Are the measures to make COVID-19 vaccine mandatory in Brazil reasonable and proportionate?

As medidas de obrigatoriedade da vacina contra a Covid-19 no Brasil são razoáveis e proporcionais?

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ABSTRACT This is an essay based on a court decision handed down by the Court of Justice of the State of Santa Catarina, Brasil, that released a municipal teacher from vaccination. The injunction in a writ of mandamus was overturned at the higher court through an interlocutory appeal authored by the State Prosecutor´s Office. This essay discusses the grounds listed by the judge for granting the injunction and the arguments presented by the appellant, while making an analysis from the point of view of public health and health law, in the light of the decision of the Supreme Court on reasonableness and proportionality of the mandatory vaccine.

KEYWORDS COVID-19. Obligatory vaccination. Right to health.

RESUMO *Trata-se de um ensaio baseado em decisão judicial do Tribunal de Justiça do Estado de Santa Catarina, que desobrigou à vacinação uma professora municipal do estado. A liminar, em Mandado de Segurança, foi cassada por meio de um agravo de instrumento de autoria do Ministério Público. Neste ensaio, são discutidos os fundamentos do julgador para a concessão da liminar e os argumentos apresentados pelo apelante, enquanto faz-se uma análise do ponto de vista da saúde coletiva e do direito sanitário, à luz da decisão do Supremo Tribunal Federal sobre a razoabilidade e proporcionalidade da vacina obrigatória.*

PALAVRAS-CHAVE *Covid-19. Vacinação obrigatória. Direito à saúde.*

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THE SANITARY CRISIS ARISING from the COVID-19 pandemic rekindled discussions on the limitation of individual rights and liberties in the name of public health protection. Among these themes, there is that of mandatory vaccination.

Recently, there was an injunction in a writ of mandamus, which was made public, regarding the release from vaccination against COVID-19 of a teacher, in face of the Municipal Secretariat of Education of Gaspar, in Santa Catarina, which by means of the Municipal Decree No. 10096/2021 made mandatory the vaccination of all education workers.

According to data from the injunction, in the Writ of Mandamus No. 5005078-302021.8.24.0025/SC the appellant claimed to have immunity against the SARS-CoV-2, verified by the ImunoScov19 exam – which points antibodies against the S protein-reactive IgG: 225 U IB-BR –, with immune response of 100%.

The magistrate's arguments expose that mandatory vaccination is unconstitutional, considering that the input is still at an experimental phase and that it does not have a definitive register at the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária – Anvisa), according to RDC No. 475/2021. It also alleges the lack of concrete scientific evidences and of researches on the security and effectiveness of vaccines against COVID-19, and refers to the website ClinicalTrials.gov, a database maintained by the United States National Library of Medicine, which registers all private and public research in the segment, worldwide.

He argues, for the grant of injunction, about the Code of Medical Ethics[1], Chapter I, of the fundamental principles, which provides that:

> In the process of professional decision-making, according to the principles of consciousness and legal provisions, the doctor will accept the patients' choices, related to the diagnostic and therapeutic procedures expressed by them, as long as these are appropriate to their cases and scientifically recognized.

He also cites Art. 24 of the same Code, which provides that:

> [The doctor is prohibited to:] Fail to ensure the patient's right to freely decide about her/himself or the own wellbeing, or to use the doctor's authority to limit it[1].

In order to fill his arguments, he mentions Art. 15 of the Brazilian Civil Code, which defines that "No one may be compelled to submit to medical treatment or surgical intervention that presents a life-threatening risk"[1].

In the judge's decision, he stresses that the Federal Supreme Court (Supremo Tribunal Federal – STF), in the ambit of Direct Actions for the Declaration of Unconstitutionality of Law No. 13.979/2020[2], defined the compulsoriness of vaccination, as long as the measures of obligatoriness are indirect, reasonable and proportional.

And to conclude his arguments, he brings to the decision the consecrated Precautionary Principle, which provides that in the absence of full scientific certainty, when there are threats of damage, it requires the implementation of measures that can prevent this damage.

As soon as the injunction was published on the Journal of Justice, the Prosecutor's Office of the State of Santa Catarina presented the interlocutory appeal, opposing the arguments of the granted injunction, exposing, without corroborating scientific data, that the inherent risks of the vaccine are less than the risks posed by the uncontrolled circulation of the virus. In addition, he states that the teacher, by refusing to be vaccinated, would put at risk of exposure the children, adolescents and staff of the municipal education system, besides jeopardizing the strategy of the State of Santa Catarina's administration and its municipalities regarding the return to presential classes.

The injunction was then reversed by the Court of Justice of the State of Santa Catarina (TJSC), which agreed with the arguments of the State Prosecutor's Office.

The obligatoriness of vaccination against COVID-19 has been present in the debates on

the political-sanitary systems and the judicial system, not only in Brazil, but also worldwide. However, the background discussion is more remote in time.

The first vaccine was developed in 1796, by the English doctor Edward Jenner, to combat smallpox, which was then considered one of the greatest health scourges. The adoption of the vaccine as a mandatory health measure to control the disease provoked a reaction of the population against it[3].

Perhaps the inaugural judicial landmark of the obligatoriness of vaccination in Brazil was the Law No. 1261, of October 31, 1904[4], when Oswaldo Cruz was nominated General Director of Public Health in the administration of President Rodrigues Alves, a position which today would be equivalent to the Minister of Health. The law conditioned the celebration of weddings, the enrollment at schools and even the formalization of work contracts to the proof of the respective vaccination.

The vaccination card was a sort of passport for the practice of civil life acts, similar to the vaccination passport recently adopted in some Brazilian states – São Paulo, Rio de Janeiro and Rio Grande do Sul – to allow people's entry to certain places. Thus, there was an indirect sanction as a means to the adherence to the vaccinal process.

This extreme measure was justified by the population's resistance to voluntarily adhere to the vaccinal process. The rejection was partially due to fake news that affirmed that those who would take the vaccine against smallpox would have their features transformed, becoming similar to bovines. The reason for this would be that the vaccine was produced with material collected from the pustules of those animals.

The fact is that the mandatory vaccination in the early twentieth century initiated the population's revolt, possibly led by the League Against the Mandatory Vaccination, which turned the streets of Rio de Janeiro into a battlefield. After two weeks of conflicts, which resulted in 945 arrests, 461 deportations, 110 injured and 5 deaths[5], President Rodrigues Alves felt obliged to reverse the mandatory vaccination.

Though sanitarily efficacious, it was an authoritarian and disastrous governmental decision that provoked in the people, who were oppressed and threatened by the official medicine, the repulsion to the scientific tyranny marked by a series of coercive measures against civil liberties. In sum, the revolt occurred because people did not accept seeing their homes be invaded and having to take the injection against their will. Unfortunately, after the attempt to make mandatory the vaccine against smallpox, there was a great reduction of the vaccination rates[5], resulting in an abrupt increase of the disease.

Vaccination is considered one of the most efficacious and cost-effective public health policies, used in the control and prevention of diseases. But it is also considered one of the most polemic and controversial biomedical techniques, especially when the vaccination is compulsorily applied to the entire population, including the reason that vaccines are not fully safe and efficacious[6]. But undoubtedly vaccination eliminates or drastically reduces the risk of falling ill or having severe manifestations, which may lead to hospitalization or even death.

According to Iriart[7], some adults' option for not being vaccinated has been raising interest in researchers who study social sciences phenomena. The decision to be or not vaccinated exposes the tension between the individual and the collective, and demonstrates the erosion of people's trust in sanitary actions promoted by the Public Administration, associated to the sentiment against the greed that moves the pharmaceutical industry. Perhaps this is why the obligatoriness of vaccination in itself already produces a contrary effect to the intention of mass vaccination. Imposed measures raise distrust and rejection in the individuals. There are some people who bet on the awareness of the population about the importance of the vaccine, which would be much

more efficient than the arbitrary imposition.

From the legal viewpoint, vaccination is part of the understanding of the right to health implicit in the triad designed in the Federal Constitution[8], in Art. 196: promotion, protection and recovery of health.

From the analysis of the generation of fundamental rights[9], it is clear that health is a right that pertains to all generations. Its dimension is transversal to the consecutive generations of rights, because the element health cannot be subtracted from these fundamental rights, being health a right directly related to life.

The Brazilian Constitution of 1988[8] itemized the second generation of fundamental rights, with health being included in its Art. 6, but did not disregard its individual dimension among the other corresponding articles. Therefore, health is undoubtedly a fundamental right of first, second, third and fourth generations, a right that must be granted by the State's positive action so that it can be fully experienced by citizens. It is configured in the Constitution[8] of 1988 as a principle, meaning that it cannot be applied in the form of 'all or nothing', but as much as possible, as long as it is not supplanted by factual and legal assumptions of other fundamental principles.

Art. 196 prescribes that these dimensions of the right to health, together or separately, should be achieved through the access to health actions and services that should be provided by the State in the adoption of social and economic public policies.

It is interesting that, although the theme of health promotion is quite prolific in intellectual-academic reflections and studies, and the same can be said of health care, the references regarding the protection of health strict sense are scarcer, and this is not coherent with the relevance that the legislator conferred to it in the constitutional text.

Why would the constituent legislator use, in a list of words, this set of expressions, as in Art. 196, in fine – the promotion, protection and recovery of health –, if there would be no specific meaning for each of them? Would these words have a legal-sanitary meaning?

In an analysis of merit, it must be concluded that, without an articulated set of policies and actions, it will be impossible to attain the fruition of the fundamental right, since these elements are essentially and complementarily constitutive of the fundamental social right to health. Besides, it is to be considered the basic principle of juridical hermeneutics, according to which the law does not contain useless words: *verba cum effectu sunt accipienda*. This means that words should be understood as having some effectiveness. Useless words are not presumed in the law. And if there is no uselessness in the words of the law, it is questioned about the contents of expressions inscribed in the Federal Constitution of 1988, especially referring to the protection of health.

Pontes and Schramm[10] alert that the principle of protection is a rescue of the State's protecting role, considered as a fundament of the contemporary Welfare State's action. This statement is true, especially regarding health. The State exerted and consolidated, during the eighteenth and nineteenth centuries, the role of guarantor of individual rights, thus defining a first level of protection. Public health arises as a matter of the State in this period, "controlling epidemics and decisively influencing the sanitary reform of urban and work environments"[10], introducing another level in the ambit of the principle of protection: the collective.

The principle of protection posed in this way has similarity with the State's duty to protect (or, not permit the violation of a right), which, applied to health, ensures a fundamental right to individuals and the collectivity, using all its institutional apparatus.

The protection of health, therefore, is a duty of the State – and a fundamental right –, which, through actions and services delivered, contributes to ensure the fruition of integral health. In this dimension, mass vaccination actions concur to ensure the right to health, thus constituting the true principle of protection of health.

There is, thus, a legal-sanitary content in the expression 'protection of health' inscribed in the Constitution, which encompasses actions and services that provide materiality and constitute a principle of protection that must be achieved as much as possible. Therefore, services and actions that aim to protect health – principle of protection – should be interpreted as a fundamental right, and should be obligatorily observed for the formulation and implementation of public policies, for the guidance of the legislative framework, including infra-legal, and the judicial decision.

Brazil configured in 1973 the National Immunization Program (Programa Nacional de Imunização – PNI), therefore previously to the recognition of health as a social human right and to the creation of the Unified Health System (Sistema Único de Saúde – SUS). In 1975, the Law No. 6259[11] provided on the competence of the Ministry of Health to establish mandatory vaccination, to be practiced systematically and free of charge. As an indirect measure, the law conditioned the payment of State family allowance to the proof by beneficiaries of having received the mandatory vaccines.

Along the years, the PNI conducted important strategies of vaccination campaigns, facing epidemics of meningitis in 1974 and poliomyelitis in 1980[12].

With the growth of the campaign of vaccination against COVID-19, supported by the country's existing legal-normative framework, added by the recent Law No. 13979 of 2020[2] – an initiative of the Executive Branch and approved by the National Congress, in an emergency regimen due to the sanitary crisis – the mandatory character of the vaccination was reinforced, being always an *ex vi legis* provision, i.e., resulting from the law.

Since then, there have been judicial decisions that achieved the release from vaccination, although the country's vaccinal reality presents better rates than the North American campaigns, where the anti-vaccine movement is very strong[13].

The STF, in the course of analyzing the constitutionality of provisions of the Law No. 13979, of 2020[2], which dispose about the compulsory vaccination as a measure to face COVID-19 emergence, took a stance in the sense of establishing the differentiation between compulsory vaccination and forced vaccination, with the consent being the degree of differentiation between the two.

However, the STF also recognized the possibility of the use of indirect measures toward stimulating the population's adherence, insofar as provisioned in the law or resulting from it, justifying possible restrictions to individual autonomy, in the duty of the State to confer concreteness to the disposed in Art. 196 of the Federal Constitution[8] of 1988. This is an irrevocable duty.

The Minister of STF Luís Roberto Barroso[14], in his vote in the Direct Action for the Declaration of Unconstitutionality No. 6586, elucidates these limits

> [...] the expression mandatory vaccination does not mean that someone can be immunized by force, with physical violence, or any other kind of coercion.
>
> The mandatory character of vaccination implies that it can be required as a condition for the practice of certain acts, such as the enrollment of a child at a public or private school, or as a condition to be a beneficiary in governmental programs, such as the income transfer Bolsa Família, or that penalties may be applied in case of noncompliance. As a general rule, the Law does not admit that the obligations are complied with the use of force – *manu militari* – by the Public Power.

From the viewpoint of sanitary law, there is no doubt that vaccination constitutes an important measure of a preventive nature, toward ensuring the right to health, notably in the collective sphere. Furthermore, it is less restrictive in rights than other actions, such as forced social distancing and/or lockdown policies. It is in this context that the adoption

of mandatory vaccination is justifiable, when the superposition of the State's will over individual rights and liberties has the scope to protect the collectivity's right.

Also to be highlighted is that the efficacy of the measure is directly conditioned to the immunization of a large number of individuals, capable of generating an appropriate security shield to reduce the risk of new contaminations and the propagation of the disease with new surges.

In another scope, the omission of the State in facing sanitary crises, such as the COVID-19 pandemic, would be far more harmful than the adoption of mandatory vaccination. What must be observed, when adopting this important preventive measure, are the scientific evidences and strategic information, besides the respect to human dignity. Precisely for this reason, coercive measures are rejected.

Therefore, in the ambit of the sanitary law, this tension between the individual and the collective is not unusual, since the State has the duty to act in order to protect and preserve the constitutionally recognized right to health and, at the same time, must respect the individual rights and liberty that are also encompassed in the Federal Constitution. This is why this conduct must be based on reasonableness and proportionality criteria.

The principle of proportionality[15], largely used for the protection of fundamental rights, in the national and international ambits, considers the existence of a balanced relation between means and ends, i.e., the adopted intervention should be confronted with the intended purpose, as to avoid excesses. This balance can be observed drawing on the evaluation of three elements or sub-principles that inform it: i) pertinence; ii) necessity; and iii) proportionality in the strict sense.

Pertinence means the adequacy itself of the elected measure for the purpose intended to be achieved. Necessity determines the limits of the adopted measure, which should be those strictly necessary to the achievement of the intended purpose. In other words, among the various measures available, the one to be elected should be the smoothest and less damaging to the interests of individuals.

Finally, proportionality in the strict sense, which establishes the very condition of legality of the act, because it repels those that are disproportionate.

In the case under analysis, the application of the principle of proportionality and its sub-principles enables to reach the conclusion that the adoption of the mandatory vaccination as a measure to combat the coronavirus complies with the parameters of reasonableness and proportionality necessary to face a sanitary crisis of such magnitude.

With the massive advance of the gratuitous vaccination in all of the country's states, the decrease of the rates of new cases and number of deaths[16] can be observed. This panorama, in its turn, also enabled the relieve of beds in Intensive Care Units (ICUs) of public and private hospitals, besides the resuming of other health actions and services that were impacted by the coronavirus pandemic.

Although the obligatoriness of vaccination interferes directly in the field of individual choices, the results achieved, especially in the face of a severe context of sanitary crisis, are clearly based on reasonableness and proportionality between means and ends.

Therefore, the protection and security of individual and collective health by means of mandatory vaccination are the expression of the State's action directed at ensuring and promoting the right to health.

Collaborators

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