



## UPDATE

## Autonomy in the *post mortem* organ donation in Brazil

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### Abstract

Since 1964, the year of the first Brazilian law on organ donation, many advances have been made by Medicine, which have provided a qualitative and quantitative extension of human life, and the improvement of transplantation techniques. The present study aimed to analyze the Brazilian legislation in order to verify the supremacy of the patient's consent regarding the post-mortem donation of organs. From a review of the literature and of the legal and ethical standards referring to the authorization for organ transplants in Brazil, it was observed that, even after the amendment of Law 9.434/1997, it is necessary to adapt the legislation in force to the constitutional principles and the rules of the Brazilian civil law. Thus, it is concluded that there is a need to update the Transplantation Law, including in its text the prevalence of the donor's will, even in the face of refusal by their relatives.

**Keywords:** Tissue and organ procurement. Personal autonomy. Legislation.

### Resumo

#### Autonomia na doação de órgãos *post mortem* no Brasil

Desde 1964, ano da primeira lei brasileira de doação de órgãos, muitos avanços da medicina aumentaram a qualidade e expectativa de vida, dentre eles o aprimoramento das técnicas de transplante. Este estudo teve como objetivo analisar a legislação brasileira para verificar a supremacia do consentimento do paciente na doação de órgãos *post mortem*. A partir da revisão da literatura e das normas jurídicas e éticas brasileiras relacionadas à autorização de transplantes, constatou-se que, mesmo após alteração da Lei 9.434/1997, é necessário adequar a legislação vigente aos princípios constitucionais e às regras do direito civil do país. Assim, conclui-se que é preciso atualizar a Lei de Transplantes, incluindo no texto a prevalência da vontade do paciente doador, mesmo diante da recusa de seus familiares.

**Palavras-chave:** Obtenção de tecidos e órgãos. Autonomia pessoal. Legislação.

### Resumen

#### Autonomía en la donación de órganos *post mortem* en Brasil

Desde 1964, año de la primera ley brasileña de donación de órganos, numerosos avances de la medicina aumentaron la calidad y la expectativa de vida, entre ellos el perfeccionamiento de las técnicas de trasplante. Este estudio tuvo como objetivo analizar la legislación brasileña para verificar la supremacía del consentimiento del paciente en la donación de órganos *post mortem*. A partir de la revisión de la literatura y de las normas jurídicas y éticas brasileñas relacionadas con la autorización de trasplantes, se constató que, incluso luego de la modificación de la Ley 9.434/1997, es necesario adecuar la legislación vigente a los principios constitucionales y a las reglas del derecho civil del país. Así, se concluye que es necesario actualizar la Ley de Trasplantes, incluyendo en su texto la prevalencia de la voluntad del paciente donador, incluso ante la negativa de sus familiares.

**Palabras clave:** Obtención de tejidos y órganos. Autonomía personal. Legislación.

Declararam não haver conflito de interesse.

Brazilian society has undergone constant transformations throughout history: in the last three centuries we have had eight constitutions, the last of which is that of 1988, called the “Citizen Constitution”, because of its respect for social and individual rights. Among the various innovations of the constituent legislator are the right to health and the principle of autonomy, which, according to legal and constitutional hermeneutics, must permeate all legislative interpretations in Brazil.

Given the relationship between the right to health and the right to life, the 1988 Constitution establishes not only the search for the best use of financial resources applied to health, but also the need for technological and human improvement to prolong life with quality. In organ transplantation, for example, great progress is observed, with the development of techniques for withdrawal and donation, as well as pharmacology capable of avoiding rejection of transplanted organs.

The Sistema Único de Saúde – SUS (Unified Health System) is the largest public transplant system in the world<sup>1</sup>. The relevance and effectiveness of surgeries confirm this fact: they are performed free of charge by teams and specialized centers, even though the number of donors is less than that of patients in the waiting queue. Therefore, despite the advances and the recognition of the importance of the donation, we live a contradiction.

Data from 2017<sup>2</sup> of the Associação Brasileira de Transplantes de Órgãos - ABTO (Brazilian Association of Organ Transplants) point to 15.9 donors per 1 million inhabitants, a low number compared to Spain, for example, with rates of over 40 donors per 1 million inhabitants. One of the factors behind this discrepancy is the lack of legislation that respects the autonomy of the person who wishes to donate his or her organs after death. Thus, the need is emphasized to adapt the current legislation to the constitutional principles and the rules of Brazilian civil law, also considering the changes in the doctor-patient relationship, in which the autonomy of the patient gains more prominence in scientific discussions and in medicine in general.

### Normative treatment of organ transplantation in Brazil

The word “transplant” was first used in 1778 by John Hunter, a researcher, anatomist, and surgeon, as he explored his experience with animal reproductive organs<sup>3</sup>. In 1954, nearly two

centuries later, the world witnessed the first organ transplant a successful kidney transplantation in the United States<sup>4</sup>. In Brazil, even though the way to ensure continuity and improve the quality of life is indisputable, organ donation only became more relevant about 10 years after the success of US physicians, with the creation of Law 4,280 / 1963<sup>5</sup>.

### Period prior to the 1988 Constitution

Law 4.280/1963 focused on non-living donors, and did not present legal aspects aimed at the living person. The normative text used expressions with strong negative connotations, such as “extirpation”, which ended up causing confusion among professionals and in the population, making it difficult to disseminate the practice. Comparing the document with the Civil Code, Andrade<sup>6</sup> criticizes the use of the term “deceased person”, demonstrating that the terms used at the time could not be part of the present order<sup>7</sup>.

Another point criticized was the lack of information regarding the gratuity of donations, which led to the hypothesis that it would be possible to sell the organs. And in another section that caused legal uncertainty, the legislator stated: *it is necessary that the death be attested by the director of the hospital where the death occurred*<sup>8</sup> However, despite inadequate writing, criticized for causing the impression that organs would be withdrawn in a violent manner, the law clearly emphasized the need for written consent of the donor, leaving the will of the family in the background<sup>9</sup>.

The first Brazilian law on donation and transplantation was revoked five years after its establishment. Instead, Law 5,479/1968 was approved<sup>8</sup>, which amended the points criticized in the previous version, especially as regards the words “extirpation” and “deceased person”, replaced by “withdrawal” and “deceased person”<sup>8</sup>. The new law also brought in other positive elements, such as the granting of donation among living persons<sup>10</sup>, provided that for humanitarian and therapeutic purposes, and the exhaustive information that donation of postmortem organs should be free of charge<sup>11</sup>.

Law 5,479/1968 maintained the autonomy of the person when requesting the consent of the donor to authorize the transplant, so that the decision of the family prevails only when the person has not manifested her/his will in life. The law also innovated by expressing that the effective

exhaustion of the patient's treatment possibilities was a condition for transplantation<sup>12</sup>.

### Period post 1988 Constitution

In 1988, twenty years after the introduction of Law 5,479/1968, the Constitution of the Federative Republic of Brazil was enacted, which, in article 199, paragraph 4, prohibited the sale of organs. Since it was not possible to exhaust the subject, the Constitution determined the creation of a law to define aspects not yet settled from the theme<sup>13,14</sup>. Four years later, in compliance with this determination, Law 8,489/1992 was approved<sup>15,16</sup>, which repealed the 1968 law in compliance with the positive precepts established therein, such as the gratuitous donation and the imposition that the transplant should only occur when indispensable to the recipient and without any kind of harm to the donor<sup>15</sup>.

The importance of including these themes in the Brazilian Constitution and its infra-constitutional treatment can be translated into the words of Maria Claudia Crespo Brauner: *the fundamental legal good that life is understood in its biological sense is protected, the right to live humanly, and in a transcendent sense, to freely develop one's personality*<sup>17</sup>. Based on this right and the development of personality, it is expressed in Law 8,489/1992 that postmortem donations must have the consent of the donor, expressed through a written document, personal or recorded in a notary's office<sup>9</sup>. And it is important to note that the legislator, in search of criteria for the moment when the donation would be authorized, adopted brain death as an objective parameter and scientifically consecrated by medicine to determine death<sup>9</sup>.

Even with all the innovations introduced in the 1992 law, technological advances in medicine and pharmacology have made it rapidly outdated, and new legislation was needed, which came in 1997 under Law 9,434<sup>19</sup>. With the clear intention of increasing the number of donations and to reduce the number of transplants, the law introduced the presumed donation of postmortem organs, that is, the resolution that Brazilians who did not manifest themselves contrary to the donation were considered presumed donors<sup>9</sup>.

The 1997 legislation stated that the manifestation contrary to the donation should be made categorically in an official document, and that the reformulation of this will was permitted<sup>19</sup>. However, the new law was not well-received by the

population. In the words of Elton Carlos de Almeida, *the new legal context did not achieve the purpose of increasing the supply of organs; on the contrary, thousands or millions have registered as "non-donors" in official documents*<sup>20</sup>.

There were people running to service stations, mainly due to the lack of information about the procedures required for donation. Responsible for altering identity documents and concerned about the situation, the public administration issued Provisional Measures 1718-1/1998<sup>21</sup> and 1959-27/2000<sup>12</sup>, subsequently sanctioning Law 10.211/2001<sup>22</sup>.

The first of the provisional measures reestablished the criterion adopted in previous laws, treating as primordial the express consent of the donor and maintaining the family decision as a subsidiary, requested only in the absence of a document with the wish of the deceased. In the words of the legislator, *in the absence of the willingness of the potential donor, the father, mother, son or spouse may manifest in opposition to the donation, which will be obligatorily accepted by the transplant and removal teams*<sup>21</sup>.

After the repeal of the measure on December 27, 2000, Law 10.211/2001 was published, which amended article 4 of Law 9,434/1997, determining the family as responsible for deciding whether or not to donate the organs of the deceased. By creating a monopoly on the decision that affected the person's autonomy, the new law removed legal protection from the manifestation of the donor's will, since, even if there was a desire expressed, the family resolution would stand out<sup>23</sup>. This hurried legal change provoked debate among the doctrinaires<sup>24</sup>.

In 2002, in a context of consolidation of constitutional principles, the current Civil Code was approved, with a text closer to that advocated by the doctrinaires. Article 14 says *that the free disposition of the body itself, in whole or in part, after death is valid for a scientific or altruistic purpose*<sup>7</sup>. By the interpretative rules of law, only when there is no previous manifestation of the possible donor must the will of family members prevail<sup>25</sup>.

Contrary to the Civil Code and the doctrinal position, Law 10.211 / 2001 does not allow the donor to express his choice, not providing a legal document to fulfill the desire of the individual, whether or not to donate their organs, i.e., take into account the real autonomy of the person. According to Alexandre Marinho, the new wording of Law 10.211/2001<sup>22</sup> to article 4 of the National Law of Organ Donation

*alleviates the possible donor of the fundamental choice of the destiny of his organs and ends up depriving him of complete self-determination*<sup>26</sup>.

Decree 2,268/1997<sup>27</sup> creates the Sistema Nacional de Transplantes - SNT (National System of Transplantation) and the Centrais de Notificação, Captação e Distribuição de Órgãos e Tecidos - CNCDO (Centers for Notification, Collection and Distribution of Organs and Tissues), members of the SUS, as well as the single national list of recipients among the states of the Federation. The decree, which regulates the current National Organ Donation Law, was not modified by Law 10.211/2001, bringing safety in determining that procedures for organ removal and transplantation should be performed by a specialized team in public or private hospitals duly accredited by the Ministry of health.

The certainty that the procedure will be monitored on the basis of precise technical criteria gives more security to the donors to authorize the procedure in life. In that sense, the document also makes the system safer<sup>9</sup>. Another innovation concerns the determination that the removal of tissues, organs and parts of the human body can only occur after brain death<sup>9,27</sup>.

Regarding postmortem donation, mention should be made of the second chapter of Law 9.434/1997, which, in addition to establishing brain death as a condition for the removal of the organs, stipulates that it must be verified and recorded by two doctors who are not part of the team responsible for the withdrawal surgery. Regarding brain death, the Conselho Federal de Medicina - CFM (Federal Council of Medicine) was responsible for regulating the criteria to verify it, also defining that the family can request the presence of a trusted physician to resolve any doubts regarding the end of the life of the donor candidate<sup>28</sup>.

Resolution CFM 1480/1997<sup>28</sup> lays down in detail the criteria for verifying death, preventing a person's life from being shortened for the benefit of another. It is known that the concept of "brain death" is not widely understood, since death is traditionally defined as the cessation of heart beat. And the presence of heartbeats, according to Almeida<sup>11</sup>, is one of the factors that lead the family to refuse the withdrawal of organs, even if the patient has declared to be a donor.

It is worth mentioning that the physicians responsible for the removal of the organs must reconstitute the body of the donor patient in order to allow a burial worthy of the deceased. In this

sense, we point out the lack of disclosure of legal procedures to be adopted and information that makes it clear to family members that there will be no mutilation of the body. This information could prevent the refusal of the donation, so it is essential to provide them in the interview with family members<sup>9</sup>.

Under the terms of the constitutional text, article 14 of the Civil Code establishes the free disposal of the body, in life and postmortem, guaranteeing a very personal right that was already used in all other laws dealing with donation and organ transplantation<sup>29</sup>. Saving the principles of our Constitution, we note in this passage of the Codex the respect for the autonomy of those who wish to donate their organs. For the desire to donate one's own organs is a right that depends on the will of the person, considered a subject with autonomy to make choices for her/his body, in life and after death<sup>9</sup>.

As there was no doctrinal consensus on the current article 4 of Law 9,434/1997 - amended by Law 10,211/2001 and by article 14 of the Civil Code, the Federal Justice Council, in the IV Civil Law Journey, published Statement 277, *in verbis*:

*277 - Art. 14: Art. 14 of the Civil Code, when affirming the validity of the free disposition of one's own body itself, for scientific or altruistic purposes, after death, determined that the express manifestation of the donor of living organs prevails over the will of the family, therefore, the application of the Art. 4 of Law no. 9,434/97 was restricted to the hypothesis of silence of the potential donor*<sup>30</sup>.

### Advance directives of will and organ donation

In 2012, with Resolution CFM 1,995/2012<sup>31</sup>, which governs the advance directives of will (ADW), the discussion on the prevalence of the patient's will has returned to the agenda. The ADWs are an efficient instrument of manifestation of the patient's will at the end of life, left written in a document (public or not) or verbal statement to the physician annotated in medical records. Considering this orientation, the family only has the power of decision on the treatment of the patient if he has never manifested his will, or when, already unable to manifest it, he has an incurable disease<sup>32,33</sup>.

The legal doctrine is divided as to the possibility of manifesting the desire to donate organs in ADW. Goiatá and Naves<sup>34</sup> understand that the manifestation of will in the ADW removes the family

decision. However, Dadalto, Tupinambás and Greco<sup>35</sup> contend that the ADWs allow the person to exercise his or her right to dispose of the postmortem organs, stating that the directives would not have included organ donation, as in the US and Spanish model.

In this case, the authors argue, the resolution would be contrary to the current Transplantation Law, which determines family authorization. In his words, the manifestation of organ donation in ADW *would generate a clash of institutes and, in addition, would denature the ADW, since they are, in essence, a legal business, with inter vivos effects, with the main objective to guarantee the autonomy of the subject to the treatment to which she/he will be subjected in the event of termination of life*<sup>36</sup>. In reinforcing the argument, Dadalto<sup>37</sup> still argues that manifesting the decision regarding organ donation in ADW is not possible in Brazilian law because it confronts the terms of Law 9,434/1997.

Therefore, although there are countries where the provision on organ donation is a legal provision in the ADW, this situation does not occur in Brazil, due to the existence of a specific law that contradicts the basic principle of the ADW: autonomy of the patient. In addition, it is important to note paragraph 3 of article 2 of CFM Resolution 1,995/19, which states that *the advance directives will prevail over any other non-medical opinion, including the wishes of the family members*<sup>31</sup>.

Contrary to the current wording of the Transplantation Law, the CFM resolution privileges the patient's autonomy, without removing the rights granted to the family<sup>38</sup>. Although it has no legal validity, such resolution had the merit of broadening the discussions on the subject. Nevertheless, in October 2017, the National Executive Branch issued Decree 9,175<sup>39</sup>, which again, and explicitly, assigns decision-making power to the family, that is, a clear retrocession to the movement to protect respect for the patient's will.

### Adequacy to bioethical aspects

The waiting list for transplants reached more than 41 thousand people in December 2016<sup>40</sup>. And even with the growth of around 12% in the donations in the first half of 2017, according to ABTO data, it is verified that the amount of people waiting for an organ is still very large<sup>2</sup>. In this context, it is necessary to affirm the sovereignty of the desire of the non-living donor, taking into account that the civil code itself is contrary to the special law. It is a function of

legislation to ensure the integrity and dignity of the person, and for this we must improve it.

Faced with this new normative reality, it is necessary to clarify the population about the donation of organs, so that especially the family knows that this altruistic act can improve and prolong the lives of other people. It is also necessary, through publicity, to encourage the potential donor to express their wish to family members, requesting that it be respected, since there is still no document for such manifestation in the Brazilian legal system.

Finally, it is imperative to discuss the need to modify the current wording of article 4 of Law 9,434/1997. Thus, it is suggested: *Art. 4 - The removal of tissues, organs and parts of the body of people deceased for transplants or other therapeutic purpose will depend on the manifestation of the donor, in life, by means of a public document. Single Paragraph: In the absence of the document referred to in the caption the consent of the spouse or relative, of age, obeying the line of succession, straight or collateral, to the second degree, signed in a document also signed by two witnesses present at the time of death verification shall be required.*

It should be noted that the wording suggested here may seem very succinct, but it is significant as far as respect for the patient's autonomy is concerned. However, it is not the intention of this paper to exhaust the theme, but rather to reflect on the possibilities of adapting the Law of Donation and Transplantation of Organs to the constitutional text.

### Final Considerations

Undeniably, organ donation and transplantation are positive developments in medicine and pharmacology. Thanks to these procedures, individuals who had a few years of survival after diagnoses such as heart or kidney failure have the expectation of living longer and with quality. The technological development that has increased the effectiveness of organ withdrawal, transport and transplantation, especially with the use of drugs that reduce rejection, could not be left without a regulatory text.

Although the health sciences are constantly evolving to provide ever more effective transplants, the country legislator remains behind in the creation of laws that respect the individual and the legal system in force. An example is the way the current transplant law treats consent for donation. There is no permission for the individual to choose what

will be done with his organs after death, leaving it completely for the family to make this choice - which denies the autonomy provided for in the Constitution and the Civil Code.

Therefore, it is a matter of adapting Law 9.434 / 1997 to the current legislation and the current thinking about the physician-patient relationship.

Such action must be accompanied by investment in educational actions and campaigns to raise awareness in the society. These initiatives should clarify the whole process of organ withdrawal and transplantation so that the decision of the patient or his/her family can be made more clearly.

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