Ethics and law: the legally incompetent individual as a bone marrow donor

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Abstract

Organ donation is a question that unfolds into a myriad of controversial issues requiring to be addressed. Considering this context, the purpose of this study is to examine and give special attention to a particular topic: the legally incompetent bone marrow donor. The Brazilian legislation does not address this matter accordingly, ignoring the scientific advances on transplant techniques and dealing only superficially and without clarity with the ethical aspects involved. We carried out a review of the literature and legislation on the subject , as well as a survey of transplant reports and court decisions on organ donation. The analysis showed the need for further legal regulation on the matter.

Keywords: Transplantation. Bone marrow. Enacted statutes. Personal autonomy. Bioethics.

Resumo

Ética e direito: o juridicamente incapaz como doador de medula óssea

O tema da doação de órgãos carrega inúmeras polêmicas passíveis de análise. O propósito deste estudo é refletir e evidenciar questão peculiar: a da doação de medula óssea por indivíduo considerado juridicamente incapaz. Verifica-se que a legislação brasileira não aborda o assunto com a devida atenção, não acompanhando a evolução científica e tratando de maneira superficial e incerta os aspectos éticos envolvidos. Analisou-se a literatura e a legislação referentes ao assunto, e posteriormente pesquisaram-se relatórios de doação de órgãos e decisões judiciais. Com base nos dados levantados, ficou demonstrada a necessidade de maior regulamentação do assunto.

Palavras-chave: Transplante. Medula óssea. Normas jurídicas. Autonomia pessoal. Bioética.

Resumen

Ética y derecho: el incapaz legal como donante de médula ósea

El tema de la donación de órganos conlleva cuestiones polémicas susceptibles de ser analizadas. El propósito de este estudio es reflejar y poner particularmente de manifiesto un tema peculiar: la donación de médula ósea por parte de incapaces legales. Se observa que la legislación brasileña no aborda el asunto con la debida atención, no acompaña su evolución científica y concede un tratamiento superficial e impreciso a los aspectos éticos intervinientes. Se analizó la literatura y la legislación relacionada con el tema y posteriormente se buscaron informes de donación de órganos y decisiones judiciales. Sobre la base de los datos recopilados, se demuestra la necesidad de una mayor regulación del tema.

Palabras clave: Trasplante. Médula ósea. Normas jurídicas. Autonomía personal. Bioética.

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The last decades saw advances in biological sciences that have surprised society. The possibility of organ transplantation, considered a triumph of contemporary surgery, raised unprecedented questions that need to be addressed and clarified, but the ethical, religious, moral and legal reflections on the matter have not kept pace with the speed of technical and scientific advances.

Organ and tissue transplantation is not only of clinical interest, but also involves basic ethical and legal principles. This study therefore addresses ethical and legal aspects regarding persons legally incompetent to be bone marrow donors, aiming to emphasize the scarce existing regulation on this subject, as well as to suggest reflections, studies and discussions concerning the fields of bioethics and biolaw.

In this study, it became clear that performing only a legal analysis would be impossible, since the medical aspects of the issue are related to legal provisions, further emphasizing biolaw as a fourth-generation human right. A medical approach is also necessary to complement legal considerations, and therefore it is inconceivable to consider this topic without an interdisciplinary approach.

Furthermore, reliable data is lacking, which may prevent strict compliance with legal provisions regarding bone marrow donation by legally incompetent individuals. It is possible that organ transplantation *inter vivos* are being performed not only illegally, but also unethically, given the vulnerability of donors, who deserve as much protection as the recipients.

Organ transplantation *inter vivos*

Organ transplantation is a legal matter, and it is thus necessary for the Brazilian legal system to address it through regulation and prevention of illegal practices. Federal Law 9,434/1997 (Transplantation Law) [1], currently in force, regulates the removal of human organs, tissues and parts for transplantation and treatment purposes, free of charge, *post mortem* or *inter vivos*, in accordance with paragraph 4 of article 199 of the Brazilian Federal Constitution [2]. Chapter III of Law 9,434, *caput* of its article 9, after amended by Law 10,211/2001 [3], establishes that:

The legally competent person shall be allowed to dispose free of charge organs and parts of the person's own living body, for therapeutic purposes or for transplantations to spouses or blood relatives up to the fourth degree, as provided for by paragraph 4 of this article, or to any other person, with judicial authorization, which is waived in relation to bone marrow [1].

Paragraph 3 of the same article clarifies that donation *inter vivos* is only allowed for *double organs,* (…) *parts of organs, tissues or parts of the body whose removal does not prevent the donor's organism from continuing to live without risk to its integrity* [1]. The donation procedure cannot also seriously impair vital functions and mental health, nor cause mutilation or unacceptable deformation. This same article also requires proof of the recipient's therapeutic need, and the donor must authorize the procedure preferably by signing a document and before witnesses, specifying the tissue, organ or part of the body to be removed [1].

For organ donation *inter vivos* to be legal, certain requirements must thus be met: 1) the donor must be legally competent; 2) the donation of the tissue, organ or part of the living body must be absolutely free of charge; and 3) the recipient must be a spouse, parent, son, daughter, sibling, grandparent, grandchild, uncle, aunt, nephew, niece, great-grandparent, great-grandchild, cousin, great-great-grandparent, great-great-grandchild, great-uncle, great-aunt, great-nephew or great-niece of the donor. If the donation is intended for anyone other than those mentioned, judicial authorization will be required, waived only in cases of bone marrow donation.

Paragraph 6 of article 9 of Law 9,434/1997 [1] and paragraph 8 of article 15 of Decree 2,268/1997 [4] regulate donation by legally incompetent donors. In this case, only bone marrow donation is allowed, requiring judicial authorization and from both parents or legal guardians, in addition to inherent medical requirements – confirmation of transplantation suitability and absence of risks to the donor's health [1]. Interestingly, the law establishes that parental authorization does not preclude judicial authorization, both are equally required – a provision that in practice is often disrespected.

Violation of legal provision

The legally incompetent as a bone marrow donor

Considering the public interest and aiming to combat illegal acts, Chapter V of the Transplantation Law [1] establishes the criminal and administrative

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penalties for legal violations. Article 16 of the same law defines as criminal the act of *performing a transplant or graft using tissues, organs or parts of the human body that are known to have been obtained in disagreement with the provisions of this law* [1]. The law establishes a prison sentence of one to six years and a daily fine of 150 to 300 days.

If the provisions of paragraph 6 of article 9 of the Transplantation Law [1] are not duly complied with, a legal precept would thus be violated, and those responsible would be committing a crime and should receive the corresponding legal penalties. It is important to note that medical teams and facilities would also be penalized with temporary or definitive suspension of activities, or even with suspension of contracts and agreements.

Doctors are also forbidden, as provided in article 45 of the Brazilian Code of Medical Ethics, from *removing an organ from a living donor when this donor is legally incompetent, even if authorized by the donor's legal representative, except in the cases permitted and regulated by law* [5]. It is astonishing, therefore, how often the law is disrespected, as well as the usual understanding that the authorization of both parents or guardians would suffice to allow the donation. It is also surprising to observe that the legal provisions mentioned are the only ones addressing legally incompetent donors. Although the law protects them from donating any organ, tissue or body part other than bone marrow, further clarifications on the matter are lacking.

The legally incompetent

Legal incapacity is a state that limits certain acts of civil life, restricting the activities of individuals who are not legally competent to perform them or enjoy certain rights. Law 10,406/2002 (Civil Code) [6], in its Book I, Title I, Chapter I, establishes that legal incapacity may be absolute or relative. Article 3 of the Civil Code [6] provides that minors under the age of 16 are absolutely incompetent to perform the acts of civil life, while article 4 lists as relatively incompetent those between the ages of 16 and 18, those with alcohol or drug addiction, people temporarily or permanently unable to express their will, and the prodigal.

Two relevant points should be considered regarding the Brazilian Civil Code [6]. The first is that paragraph 6 of article 9 of the Organ Transplantation Law [1] does not differentiate between absolute or relative legal incapacity, referring only to the "legally incompetent". The second point concerns changes in the legal capacity regime introduced by Law 13,146/2015 [7]. Article 114 of the latter amended the text of the Civil Code's article 3, revoking its item II, which also listed as absolutely incompetent those who, due to illness or mental disability, do not have the necessary discernment to perform certain acts [7].

Therefore, the assumption is that disability does not limit *a priori* civil legal capacity. Bone marrow donation, however, is not specifically addressed, as this provision concerns not only the autonomy of the disabled person for organ donation purposes, but also anatomical, biological and physiological aspects resulting from the disability.

Thus, the conclusion is that the legally incompetent individuals that are subject to legal limitations as bone marrow donors will be minors under the age of 18, those with alcohol or drug addiction, the prodigal and those temporarily or permanently unable to express their will. For the purpose of clarification, the law considers "prodigal" people who spend money in a recklessly way, compromising their assets.

What is bone marrow?

Necessity and what is organ transplantation

In the 1950s, the first attempts to transplant the bone marrow in humans took place. In Brazil, the first bone marrow transplant was carried out in 1979, at the *Hospital das Clínicas* of the Federal University of Paraná, in Curitiba [8]. Bone marrow, also known as "marrow," is the semi-solid tissue found inside the bones. Rich in stem cells, it is responsible for producing blood components – erythrocytes (red blood cells), leukocytes (white blood cells) and platelets [9].

Red blood cells carry oxygen from the lungs to cells throughout the body, and transport carbon dioxide from cells to the lungs to be exhaled. White blood cells are the most important agents in the body's defense system, and platelets are part of the blood coagulation system. Bone marrow is continuously producing new blood cells, being responsible for the constant blood renewal .

Diseases affecting the bone marrow may occur due to either excess in cell production (leukemia) or decreased cell production (anemia). Depending on the severity of the health condition, bone marrow transplantation may be the most suitable procedure for people with diseases affecting blood cells [9]. Basically, this procedure consists of replacing the diseased bone marrow with normal cells of a healthy bone marrow, using the so-called "hematopoietic

stem cells".[10] *A priori*, there are two ways to perform this: an autologous transplant, when the patient's own bone marrow is used, or allogeneic, when it comes from a donor – in the cases where the donor is the recipient's identical twin sibling, it is called a syngeneic transplant[10].

In autologous transplantation, part of the patient's bone marrow is removed, treated, properly stored and replaced, while what remains of it in the body is destroyed. This treatment aims to preserve the spinal cord while it undergoes myeloablation, a shock treatment with high doses of chemotherapy and radiation to eradicate diseased cells. Stem cells, which were removed at the beginning of the treatment, are then reintroduced to recompose the bone marrow[11]. The main issue of this procedure is that the disease affects cells located within the bone marrow, and it is difficult to completely eliminate the diseased cells; therefore, remnants cells may proliferate, causing a relapse.

Allogeneic transplantation also involves the destruction of diseased bone marrow cells by myeloablative procedures, but with transplantation of a donor's healthy bone marrow cells. This happens through blood transfusion, with the cells of the marrow migrating to the bones, functioning as a graft. On average, it takes two weeks for new blood cells to be produced[11].

Allogeneic transplantation and its ramifications

The bone marrow has certain peculiarities regarding graft rejection. In other types of organ transplantation, the recipient's organism may reject a transplanted organ that is not fully compatible, whereas in bone marrow transplantation the process has opposite characteristics: the patient receives a new immune system through the production of white blood cells, which may recognize the recipient's tissues as foreign and thus start to destroy them.

This phenomenon, called "graft-versus-host disease," is responsible for the highest mortality rate in this type of transplant, and directly influences the patient's life expectancy[11]. Due to this delicate situation, it is crucial that the donor and recipient have the same "genetic signature," to minimize the risk of harm as much as possible.

The problem of histocompatibility

The compatibility of the human leukocyte antigen system, necessary for bone marrow transplantation, is determined by a set of genes located on chromosome 6, which must be the same in both donor and recipient. This matching, called "histocompatibility," is assessed by specific laboratory tests, using blood samples that can be of different types[12].

Based on genetic inheritance, there is a 25% chance of finding a histocompatible donor among siblings of the same father and mother. Therefore, the more siblings the patient has, the greater the probability of finding a donor[11]. As it happens, current trends point to increasingly smaller nuclear families. Expanding the search for histocompatibility to other close relatives, the chance of finding a fully compatible donor is 7% to 10%[11].

Part of the problem is that the patient's parents cannot be considered potential donors, as they share only half of their genes with their children. The search then usually extends to voluntary donor registries or to public umbilical cord and placental blood banks. But the probability of finding a fully compatible donor outside the family is unfortunately small.

The National Registry of Bone Marrow Donors (Redome), coordinated by the Brazilian National Cancer Institute (Inca), which is subordinated to the Ministry of Health, collects data from more than 4 million individuals and is the third largest bank of this type in the world (the first two are in the USA and Germany). Redome searches for donors in Brazil and in foreign registries, totaling more than 25 million volunteers[12]. Miscegenation in Brazil is another factor that makes it difficult to find compatible donors, showing the importance of having a good amount of volunteers registered in the system.

Ramifications of the issue of histocompatibility

The difficulties in finding fully compatible donors lead to a search for alternatives. A new type of transplant, called "haploidentical transplant," was developed to address the lack of black, indigenous and Asian donors. The procedure, which uses bone marrow from a donor that is not completely compatible, is considered experimental in Brazil and should be viewed with caution; it is currently considered only when no other donor is found[13].

Haploidentical transplants are exclusively from family members (especially from mother, father and siblings), being performed when there is a half match between donor and recipient[13]. The technique focuses mainly on the patient's mother as a donor, because her having gestated the child for nine

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months, without tissue rejection, already evidences higher tolerance [13]. The procedure, however, is only suitable for some types of bone marrow diseases, and should only be considered in certain situations. The risk of failure is extreme, and the chances of relapse are higher.

All these difficulties related to histocompatibility in allogeneic transplantation show the relevance of the ethical and legal aspects of bone marrow donation by a legally incompetent individual.

Ethical-legal considerations

Autonomy of the legally incompetent donor

As transplants between siblings show better results, and considering the applicable legal provisions, it should be determined whether a patient's sibling identified as a compatible donor is legally incompetent (persons under 18 years old, addicted to alcohol or drugs, prodigal, or who are temporarily or permanently unable to express their will). Those addicted to alcohol or drugs will not be addressed in this article, since their health condition may itself prevent them from being donors; the prodigal will also be disregarded, as their incapacity, due to excessive spending and related compromised assets, would demand a complex discussion beyond the scope of this study.

The potential donors addressed here, therefore, are minors and persons unable to express their will. Focusing on the practice of denying donors the exercise of consent, thus depriving them of the autonomy conferred by law, we question to what extent it is legal and ethical to entrust the power of decision to third parties, even parents. These considerations led to legislation aimed at protecting these individuals from the misuse of their bodies.

Moreover, we must consider the contributions of the bioethics of protection [14,15], particularly those concerning the condition of vulnerable individuals. Bioethics is practical or applied ethics, as it aims to settle practical moral conflicts. While describing dilemmas between norms and practice, bioethics is aimed at prescribing and proscribing behaviors, based on criticism and justification. Schramm [15] emphasizes the protective function of this field of knowledge, which recovers the more archaic meaning of the Greek word *ethos*: an "accustomed place" or "den," which shelters animals from weather and predators and, by extension, protects humans from external threats. This approach can be leveraged as a social device to facilitate access to updated statistics on medical procedures and judicial authorizations for bone marrow transplants [9].

Exercise of the bioethical principle of autonomy by the legally incompetent

The donation of organs, tissues and other parts of the human body is a legal transaction that constitutes an exception to the transfer of personality rights. To be valid, it must be characterized by the free provision of the item to be donated and be based on the principle of autonomy of the will. The presumed free manifestation of the individual's autonomy is what calls into question bone marrow donation by the legally incompetent, because of an absence of full volitional capacity.

According to Santo, *basic human rights are involved from the donation* (…) *to the transplantation* (…)*, with respect to life, health, physical integrity, freedom of conscience, personality development, and the right to one's own body* (…), *it is up to the donor to decide whether or not to donate* (…)*, as long as such a decision does not harm the donor* [16]. The law requires the donation to be expressly authorized, which presupposes the autonomy of the will operating in the donors' considered and deliberate decision to donate their organs.

The right to the parts of one's own body, whether dead or alive, is an integral part of one's personality [17]. This raises the issue of the transfer of personality rights, especially the right to the unavailability of one's own body. This aspect is essential, since the surgery of living donors is the only case in which such a big medical operation is performed on healthy individuals.

Item III of article 1 of the Brazilian Federal Constitution [2] provides for the principle of human dignity, which is at the basis of the Brazilian legal system. The main section of the Federal Constitution's article 5 [2] addresses the basic individual rights and guarantees, emphasizing the inviolability of the right to life and freedom. Specifically, paragraph 4 of article 199 establishes that the law will regulate the availability of parts of the human body [2].

The integral elements of an individual's personality are absolute, non-transferable, irrevocable, unseizable and inalienable; however, the sole paragraph of article 13 of the Brazilian Civil Code [6] makes an exception for the act of offering one's own body for transplantation purposes, in accordance with the specific law regulating the matter. Civil Code's article 15 [6] expands the protection to the inviolability

of the human body, emphasizing the individual's freedom of choice in the decision. That said, it is necessary to discuss the doubts and implications surrounding the autonomy of a person considered legally incompetent by the Brazilian legal system, including aspects related to ethical legitimacy within the context of organ and tissue donation.

In addition to being one of the Brazilian Federal Constitution's basic principles, personal autonomy is also at the basis of bioethics and biolaw. Regarding one's health, it is the expression of the person's will, allowing the freedom to deliberate, consent and act. Considering that autonomy is integral to the individual (*autos* = own; *nomos* = norm), in the case of legally incompetent bone marrow donors, it should be considered whether the capacity for autonomy is not absent or, at least, diminished and controlled by third parties [18].

Considering that donating organs, tissues and parts of the body for transplantation is the donor's prerogative, a gesture of conscious solidarity – which must be both explicit and free from any constraint or coercion, or incur the risk of violating basic human dignity standards –, this calls attention to decisions made by third parties, as with legally incompetent donors. Such a sensitive situation raises several hypotheses, reflections, doubts and shocks of proportionality, making it difficult to exhaust the issue or reach definitive conclusions about it.

The planned sibling

The possibility of manipulating genes, introduced by genetic engineering, brought about new approaches to some ethical principles, as well as the need to enact new laws. The Brazilian Federal Council of Medicine (CFM), through Resolution 1,358/1992 [19], established the first Brazilian ethical standards for assisted human reproduction, later repealed by Resolution CFM 1,957/2010 [20].

The recent advancement of these techniques is highly controversial, especially as an alternative for parents seeking a compatible individual to donate bone marrow to their child, as it is now possible to conceive a genetically planned human being histocompatible with the sick sibling. Clearly, before making such a decision, it is necessary to first try all other alternatives, because *when a human life is at stake and doubts arise as to the lives of others, we begin to thread a path of transcendent meanings* [21].

To find a viable donor, some parents have resorted to *in vitro* fertilization, genetically selecting an embryo to generate a baby compatible with the sick child. This situation has already been the subject of media reports, films, soap operas and books, mainly focusing on ethical discussions. Some theoretical approaches – such as the natalist, the conditional personality and the conceptionist – have addressed the beginning of the legal personality and the rights of the unborn child. The Brazilian Civil Code [6] establishes in its article 2 that, although the legal personality begins only with the birth of a living child, the rights of the unborn child must be guaranteed since conception. Thus, it is necessary to examine the situation of embryos genetically engineered to produce histocompatible donors: are they entitled to rights or do they have no rights at all?

Such potential violation of basic human rights should be addressed in line with the principles of the child's best interest and of the autonomy of the will, which prevent the use of a human being as a mere tool for healing others. Also inescapable is the fact that, although genetically engineered, the new child may prove to be incompatible with the recipient, thus becoming undesirable for the parents. Another issue is whether the engineering of genetically selected embryos, even for the sake of the greater good, would not constitute eugenics, a practice disapproved by both the CFM and the principles of bioethics [22].

It is worth reflecting on what would be the tolerable limit for this design of human beings, as well as what would be the parameters for determining the situations in which the value of a human life is no longer absolute. For example: how ethical and fair would it be to discard healthy but incompatible embryos? Clearly, the possibility of selecting an embryo in the laboratory by genetic criteria is a scientific milestone. However, as pointed out, there are many ethical conflicts that must be considered according to the principles of proportionality and reasonableness.

In Europe, this same line of reasoning is being followed. Assche and collaborators [23] point out the need to improve the European regulatory framework, considering the best interests of the donor child [24]. Unlike civil law countries, such as Brazil, which establishes positive standards for the matter, the approach of common law countries is based on legal precedents. Therefore, as to organ transplantation involving legally incompetent donors, what prevails is the test of the child's best interests. Thus, without specific legislation, judicial authorizations must be obtained.

Rubeis and Steger [25], in turn, conclude that the main conflict occurs between the bioethical principles of autonomy and non-maleficence regarding the planned sibling and of beneficence regarding the receiving sibling. The authors also observe that decision-making is a complex issue, and that the health professionals involved should know how to assess the different levels of vulnerability of children, which varies depending on their age [25].

Statistical data

In Brazil, there are two transplant databases, which collect data produced by transplant centers accredited by the Ministry of Health. They are managed by the Brazilian Association of Organ Transplantation (ABTO), which also publishes the Brazilian Transplant Registry (RBT), and by the Informatics Department of the Unified Health System National Health (Datasus). These databases are complementary: while Datasus is limited to transplants financed by the public healthcare system, RBT collects data on procedures paid directly or covered by other financing arrangements [26].

According to RBT data [27], for the period from January to September 2016, 1,577 bone marrow transplants were performed in Brazil, of which 1,003 were autologous and 574 allogeneic. The states in which allogeneic transplants were performed over this period were São Paulo (310), Paraná (92), Pernambuco (56), Minas Gerais (20), Distrito Federal (20), Bahia (19), Ceará (19), Rio Grande do Sul (19), Goiás (8), Rio de Janeiro (7), and Rio Grande do Norte (4)[27].

Judicial authorizations in state court decision databases

A search was conducted using the keyword "bone marrow transplantation" in state databases collecting court decisions, judicial acts and cases in progress in the states mentioned in the previous section. The search was limited to entries from December 31, 2015, to October 1, 2016, a period close to the survey conducted in the RBT database. As discussed, only the legally incompetent need judicial authorization to donate bone marrow; however, not all search results concern authorizations, also including excerpts from the legislation, such as quotations of decisions in other transplant cases.

The search on the database of the São Paulo State Court of Justice [28] produced 110 results, but only two referred to authorizations for bone marrow donation by a legally incompetent individual. In the database of the Rio Grande do Sul State Court of Justice [29], the search generated 41 results, with only one issued a transplant authorization of this type. In the databases of the Paraná State Court of Justice [30], with four results, as well as those of the State Courts of the Federal District [31] (three results) and Goiás [32] (15 results), no documents were found concerning the subject of this study.

The search in the databases of the State Courts of Minas Gerais [33] and Ceará [34] produced no results for the searched term, and the database of Pernambuco [35] was outdated, which prevented the search for the defined period. The State Courts of Bahia [36], Rio de Janeiro [37] and Rio Grande do Norte [38] had no data available on organ transplant authorizations.

Comparing the results obtained showed that of the 310 allogeneic transplants performed in the state of São Paulo, two received judicial authorization, and of the 19 performed in Rio Grande do Sul, one received the same authorization. Thus, of the 574 allogeneic transplants performed between January and September 2016, only three seems to have involved legally incompetent donors, but there is no consolidated database to confirm this data. The databases of Paraná, Distrito Federal, Goiás, Minas Gerais and Ceará showed no results for our search; and those of Pernambuco, Bahia, Rio de Janeiro and Rio Grande do Norte do not even provide information that can be analyzed.

Although there may have been only three bone marrow donations by legally incompetent individuals in the period considered, there is still the possibility that such transplants may have been performed without due authorization, violating the legal provisions on the matter. The lack of credibility of the current data systems suggests the hypothesis of under-reporting.

The flaws in data collection led the Ministry of Health's National Transplantation System to start collecting information on bone marrow transplant services in Brazil in 2017, to conduct a more precise assessment of their functioning [39]. This evaluation is expected to finally reveal the actual overall legal situation of bone marrow donation by legally incompetent individuals.

Final considerations

In view of the recent scientific advances, the new knowledge generated and its potential applications, the need for an improved legal

framework is clear. The right to health, in a broader sense, obliges the public authorities to improve the population's general living conditions. However, the new conception of private law should be examined to address the current chaos in the Brazilian public health system.

Private law has been subordinated to the collective interest for some time, since this interest goes beyond the scope of public law. The state, however, cannot escape its obligation, being responsible for supervising health services such as organ transplantation by legislating on its requirements, conditions and procedures.

For recipients, the transplant means a chance of survival. There is no arguing that, in urgent cases, less bureaucratic and more efficient measures should be taken, but ethical principles must not be ignored in the process. There are numerous questions still open to discussion, but the Brazilian legal system remains unprepared, in some respects, to follow the progress of biological sciences, dealing only in generic terms with organ donation. An approach to this matter based on the current legislation is certainly valid; however, experience will show gaps requiring further legal regulation. Thus, the importance of how the state addresses actual cases grows, basing its interventions on an awareness of the legally incompetent individuals' vulnerability and on their need for protection [40].

It is essential to consolidate the norms and adjust the legislation on these new issues, considering situations of vulnerability arising from violations of the basic human rights of the Federal Constitution. By combining data from transplant reports with court decisions, this study showed that it is impossible to ascertain how many bone marrow donations from legally incompetent individuals actually occurred.

Given the flexibility of the organ transplantation law [1], which aims to encourage donation by avoiding unnecessary bureaucracy and complications, it is only fair that the most vulnerable people involved in this situation, the legally incompetent donor, should receive protection and special attention. ABTO reports, for example, could introduce a special section to facilitate the search for judicial decisions. By exercising criticism and reflection, solutions like this can be developed and safely executed, with due legal support and observing ethical parameters.

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