

The obligatoriness of the vaccination in the brazilian legal system: Compulsory and organization, a comparative analysis of the normative development of the current regulatory framework



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ABSTRACT

The present article explores analytically the Brazilian legal system about the obligatoriness of the vaccines. The aim of this article is to present the positive evolution of the system of rules on the mandatory vaccine in the Brazilian legal system. The problematization involves questioning how this evolutionary situation occurred and how the rules have been enacted in the national legal system. The inductive methodology of the work was carried out by individualized collection of positive normative documents until the construction of a general framework of all the evolution of norms on mandatory vaccination. The postulate developed on the text seeks to analyze the nature and features of the vaccine compulsoriness, since the questioning about if there is this obligatoriness until the nature of it (administrative nature or criminal nature). The sources used on the essay of the text were bibliographic and documentary sources (various legal texts, such as constitutional, legislative and administrative). The results and conclusion are presented in a synthesis of analysis on the nature and feature of the mandatory vaccination in Brazilian legal system.

Keywords: Rule, Brazilian law, Obligatoriness, Vaccine.

1 INTRODUCTION

The article will explore the set of positive norms in the Brazilian system on the mandatory and compulsory nature of vaccination. The central problem will be to verify how the evolution of the positive vaccination health norms has evolved, questioning from the nature of these norms, mandatory, punitive, and what the specific nature is: administrative, sanitary or penal norms. The approach is justified by the recent scenario of the COVID-19 pandemic and the questions that have arisen about the nature of the vaccine requirement. This is a qualitative research with the construction of the work using the inductive method. The norms that have been established in the national system throughout



the twentieth and twenty-first centuries will be collected in order to establish a general, categorical and analytical framework of norms and obligation. The arguments will be built with the exploration of two views on the positive norms: the general evolution of norms in the system, including the analysis of the content of the norms, as well as the institutional framework in which they are inserted; the nature of the obligations and compulsory behaviours established by the rules in force. At the end, in the conclusion, after the exploration of the normative and institutional data, there will be the elaboration of analytical syntheses on the vaccination norms in the national order.

2 THE THEORETICAL CONTEXTUALIZATION ON THE SUBJECT.

The article explores the evolution of the positive norms on the mandatory nature of the vaccine, or its compulsoriness. Despite the differences in the period, there is a general and common framework of the discussion that involves the following matters: the obligation involves, throughout the periods investigated, the limits established by the State's Right to sanitary action; likewise, the federal, state and municipal competences to carry out sanitary actions; The subject also involves how state services and activities are carried out and what is the scope, especially health actions; on the other hand, there is the discussion about Fundamental Rights as an intangible sphere by state action, freedom (amplitude, religious freedom and health action, among many others), the right to life and health as a right to life, and bodily intangibility¹.

3 THE SYSTEM OF RULES ON MANDATORY VACCINATION. THE PERIOD OF THE INITIAL INSTITUTION OF MANDATORY VACCINATION.

The initial time frame establishes the first positive norms on vaccination at the beginning of the twentieth century. The following expressions or ideas are used to designate this initial period of norms and institutions:

a) The normative system provided for vaccination as a corrective measure, rather than as a measure of protection and prevention;

¹ MANIACI, G. Algunas notas sobre coherencia y balance en la teoría de Robert Alexy. Isonomía - Revista de teoría y filosofía del derecho, n. 20, 2004, p. 141-145; PELÁEZ MEJÍA, J. M. The conceptual differences and practices between the "balancing" by Ronald Dworkin and the "weighing" by Robert Alexy. Ius et Praxis, v. 25, n. 3, 2019, p. 170-173; p. 175-182; PIRES GAVIÃO FILHO, A.; PREVEDELLO, A. Defeatability in the theory of principles. Pensar - Journal of Legal Sciences, v. 24, 2019; RESENDE, J. R. V.; SOUZA ALVES, R. V. THE LEGITIMACY OF THE REFUSAL OF BLOOD TRANSFUSION FOR RELIGIOUS REASONS IN THE LIGHT OF THE RIGHT TO HEALTH IN THE 30 YEARS OF THE CONSTITUTION. Journal of Human Rights and Democracy, v. 8, n. 15, 2020. Passim. RIBEIRO, J. C. THE THEORY OF PRINCIPLES IN BRAZILIAN LEGAL THEORY: THOMAS BUSTAMANTE'S CONTRIBUTIONS TO THE DEBATE. Theories of Law and Legal Realism, v. 7, n. 1, 2021; SACRAMENTO, B. The weighting of rules and some problems of Robert Alexy's theory of principles. Revista Direito GV, v. 15, n. 2, 2019.



- Vaccination was a measure inserted among many others of sanitization and sanitation, and compulsoriness came as a complementary coercive measure, and not as a comprehensive vaccination policy;
- c) The design of the institutions showed the teleology of repressive and hygienist administrative action, with little emphasis on proposals for promotional policies or health education;²
- d) The norms and institutions were edited in the peculiar context of urban and economic transformation, verticalized and elitist, with ³ emphasis on the then federal capital, but also with a national scope.

After this evolutionary exploration, there will be, in the conclusions part of the text, the general lines on mandatory vaccination. The concluding part will allow, based on the information developed with the material, throughout the writing, the outline of the analytical framework on mandatory vaccination in the Brazilian system.

² 'It is necessary to understand that vaccination is an object of difficult apprehension, constituting, in reality, a phenomenon of great complexity where the most varied political, scientific and cultural beliefs and conceptions are associated and intertwined. In fact, far from being an isolated act, subject only to the parameters of measurement and decision of medicine or biomedical sciences, vaccination is also, due to the sociocultural and moral implications it involves, the result of historical processes in which multiple interactions are woven and where antagonistic representations of collective and individual rights concur. on the relations between the State, society, individuals, companies and countries, on the right to information, on ethics and especially on life and death. Potentially controversial, the vaccine and its uses also contemplate geopolitical and macroeconomic interests, having lately been associated with conflicts between nations and bioterrorism. PORTO, Â.; PONTE, C. F. Vaccines and campaigns: the images of a story to be told. Vaccines and campaigns: the images Janeiro. betold, Rio de 2003. 725-742. Available a story toat: <a href="mailto:/www.scielo.br/scielo.php?script=sci_arttext&pid=S0104-59702003000500013&lng=en&nrm=iso>. Accessed: Sept. 2020.

³ The third mechanism for removing the threat posed by the crowd to the federal government was suggested by Campos Sales to his successor in the presidency of the Republic: to take advantage of the reform of the port of Rio de Janeiro to remodel the urban center of the city. It had to be purged of both epidemics and the dangerous classes that inhabited it, in order to reclaim it as a space for the representation of a modern and civilized society. The reurbanization of Rio de Janeiro would conjure up the threat to the Republic consisting of "an indomitable crowd, composed of adventurers, mestizos, blacks and poor immigrants", of which the plebs of its capital were composed (Sevcenko, 2010, p. 80). It would be up to the State "to transform, by force, the undisciplined 'barefoot' crowd into citizens cut out according to the stereotypes that served the European bourgeoisie for the exercise of its domination." Thus, the urban reform also involved a reform of customs, which aimed to combat the profane and sacred popular festivals, such as "carnival, serenade, bohemia and candomblé", also putting an end to begging, shirtsleeves and barefoot in the city (Benchimol, 2006, p. 264). It was precisely in the middle of this endeavor, presided over by Rodrigues Alves, assisted by Lauro Müller, Pereira Passos and Oswaldo Cruz, that the Vaccine Revolt broke out. In the context of the demolition of thousands of old townhouses and tenements that, in order to open new routes for the flow of goods from the port, expelled the poor population from the heart of the city from one day to the next, the popular revolt began against the law of mandatory vaccination and ended up being swelled by a military rebellion. This was the moment when the demophobia of the republican political class reached its peak. The parliamentary speeches made on this occasion are valuable because the circumstances forced the frightened and then indignant speakers, in the heat of the moment, to frankly reveal their feelings in the face of the reality of the armed crowd against the regime they supported. In this moment of clarification, of unveiling, the aristocratic political class of the First Republic, which legitimized itself in the name of democracy, allowed itself to openly manifest its demophobia. LYNCH, C. E. C. The crowd is crazy, the crowd is a woman": the oligarchic-federative demophobia of the First Republic and the theme of the change cienc. saúde-Manguinhos, Rio de Janeiro, 2013. 1491-1534. Hist. Available http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0104-59702013000401491&lng=en&nrm=iso>. Accessed: Sept. 2020.



3.1 THE FIRST RULES ON VACCINATION.

The enactment of the 1904 compulsory vaccination law occurred in the context of the enactment of Decree No. 1,151, which presented several rules for health administration. It is important to situate the edition of the Decree within the policy of cleaning, cleanliness, prophylaxis and sanitization in Brazil, and especially in Rio de Janeiro, DF, at the time.⁴ The problems of yellow fever and smallpox were highlighted, as well as the general precariousness of the sanitary conditions of homes and cities. The Decree established the rules of the health administration bodies and provisions on health administrative actions:

Art. 1 The General Directorate of Public Health is reorganized, and in addition to the current attributions, everything that in the Federal District concerns home hygiene, sanitary police of homes, places and public places, everything related to the general and specific prophyxia of infectious diseases, and the Government may make the installations it deems necessary and put into practice the current municipal postures related to hygiene. § 1 The Government shall regulate all the services dependent on the General Directorate of Public Health, admitting the personnel listed in the annexed table, establishing the necessary repressive measures in order to make effective the notification of infectious diseases, the sanitary surveillance and police, and finally all the necessary executive measures and regulatory provisions.

Hospital isolation will only take place when the patient's residence does not comply with the sanitary measures required by the regulations; and, in the case of hospitalization in hospital, the family will have the right to accompany the patient, all resources being provided to them at the expense of the State, and medical treatment may be directed by the patient or his family as he wishes, according to the therapeutic process that he wishes, respecting the internal discipline of the establishment.

[...]

- § 3 The Government is hereby authorized to promulgate the Sanitary Code, in accordance with the following bases:
- a) regulating everything related to urban and home hygiene;
- b) ensuring the general and specific prophylaxis of infectious diseases;
- c) Establishing Service Sanitario dos Portos e a Prophylaxia Sanitaria Internacional;
- d) regulating the practice of medicine and pharmacy;
- e) encompassing the Pharmaceutical Code;
- f) establishing as penalties for sanitary infractions fines of up to two contos de réis (2:000\$), which may be converted into imprisonment up to a maximum period of three months, as well as, cumulated or not and even as a preventive measure, apprehension and destruction of foodstuffs deterinated or considered harmful to public health, kidnapping and sale of animals or objects whose existence in homes is prohibited, revocation of license, closure and interdiction of buildings, works and constructions.
- 1. The seizure and destruction of foodstuffs that have been spoiled or considered harmful to health, as well as the revocation of the closure license, shall be carried out by simple acts of the administrative authority; The seizure and sale of animals or objects whose existence in the dwellings is prohibited, after the competent apprehension by the administrative authority, shall be carried out by the judicial authority by means of the procedure that is established.
- II. The declaration of interdiction of buildings, works and constructions by the administrative authority shall have the effect:

As for the buildings:

- 1° To be vacated amicably or judicially by the tenants within one to eight days, according to the urgency;
- 2° Be repaired or demolished by their owners within the period assigned to them. If they refuse to do so, repairs or demolitions will be made at their expense, and in either case the building

⁴ SOUZA, L. M. B. DE; GLOECKNER, R. J. Biopolitics and Governmentality in the Belle Époque of Rio de Janeiro: Some initial notes on the medical control of the population and urban space. Brazilian Journal of Political Studies, v. 113, n. 0, 2016, passim.



or land legally occupied by them will be hypothecated to guarantee the expense made, class the day of the declaration of the interdiction.

As regards the works and constructions:

1° To be immediately suspended;

2° Be repaired or demolished under the same conditions and with the same burdens as the buildings. ⁵

As stated above, the norm was produced within the 'sanitization' and 'sanitization' movement that took place in the – then – Federal Capital.⁶ The federal norm had the territorial scope of validity throughout the national territory, but it was related to the process of 'cleaning' and 'sanitization' of the then Federal District.⁷ It should be noted that there was concern about sanitary measures at national entrances, especially in the national port system.⁸

A detailed approach to the health, social, economic and political factors of this action will not be carried out. Just as an illustration for the contextualization of the reasons for editing the standard, the following elements are aligned:

⁵ BRAZIL - DECREE NO. 1,151, JANUARY 5, 1904. DECREE NO. 1,151, JANUARY 5, 1904. *House Legislation*, 1904. Available at: https://www2.camara.leg.br/legin/fed/decret/1900-1909/decreto-1151-5-janeiro-1904-583460-publicacaooriginal-106278-pl.html. Accessed on: 10 set. 2020.

⁶ This norm fit into the sanitization process of the federal capital, then Rio de Janeiro. In the text there is mention of both smallpox and yellow fever. The administrative actions resulted in the vaccine revolt.

⁷ On the vaccine revolt and the context of compulsory vaccination see: Nicholas Sevcenko; Jeffrey D. Needell. "In fact, there were two urban reforms: one carried out by the municipal government, and the other carried out by the federal government, both with different ideals. Some authors, such as Jaime Larry Benchimol (1992), Oswaldo Porto Rocha (1995), Sônia Gomes Pereira (1992) and André Nunes de Azevedo (1998, 2003), have already reported the existence of these two urban projects. However, the latter author addressed in more detail the differences between these two projects, which will be discussed below. The municipal reform, managed by Pereira Passos, although it did not leave aside the urban and sanitary aspects, gave a lot of importance to the behavioral aspects, largely due to the concept of civilization that governed the mayor's reform. According to (SEVCENKO, 2010)(NEEDELL, 1987)Azevedo (1998, 2003), an objective of the municipal government was the connection of the various parts of the city, associated with an attempt to spread civilization, since the Center is considered a civilizing place. [...] The federal reform, which took place during the government of Rodrigues Alves, directed mainly by Lauro Muller and Francisco Bicalho, prioritized urban and sanitary aspects. Second Azevedo (1998, 2003), she was in charge of the modernization of the port, the sanitation program, the extension of the mangrove canal and the opening of three avenues: Avenida do Cais (now Rodrigues Alves), Avenida do Mangue (now Francisco Bicalho) and Avenida Central (now Rio Branco). The main work of the federal government was the modernization of the port, as a result of which the other works were carried out, since it was necessary to restructure the road system of the port area to facilitate the distribution of goods. The federal reform had as its ideal the mechanism, with this the road relationship of the city was part with part, that is, the city was not thought of as a whole, and the part could gain greater importance than the whole, as was the case with the port. The port was the most important work and the symbol of progress, a concept that governed the reform carried out by the federal government. The port has always been an important source of wealth, and its modernization would be ideal for economic development of the country and attract immigrants, but it would be necessary to improve Brazil's image abroad, starting to be seen as healthy and modern.' SILVA, M. G. C. F. D. Some considerations on urban reform Pereira Passos. Rev. Bras. Gest. Urban Curitiba, 2019. Available at: knrm=iso. Accessed: Sept. 2020, online.

⁸ At the time, it was the main entry of people and the main route for the flow of national production, and the import of goods.



- a) The sanitary interventions were necessary given the unhealthy and serious situation of the general health situation in the capital and in the country;⁹
- b) The interventions were verticalized and without the participatory and integrated construction of the population;¹⁰
- c) Parallel deficiencies such as lack of housing, lack of sanitation structure, these were faced vertically or exclusively;
- d) There was a picture of depression in the economy, after the deflationary policy of the previous government, of Campos Sales, and the data on the growth of per capita income for the period illustrate the picture: ¹¹

1902/-3,35
1903/-1,12
1904/-1,71
1905/ 0,02

The Sanitary Code provided for in the previous Decree was issued in March of the same year, 1904, and had provisions on vaccination. What seemed to preside over the framework of the norm was that vaccination fell within the general sphere of powers of the administration, of a repressive, supervisory and sanctioning nature:¹²

Art. 22. [...] X. To try during systematic visits, and by suasive means, to apply vaccination against smallpox and plague, taking all the notes, according to the respective record books, so that the statistics may be organized;

[...] Art. 27. The health precinct will operate at its headquarters, which will be within one of the circumscriptions that constitute it, every working day, from 7 a.m. to 9 p.m. Within this period of time, the sanitary inspectors will take turns on duty, with the special purpose of attending to complaints, receiving parts and notifications from clinicians, proceeding with smallpox vaccination, attesting to its results, as well as applying vaccina against other epidemic diseases, giving an account of everything in special books existing for this purpose. [...]

Art. 200. When a case of plague is notified, the health delegate, or whoever takes his place, will proceed as follows: [...] III. It will immediately proceed to the foc, taking what is necessary for serum injection and for serum vaccination; [...] *Smallpox*

Art. 207. In the case of smallpox, the health inspector shall proceed in accordance with the Nos. I, II, VII and VIII of Article 200, Chapter II, Title III, Part III, of these Regulations.

Art. 208. The health inspector shall be fitted with anti-smallpox vaccination and shall invite all persons residing in the plant to undergo vaccination and revaccination.

⁹ Mentioning that there was a need does not mean agreement with the form of execution and realization.

¹⁰ BATISTA MOUTINHO, F. F. CONFLICTS OF BRAZILIAN SOCIETY WITH HEALTH STANDARDS: A PARALLEL BETWEEN THE VACCINE REVOLT AND THE COVID-19 PANDEMIC. Hygeia - Brazilian Journal of Medical and Health Geography, 2020, passim. CANTISANO, P. J. Lares, Tribunais e Ruas: A Inviolabilidade de Domicílio e a Revolta da Vacina / Homes, Courts and Streets: The Inviolability of the Home and the Vaccine Revolt. Journal of Law and Praxis, v. 6, n. 11, 2015. p. 299-300.

¹¹ IBGE -. STATISTICS OF THE TWENTIETH CENTURY. *IBGE - STATISTICS OF THE TWENTIETH CENTURY*, 2020. Available at: https://seculoxx.ibge.gov.br/economicas/contas-nacionais. Accessed on: 11 set. 2020.

¹² The general idea of administrative police power.



Art. 209. Persons who do not wish to comply with the prophylactic measures contained in the preceding article shall be taken to an appropriate building for twelve days under observation, at the expense of the stay at the expense of the isolated persons, for which the head of the family or whoever may take his or her place will be responsible, who shall deposit the sum corresponding to the person's stay in the observation house.

Art. 211. During the visits of the sanitary police and medical surveillance, the sanitary inspectors shall promote, by all suasive means, the revaccination, and shall ensure strict execution of the provisions of the federal and municipal laws that regulate the matter. [...]

Art. 216. Vaccination and revaccination can only be proven by means of certificates registered with the General Directorate of Public Health.

Art. 217. Any doctor who provides a false certificate of vaccination or revaccination will be fined \$1,000 in addition to the penalties he may incur under the Penal Code. [...]

Art. 237. Whenever abnormal and causeless rat mortality appears in any house and its vicinity, the head of the family or the owner of the house is obliged to report the fact to the health delegate. [...] c) he will invite the people living in the house to undergo the anti-plague vaccination after having organized the list of these people; [...]

Art. 239. When the health authority becomes aware of the presence of anthrax in any animal storage, it shall proceed as follows:

- (a) carry out a thorough disinfection of the site, if possible;
- (b) abandon, temporarily or permanently, the pastures considered to be infected, at the discretion of the bacteriological laboratory;
- c) Cause the cattle to be subjected to anthrax vaccination before they come to the points considered contaminated. 13

After the issuance of the Decrees with the organizational measures of the Sanitary Administration, and the Sanitary Code, there was the enactment of the specific Law on the compulsoriness of vaccination. Therefore, the law presented itself as something punctual, and dedicated, to strengthen the action of the Public Administration, in the specific eradication of smallpox. It should be noted that compulsoriness is dedicated to smallpox since Article 1:

Article 1 Vaccination and revaccination against smallpox are mandatory throughout the

Article 2 The Government is hereby authorized to regulate it on the following grounds:

- a) Vaccination shall be practised until the sixth month of age, except in proven cases of illness, in which case it may be carried out later;
- b) The revaccination shall take place seven years after the vaccination and shall be repeated for septennios;
- (c) Persons who are over six months of age shall be vaccinated unless they can prove that they have profitably carried out this operation within the last six years;
- d) All officers and soldiers of the armed classes of the Republic shall be vaccinated and revaccinated, and the commanders shall be responsible for the fulfillment thereof;

DECREE N. 1270 - OF NOVEMBER 16, 1904Decrees the state of siege, for up to thirty days, in the territory of the Federal District and in the district of Nitheroy, in the State of Rio de Janeiro, and authorizes the Executive Branch to suspend it within the period set, provided that it no longer requires the exceptional measure. The President of the Republic of the United States of Brazil: I hereby inform you that the National Congress has decreed and I promulgate the following resolution: Art. 1 The territory of the Federal District and the district of Nitheroy, in the State of Rio de Janeiro. Art, are hereby declared to be in a state of siege for up to thirty

¹³ BRAZIL - DECREE NO. 5,156, OF MARCH 8, 1904. Decree No. 5,156, of March 8, 1904. *House Legislation*, 1904. Available https://www2.camara.leg.br/legin/fed/decret/1900-1909/decreto-5156-8-marco-1904-517631-2004 publicacaooriginal-1-pe.html>. Accessed on: 11 set. 2020.



days. 2° The Executive Branch is authorized to suspend the state of siege within the period set, provided that it no longer requires the exceptional measure. 14 15

The compulsoriness generated the revolt because information about physical embarrassment, about undue bodily intrusion of syringes and needles, about the inoculation of the smallpox virus itself (incomprehensible to many), and about home invasion was disseminated. The revolt was fueled precisely by the physical and moral constraint to which people who were forcibly determined to be vaccinated, or had their homes invaded, were subjected. With the uprising, the measures of physical constraint were relaxed. The normative measures, however, involved, in fact, in addition to physical constraint and entering homes, various administrative restrictions: requirement for school enrollment; to marry; for formalization of employment; for travel; for lodging, among many others. The invalidation of employment is provided in the constraint and entering homes, various administrative restrictions: requirement for school enrollment;

4 THE SYSTEM OF RULES ON MANDATORY VACCINATION. THE REFORMULATION OF THE HEALTH SYSTEM FROM THE 1920S ONWARDS.

After the initial structuring period, during the presidential administration of Rodrigues Alves, in the 1920s, the health administration system underwent transformations. In the 1920s, the health system was structured with a relaxation of the repressive and police nature, with the insertion of broad contents and purposes, more focused on the promotion of health as a State policy. This implied a change in the context of compulsory vaccination. In the 1930s, there was an administrative health structure with the placement of state action as a true promotional policy. With the 1988 Constitution, it is promoted to the status of a Fundamental Right.

Law No. 3,987 of January 1920 reformulated the national health system. The new structure included specialized areas and determined specific competencies for health needs:

¹⁴ BRAZIL - DECREE N. 1270 - OF NOVEMBER 16, 1904. DECREE N. 1270 - OF NOVEMBER 16, 1904. Portal of legislation, 1904. Available at: <DECREE N. 1270 - OF 16 NOVEMBER 1904>. Accessed on: 12 set. 2020.

¹⁵ It was extended for 30 days by Decrees No. 1,297, of December 14, 1904; 5,432, of January 14; and 5,461, of February 15, 1905. The definitive suspension with Decree No. 5,479, on March 14, 1905.

¹⁶ In HC No. 2244, the STF ruled unconstitutional the entry of State agents into the Patient's home, without his express authorization: 'Habeas Corpus filed in favor of Manoel Fortunato de Araújo Costa, alleging threat of illegal constraint for the fact that he had received for the second time the summons of a sanitary inspector to enter his home and disinfect the mosquito that causes yellow fever. The Court considered unconstitutional the provision that allowed the health authorities to enter a private person's home to carry out mosquito purging operations without the owner's permission. The appeal was granted, by a majority, to grant preventive habeas corpus, to prevent the entry of the health authority into the patient's home, without his consent.' SUPREME COURT - HABEAS CORPUS NO. 2244. Habeas Corpus No. 2244. STF - Historical

Judgments,

1905.

Available

at:

< http://www.stf.jus.br/portal/cms/verTexto.asp?servico = sobreStfConhecaStfJulgamentoHistorico&pagina = STFdescricao HC2244>. Accessed: Sept. 2020.

¹⁷ The penal code of 1890 had no specific type that encapsulated vaccination. From articles 156 to 164 there was a typology of crimes against public health, but none of the types specifically encompassed vaccination. From articles 134 to 135 there were types of obedience/disobedience to authority, also types that were not able to encapsulate the specific vaccination situation. BRAZIL - PENAL CODE OF 1890. DECREE NO. 847 OF OCTOBER 11, 1890. *Chamber Legislation*, 1890. Available at: https://www2.camara.leg.br/legin/fed/decret/1824-1899/decreto-847-11-outubro-1890-503086-publicacaooriginal-1-pe.html. Accessed: Sept. 2020.



Article 1 The National Department of Public Health is hereby created, reporting directly to the Minister of Justice and Interior Affairs, comprising:

- a) The services of hygiene in the Federal District, which should cover the general and specific prophylaxis of communicable diseases, the execution of measures of an aggressive or defensive nature, those aimed at home hygiene, the sanitary police of private and collective dwellings, factories, offices, colleges, commercial and industrial establishments, hospitals, health homes, maternity hospitals, slaughterhouses, markets, public places, hotels, restaurants and the supervision of foodstuffs;
- b) services sanitary ports, maritime ports and fluviaes;
- c) the rural prophylaxis in the Federal District, in the States and in the Territory of Acre;
- d) the study of nature, etiology, treatment, and prophylaxis of communicable diseases, as well as any scientific research of interest to Public Health;
- c) Supply of serums, vaccins, and other etiological products intended to combat epidemics in any region of the country, and to supervise the preparation of these products in private institutes and laboratories;
- f) Supplies of medicines Officials in accordance with Decree No. 13,159, of August 28, 1918, through the Oswaldo Cruz Institute;
- g) The Exam foodstuffs of national origin and foreign foodstuffs imported for consumption.
- h) the medical inspection of immigrants and other passengers bound for the ports of the Republic:
- i) assistance to morphetics and patients who, in the Federal District, due to the nature of the disease, must be isolated;
- j) the organization of the demographic and health statistics and the publication of the respective bulletins;
- k) the sewer inspection service and the construction of new networks in the Federal District;
- l) the supervision of pharmaceutical products of serums, vaccins and any other biological products, offered for sale;
- m) The organization of the Sanitary Code, which will be submitted to the National Congress for approval; Article 2 The Director of the National Department of Public Health shall be freely appointed by the President of the Republic from among physicians of recognized knowledge, and may serve on commission, and shall be responsible for the superintendence of the federal health services in Brazil. ¹⁸

The reform established the responsibility of 3 Directorates for health policies, including vaccination: 'Directorate of Land Health Services in the Federal Capital; Directorate of Maritime and River Health Defense; and, Directorate of Sanitation and Rural Proyhylaxia'. ¹⁹ ²⁰

 $pl.html\#:\sim: text=Reorganiza\%20os\%20 servi\%C3\%A7os\%20 da\%20 Saude\%20 Publica.\& text=o\%20 exame\%20 chimico\%20 dos\%20 generos, estrangeiros\%20 importados\%20 para\%20>. Accessed on: 11 set. 2020.$

¹⁸ BRAZIL - LAW NO. 3,987, JANUARY 2, 1920. LAW NO. 3,987, JANUARY 2, 1920. *House Legislation*, 1920. Available at: https://www2.camara.leg.br/legin/fed/lei/1920-1929/lei-3987-2-janeiro-1920-570495-publicacaooriginal-93627-

¹⁹ BRAZIL - LAW NO. 3,987, JANUARY 2, 1920. LAW NO. 3,987, JANUARY 2, 1920. *House Legislation*, 1920. Available at: https://www2.camara.leg.br/legin/fed/lei/1920-1929/lei-3987-2-janeiro-1920-570495-publicacaooriginal-93627-

pl.html#:~:text=Reorganiza%20os%20servi%C3%A7os%20da%20Saude%20Publica.&text=o%20exame%20chimico%20dos%20generos,estrangeiros%20importados%20para%20>. Accessed on: 11 set. 2020.

²⁰ For the prophylaxis of smallpox, according to the same legislation, an agreement was provided for with the state health authorities, who would be responsible for carrying out the specific measures in ports and rural areas. With regard to smallpox vaccination and revaccination, this agreement stipulated that they should be carried out intensively and systematically, starting at six months of age, and every seven years thereafter, also covering all contacts of the sick. The vaccine with lymph of animal origin should be administered by qualified doctors or persons qualified by the health authorities, and produced by official or officially authorized establishments which, after proving the effectiveness of the method, were responsible for issuing the vaccination certificates, free of charge, printed by the health department. In the federal capital, vaccination should also be carried out at the headquarters of the health police stations, by technicians trained for the task. The presentation of the vaccination certificate was mandatory for the individual's admission to federal, state or municipal public functions, entry into military service and the Navy, educational institutions, nursing homes and



The position of the Health Boards was modified with the creation, in the 1930s, of the new Ministry of Public Health. The new Ministry concentrated the social actions of education and public health, including the absorption of health issues involving education and health:

> Article 1 A Secretariat of State is hereby created under the name of Ministry of Education and Public Health Affairs, with no increase in expenditure.

> Article 2 This Ministry shall be in charge of the study and dispatch of all matters relating to education, public health and hospital care.

> Article 3 The new Minister of State shall have the same honors, prerogatives and salaries as the other Ministers.

[....]

Article 5 The establishments, institutions and public offices that propose to carry out studies, services or work specified in Article 2 will belong to the new Ministry, such as, among others, the Department of Education, the Benjamin Constant Institute, the National School of Fine Arts, the National Institute of Music, the National Institute for the Deaf and Dumb, the School of Apprentice Craftsmen, the Venceslau Braz Normal School of Arts and Crafts, the Superintendence of Commercial Education Establishments, the Department of Public Health, the Osvaldo Cruz Institute, the National Museum and Hospital Assistance. ²¹

In 1941 the National Health Department was structured into several services. From then on, sanitary and vaccination actions were subsumed under the new health structure, with greater specialization than that which existed until then:²²

> Article 1 The National Department of Health, subordinated to the Minister of Education and Health, is responsible for:

- promote surveys, research and studies on the conditions of health, on sanitation and hygiene issues, as well as on the epidemiology of diseases in the country and the methods of their prophylaxis and treatment;
- supervise the administration of the federal services responsible for carrying out the activities mentioned in the previous paragraph, as well as those aimed at promoting, in any way, measures for the conservation and improvement of the health, as well as, specifically, the prevention or treatment of diseases;

religious institutions, formal work, and in hotels, inns, inns, rooming houses and other types of collective housing, and to obtain an identity card, passport or birth certificate. These measures were extended to the entire population and to foreigners disembarked in the national territory'. FERNANDES, T. M. D.; CHAGAS, D. C.; SOUZA, É. M. D. Smallpox and vaccine in Brazil in the twentieth century: institutionalization of health education. Ciênc. saúde coletiva, Rio de Janeiro, 2011. Available http://www.scielo.br/scielo.php?script=sci arttext&pid=S1413feb. 81232011000200011&lng=en&nrm=iso>. Accessed: Sept. 2020.

²¹ BRAZIL - DECREE NO. 19,402, OF NOVEMBER 14, 1930. Decree No. 19,402, of November 14, 1930. House Legislation, 1930. Available at: <a href="https://www2.camara.leg.br/legin/fed/decret/1930-1939/decreto-19402-14-novembr 1930-515729-publicacaooriginal-1-

pe.html#:~:text=Cria%20uma%20Secret%C3%A1ria%20de%20Estado,da%20Educa%C3%A7%C3%A3o%20e%20Sau de% 20Publica.&text=1% C2% BA% 20Fica% 20criada% 20uma% 2>. Accessed: Sept. 2020.

²² 'The most definitive milestone in the process of institutional construction of public health as a state policy was the management of Gustavo Capanema in the Ministry of Education and Public Health (1934-45), the longest permanence of a minister in the education and health portfolios. It was the reform of the Ministry that, proposed in 1935 and implemented by Capanema from January 1937 onwards, defined directions for public health policy, reformulating and consolidating the administrative structure and adapting it to the basic principles that had defined the social policy of the Estado Novo. It was after this reform that the Ministry was renamed the Ministry of Education and Health (MES). The second major reform took place in 1941 with the creation of the National Services, which verticalized the campaigns to combat specific diseases and major endemic diseases. Therefore, it will be these two reforms undertaken by Capanema - one more general in the structure of the MESP and the other more specific in health actions - that will define and consolidate the administrative and institutional structure of public health, which remained almost unchanged until the creation of the Ministry of Health in 1953, and to a certain extent until the end of the 1980s. HOCHMAN, G. Health reforms, institutions and policies. Educate, 2005. Available at: https://www.scielo.br/pdf/er/n25/n25a09.pdf>. Accessed: Sept. 2020.



- c) to establish the coordination of state and municipal offices and institutions of private initiative, which are intended to carry out any activities related to the health problem, to animate, supervise, guide and guide them. to assist them technically, and also to study the criteria to be adopted for the granting of federal aid and subsidies to carry out these activities, and to control the application of the resources granted;
- d) Organize further training courses on medical and health issues. [....] ²³

The enactment of the Penal Code, in the previous year, 1940, was also made with the insertion of a provision of a criminal nature, in the Chapter of Crimes Against Public Health, of article 268. In an open manner, subject to remissions, the penal discipline embodied the idea of obligations to the sanitary regulations of the Government, including vaccination (although it depends, precisely, on the definition of vaccines, or vaccines of mandatory determination). Unlike the previous Code, the CP of 1940 brought provisions with types of easier reference and integration with health standards:²⁴

Article 268 - Violating a public authority order aimed at preventing the introduction or spread of a contagious disease:

Penalty - imprisonment, from one month to one year, and fine.

Sole Paragraph - The penalty is increased by one third if the agent is a public health official or works as a doctor, pharmacist, dentist or nurse. 25

However, despite the publication of the CP in 1940, the normative and institutional matrix of the 1930s and 1940s had a change in conception from the previous one. The state action became the action of promotion and offer of services and material provision: campaigns and massive vaccination supply. Thus, the motto of state action was deconcentrated from a repressive posture to a promotional posture. The institutional and normative model instituted in the Vargas era was maintained in later decades. In the following decades, there were vaccination campaigns for various diseases with national population and territorial coverage. ²⁶

²³ BRAZIL - DECREE-LAW NO. 3,171, OF APRIL 2, 1941. *House Legislation*, 1941. Available at: https://www2.camara.leg.br/legin/fed/declei/1940-1949/decreto-lei-3171-2-abril-1941-413188-publicacaooriginal-1-pe.html>. Accessed: Sept. 2020.

²⁴ And the definition may be heterogeneous, or homogeneous, depending on the type of regulation to be produced defining vaccination coverage and action. According to Karlos Alves' presentation, the following can be aligned as criminal types that orbit around the vaccination issue: Art. 131, Danger of contagion of serious disease; Art. 132, Danger to the life or health of others; Article 267, Causing an epidemic by spreading pathogenic germs; Article 268, Violation of Preventive Health Measure; Article 269, Omission of notification of disease; Article 330, Disobedience. BARBOSA, K. A. *Criminal legislation and compulsory vaccination*. Uberlândia: [s.n.]. 2020.

²⁵ BRAZIL - DECREE-LAW NO. 2,848, OF DECEMBER 7, 1940. DECREE-LAW NO. 2,848, OF DECEMBER 7, 1940. *Planalto Legislation*, 1940. Available at: http://www.planalto.gov.br/ccivil_03/decreto-lei/del2848compilado.htm. Accessed: Sept. 2020..

²⁶ Ordinance No. 49 of 1962 instituted the National Smallpox Vaccination Campaign. Article 1 The Smallpox Eradication Campaign (CEV) is hereby instituted in the Ministry of Health, under the terms of articles 1 and 2 of Law No. 5,026, of June 14, 1966, and in accordance with the plan approved by the Minister of Health, directly subordinated to the Director-General of the National Department of Health and intended to intensify and coordinate, throughout the national territory, public and private activities to prevent and combat smallpox, in all its clinical forms, with the aim of achieving the eradication of this disease'. Smallpox was considered eradicated in Brazil in 1973.' The completion of the smallpox eradication program in Brazil, with certification by the World Health Organization (WHO) in 1973, was a fundamental milestone in this trajectory. The CEV, which had an autonomous executive structure directly subordinated to the Minister of Health, mobilized major national efforts in the development of mass vaccination strategies, supported the production and quality control of the smallpox vaccine, introduced the application of the then recent concepts of epidemiological surveillance, and established mechanisms for evaluating the program. TEMPORAO, J. G. The National Immunization



It was in the 1970s that the comprehensive model of immunization was normatively defined as a government plan. Law No. 6,259 of 1975 established the framework of the National Immunization Program. The Law disciplined the compulsory nature of vaccination as a sanitary-administrative obligation:²⁷

Article 3 The Ministry of Health is responsible for the elaboration of the National Immunization Program, which will define vaccinations, including those of a mandatory nature. Sole paragraph. Mandatory vaccinations will be practiced systematically and free of charge by public bodies and entities, as well as by private entities, subsidized by the Federal, State and Municipal Governments, throughout the national territory. [...]

Article 5 Compliance with mandatory vaccinations will be proven by means of a Vaccination Certificate.

- § 1 The Vaccination Certificate shall be issued by public health services or by physicians in private activities, duly accredited for this purpose by the competent health authority.
- § 2 The Vaccination Certificate, in any case, shall be provided free of charge, with a determined period of validity, and may not be retained, for any reason, by an individual or legal entity, under public or private law.
- § 3 Annually, for the payment of the family salary, the insured will be required to present the Vaccination Certificates of their beneficiaries, which prove the receipt of mandatory vaccinations, in the form that may be established in regulation.

Article 6 State governments, with a prior hearing of the Ministry of Health, may propose complementary legislative measures aimed at complying with mandatory vaccinations by the population within their territories.

Sole paragraph. The measures referred to in this article shall be observed by federal, state and municipal, public and private entities, within the scope of the respective State.²⁸

Law No. 6,258 referred to Decree-Law No. 785 of 1969. This legal document determined the penalties for 'violations of health regulations and related penalties'. The rule was also administrative in nature and included the obligation as an administrative matter:

rogram (DNI); or

Program (PNI): origins and development. (BRASIL - DECRETO Nº 59.153, DE 31 DE AGOSTO DE 1966, 1966) Hist. Health-Manguinhos, Rio Janeiro, 2003. Available cienc. de <a href="mailto:/www.scielo.br/scielo.php?script=sci_arttext&pid=S0104-59702003000500008&lng=en&nrm=iso>. Sept. 2020. In 1971, the National Polio Control Plan was instituted: 'In 1971, in view of the occurrence of repeated outbreaks of the disease in various parts of the national territory, the Ministry of Health instituted the National Polio Control Plan. This plan was the first nationally organized attempt to control polio in Brazil. That year, a pilot project implemented in the state of Espírito Santo included a study to evaluate the serological response to the vaccine and to introduce the methodology of state campaigns carried out in a single day (Ministério da Saúde, 1993, p. 12). The federal government ensured the supply of vaccines and technical supervision, adopting the strategy of mass vaccination in a single day, in urban areas, and establishing three annual stages of vaccination of the age group from three months to four years of age, carried out in different periods in the various states. As the implementation was the responsibility of the states and municipalities, it would be necessary to raise awareness among local authorities and convince the population, including to mobilize community resources.' CAMPOS, A. L. V. D.; NASCIMENTO, D. R. D.; MARANHÃO. The history of poliomyelitis in Brazil and its control by immunization. Hist. cienc. Health-Manguinhos, Rio de Janeiro, 2003. Available at: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0104-59702003000500007&lng=en&nrm=iso.

²⁷ The Decree regulating the Law also had mandatory provisions: 'Art. 27. Vaccinations as such defined by the Ministry of Health against diseases controllable by this prevention technique, considered relevant in the national nosological framework, will be mandatory throughout the national territory. Sole paragraph. For the purposes of the provisions of this article, the Ministry of Health shall draw up lists of the types of vaccine whose application will be mandatory throughout the national territory and in certain regions of the country, according to the epidemiological behavior of the diseases. BRAZIL - DECREE NO. 78,231, OF AUGUST 12, 1976. DECREE NO. 78,231, OF AUGUST 12, 1976. Planalto legislation, 1976. Available at: <DECREE No. 78.231, OF AUGUST 12, 1976.>. Accessed: Sept. 2020.

²⁸ BRAZIL, LAW NO. 6,259, OF OCTOBER 30, 1975. LAW NO. 6,259, OF OCTOBER 30, 1975. House Legislation, 1975. Available at: https://www2.camara.leg.br/legin/fed/lei/1970-1979/lei-6259-30-outubro-1975-357094-norma-pl.html>. Accessed on: 21 set. 2020.



Art. 1 Violations of health regulations are governed by this Decree-Law, unless expressly determined by law and regardless of the applicable criminal sanctions.

Article 2 For the purposes of this Decree-Law, disobedience or non-compliance with the provisions of the legal, regulatory and other norms that, in any way, are intended to preserve health is considered an infraction.

Sole paragraph. Fraud, falsification and adulteration of raw materials and pharmaceuticals, dietetic, hygiene products, perfumes, cosmetics and the like, sanitizers and detergents and their congeners, any products, substances or inputs and others that are of interest to public health are also infractions.

Article 3 The infractions shall be determined in an administrative proceeding, initiated with the issuance of the notice of infraction, and the penalties to be imposed are as follows: [...] Art. 8 The following are infractions of a sanitary nature:

[....] VII - prevent or hinder the application of sanitary measures related to communicable diseases and the sacrifice of domestic animals considered dangerous by the health authorities; VIII - failing to implement, hinder or oppose the implementation of sanitary measures aimed at the prevention of communicable diseases and their dissemination, the preservation and maintenance of health;

IX – oppose the requirement of immunological tests or their execution by the health authorities;²⁹

This document was replaced by Law No. 6,337 of 1977. This legal text also stamped the administrative sanctions for 'infractions of federal health legislation, establishes the respective sanctions'. The text maintained the provisions for sanctions related to immunization:

VII - prevent or hinder the application of sanitary measures relating to communicable diseases and the sacrifice of domestic animals considered dangerous by the health authorities: [...]

VIII - withholding a certificate of mandatory vaccination, failing to execute, hindering or opposing the implementation of sanitary measures aimed at the prevention of communicable diseases and their dissemination, the preservation and maintenance of health:[....]

IX – to oppose the requirement of immunological tests or their execution by the health authorities:[...]

X - hinder or hinder the inspection action of the competent health authorities in the exercise of their functions: 30

In the 1980s, the Constitution included health as a fundamental right and health actions as duties of the State. It did so both with the inclusion in Title II, in the list of Fundamental Social Rights, and with the discipline part of the Health System in Title VIII, of the Social Order. It is during this text that the Statute of the Child and Adolescent is issued, which also points out the vaccination obligation:³¹

Art. 14. The Unified Health System will promote medical and dental care programs for the prevention of diseases that commonly affect the child population, and health education campaigns for parents, educators and students.

²⁹ BRAZIL - DECREE-LAW NO. 785, OF AUGUST 25, 1969. DECREE-LAW NO. 785 OF AUGUST 25, 1969. Planalto legislation, 1969. Available at: http://www.planalto.gov.br/ccivil_03/Decreto-Lei/1965-1988/Del0785.htm. Accessed: Sept. 2020.

³⁰ BRAZIL - LAW NO. 6,437, OF AUGUST 20, 1977. LAW NO. 6,437, OF AUGUST 20, 1977. Planalto Legislation, 1977. Available at: http://www.planalto.gov.br/ccivil_03/LEIS/L6437.htm#art40. Accessed: Sept. 2020.

³¹ MEDEIROS, M. F. THE ANTI-VACCINATION MOVEMENTS IN BRAZIL AND THE MANDATORY VACCINATION LAW: A CRITICAL ANALYSIS BASED ON THE RIGHTS OF CHILDREN AND ADOLESCENTS AND THE RISK OF EPIDEMIC OUTBREAKS OF INFECTIOUS DISEASES PREVIOUSLY CONTROLLED BY VACCINE COVERAGE. Revista Dissertar, v. 1, n. 32, 2019. p. 94.



Sole paragraph. Vaccination of children is mandatory in cases recommended by the health authorities. 3233

Recently, under the impact of the Covid-19 pandemic, a law was enacted on the subject of vaccination, related to the difficulties of this health problem:

Article 3 In order to address the public health emergency of international concern referred to in this Law, the authorities may adopt, within the scope of their competences, among others, the following measures:

I - insulation;

II - quarantine;

III - determination of compulsory performance of:

(a) medical examinations;

b) laboratory tests;

c) collection of clinical samples;

d) vaccination and other prophylactic measures; or

(e) specific medical treatments; [...].³⁴

In the recent period of the pandemic, the STF produced decisions on several topics on the matter. Thus, the STF understands that: philosophical or religious conviction cannot be an obstacle to vaccination; Compulsory vaccination should be differentiated from forced vaccination, since the latter would be the constraint and bodily reduction to state action; there is no unconstitutionality of vaccination obligation rules, including the ECA; there is the possibility of applying a sanction to the responsible parent who does not comply with a compulsory vaccination measure; there is municipal competence for local and regional entities to carry out vaccination (respecting the coordination of the Union). ³⁵

5 CLOSING CONSIDERATIONS. CONCLUSIVE TABLE.

The essay allows the elaboration of the following considerations about the norms of the Brazilian vaccination system and its cogent nature:

a) The initial normative provisions reflected the interests of sanitization of the capital and the entrances to the national territory, notably the ports. There was a strong concentration of resources and interests in the remodeling of the federal capital, of the then Federal District, Rio de Janeiro. From the 1930s onwards, there was a transformation of the health system and the vaccination action began to be contextualized within a broad archetype of health

³² BRAZIL - ECA - LAW NO. 8,069, OF JULY 13, 1990. LAW NO. 8,069, OF JULY 13, 1990. Planalto legislation, 1990. Available at: http://www.planalto.gov.br/ccivil_03/leis/18069.htm>. Accessed: Sept. 2020.

³³ The paragraph was renumbered to § 1.

³⁴ BRAZIL - LAW NO. 13,979, OF FEBRUARY 6, 2020. LAW NO. 13,979, OF FEBRUARY 6, 2020. Planalto legislation, 2020. Available at: http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/lei/113979.htm. Accessed: Sept. 2020.

³⁵ MEDEIROS, M. F. The anti-vaccination movements in Brazil and the mandatory vaccination law: a critical analysis based on the rights of children and adolescents and the risk of epidemic outbreaks of infectious diseases previously controlled by vaccine coverage. Revista Dissertar, v. 1, n. 32, 2019. p. 241-242.



- policy, with a cooling of the repressive character, and an emphasis on the promotional aspect. Since the enactment of the 1988 Constitution, the health system has been included in the teleology of the promotion of Fundamental Rights, that is, in addition to the promotional character, the contents of substantiation have been added.
- b) The first cogent norm, of mandatory vaccination, was in the campaign against smallpox, in 1904. The rule mentioned the obligation without specifying the forms of constraint, or the coercive elements to be employed. The implementation of the preceptive commands of this norm was initially carried out with physical constraint, or forced use of the physical disposition to enter the home sphere, on the part of the State Agents, against those refractory to vaccination (or other sanitary measures such as the application of insecticides, or drainage that also involved entry into the households). The popular reaction led to the adoption of exceptional measures, such as the State of Siege, given the non-compliance with physical constraint and home violation. Coercive measures that did not involve physical constraint, or entering homes, involved general administrative measures, limiting access to public services, or restricting the enjoyment of rights, among others.
- c) Changes in the national health system from the 1930s onwards structured vaccination as a state policy, with national coverage. This new system had the axiology and teleology of a promotional system, of universalization of access to services, accentuating the promotional character of vaccination. Therefore, despite the enactment of the CP in 1940, the penal norms, as sanctioning conducts refractory to administrative health actions, did not contain/contain a specific type on vaccination. Criminal law provides comprehensive protection over health matters.
- d) There is no specific criminal type built on the factual vaccination hypothesis. The provisions contained in the Chapter of the PC on sanitary measures are open and do not include the description of a specific hypothesis on vaccination. The penal norm points to the need for the measure to be flanked by another norm/s that define the sanitary obligation vaccination. The norms to complement the criminal norm can be either legal norms, as is the case of the recent enactment of the law, in the year 2020, or there is also the possibility of editing the general administrative regulations determining vaccination administrative action.
- e) In the Brazilian legal system, there is a provision for administrative rules determining the obligation of vaccination. Thus, the system of administrative rules places proof of vaccination as a requirement for the enjoyment of services, as a condition for access to rights. In addition, there is a provision for the application of general sanctions, of an

³⁶ A classic case of a norm dependent on another norm for the production of effects.



administrative nature, to those refractory to vaccination. In the case of the ECA, the non-implementation of the vaccination obligation may subject the parents, or guardians, to the sanctions of protective protection of the child and adolescent (as is typical of the nature of protection of the Fundamental Rights of the child and adolescent).

7

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