JUDICIAL LIMITS OVER THE ADMINISTRATIVE DISCRETIONARY ACT: ANALYSIS OF THE DECISIONS OF THE INJUNCTIONS GRANTED IN ACO 3.451/DF BY THE BRAZILIAN SUPREME COURT

LIMITES JUDICIAIS AO ATO ADMINISTRATIVO DISCRICIONÁRIO: ANÁLISE DAS TUTELAS DE URGÊNCIAS DEFERIDAS NA ACO 3.451/DF PELO SUPREMO TRIBUNAL FEDERAL BRASILEIRO

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Edgar Meira Pires de Azevedo[1] – *https://orcid.org/0000-0001-6131-1687*
Maria Esther Alencar Advíncula D'Assunção[2] – *https://orcid.org/0000-0001-5338-0543*
Ana Beatriz Ferreira Rebello Presgrave[3]– *https://orcid.org/0000-0002-8801-994X*

Abstract
The serious health situation resulting from the Covid-19 pandemic, in addition to the global health emergency, also generated deep crises in the economic, political-ideological and governance fields, which led to the Judiciary several issues that, in a normal situation, would not be within its jurisdiction. Therefore, this paper aims to address the decision rendered by the Federal Supreme Court (STF) in ACO 3.451/DF, in which the Court allowed the automatic authorization for the State of Maranhão to import and distribute the Sputnik V vaccine for its population. Consequently, the central problem of this research is to analyze whether this position, in addition to promoting a re-reading of the control of the administrative act by the Judiciary, is in accordance with the constitutional provisions. This is a research of strategic basic purpose, descriptive and exploratory objective, under the deductive method, with a qualitative approach and performed through bibliographic and documental procedures. In the end, it is verified that the decision taken by the STF in the judgment of ACO 3451/DF affronts the principle of the functional division of power, expressed in art. 2 of the Federal Constitution, and also culminates in violating the right to health itself, set forth in art.

[1] Specialist in Constitutional and Taxation Law at UNP, Master student in Law at Universidade Federal do Rio Grande do Norte (UFRN), CEP 59075-000, Natal, Rio Grande do Norte, Brazil, Public servant at the State Court in the State of Rio Grande do Norte (TJRN), Brazil, edgarmpa@hotmail.com. https://orcid.org/0000-0001-6131-1687

[2] Specialist in Constitutional and Taxation Law at UNP, Master student in Law at Universidade Federal do Rio Grande do Norte (UFRN), CEP 59075-000, Natal, Rio Grande do Norte, Brazil, Professor of Law at Universidade Estadual do Rio Grande do Norte (UERN), CEP 59.120-200, Natal, Rio Grande do Norte, Brazil, lawyer, esther.dassuncao@gmail.com. https://orcid.org/0000-0001-5338-0543

[3] Doctor in Law at UFPE, Post-Doctoral internship at Westfälische Wilhelms-Universität, Professor of Law for graduation and master students at Universidade Federal do Rio Grande do Norte (UFRN), CEP 59075-000, Natal, Rio Grande do Norte, Brazil, ana.beatriz.presgrave@ufrn.br. https://orcid.org/0000-0002-8801-994X

196 of the Constitution. Moreover, the greatest contribution of the research is, precisely, in enabling the discussion of the position adopted by the Court before the ineffective management of the Executive due to the health crisis that has been established with the Covid-19 pandemic.
Keywords: Administrative act. Power of review. Administrative act control. Constitutionality.
Resumo

A grave situação sanitária decorrente da pandemia de Covid-19, além do quadro de emergência mundial de saúde também gerou crises profundas nos campos econômico, político-ideológico e de governabilidade, o que levou ao Judiciário diversas questões que, em situação de normalidade, não seriam de sua alçada. Diante disso o presente trabalho objetiva abordar a decisão proferida pelo Supremo Tribunal Federal (STF) no julgamento da ACO 3.451/DF, na qual a Corte possibilitou a autorização automática para que o Estado do Maranhão importasse e distribuísse a vacina Sputnik V para a sua população. Por decorrência, a pesquisa tem como problemática central analisar se referida postura, além de promover a releitura do controle do ato administrativo pelo Judiciário está de acordo com os dispositivos constitucionais. Realiza-se então uma pesquisa de finalidade básica estratégica, objetivo descritivo e exploratório, sob o método dedutivo, com abordagem qualitativa e realizada pelos procedimentos bibliográficos e documentais. Ao fim, verifica-se que a decisão tomada pelo STF no julgamento da ACO 3451/DF afronta o princípio da divisão funcional do poder, expresso no art. 2º da Constituição Federal, bem como culmina por violar o próprio direito à saúde, disposto no art. 196 da Carta Maior. Ademais, a maior contribuição da pesquisa está, justamente, em possibilitar a discussão da posição adotada pela Corte diante da inefetiva gestão do Executivo em razão da crise sanitária que se instaurou com a pandemia de Covid-19.
Palavras-chave: Ato administrativo. Poder de revisão. Controle de atos administrativo. Constitucionalidade.

1 INTRODUCTION

In the late 2019, the world was surprised by of a new virus that rapidly spreading across the globe. Within a few months, the new virus SARS-CoV-2 had spread virtually everywhere. It was unprecedented, and in March of 2020, the World Health Organization (WHO) declared a pandemic. The virus affected all areas of society, and people questioned government's role in moving into this uncharted territory.

During this period of instability and uncertainty, the government was pressed daily to completely new situations, or situations that were not a problem before the pandemic. For this reason, the Brazilian Judiciary has proceeded with a judicial review of administrative discretion, radically changing the perspective adopted until then. In the same way, the other branches of the Republic have had to review their position since the performance of the Brazilian Executive branch has proven to be quite inexpressive. In response to the escalating chaos, the Brazilian Federal

Supreme Court (STF) in the judgment of ACO 3.451/DF, presented an unexpected reinterpretation of the long-standing position regarding some classic legal institutes, shifting the precedent to the limits of the judicial review and control of administrative acts, especially discretionary ones. In the case, the reporting justice Ricardo Lewandowski granted the State of Maranhão an "automatic authorization" to import and distribute the Sputnik V vaccine the prior sanitary control of ANVISA (the autarchy responsible for sanitary issues in Brazil).

The question that will be answered with this paper is whether this decision, taken in this specific case during the pandemic, is following the Constitution and whether it represents the STF's latest interpretation of the limits of judicial review. The work, therefore, will also analyze whether this "automatic authorization" to import and distribute potentially dangerous products offends articles 2º and 196 of the Brazilian Constitution, namely, the division of powers and the right to health.

To approach the theme, the following specific objectives: (a) analysis of the administrative discretion under the doctrine of the Democratic State of Law; (b) analysis of the previous and current Brazilian judicial review of administrative discretion; (c) evaluation of the context in which the decisions were made and (d) analysis of the constitutionality of the decision that was adopted in ACO 3.451/DF.

The research starts form the hypothesis that the assumption of executive functions, notably that of ANVISA, by the Judiciary infringes the Constitution. In this context, the paper will confront the decisions taken in ACO 3.451/DF with the basis of Brazilian Constitutional framework.

The limits of the administrative discretion will be the focus of the section 2, establishing theoretical premises to guide the conduct of the research. Sections 3 and 4 will deal with the grounds for the judicial review and present the case under study (ACO 3.451/DF). Sections 5 and 6 will analyze the legal and constitutional aspects of the decision.

In the end, the research confirms the hypothesis under discussion. It concludes that, despite the unique scenario and the pressures involved, granting automatic authorization for the importation and distribution of vaccines in the concrete case was not compatible with the Constitution, notably art. 2º and art. 196, despite the ineffectiveness of the Brazilian Executive at the time in facing the severe health crisis caused by covid-19.

2 THE ADMINISTRATIVE DISCRETION

Administrative discretion is a consequence of the separation of powers. The concept of the rule of Law is built on the premise that each of the powers will respect the limits – and obligations – imposed by the Constitution.

The idea of the separation of powers, as it is known today, was conceived in the context of the French Revolution, in order to cement the power of the state

through popular sovereignty, which is the central idea of the Modern State[4]. The separation of powers doctrine introduced a system of checks and balances to prevent abuses[5]. The core of the doctrine is based on Aristotle's classical theory, which was revisited by Locke's liberal doctrine and was enshrined Montesquieu in his classical definition. The doctrine aims to prevent any individual or institution from holding all power and restore integrity and accountability of the political and legal systems. Working together and independently, the three powers would structure the state[6].

Administrative discretion, as highlighted, is a consequence of that separation of powers. Although the law was intended to establish general rules to be obeyed, discretion is a crucial instrument to fulfill the state's objectives based on criteria of convenience and opportunity.

In the Welfare State, the separation of the powers and the idea of discretionary powers underwent a severe reformulation. Due to the hypertrophy of the State and the increase in social needs, these concepts had to be reinterpreted.

2.2 Scope of Administrative Discretion: Discretionary Power

Discretion, used as a tool to advance the functions of the State, includes the coexistence between the judgment of legality and the sense of opportunity[7] and is not an exclusive power of the administrative function *strictu sensu.* Discretion should be treated as a power inherent to the government so that it can be used for to develop legislative, executive, and judicial functions.

Concerning the Legislative branch, the discretion is broad because the legislature has an infinite supply of diverse and unique social materials to present and address in the legal form of laws and regulations. In the Democratic Rule of Law, the basic premise is that the sovereign entity must follow its own decisions. However, concrete reality shows that discretion and submission vary according to the political ideals of those in power.

There is increasing pressure for the Legislative Branch to act in the face of its omission, whether employing a "*writ of the injunction*", or a "*right action of*

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4 "[...] p*recisava-se sepultar nos espíritos a Idade Média, o corporativsimo, a feudalidade e seus privilégios, o absolutismo do rei e sua contradição com a liberdade moderna*". (BONAVIDES, Paulo, *Do estado liberal ao estado social*, 11th ed., São Paulo, Malheiros, 2013, p. 66).

5 "In both the narrow and the broad definitions, the term "checks and balances" usually encompasses a wide range of tools such as judicial review, presidential veto, impeachment, court decisions overturning executive actions, constitutional amendments to reverse court decisions, consent of the senate on appointments and treaties, no confidence votes in parliamentary democracies, oversight hearings, congressional investigative committees, and so forth and so on." DA ROS, Luciano, TAYLOR, Matthew M. "Checks and Balances: The Concept and Its Implications for Corruption". *Revista de Direito GV.* São Paulo, v. 17, n. 2, 2021, p. 6. Available at https://doi.org/10.1590/2317-6172202120. Accessed in 03/09/2023.

6 Even then, there already were skeptical scholars towards the strict majority rule and that already were interested in the constitutional role of the courts, such as the American Founding Father, Alexander Halmilton, and later on Benjamin Constant, Alexis de Tocqueville and John Stuart Mill. For further information: Tate, C. Neal, and Torbjörn Vallinder. The Global Expansion of Judicial Power. New York University Press, 1995, p. 17-18.

7 FRANÇA, Estrutura e Motivação do ato administrativo, São Paulo, Malheiros, 2007, p. 85.

unconstitutionality by omission"[8] or on the premise that the "*Legislative Branch*", in its typical function, is not obliged to act[9]. It is important to emphasize that these remedies do not take away the legislator's discretion about the themes and subjects of a new law.

For the Judiciary, the question is whether that Branch has discretion to act. Regardless, a judge should never be viewed as a robot[10], especially when the applying a legal rule involves subjective activity by the judge to achieve the rule's objective. Moreover, evolving norms may introduce new judicial concepts that must be addressed.

Discretion allows the State to perform its functions more efficiently, especially when some legal concepts are intentionally vague, allowing for adaptation in social, economic, political, and cultural settings[10]. As a result, the law enforcer must interpret and apply the content of the expression according to the situation.

The Executive Branch's discretionary power is fundamental to developing the administrative function and making the state's actions more effective and efficient.

Therefore, due to its importance, the misuse of discretion power tarnishes the act, turning it arbitrary. From then on, discretionary power must be exercised with caution, obeying the limits established in the legal system. In case of non-compliance with the discretionary limits by the administrator, the Judiciary Power may be called upon to review the act. However, if the limit of discretion power is not exceeded, the Judiciary does not have the authority to review it.

2.3 Administrative Discretion and Technical Discretion

Traditional Brazilian doctrine considers central the distinction between administrative and technical discretion. Initially outlined by the Austrian Bernatzik; in Italy, Alessi and Maximo Giannini are examples of essential scholars to deepen the study on the concept of each type.

Administrative discretion brings the classical and usual concept of discretion as a power duty conferred to the administrator by the law and limited by it, composed of a sense of deciding on the convenience and opportunity to act in a specific case. Technical discretion, on the other hand, arises when the administrator needs to make use of specific, if not also complex, knowledge.

If more than one solution is technically adequate, there is no discretion for the administrator. However, convenience and opportunity judgment can occur in situations in which the technical solution presented allows more than one adequacy option. This implies that the administrator must use scientific and technical expertise and only decide within the law and technical limits. For example, if a technical body

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[8] Both are remedies established in the Brazilian Constitution in cases of legislative omission, however, the Legislative is not truly coerced to act.

[9] SILVA, Almiro do Couto e, *Conceitos fundamentais do direito no Estado constitucional*, São Paulo, Malheiros, 2015, p. 169.

[10] "*Ele não se refere a uma coisa certa, mas a uma significação*". DI PIETRO, Maria Sylvia Zanella, *Discricionariedade Administrativa na Constituição de 1988*, 3rd ed., São Paulo, Atlas, 2012, p. 90.

considers that a building structure is at risk of collapsing, the administration must decide whether this situation comprises of danger that also affects the public interest[11].

3 FOUNDATION OF THE JURISDICTIONAL CONTROL OVER THE ADMINISTRATIVE DISCRETIONARY ACT IN BRAZIL

The understanding of Democracy gained an important dimension due to the normativity of fundamental rights and their binding force. Thus, as Bonavides[12] elucidates, one finds the substratum of the Contemporary Constitutional State in the fundamental rights and in the justice of the principles. Therefore, understanding the meaning and scope of administrative discretion requires understanding the Rule of Law[13].

The entire discussion about what it is, why it exists, and the origin of the authority of the State and the Law today falls on the theories of Democracy and fundamental rights[14]. The legal system limits all activity of the Public Administration, which means that the law and all precepts of this system are mandatory[15]. In concretizing these legal precepts, administrative discretion is born, developed, and understood as objective of seeking and achieving the State's purpose from the alternatives presented in the concrete case[16].

The legality thus understood is called in Brazil as "*juridicidade administrativa*", when its guidelines are not followed; the act is, at least, invalid.

In Brazil, the control within the Administration, called the "*princípio da autotutela*", comprises the enforcement powers to annul, convalidation, and revoke administrative acts, including disciplinary power. Suppose the administrator fails to use the power inherent to the "*princípio da autotutela*". In that case, the central problem of this research becomes evident: can the Judiciary act positively, interfering in the judgment of convenience an opportunity incumbent on the Administration?

As far as the traditional Brazilian doctrine is concerned, the administrative act comprises in its content (or objective) the expression of the individual, concrete, and personal will of the State as Public Power for the attainment of its objective, that is, the fulfillment of the public interest, doing so in directly and immediately for the production of legal consequences[17]. Furthermore, in Brazil, the administrative act

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11 DI PIETRO, Maria Sylvia Zanella, *Discricionariedade Administrativa na Constituição de 1988,* 3rd ed., São Paulo, Atlas, 2012, p. 107.

12 BONAVIDES, Paulo, *Teoria Geral do Estado*, 10ª edição, São Paulo, Malheiros, 2015, p. 57.

13 FRANÇA, Vladimir da Rocha, *Invalidação Judicial da Discricionariedade Administrativa no regime jurídico-administrativo brasileiro*, Rio de Janeiro, Forense, 2000, p. 17.

14 BINENBOJM, Gustavo, *Uma teoria do direito administrativo*, 3rd ed., Rio de Janeiro, Renovar, 2014, 49.

15 FRANÇA, Vladimir da Rocha. "Reflexões sobre a competência normativa da Agência Nacional de Águas", *Revista Brasileira de Direito Administrativo e Regulatório*, v. 3, 2011, p. 207.

16 MELLO, Celso Antônio Bandeira de, *Discricionariedade e Controle Jurisdicional*, 2nd ed., São Paulo, Malheiros, 2017, p. 15.

17 MELLO, Oswaldo Aranha Bandeira de, *Princípios Gerais de Direito Administrativo*, vol. 1: Introdução. 3rd ed., São Paulo, Malheiros, 2010, p. 476.

comprises five essential elements listed in 2nd article of Law nº 4.717/1965: competence, form, purpose, motivation and object. In summary, *Competence* is the obligation attributed by law to act in that specific matter or situation; *form* is the external expression of the act; *the purpose* is the desired desideratum; *motive* is the reason for causing the action and, finally, *the object* and material objective desired with the practice of the act.

The traditional Brazilian specialized doctrine considers competence, form, and purpose binding. At the same time, motivation and object may be left to the discretion of the administrator's judgment of convenience and opportunity. However, part of the Brazilian administrative doctrine criticizes this division of administrative acts into mandatory elements (competence, form and purpose) and discretionary elements (motivation and object). For Andreas Krell, the subdivision above of administrative acts into five elements has contributed little to a better understanding of the scope and control of discretionary acts[18] since it generalizes and simplifies to the extreme the line separating mandatory and discretionary actions.

In Brazil, in the early 1940s, Miguel de Seabra Fagundes, in a seminal way, reviewed the discretionary dimension of administrative acts. For Fagundes, judicial control occurs through judicial intervention in implementing the Law since the acts of execution will be reviewed the Executive by the Judiciary[19].

In analyzing the merit of the administrative act, the traditional doctrine holds that the judicial review should be limited to controlling the mandatory elements (competence, form and purpose) and that the Judiciary could act only to control its legal aspects. On the other hand, modern thinking defends control over the discretionary acts based on reasonableness, proportionality, and morality.

However, the doctrines mentioned above still need to be improved. In today's plural society, whose interests are increasingly fluid and diverse, Phillip Gil França defends the expansion of the legal spectrum of merit control by the Judiciary, through an objective element, by demonstration the causal link between the production of the act and the substantial public interest promoted[20].

By choice of "*Poder Constituinte Originário*"[21], Brazil is a Democratic Republic of Law. Therefore, as a cornerstone of the administrative and legal system, none of the state functions should act against the interest of society (strict observance of the public interest). All Powers of the State (Legislative, Executive and Judicial) must play their part role according to the established canons, avoiding subjective options, voluntarism, and ruling out any intention that might collide with

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18 KRELL, Andreas Joachim, *Discricionariedade administrativa e conceitos legais indeterminados: limites do controle judicial no âmbito dos interesses difusos*, 2nd ed., Porto Alegre, Livraria do Advogado, 2013, p. 26.

19 FAGUNDES, Miguel de Seabra, *O controle dos atos administrativos pelo Poder Judiciário*, 5th ed., Rio de Janeiro, Forense, 1979, p. 106.

20 FRANÇA, Phillip Gil, *Ato administrativo e interesse público: gestão pública, controle judicial e consequencialismo administrativo*, 3rd ed., São Paulo, Revista dos Tribunais, 2017, p. 179.

21 In Brazil, the Constituent Power can manifest in three ways, the Original Power created the Constitution in 1988, the Revision Power (could alter the constitution during specific time frame, right after its enactment and had a broader spectrum of change) and the only currently available power (as the previous ones can no longer be used with this Constitution), the Amendment Power.

the intangibility of the public interest principle. That is why the main link between a rationalized administrative intervention and its judicial review is the adequate motivation and grounds for the administrative act[22].

With this premise, the Judiciary reaches the so-called intangible core of the administrative act, even if the case involves discretionary power (administrative merit), since the Judiciary may, in some cases, examine the judgment of convenience and opportunity revealed to the administrator.

However, the Judiciary must employ adequate grounds, which can only occur if there is substantial motivation in the administrative act, to allow an adequate analysis. The most significant concerns arise when technical and complex evaluation prevails ins the search for a solution. Even if the Judiciary is not equipped to deal with this routinely, it can call on experts and/or technical bodies to assist judges and courts nationwide. And, to cope with the notorious slowness, which is known to cause high risks and costs to the State machine, the party in the case may avail itself of procedural devices available to allow the urgent decision, such as "*tutela de urgência*" and "*tutela de evidência*"[23].

For all these reasons, to avoid arbitrariness and enable the State to provide the services adequately and also to avoid economic and financial losses, violations of the fundamental principles of the State, and the protection of the individual rights, any distortions should be analyzed within the administration ("*poder de autotutela*") or outside it, by the Judiciary. Judicial review would then seek to reveal not only (a) the concrete benefit for an equal state participant, (b) the development of a correct social interest, (c) the causal nexus between the production of the act and the public interest, but the judicial review also (d) the appropriate legal moment and (e) the efficient and effective administrative response.

The judicial control of the administrative act in the current Democratic State of Law and Republican Regime of Government should be broad and deep, including concerning the administrative merit (sense of convenience and opportunity). The Judiciary, when provoked, must be able to seek and find in the motivation of the administrative act the appropriate use of the principles of reasonableness, proportionality, and morality. The analysis, then, will consider the mandatory and comprehensive motivation of the act and weigh the objective elements used in the concrete case.

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[22] FRANÇA, Phillip Gil, *Ato administrativo e interesse público: gestão pública, controle judicial e consequencialismo administrativo*, 3rd ed., São Paulo, Revista dos Tribunais, 2017, p. 178.

[23] In Brazil, the civil code of procedures allows interlocutory decisions to prevent deleterious effect a long wait can bring to the effectiveness of the final decision on the case. It must be expressly and fundamentally requested, even before the legal case is presented, through preventive and interlocutory injuctions. Sometimes, urgencies is not even necessary, that would be the case of a "*tutela de evidência*". The matter is regulated in *Livro V – Da Tutela de Urgência*", from art. 294 on.

4 REREADING OF THE REVISION OF THE ADMINISTRATIVE ACT PROMOTED BY STF'S DECISIONS ON THE PRELIMINARY INJUCTIONS IN ACO 3.451/DF

The sanitary emergency caused by the new coronavirus (Sars-CoV-2) peaked when the World Health Organization (WHO) declared, on March 11, 2020, the Covid-19 pandemic. The awaited vaccines would appear throughout 2021, agitating even more, the unstable melting pot society became. No different from generally elsewhere, in Brazil, the sanitary situation was severe and to be followed by a grave crisis. In this chaotic scenario, society pressured the Judiciary branch. Mass-oriented claims for matters that typically the State could have attended without the participation of the Judiciary were flooding the courts.

In December 2020, the federated State of Maranhão initiated "Ação Cível nº 3.451/DF"[24] before the "Supremo Tribunal Federal" – STF (Brazilian Supreme Court), aiming (i) the declaration that it could purchase vaccines and launch its vaccination program within its territory; (ii) the declaration that the Federal Union must grant financial aid for the acquisition of said vaccines to its population or must do the compensation, with the Federal debts, both secured and unsecured bonds, and (iii) the order to prohibit the Federal Union to undertake any measures to restrict or prevent State of Maranhão to launch its vaccination program towards its population.

In Brazil, even though the courts should decide matters in collegiate, due to pressing time and hypertrophy of the Judicial demand, more and more norms are being issued to allow the singular justices in courts to solely decide matters to the latter, if necessary, submit the decision to collegiate appreciation. That also happened in the case under examination.

Supreme Court Justice Ricardo Lewandowski, who was assigned to the case, analyzed and decided, in December 2020, as an urgent injunction request only the claim regarding authorization for the acquisition of immunization and launching of the vaccination program[25].

The reporting justice, in examination prima facie the merits of the claim, made his stance very clear, allowing the adoption of the local vaccination program when and if (i) "Plano Nacional de Operacionalização contra a Covid-19" was unfulfilled or not enforced promptly and with sufficient coverage, that would allow the State of Maranhão to purchase and administer vaccines, as long as ANVISA would have already approved those vaccines and (ii) in case the autarchy would not have approved the vaccine yet, ANVISA would have 72hs from the submission request of the vaccine to the decision, after what State of Maranhão would automatically be authorized to import and distribute the vaccines in question, if they were registered by, at least, one foreign authority and already in commercial distribution within said country. On April 13, 2021, the mentioned decision was

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[24] This case is public and the decisions can be accessed at: <https://portal.stf.jus.br/processos/detalhe.asp?incidente=6067919>.

[25] BRASIL, Supremo Tribunal Federal, *Ação Civil Originária n. 3.451/DF*, Autor: Estado do Maranhão, Réu: ANVISA e União Federal, Rel. Min. Ricardo Lewandowski. Avaliable at https://portal.stf.jus.br/processos/downloadPeca.asp?id=15345314163&ext=.pdf (1st decision)

submitted to the collegiate and unanimously by it referenced[26], demonstrating the consolidation of the STF's position towards the legality of the commercialization of vaccines before any validation by the national competent regulatory body – ANVISA.

Some extracts from the judicial decisions must be highlighted, as the Court's adopted position, in this case, was a significant turning point in the understanding of the Brazilian Supreme Court regarding the review and control of the administrative act.

In his vote, the reporting Justice mentioned various international human rights documents, to which Brazil is a signatory State, and referred to the Brazilian Constitution, art. 196, to point out that the constitutionally protected social right to health imposes to all units of the Federation its promotion and implementation as co-chairs. The reporting Justice asserts that the social right to health is situated above the authority of the episodic ruler since it is a duty attributed to the State[27].

Another central premise to the vote is the existing Federal System in Brazil. According to the reporting justice, the "federalism cooperative" existent in Brazil imposes that the federal entities become mutually supportive, leaving behind ideological or political differences, to promote better immunization policy for all communities.

Finally, the center of the decision lies in the complete application of Law n. 13.979/2020, art. 3º, VIII, "a" and §7º-A, with the changes introduced by Law n. 14.006/2020[28].

Art. 3º of Law n. 13.979/2020 lists measures to be taken by the authorities to face the public health emergency of international greatness. Item VIII of said article empowers the authority to, temporarily and exceptionally, import and distribute medication and materials of the health sector that are not yet authorized by ANVISA, notwithstanding being subject to health monitoring. These products must be considered essential to the fight against the pandemic to fit the exceptional criteria and, as stated in subitem "a)" (art. 3º, VIII), they ought to already be registered by one of the following foreign health authorities: 1. Food and Drug Administration (FDA); 2. European Medicines Agency (EMA); 3. Pharmaceuticals and Medical Devices Agency (PMDA); e 4. National Medical Products

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[26] BRASIL, Supremo Tribunal Federal, *Ação Civil Originária n. 3.451/DF*, Autor: Estado do Maranhão, Réu: ANVISA e União Federal, Rel. Min. Ricardo Lewandowski. Available at https://portal.stf.jus.br/processos/downloadPeca.asp?id=15345861512&ext=.pdf (1st referendum)

[27] BRASIL, Supremo Tribunal Federal, *Ação Civil Originária n. 3.451/DF*, Autor: Estado do Maranhão, Réu: ANVISA e União Federal, Rel. Min. Ricardo Lewandowski. Avaliable at <https://portal.stf.jus.br/processos/downloadPeca.asp?id=15346151576&ext=.pdf>. Accessed in 03/09/2023 (2nd referendum)

[28] BRASIL, *Lei n. 14.124/2021, de 10 de março de 2021*, Dispõe sobre as medidas excepcionais relativas à aquisição de vacinas e de insumos e à contratação de bens e serviços de logística, de tecnologia da informação e comunicação, de comunicação social e publicitária e de treinamentos destinados à vacinação contra a covid-19 e sobre o Plano Nacional de Operacionalização da Vacinação contra a Covid-19, Diário Oficial da União, Brasília March 10th, 2021. Available at https://www.in.gov.br/en/web/dou/-/lei-n-14.124-de-10-de-marco-de-2021-307745858. Accessed in 01/16/2023.

Administration (NMPA) and already be in commerce within the respective State of the foreign agency taken as reference.

In addition, to assure expeditious posture by the Executive branch, §7º-A established the pressing 72hs deadline, counted from the submission request, in which ANVISA ought to decide upon a temporary and exceptional authorization. If ANVISA would bestowal such authorization, no other would be needed from any other direct or indirect body from public administration. The decision states that if ANVISA does not appreciate the request within the set hourly timeframe, the autarchy's silence will imply automatic authorization.

After the deferral of the request prima facie regarding the merits of the claim, in a last petition, the State of Maranhão requested not to be obliged to present to ANVISA the report by a foreign authority (as determined in the Law) over technical evaluation for the vaccine (in case Sputnik V) as well as any other information regarding other aspects of such vaccine, for instance, quality, safety and effectiveness.

Lewandowski granted the urgent request and established a 30 (thirty) days deadline, counted from March 29, 2021, in which ANVISA ought to decide upon the exceptional and temporary importation of the Sputnik V vaccine by the plaintiff, after what the federated State would, as interpreted by this Justice, be automatically authorized to acquire the immunizing and deflagrate its vaccination program[29].

In this second urgent analysis, two were the focal points of the decision. First was the critical situation in Brazil in 2021, with an unstoppable increase in death and hospital admissions due to Covid-19 disease. Second, Law n. 14.124/2021, art. 16, § 4º, entered into force after the first decision was given.

About Law n. 14.124/2021, the mentioned article imposes ANVISA a broader timeframe to decide, 30 (thirty) days, if there is no foreign agency report to adhere to, *in verbis*:

> *Art. 16. A Anvisa, conforme estabelecido em ato regulamentar próprio, oferecerá parecer sobre a autorização excepcional e temporária para a importação e a distribuição e a autorização para uso emergencial de quaisquer vacinas e medicamentos contra a covid-19, com estudos clínicos de fase 3 concluídos ou com os resultados provisórios de um ou mais estudos clínicos, além de materiais, equipamentos e insumos da área de saúde sujeitos à vigilância sanitária, que não possuam o registro sanitário definitivo na Anvisa e considerados essenciais para auxiliar no combate à covid-19, desde que registrados ou autorizados para uso emergencial por, no mínimo, uma das seguintes autoridades sanitárias estrangeiras e autorizados à distribuição em seus respectivos países: […]*
>
> *§ 4º Na ausência do relatório técnico de avaliação de uma autoridade sanitária internacional, conforme as condições previstas no § 3º deste artigo, o prazo de decisão da Anvisa será de até 30 (trinta) dias. (Highlight not present in the original text)*

[29] BRASIL, Supremo Tribunal Federal, *Ação Civil Originária n. 3.451/DF*, Autor: Estado do Maranhão, Réu: ANVISA e União Federal, Rel. Min. Ricardo Lewandowski. Available at <https://portal.stf.jus.br/processos/downloadPeca.asp?id=15346151576&ext=.pdf> (2nd decision)

The article does not empower automatic authorization if ANVISA fails to analyze the request within 30 days. Do note that, to imply automatic authorization, one would dangerously disregard ANVISA's mandatory duty to assess the risk level of any product.

ANVISA, created by federal Law n. 9.782, is an independent autarchy (art. 4) linked to the Ministry of Health and part of the Brazilian National Health System (SUS); it is responsible for the coordination of the Brazilian Health Regulatory System (SNVS)[30]. Its obligations are listed in the art. Seven, and it exists to "promote the protection of the population's health" and does so "by executing sanitary control of the production, marketing, and use of products and services subject to health regulation, including related environments, processes, ingredients, and technologies, as well as the control in ports, airports, and borders"[31].

As commonly known, lawfulness is verifiable when a decision or action conforms to the already set legal order. In Brazil, ANVISA cannot be an abstract subject to any form of mandatory obligation to authorize the importation and distribution of products whose nature must be monitored, which could potentially present risks to human beings and the environment. For all this, the bestowal of an automatic approval is an interpretation that collides directly with the infra-constitutional norm and is incompatible with the previously set legal order.

Unlike the previous decision, even though the Court's composition did not change, the referendum by the collegiate was not unanimous, as Justice Nunes Marques presented dissenting vote[32].

As the Law in question does not address the consequence of ANVISA's omission after the deadline, the decisions under analysis show prospective overruling (superação prospectiva)[33]. The Court's previous positioning on this matter was not maintained. The decision to automatically authorize the importation of vaccines and other medical products before the safety and effectiveness verification by the competent national technical body – ANVISA, is, in truth, a complete rereading of the jurisdictional control by the Judiciary over the ordinary executive function. Even if discretion versus arbitrariness was not of the essence of the

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30 BRASIL, *Lei nº 9.782, de 26 de janeiro de 1999,* Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências, Diário Oficial da União, Brasília, January, 27th, 1999, art. 4th. Available at <https://www.planalto.gov.br/ccivil_03/leis/l9782.htm>. Accessed in 03/09/2023.

31 BRASIL, ANVISA. Available at <https://www.gov.br/anvisa/pt-br/english>. Accessed in 03/09/2023.

32 BRASIL, Supremo Tribunal Federal, *Ação Civil Originária n. 3451/DF*, Autor: Estado do Maranhão, Réu: ANVISA e União Federal, Rel. Min. Ricardo Lewandowski. Available at <https://portal.stf.jus.br/processos/downloadPeca.asp?id=15346654619&ext=.pdf>. Accessed in 03/09/2023.

33 Brazil adopts the civil law system and yet imports concepts and institutes typical from the common law system. This creates a peculiar scenario within Brazil whereas a binding decision by the Supreme Court can come from a handful cases especially selected for this purpose whilst, in a typical common law adopting country, the force of jurisprudence comes from its long lasting repetition throughout the system. The superior courts in Brazil also edit binding summary statements (*enunciados de súmulas vinculantes*) (Brazilian Civil Code of Procedures, art. 927), enforceable throughout the country, concentrating the chosen ration for selected matters.

decision, the core objective of the Court was substituting ANVISA's technical duty with its own political will..

5 INFRA-CONSTITUTIONAL VIOLATIONS TO THE ELEMENTS OF THE ADMINISTRATIVE ACT IN THE JUDGMENT OF ACO 3.451/DF

In Brazil, ANVISA holds the absolute power to decide whether or not to authorize and import health products, such as vaccines, as the final step of a complex technical procedure. The mandatory administrative procedure then produces an "ato administrativo discricionário" that, in this case, must be unilateral as it will be precautionary assured the exercise of determined activity[34].

The initial position considered the review by the Judiciary over the merit of discretionary acts, such as bestowal or not of authorizations by the competent technical body, to be restricted to the aspects of reasonableness, proportionality, and morality, as the Judiciary was not allowed more in-depth since it lacked the necessary expertise and also due to the separation of powers.

This case is of unquestionable prospective overruling by the Brazilian Supreme Court. STF encroached on ANVISA's competence when authorized the automatic importation and distribution of the Sputnik V vaccine before any positioning from the national body legally assigned to do this technical and complex appraisal. Shockingly, the decisions were not even preceded by expert consultation.

This judicial decision does infringe on ANVISA's competence. It brings into light some significant concerns, as it violated mandatory elements of the administrative act: (a) finality, jeopardizing the right to health of the affected population because the automatic bestowal to purchase vaccines and launch the program did not count on any previous technical consultation over potential hazardousness effects nor its intended effectiveness; (b) competence, as the Judiciary is not a competent body nor has consulted one before deciding on automatic authorization; (c) form as Sputnik V vaccine's authorization did not derive from the regulated administrative due process of law for such produce.

It also violated the merit of the administrative act (objective and motive) because STF completely depleted ANVISA on having a saying and decided the merit before any expert's opinion on this technical matter.

Concerning the fragmentation of the discretionary act, regarding the presence or not of minimum criteria to consider legally valid STF's decision under challenge, there also was a violation of (d) objective, as the controversial decisions unforgivingly lack the mandatory technical assessment over quality and effects of the vaccine and (e) motive, as the decisions gave automatic authorization to a possible event in the future (absence of authorization). Hence, the Court took as premise eventual e future possible administrative failure to comply with the Court and did not consider it essential to consider expected side effects for this sort of product or even a lack of efficiency.

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[34] MELLO, Oswaldo Aranha Bandeira de, *Princípios Gerais de Direito Administrativo,* vol. 1: Introdução. 3rd ed., São Paulo, Malheiros, 2010, p. 560.

It is pertinent to point out that what is under analysis is not a specific vaccine. The critique is against the enormous health risk, affecting millions, taken by STF without minimum technical support and invading the domain of the Executive function. In fact, from the decisions under analysis, one is bound to conclude that STF did willfully replace the duty and will of ANVISA[35], meaning its obligation and discretion by its agenda, and did so without any technical support. In addition, this is incompatible with the separation of branches and checks and balances and does not even fit as a judicial review because STF acted entirely in replacement of ANVISA.

6 THE UNCONSTITUTIONAL POSITIONING OF THE BRAZILIAN SUPREME COURT

As one could foresee, the current take by the Brazilian Supreme Court in the appraisal of the urgent injunctions' requests in ACO 3.451/DF bewildered the juridical community because they completely shuddered the floor under its own previous and widely standardized premises. Overruling itself does not necessarily mean breakage in the rules of interpretation nor violation of laws or the Constitution. Therefore, the critique is not on the possibility of a Court changing its standardized jurisprudence; it is upon the distortion and absence of mandatory elements and criteria to subsidize the conclusion of the Court.

The Constitution limits the jurisdiction. Exceptional situations such as ones brought by Covid-19 must be addressed within the constitutional limits imposed. As Presgrave has perfectly said, the pandemic and social isolation do not justify any violation of the fundamental rights assured in the Constitution for the lawyers and parties to a case, which also includes those directly affected by the decision of the Court even if they are not a part of the legal case[36].

In these decisions, STF violates the functional division of branches in Brazil, which is expressly present in the Constitution, art. 2nd[37]. Notwithstanding the unquestionable goodwill of the Court, it cannot be denied that the judicial decisions took away, in the abstract, from the executive branch the discretion to decide and act over pertinent matters concerning its ordinary function. The Court, before deciding, did not summon ANVISA or any experts regarding the quality and safety of the vaccine in question. That means the judicial decision is completely depleted of any merit element that was the mandatory element of the validity of an administrative discretion act by ANVISA, such as safety and expected effects concerning high-level risk products under its competence to monitor.

Even when considering that the judicial decision is based on an exceptional law, the relevant legal provisions (Law n. 13.979/2020, art. 3º, VIII, "a" and §7º-A, as changed by Law n. 14.006/2020) also are, from its origin, unconstitutional. The

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35 Established by Law n. 9.782, art. 7.

36 PRESGRAVE, Ana Beatriz Ferreira Rebello, OGUSUKU, Alexandre, "Audiências virtuais: A cloroquina judiciária para a Covid-19" in *Revista Consultor Jurídico*, May 16th, 2020. Available at: https://www.conjur.com.br/2020-mai-16/audiencias-virtuais-cloroquina-judiciaria-covid-19. Accessed in 02/03/2023.

37 BRASIL, *Constituição* da *República Federativa do Brasil de 1988*, October 5th, 1988. Available at <https://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm>. Accessed in 26/02/2023.

incompatibility to the legal system is also verifiable when confronted with the Constitution, art. 196, as authorization to import and distribute health products without careful revision, is an undeniable violation of the right to health, as stated in the mentioned art. 196, even if the decision in ACO 3.45/DF states the contrary.

STF's current take on the review of the administrative act and the possibility of completely replacing the future exercise of discretion by ANVISA by the will of the Court shows encroachment to the function of the Executive branch. The Judiciary acted proactively and with no technical support on a significant health issue potentially affecting millions of lives when there was no previous voice of the Executive on the specific matter of the safety or effectiveness of the vaccine in question, Sputnik V. No expert or capable body (ANVISA) was ever heard on regards to the safety of matter prior the decisions.

Without doubting the goodwill and capabilities of foreign authorities, it was evident that climate, culture, and demographic characteristics impact the success of any health measures to be taken. The sovereignty is also affected, as the legislation, at its core, opts to trust foreign agencies on strict national monitoring. This affects the internal distributions of competencies and, thus, is unconstitutional. In this case, STF did not undertake to consider the care to even inquire on mandatory aspects of the health products.

There is a distortion if the constitutional matter is raised to secure power positions to corporations and state bodies or semi-public organizations. Sundfeld names it "Consitucionalismo Chapa Branca"[38]. The controversial decisions can be comprehended as such because they were given in a time of undeniable and severe institutional crises and when the posture adopted by the Executive power concerning Covid-19 was subject to many critiques and constant judicial challenge, which also included the constant change of the head of the Ministry of Health.

The health crisis expanded to other areas one would not, at first, consider being that impacted by it. Severe damage was found in the economy, politics, and governability. In all spheres of the Judiciary, there were claims relating to the administration and the pandemic. Political and ideological conflict was everywhere.

The health crisis expanded to other areas one would not, at first, consider being that impacted by it. Severe damage was found in the economy, politics, and governability. In all spheres of the Judiciary, there were claims relating to the administration and the pandemic. Political and ideological conflict was everywhere.

Before Covid-19, based on predictability taken from previously tried cases, one would not expect STF to conduct a total review of an administrative discretionary act that didn't even exist (abstract analysis), dismissing any technical opinion on such a grave and complex matter, such as safety and effectiveness (of vaccines produced against a newly discovered virus and put into market in pressing speed). Again, the critique is not about the vaccine itself. It is about the absence of an act to be assessed by the Judiciary before the bestowal of the automatic authorization to purchase and distribute the vaccine.

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[38] SUNDFELD, Carlos Ari, *Direito Administrativo para céticos,* São Paulo, Malheiros, 2012, p. 56.

Moral valuation of the judicial decisions should have been considered in this work. The analysis and the conclusion show that all these formal and material distortions taint the judicial decision with many vices, reaching the peak of the legal hierarchy when it also directly violates the Constitution.

7 FINAL CONSIDERATIONS

Covid-19 became a milestone in many aspects of life, to the individual and society, reaching far beyond a single health emergency. The unprecedented situation undeniably overstressed the constitutionally set powers. When the other powers failed to urgently tackle their functions to address the claims involving Covid-19's circumstances and consequences, individuals, groups, companies, administrative bodies, etc., turned to the Judicial branch pressuring for political positioning.

In this context, STF broke away from its consolidated understanding of the limits to the judicial review of discretionary power in an administrative act. The studied decisions authorized, in the abstract, the importation and distribution of vaccines and related health materials concerning the fight against the pandemic, the first one giving ANVISA a deadline of 72hs to decide about it, and the second one, the deadline of 30 days. If ANVISA is in the given timeframe did not decide, the mentioned judicial pronouncements authorized the federated state of Maranhão (plaintiff) to import the immunizing Sputnik V and launch the vaccination program.

The general objective of the research was the analysis of STF's current position in light of the legal system, especially regarding the functional division of power established in the Constitution, art. 2º, and in regards to the right to health, established in art. 196.

The first specific objective, concerning the foundation of administrative discretion, was dealt with in section 3 of this article, covering the theory over the matter according to the traditional Brazilian doctrine.

The second specific objective consisted of analyzing the Brazilian judicial control over the administrative discretionary act, which was also achieved in light of traditional and modern theory and the Democratic State of Law.

The third objective concerns the social context in which the decisions were made and the reinterpreting done by the Brazilian Supreme Court through prospective overruling. It was taken into account that (a) the unprecedented institutional crisis was further stressed by the already high and ever-increasing rates of Covid-19 infection and mortality rate; (b) occurred the total replacement of ANVISA'S technical discretion by the Court's will and (c) there was the presence of political interests emerging from institutional crises caused by the ideological dispute on how to address the pandemic and its effects.

The fourth specific objective, regarding the constitutional analysis over the current understanding of the judicial limits to control the administrative act, was also accomplished, proving that STF's present-day understanding needs to meet constitutional standards. It was found that the constitutional principles regarding the division of functions and the right to health of the population within the federated

state of Maranhão were violated because no technical assessment was requested prior to the decisions under examination.

The hypothesis challenged the constitutionality of the decisions. The study took as starting point that the decisions did provide the affected population with prompt response, as the state of Maranhão was authorized to import and distribute the vaccine automatically if ANVISA did not attend the given deadline. On the other hand, the mentioned decisions usurped Federal Executive's function in controlling the safety of potentially hazardous products nationwide, which legally includes health products such as medications and vaccines. In the development of the study, STF's understanding of the mentioned decisions within ACO 3.451/DF over the judicial limits to the administrative act (or the total absence of a limit found in the case) was proven unconstitutional.

The research also established that the decisions were, in fact, a complete replacement of the deciding power assigned to the Executive. The findings are based on violating the fundamental division of function and severely threatening the right to health. The judicial bestowal of an automatic authorization to import and distribute substances subject to control by ANVISA (an autarchy composed of a body of experts to the specificity of the matter), without hearing an expert's opinion, potentially brings to the affected population threatening to their right to health.

The proposed question was unquestionably answered, as the Judiciary acted aside from the constitutional and infra-constitutional assigned functions. In contrast, it did develop the Executive function to monitor and control potential hazardous substances in the case of a vaccine. It did so with no verifiable merit, as not even a single expert's opinion over the technical content was heard before the bestowal of an automatic authorization after the set deadline. STF surpassed all limits to review and acted in replacement of an extremely delicate executive function concerning highly technical and complex matters.

As to the methodology, no alterations were necessary. The set premises concerning administrative discretion and limit to judicial control were analyzed through the deductive method, using a qualitative approach to describe the effect on the affected population of STF's adopted understanding in ACO 3.451/DF.

Limitations to work occurred as the study analyzed the prospective overruling that occurred just recently. The specific doctrine on this matter, books, and articles are still in the making.

Lastly, the findings of this research suggest the paramount importance of further dwelling on the matter, as doctrine and jurisprudence must take action regarding the critical points, especially the constitutional violations, found in the judgment of ACO 3.451/DF.

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