. RE 657718.

This decision, as a general rule, does not totally prevent the supply of unregistered medicine by creating exceptions, analyzed in item 5. But the general rule is that only medicine registered with Anvisa can be supplied to the claimant by court decision. The STF itself had already decided in the judgment (Direct Action of Unconstitutionality — ADI 550111, of 2016) that suspended the effectiveness of Law No. 13,26912, of 2016, which obliged the State to supply phosphoethanolamine, as it is not admissible the free circulation in the Country and the supply by SUS of medicines without registration with Anvisa, as a health security measure, pursuant to the provisions of Law No. 6,360, of 1976, article 12. If only medicines with registration with Anvisa can circulate freely, a law could not impose the circulation of a given drug without submitting it to the analysis of the competent body as a health security measure.

On the other hand, there are some decisions recorded in the Justices’ votes that deserve to be highlighted, as is the case of Justice Barroso, proposing cumulative requirements to be observed by the judiciary when granting a certain provision of health services, such as the decision that ‘high-cost medicines not incorporated into the SUS are under the responsibility of the Union’. This vote is important because it demonstrates a change in the STF’s understanding of the need for balance in the joint liability thesis, based on the ruling mentioned herein, as analyzed in item 1. It is also important to highlight the fact that Justice Barroso referred to a drug ‘not incorporated into the SUS’ and not a drug ‘without registration with Anvisa’. If the competence to incorporate a drug registered with Anvisa belongs to the Union, the Justice understands that if the Judiciary decides on its pertinence, it will be up to the Union to bear its cost, since its incorporation is competence of such entity. We will return to this theme later in this work. This decision modulates the joint responsibility between federative entities in the duty to guarantee health.

5 - It is possible, exceptionally, the judicial granting of medicine without health registration, in case

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5 - It is possible, exceptionally,
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of unreasonable delay by Anvisa in considering the request (term greater than that provided for in Law No. 13,411/2016), when the requirements for the existence of a registration request are met, except in the case of orphan drugs for rare and ultra-rare diseases; the existence of registration of the drug in renowned regulatory agencies abroad; and the lack of a therapeutic substitute registered in Brazil.

This is the exception to the general rule mentioned in item 4, highlighted in this item given its relevance. It allows the judge to compel the State to provide medicine ‘without registration with Anvisa’. This is, exclusively, a situation of ‘unreasonable delay’ in the examination of a request for registration of the drug in Brazil, and in which there is registration in renowned international health agencies and there is no therapeutic substitute registered in the country. Unreasonable delay is linked to Law No. 13,411, of 2016. Thus, the rule is the ‘non-supply of medicines without registration with Anvisa’, except in the situation provided for above, concurrently fulfilling the established requirements. The above items are expressed in RE 657718

1. The State cannot be obliged to provide an experimental drug. 2. The absence of registration with Anvisa prevents, as a general rule, the supply of medication by court decision. 3. It is possible, exceptionally, the judicial granting of medicine without health registration, in case of unreasonable delay by Anvisa to consider the request (longer than expected for in Law No. 13,411/2016), when three requirements are met: (i) the existence of 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 in renowned regulatory agencies abroad; and (iii) the lack of a therapeutic substitute registered in Brazil. 4. Actions that demand the supply of medicines without registration with Anvisa must necessarily be proposed to the Union.

This STF decision, an exception to the general rule that only medicines registered in the country can be supplied by court decision, has in the ‘unreasonable delay’ the aspect for breaking the rule and that it must comply with the criteria established by the STF, as mentioned above. This exception causes a problem for the national director of the SUS, since, if Anvisa delays the analysis of an application for registration of medication, the Ministry of Health will be responsible for this delay, since these demands must be proposed against the Union.

On June 18, 2021, the STF, in a virtual session, decided as an exceptional measure, in RE 1165959, that the State was obliged to provide a drug that,

Although it is not registered with Anvisa, its importation is authorized by the sanitary surveillance agency, provided that there is proof of the patient’s economic incapacity, the clinical indispensability of the treatment, and the impossibility of substitution by another similar in the SUS’ official drug dispensing lists and therapeutic intervention protocols.

With the SUS being underfunded, as everyone knows, the Federal Court of Auditors (TCU) itself mentioned the increasing cost of judicialization in health expenses, adding amounts of unregistered medicines in the country, which did not even go through the National Commission for the Incorporation of Health Technologies (Conitec), (Law No. 12,401, 2011), which has the duty to analyze cost-benefit, among other aspects, imposes an excessive burden on the SUS. Because this expense that should burden the body in delay, that is, Anvisa, will aggravate the expenses to the health fund intended for annual health programs. It would be better to impose a fine on Anvisa itself, burdening its own budget, due to the delay, without
generating new financial obligations to the national leader of the SUS pressed by the health spending ceiling. This is a complex decision for SUS.

6 - The State is not obligated to provide high-cost medications claims in court when they are not included in the official SUS lists of medications. RE 566471.

RE 566471\textsuperscript{16}, which was judged on March 11, 2020, decided that the State is not obliged to provide high-cost medications requested in court, when they are not provided for in the SUS’ list of the Exceptional Drug Dispensing Program. Exceptional situations will be defined in the formulation of the thesis with general repercussion. The non-concession as a general rule makes perfect sense as it respects the SUS’ official list of drugs, as provided for in ordinances and Decree No. 7,508\textsuperscript{7}, of 2011. It so happens that exceptional situations will still be defined and these are the ones that end up creating predicaments to the SUS, as we saw in item 5. Exceptions are not always in line with collective health needs, with inter-federative agreements that occur in inter-managerial committees, with SUS legislation, as is the case with analyzes at Conitec, which are always affected by exceptions.

These legal obligations imposed on health without adding sufficient resources to SUS financing to bear all its responsibilities, deepen the inequalities in the guarantee of the right to health, given the individual and non-collective character of the legal demands. Demands in health are endless, and resources are increasingly restricted and insufficient, even more so because of the ceiling on spending by EC 95. Microjustice in health puts macro justice at risk, which is delayed by meeting individual demands, greater object of the judicialization of health, to the detriment of a universal and egalitarian system. Remember that the exceptions have not yet been formulated in the general repercussion thesis.

The complex view of judicialization on the SUS

There are countless demands for medicines, products, supplies, technologies and services in relation to the SUS. Judicialization often looks at SUS in an inadequate way, biased, without paying attention to certain norms, to interfederative agreements and to its low funding, which is a reality and one of the main causes of the inadequacies of health services that end up being judicialized.

The completeness of care itself finds some limits in the law itself, such as the requirement for an opinion from Conitec for the incorporation of products, medicines, technologies in the SUS; official drug listings; the budget. Therefore, it is argued that there must be parameters, guidelines for the interpretation of what the concept of completeness of health care comprises, as defined in article 7, II, of Law No. 8.080\textsuperscript{18}, of 1990, as it is an imprecise legal-administrative and sanitary concept\textsuperscript{19}, due to the range and fluidity of the concept of ‘health’, as seen in the definition of the World Health Organization (WHO).

This lack of definition about what completeness requires from the person in charge of applying the rules, from the administrator, the adoption of parameters, of beacons, that can modulate it, that contain such fluidity and enable, in compliance with the principles and guidelines of the SUS, to manage a public system that is able to serve everyone in a sober, rational, solidary and quality way, without excess and without stifling the law.

Therefore, the real causes of insufficiency of services need to be faced by the Legislative and Executive, the main one being the underfunding of health, of public and notorious knowledge, aggravated, as mentioned here, by EC 95 and its disastrous consequences for the
assurance of constitutional rights. Without acting on the causes, the judicialization of health will continue to be discussed without the intention of truly solving it.

It is important to stress that cooperative federalism in our country has been marked by an imbalance in relation to the federative entity providing the service (state and municipal), which is in charge of services, which in real life has to serve the population, guaranteeing sufficient, quality and timely services, emphasizing the responsibility of the federal entity in relation to the constitutional obligation of guaranteeing the right to health, which requires it to co-finance the system in a balanced way. The balance pendulum has not had the necessary balance, overloading subnational entities.

The decision that puts the Union as being responsible for the incorporation of medication in the SUS at the national level, after the technical, scientific and economic analysis carried out by Conitec, minimally recomposes the path that should have been adopted on the subject. It has always been the competence of the Union to incorporate, at the national level, medicines in the National List of Essential Medicines (Rename) and in other official lists, allowing states and municipalities to incorporate them in their own complementary lists, at their own expense. It is always and primarily the Union’s competence the incorporation of any medicine and not just high-cost ones.

In an article published ‘The financing of health in the 1988 Constitution: a study in search of the effectiveness of the fundamental right through the federative equalization of the duty of its minimum cost’

It is quite complex, since it violates the rule of free health actions and services. If the above decision prevails in the exceptions to be formulated in the thesis of non-concession of drugs not insured by the SUS, it will certainly be, as it has been so far, the most controversial decision of the Supreme Court for violating the constitutional principles of equal care and universal access highlighted in the public hearing mentioned in this work, which dealt with the ‘class difference’.

The STF, in that ruling, based its decision on the principles of universal access and equal service provided for in Article 196 of the Constitution. Being the access to health actions and services universal, equal, integral and free, as expressed in article 2, I, of Complementary Law No. 141, of 2011 — which does not allow to consider in the minimum constitutional expenditures on health actions and services that are not free — to impose the financial condition as a necessary element for the satisfaction of the fundamental right to health, is to reject
the equality of care and the gratuitousness of the services provided in the scope of the SUS.

Although it can be argued that it is a ‘high-cost drug not incorporated into the SUS’, the precedent is serious for allowing, at first, that high-cost drugs ‘not incorporated into the SUS’ are guaranteed to everyone who cannot afford its costs, colliding with the rules for incorporation in the list of SUS services, which require technical-scientific and cost-effectiveness analysis, compared to drugs already incorporated, carried out by Conitec.

By introducing into the SUS the economic situation of its user so that he or she may or may not be entitled to the right, it creates a serious precedent for the rules of incorporation in the list of actions and health services of the SUS and for the breach of gratuity and equality principles. Not to mention the concept of completeness that must be for everyone, without exception; in the universality of access, restricted in this concept to those who cannot pay. Here, there are several conflicting elements, such as: the SUS is not obliged to provide medicines not registered with Anvisa and not incorporated into the SUS. Henceforth, if the drug is expensive and is not incorporated, it may be provided by court decision. All of them? And how to define who has or does not have the financial conditions for its acquisition? Who is responsible for this task?

This aspect of the RE’s decision prejudged part of the decision that is still pending judgment on medicines for rare diseases — all of which are always high cost — without incorporation by the SUS. In any case, the decision to make the supply of high-cost non-incorporated drugs mandatory for those who cannot afford their costs can lead to the paradox of the Union preferring not to incorporate them because, thus, it will only be obliged to supply these medicines for people who demand it in court and cannot afford them and, without a doubt, it is a refutable breach of the principle of equality of care in the SUS, as mentioned above. Expenses with medicines provided only to those who cannot afford their costs, cannot, in turn, be accounted for in the minimum health expenditure due to the breach in the universality of access and gratuity, under the terms of Complementary Law 141\cite{2}, mentioned herein. The decision of Justice Alexandre de Moraes in the RE 1165959 mentioned here follows this line.

Conclusions

The judicialization of health has a positive side – which is the citizen’s awareness of their health rights – and has its negative side, which is its excess, controversial court decisions, misunderstandings of the SUS, among other aspects. We saw right and wrong in these rulings by the STF. Another aspect to be highlighted is that the judicialization of health always has an individual character, aggravating the reach of macro justice, of the collective care in benefit of the individual. This aggravates the structural difficulties of the SUS, such as its underfunding. By guaranteeing high-cost medicines not incorporated into the SUS, individually, resources will certainly be withdrawn from the health budget, impacting collective or equal health services.

In most cases, excluding the abuses that occur in judicialization, there may even be justice in the plaintiff’s request, however, without facing the causes of the inadequacy of health actions and services to the needs of people, most of them affected by the lack of resources, the quibble about the proper fulfillment of the right to health will continue. Saying that there are problems with management and corruption does not solve the real issue of low funding; it aggravates it, but neither saves nor mitigates it.

Each one of them must be faced, such as the fragility of public controls that care more for form than for content; the daily bureaucratic web, which in order to avoid corruption – which it does not – makes public action unfeasible. It is therefore necessary to have more resources for health; to face bad management
fighting insignificant rules, merely bureaucratic and insensitive to the reality of the world, which are of no use, except to infantilize the manager. It is necessary to remodel the public control system, which should focus more on the qualitative delivery of health services to the population and effectively punish administrative misconduct. Mismanagement does not make up for a lack of resources.

Finally, the judicialization of health when correcting the failures of the Public Administration is necessary and important; on the other hand, it can be bad, from the point of view of excessive granting of injunctions, individualized justice, microjustice, which does not solve the health system as a whole, in its macro view. It is necessary to fight for the improvement of health services in a collective way, which would certainly contribute to the reduction of judicialization and to the greater satisfaction of users of public health services, with the strengthening of the SUS.

Collaborator

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