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Balancing Bioethics and Legal Frontiers: A Case Study of Brazil's Supreme Federal Court Decision on Embryonic Stem Cell Research

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Abstract

Background. The present work focuses on the need to protect prenatal life, which is intricately entwined with delineating the precise biological and legal juncture marking an embryo's transition into personhood. Drawing upon bioethical insights from domestic frameworks and international jurisprudence, we compare diverse perspectives on the moral and legal standing of the embryo, including its right to life, and invoking legal principles in the context of cellular and regenerative medicine.

Aim. The goal of this article is to investigate the various biosafety policy approaches governing embryonic stem cell research, ranging from outright prohibition to authorization solely for therapeutic or scientific ends. Through our analysis, we focus on the unique national context of Brazil to scrutinize the underlying rationale behind a specific legal challenge questioning the constitutionality of the Biosafety Law. This law, which permits the utilization of human embryonic cells for research and therapeutic purposes, raises concerns about potential infringement upon the inviolability of the right to life.

Methodology. The research is based on deductive reasoning alongside formal-legal methodologies, including textual interpretation and comparative-legal analysis. The research process involved documentary, bibliographic, and virtual analytical inquiries utilizing a variety of resources such as legislative texts, monographs, academic articles, databases, and online libraries.

Results. Through our examination in a distinct national context, we delineate the theoretical-philosophical and normative-ethical foundations underpinning the stances of Brazilian Supreme Court justices concerning the utilization of embryonic stem cells. Their arguments predominantly invoked significant constitution-

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al liberties such as freedom of family planning, scientific research, and academic pursuits, intertwined with considerations of human dignity and the sanctity of life. Additionally, some justices cautioned against the potential hazards inherent in genetic manipulation.

Implications. The legal and ethical ramifications of Brazil's approach to biosafety legislation concerning embryo rights invoke the necessity for conducting neutral, unfettered scientific inquiry and regenerative therapies according to specific operational parameters. These include safeguarding the integrity of genetic inheritance, preemptive evaluation of potential risks and benefits (adherence to the precautionary principle), and ensuring informed consent for treatments. A significant hurdle consists in the need to establish robust mechanisms for overseeing research involving human embryos within the domains of biomedicine and regenerative cell therapy.

Keywords: bioethics, biosafety, embryonic stem cells, human cloning, genetic engineering, court decision, therapeutic advancements, cellular or regenerative medicine

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Баланс между биоэтикой и правовыми границами: анализ решения Верховного федерального суда Бразилии об исследованиях эмбриональных стволовых клеток

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Аннотация

Контекст. Центральное место в нашем исследовании занимает необходимость усиленной защиты пренатальной жизни, неразрывно связанная с определением точного биологического и юридического момента, отмечающего переход эмбриона в личность. Опираясь на накопленные биоэтические знания в отечественной практике и международной юриспруденции, мы находим различные точки зрения на моральное и юридическое положение эмбриона, включая его право на жизнь и соблюдение правовых принципов в сфере клеточной и регенеративной медицины.

Целью этой статьи является исследование различных моделей политики биобезопасности, регулирующих исследования эмбриональных стволовых клеток: от запрета до разрешения исключительно в терапевтических или научных целях. В ходе нашего анализа мы концентрируемся на уникальном национальном контексте Бразилии, чтобы тщательно изучить основную причину конкретной проблемы, связанной с конституционностью Закона о биобезопасности. Этот закон разрешает использование эмбриональных клеток человека в исследовательских и терапевтических целях, что вызывает обеспокоенность по поводу потенциального нарушения неприкосновенности права на жизнь.

Методология. Для достижения поставленных целей в статье наряду с формально-правовыми методологиями, включая интерпретацию текста и сравнительно-правовой анализ, использованы дедуктивные рассуждения. Процесс исследования включал документальные, библиографические и виртуальные аналитические запросы с использованием различных ресурсов, таких как законодательные тексты, монографии, научные статьи, базы данных и онлайн-библиотеки.

Результаты. Изучая различные национальные контексты, мы очертили теоретико-философские и нормативно-этические основы, лежащие в основе позиции судей Верховного суда Бразилии относительно использования эмбриональных стволовых клеток. В основном их аргументы ссылались на важные конституционные свободы, такие как свобода планирования семьи, научных исследований и академической деятельности, переплетающиеся с соображениями человеческого достоинства и неприкосновенности жизни. Кроме того, некоторые судьи предостерегали от потенциальных опасностей, присущих генетическим манипуляциям.

Выводы. Юридические и этические последствия подхода Бразилии к законодательству о биобезопасности, касающемуся прав на эмбрионы, подчеркивают необходимость проведения нейтральных, ничем не ограниченных научных исследований и регенеративной терапии в рамках конкретных операционных параметров. К ним относятся защита целостности генетической наследственности, упреждающая оценка потенциальных преимуществ (соблюдение принципа предосторожности) и обеспечение информированного согласия на лечение. Серьезным препятствием остается создание надежных механизмов для надзора за исследованиями с участием человеческих эмбрионов в области биомедицины и регенеративной клеточной терапии.

Ключевые слова: биоэтика, биобезопасность, эмбриональные стволовые клетки, клонирование человека, генная инженерия, решение суда, терапевтические достижения, клеточная или регенеративная медицина

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Introduction. Philosophical and ethical aspects

The philosophical perspective of Michael Tooley asserts that the attribution of the status of a "human being with the right to life" to an organism necessitates the presence of a defining characteristic, which he identifies as the concept of self. Within Tooley's framework, an organism qualifies as a human being if it manifests itself as a subject in a state of continuous existence. (Tooley, 2012, p. 390)

Awareness of and engagement with various mental states, coupled with the recognition of its status as a "continuing entity", further contribute to the delineation of an organism as a human being. According to this viewpoint, an unborn child, including an *in vitro* embryo, attains personhood and the right to life when it recognises its existence and experiences mental states in alignment with its physical development. (Travieso, Ferraro, Trikoz, Gulyaeva, 2021, pp. 85–98)

Despite the imperative to safeguard a child's life, even prenatally, the legal determination of the precise moment at which an embryo transforms into a human being remains challenging. The 1989 Convention on the Rights of the Child, in Article 1, defines a child as "a human being below the age of 18 years" – unless national law stipulates an earlier age of majority. This leaves an ambiguity regarding the onset of human life. The American Convention on Human Rights, in Article 4, paragraph 1, articulates a definitive standpoint, asserting that the right to life is protected by law "from the moment of conception, thus establishing the commencement of human life". (Antkowiak, Gonza, 2017, p. 5) This legal determination assumes significance in the context of abortion, categorising artificial termination of pregnancy as a potential infringement upon the right to life of an embryo or foetus. A lack of precision in international instruments for guiding the determination of the starting point of life contributes to the legal vacuum.

The moral status of the embryo is a pivotal consideration shaping perspectives on its legal standing. Two primary viewpoints exist: the first denies the embryo recognition as a human being, resulting in only relative legal protection, while the second, in attributing the same "moral status" to the human embryo as to a fully developed human being, creates a basis for their equal legal protection.

In 1986, the Council of Europe released Recommendations on the Use of Human Embryos and Foetuses for Diagnostic, Therapeutic, Scientific, Industrial, and Commercial Purposes. The document acknowledges that "from the moment of fertilisation of the ovum, human life develops in a continuous manner, making it inherently challenging to distinctly delineate the initial (embryonic) phases of its development, necessitating a determination of the biological status of the embryo."[1] In light of these considerations, EU Member States have advocated for specific measures, including the prohibition of sustaining embryo life *in vitro* beyond 14 days from fertilisation (point 14.1.4), and restricting the utilisation of human embryos, foetuses, materials, and tissues whether in industrial applications or for therapeutic purposes (point 14.1.2). Consequently, the prevailing consensus among Member States implies that if an *in vitro* embryo is spared from sale and experimentation, it is construed as a human being with the inherent right to life. (Trikoz, Gulyaeva, 2023, pp. 24–26)

During the formulation and endorsement of the Convention on Human Rights and Biomedicine, the Council of Europe encountered difficulties in establishing a unanimous definition for the term "embryo". The European Court of Human Rights (ECtHR) determined that the legislative evolution in this domain was left to the discretion of the States Parties, except for the provision in paragraph 1 of Article 18, which stipulates that "if the law authorises research on embryos *in vitro*, it must also provide for adequate protection of the embryo".[2]

Under English law, embryos are devoid of rights or interests, precluding an assertion of their right to life under Article 2 of the 1950 Council of Europe Convention. Consequently, embryos involved in the case of Evans vs. The United Kingdom were deemed not to possess a right to life within the context of that article. (Guide on Article 2, p. 17) This legal dispute arose from the complainant's contention that UK law permitted his former partner to revoke consent for the storage and utilisation of jointly created embryos. Genome editing has been sanctioned in the UK since 2016, allowing the use of embryos in scientific stem cell research subject to approval from the Human Fertilisation and Embryo Authority (HFEA). The objectives of human embryo research are clearly delineated in the UK Human Embryology Acts of 1990 and 2001. (Knapton, 2016)

Germany and Italy uphold more conservative bio-legal policies, strictly proscribing the trafficking of human embryonic stem cells. The editing of embryonic genome sparks intense debate due to legal prohibitions against interference with the human germline.

In countries such as the United States, individuals have widespread access to donor sperm, surrogate recruitment, and subsequent fertilisation processes. Some nations offer specific "IVF embryo donation" programs, while lax regulations in certain regions have led to the proliferation of "reproductive tourism".

[1] Parliamentary Assembly. (1986). Recommendation 1046. *Use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes. Available at:* http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=15080&lang=en

[2] European Court of Human Rights. (2004, July 07). *Case of Vo. v. France. Judgment*. (App. no. 53924/00). Available at: https://hudoc.echr.coe.int/fre?i=001-61887

The Russian Federation has established the Fundamentals of State Regulation and Basic Principles in the sphere of ensuring biological safety, implementing measures to shield the population and environment from hazardous biological factors and prevent biological threats. Federal Law No. 180-FL 'On Biomedical Cell Products' dated 23 June 2016 encompasses products comprising cultured living human cells. Such products find applications in diverse research endeavours and medical contexts. It is noteworthy that the stipulations of the law do not extend to technologies associated with reproduction (e.g., artificial insemination) or transplantology (e.g., transplantation of bone marrow, skin, liver, kidneys, and other organs and tissues). The law additionally excludes the use of cell technologies for purely scientific and educational purposes.

The recently enacted Federal Law No. 466-FL, dated 04/08/2023, abolishes the mandatory requirement to register biomedical cellular products intended for individual use by clinics for specific patients with the administering medical organisation. Additionally, this law specifically excludes high-tech medicinal products and transplantation objects from the purview of Federal Law No. 180, aligning its provisions with the regulations set forth by the Eurasian Economic Union (EEU). Within the legal framework of Russia, an embryo receives official recognition as a human foetus at up to eight weeks of development, as stipulated in paragraph 3 of Article 2 of the Federal Law titled 'Temporary Prohibition on Human Cloning'.[3] The moment of birth is formally defined as the separation of the foetus from the mother's body during childbirth, as per clause 1, Article 53 of the Federal Law 'On the Fundamentals of Health Protection of Citizens in the Russian Federation'.

Legal positions and dissenting opinions in a Brazilian case law

The scientific research with embryonic stem cells aims to address and cure pathologies and traumas that severely limit or degrade the lives of a significant population, resulting in torment, unhappiness, despair, including but not limited to progressive spinal atrophies, muscular dystrophies, multiple sclerosis, amyotrophic lateral sclerosis, neuropathies, and motor neuron diseases. This paper refers to a direct claim of unconstitutionality No. 3510 – Federal District (ADI) against Article 5 of Law No. 11.105, March 24, 2005 (Biosafety Law) that permits, for the purposes of research and therapeutic advancements, the use of embryonic stem cells obtained from human embryos produced through *in vitro* fertilisation and not used in the proceeding. The article is hereby drafted as follows[4]:

Article 5. The use, for research and therapeutic purposes, of in vitro obtained embryonic stem cells from human embryos produced but not used is allowed, provided the following conditions are met:

Item I – they are non-viable embryos; or

Item II – they are embryos frozen for 3 (three) years or more, as of the publication date of this Law, or, if frozen on the date of this Law's publication, have completed 3 (three) years, counted from the freezing date.

[3] *Federal Law of 20.05.2002 № 54-FZ 'Temporary Prohibition on Human Cloning'. Available at:* https://base.garant.ru/184467/. *(In Russ.).*

[4] Brazil. Presidency of the Republic. (2005, March 24). *Law No. 11.105.* Available at: https://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/l11105.htm. *(In Portuguese).*

Paragraph 1. In any case, consent from the parents is required, which must be obtained after the date of the embryos' freezing.

Paragraph 2. Research institutions and health services conducting research or therapy with embryonic stem cells must submit their projects for evaluation and approval by the respective research committees.

Paragraph 3. The commercialisation of the biological material referred to in this article is prohibited; engaging in such practices constitutes a crime defined in Article 15 of Law No. 9434, dated February 4, 1997.

Embryonic stem cells are those found in a cluster within each human embryo up to 14 days old (other scientists reduce this time to the blastocyst stage, occurring around 5 days after the fertilisation of a female ovum by a male sperm). These embryos result from human manipulation in an extracorporeal environment, since they are produced in a laboratory or *in vitro*, rather than spontaneously or *in vivo*.[5]

The plaintiff in this case argued that the challenged provisions contravene the inviolability of the right to life, since a human embryo is human life, and thus undermine a fundamental basis of law, which is based in the preservation of human dignity. He additionally argued that research based on adult stem cells is more promising than that conducted with embryonic stem cells. The plaintiff further asserted that: (a) "human life occurs at, and from, fertilisation", developing continuously; (b) the zygote, consisting of a single cell, is an "embryonic human being"; (c) it is at the moment of fertilisation that a woman becomes pregnant, receiving the zygote and providing it with a suitable environment for its development; (d) research with adult stem cells is objectively and certainly more promising than research with embryonic stem cells.[6]

The vote of the Justice-Rapporteur *Carlos Ayres Britto* addressed various points related to the constitutional validity of norms regarding research in the field of cellular or regenerative medicine, especially in the context of embryonic stem cells. He highlighted that the Biosafety Law establishes rigorous conditions for conducting research, such as the non-utilisation for reproductive purposes of the frozen embryo, its reproductive nonviability, and the express consent of the donating couple. Additionally, the Justice emphasised that the law prohibits practices such as human cloning and genetic engineering in certain contexts.

Justice Ayres Britto also argued that the dignity of the human person is a fundamental principle and that the law aims to contribute to the recovery of the function of organs and systems of the human body, benefiting the health of patients with various conditions, such as spinal atrophies, muscular dystrophies, multiple sclerosis, among others. Furthermore, the Justice highlighted the importance of academic freedom, scientific research, and family planning, which are all supported by the Constitution.[7]

Justice Ellen Gracie argued that there is no constitutional definition of the initial

[5] Brazil. Supreme Federal Court. (2008, May 29). *Prosecutor General v. President of the Republic and National Congress.* (ADI No. 3510).
[6] Ibid.
[7] Brazil. Supreme Federal Court. (2008, May 29). *Prosecutor General v. President of the Republic and National Congress.* (ADI No. 3510).

moment of human life, and it is not the role of the Supreme Court to establish concepts not explicitly or implicitly outlined in the Federal Constitution of 1988. She emphasised that introducing any of the proposed scientific milestones into the legal system is an exclusive legislative exercise, subject to scrutiny for compliance with the Federal Constitution. In this context, the Supreme Court's task is to examine the harmony of Article 5 of Law No. 11.105/2005 with the current constitutional text.

According to Justice Ellen Gracie, the parameters for verification include the foundation of human dignity, the guarantee of the inviolability of the right to life, the right to free expression of scientific activity, the right to health, and the duty of the State to promote scientific development. Before debating the use of human embryos in stem cell research, she highlighted the importance of questioning the acceptance of surplus fertilised ova as a necessary cost to overcome infertility. In this respect, the reasonable and cautious legislative treatment given to the matter, finding no violation of human dignity in using inviable pre-embryos or those frozen for over three years in stem cell research, was acknowledged.[8]

In his vote, Justice Menezes Direito highlighted the undoubted significance of the issue submitted to the judgment of the Supreme Court, requiring that a prudent reflection be undertaken by each judge from the depths of his or her conscience. On the other hand, the diversity of viewpoints it invokes should not be diminished, indicating solutions and paths that reveal the essence of the plural society that must be respected and encouraged. What the Supreme Court of Brazil is challenging is, therefore, not a religious, but a legal question, which is placed in the realm of constitutional interpretation concerning the protection of life and human dignity.

In her vote, Justice Cármen Lúcia emphasised the judge's commitment to adhere to the current constitutional order and act in such a way as to make it prevail. She stated that she sees the Constitution as her bible and Brazil as her only religion. A judge, when in the courtroom, worships the law. Given the secular state, plural society, neutral science, and impartial law, she argued that the core constitutional question in this case is the freedom guaranteed by the challenged law to undertake research and therapy with embryonic stem cells according to Article 5 of Law No. 11.105/2005.

In her vote, Justice Cármen Lúcia highlighted that embryonic stem cells have human characteristics, requiring an acknowledgement of the importance of adhering to principles such as necessity, integrity of the genetic heritage, prior evaluation of potential benefits, and informed consent in research and treatment. Thus, she argued that, when based on established scientific principles, the use of embryonic stem cells for research and subsequent treatment does not violate human dignity, but instead enhances it.[9]

Justice Ricardo Lewandowski contended that the discussion should revolve around the right to life perceived as a collective good, which is owned by society or even humanity. This perspective is particularly important

[8] Ibid.
[9] Ibid.

considering the potential risks stemming from the manipulation of the human genetic code. When contemplating the preservation of life on a broader scale, encompassing not only the national, but even the planetary level, the "precautionary principle" becomes relevant. This principle currently guides the actions of those operating in the realms of environmental protection and public health. Despite not being explicitly formulated, it finds support in Articles 196 and 225 of the Federal Constitution of 1988.[10] Based on Comparative Law, he believes it is not advisable to allow those directly involved in research to make decisions in this important scientific area according to their own designs, without the oversight of public authorities and representatives of the community.[11]

In his vote, Justice Eros Grau affirmed the constitutionality of Article 5 of the Biosafety Law. However, he stated three reservations: the creation of a central committee within the Ministry of Health to oversee research, the fertilisation of only four ova per cycle, and the acquisition of embryonic stem cells from non-viable fertilised ova or without causing harm to viable ones.[12]

For Justice Joaquim Barbosa, the analysis of the legal text makes it clear that not every embryo can be the subject of scientific research. Likewise, there is no obligation for parents to donate their embryos for research purposes. Most importantly, the creation of embryos intended for research is strictly prohibited. The regulation of the use of embryonic stem cells through a law that upholds private autonomy within predefined objective parameters does not invoke the alleged constitutional flaw. On the contrary, considering the seriousness of utilising human embryos in scientific research, or any form of inquiry, it is imperative for the legislator to establish suitable guidelines. By implementing effective mechanisms for overseeing such research, these should ensure the protection of private autonomy and the responsible development of science in the country.[13]

In his vote, Justice Cézar Peluso observed that there are several potential subjects of the right to life to be considered in the context of this case: the frozen embryo, the implanted embryo and the foetus, and finally, the fully developed human being, whether a child or an adult, who possesses attributes that the constitutional order recognises as conferring personhood. The most important question that the Court must address is whether the constitutional protection of life applies in its entirety to the category of embryos – more specifically, to non-viable embryos and those subjected to cryopreservation. He is convinced that the attribute of humanity is already present in both the embryo and in the subsequent stages of its development.[14]

In his vote, Justice Marco Aurélio affirmed that Article 5 of Law No. 11.105/2005 address-

[10] Brazil. Chamber of Deputies. (1988, October 5). *Constitution of the Federative Republic of Brazil. Available at: https://www.globalhealthrights.org/wp-content/uploads/2013/09/Brazil-constitution-English.pdf*

[11] Brazil. Supreme Federal Court. (2008, May 29). *Prosecutor General v. President of the Republic and National Congress. (ADI No. 3510).*

[12] Ibid.

[13] Brazil. Supreme Federal Court. (2008, May 29). *Prosecutor General v. President of the Republic and National Congress. (ADI No. 3510).*

[14] Ibid.

es the use of human embryos produced through *in vitro* fertilisation, excluding those naturally conceived in the uterus. Additionally, with its numerous precautionary and prohibitive clauses, such as those pertaining to cloning, the law limits research to embryos not usable in the insemination process. As well as explicitly considers only non-viable embryos and those frozen for three years, it requires consent from ovum and sperm donors, and prohibits commercialisation under pain of various associated criminal offenses. Viability, or a lack thereof, directly relates to the ability to develop into a human being. From a biological perspective, the commencement of life involves not only the fertilisation of the ovum by the sperm, but also the aforementioned viability, which is non-existent without what is understood as human pregnancy.[15]

Justice Celso de Mello highlighted that embryonic stem cells have stable genes, which are resistant to biochemical changes during therapeutic processes. Due to their unlimited potential, these cells can be applied in the treatment of various serious conditions. The constitutional dispute is unrelated to abortion. Considering the bioethics of the beginning of life, the interpretation depends on various theoretical formulations. The interpreter who is detached from religious considerations can choose a conception that aligns with the public interest, social requirements for scientific research, and community well-being. This approach aims to give real meaning to the principle of human dignity and concretely uphold constitutional proclamations recognising the right to life and health as fundamental rights. (Korff, 2006)

Finally, according to Justice Gilmar Mendes, Law No. 11.105, March 24, 2005, establishes safety standards and oversight mechanisms for activities involving Genetically Modified Organisms (GMOs) and their derivatives. In its preamble, the law sets forth guidelines that form the basis of its regulations: promoting scientific progress in biosafety and biotechnology, protecting human, animal, and plant life and health, and adhering to the precautionary principle for environmental protection.

Throughout the body of the law, Article 5 is dedicated to regulating the use of embryonic stem cells obtained from human embryos produced by *in vitro* fertilisation for research purposes. It is evident that the law was careful in its regulation of certain aspects, requiring that research be conducted only with so-called "non-viable" human embryos, as well as subject to parental consent and project approval by ethics committees. The commercial use of such biological material is expressly prohibited.

He concluded by underscoring that Article 5 of Law No. 11.105/2005 should be interpreted to mean that permission for research and therapy with embryonic stem cells obtained from human embryos produced by *in vitro* fertilisation must be subject to prior approval and authorisation by the Central Ethics and Research Committee affiliated with the Ministry of Health.[16]

As decided by the Supreme Federal Court in ADI 3510, the Brazilian Federal Constitution of 1988 does not provide for the beginning of human life or recognise the precise mo-

[15] Ibid.
[16] Ibid.

ment when it begins. It does not make every stage of human life an autonomous legal right, but considers life as inherent to a concrete person who is already born (natalist theory, as opposed to conceptionist or conditional personality theories).

However, on the other hand, the Brazilian Civil Code of 2002, in its Article 2, adopts the natalist theory by stipulating that "the civil personality of a person begins at birth with life; but the law safeguards, from conception, the rights of the unborn".[17]

It was emphasised in the decision that the best interpretation of the Federal Constitution of 1988 was in the sense of referring to "rights of the human person" and even "rights and individual guarantees" as an entrenched clause; here, it is speaking of the rights and guarantees of the individual person, who becomes the recipient of fundamental rights such as "the right to life, liberty, equality, security, and property" among other rights and guarantees equally distinguished with the mark of fundamentality (such as the right to health and family planning).

The Brazilian Supreme Federal Court further stated that research carried out with embryonic stem cells, due to the pluripotency of such cells – in other words, they can generate any human tissue, as they can differentiate into other cells – cannot be replaced by other research programs, like those carried out with adult stem cells, which have low degree of differentiation. The Supreme Federal Court also explained, in conclusion, that research with stem cells is carried out in accordance with the Federal Constitution, in which it is established that the State must promote and encourage scientific development and technological research (article 218) as well as ensure the right to health (article 196), and that such research constitutes an instrument to implement this right.

The stance taken by the Justice-Rapporteur Ayres Britto appears to be grounded in a theoretical consideration: when faced with an embryo strictly within the parameters of Article 5 of the Biosafety Law, what do we have? According to him, the answer is a vegetative life that precedes the development of the brain. The brain has not yet formed, and neither has maternity; moreover, neither will ever happen. However, something resulting from the fusion of material collected from two human beings still exists within cylindrical and frozen test tubes. While it continues to exist, there is no possibility whatsoever for it to evolve into a natural person.

Furthermore, if ordinary law is allowed to equate brain death with the cessation of the life of a specific human individual, and if it is already established that brain death is the precise endpoint of personalised human existence, justifying the removal of organs, tissues, and parts from the still physically pulsating body for transplantation, research, and treatment, then, in essence, the human embryo referred to in Article 5 of the Biosafety Law is an entity entirely devoid of any semblance of brain life. In this context, the assertion of the legal statute's incompatibility with the Brazilian Federal Constitution of 1988 is to be categorically and promptly dismissed.

Justice Cézar Peluso challenged this interpretation, deeming the rhetorical analogy attempting to establish a connection between the moments of so-called brain death and, conversely, the onset of life, which is

[17] International Center for Not-for-Profit Law (ICNL). (2002). *Excerpt from Law 10,406 – Civil Code.* Available at: https://www.icnl.org/research/library/brazil_exlaw10406/

suggested to occur during neurulation or the embryonic stage of the nervous system, as insufficient. Hermeneutical approaches seeking to interpret the Federal Constitution of 1988 in light of subordinate norms also carry no weight in this context. The concepts of life and personhood – in this case, comprising integral elements of the *quaestio iuris* – must be constructed or reconstructed within the highest material confines of the constitutional framework. This is precisely why a dogmatic stance that attempted to grade the right to life under the pretext of the relativity of constitutional rights would be of no avail. Such a position suggests that since, due to positive law, the crime of homicide carries a higher penalty than that prescribed for abortion, intra-uterine life and, a fortiori, embryonic cells would have lower legal-constitutional dignity.

Both bioethics and biolaw are grounded in the Brazilian Federal Constitution. Here, it is the constitutionalisation of the right to life and the emphasis on the foundational and substantive principle of human dignity that ensure the basis for the inviolability, sacredness, and responsibility of human life. As concluded by Justice Cármen Lúcia, this foundation should be taken into account by norms, doctrines, jurisprudential decisions, and practices of any nature (including private biomedical practices) that relate to human life.

Another interesting point is advocated by Justice Ellen Gracie in her opinion, which drew attention to the debate about the use of human embryos in stem cell research. This discussion must necessarily begin by questioning the acceptance of the surplus of fertilised ova as a necessary cost for overcoming infertility.

In lieu of a conclusion

In Brazil, the ruling in case ADI 3,510-DF, addressing the constitutionality of the scientific-therapeutic use of embryonic stem cells, grappled with the fundamental issue of the separation of powers in a rule of law. By imposing constraints on the provisions of the Brazilian Biosafety Law in order to assess its constitutionality, the Justices hinted at the potential for the Supreme Federal Court to indirectly shape legislation, thereby manifesting a distinct form of judicial activism. Another salient point was the deliberate exclusion of religious considerations from the legal determination.

The rapid advancement of the biotechnological revolution in laboratories outpaces the development of corresponding national legislation. In the forthcoming decades, a significant proportion of offspring is predicted to originate from laboratory-assisted conception methods, enabling the prospect of birth without the direct involvement of a woman's body.

However, the intricate matter of establishing a comprehensive legal framework for the status of the embryo prior to its implantation in a woman's uterus remains inadequately addressed by legal doctrine and the expert community. This regulatory void underscores the necessity of safeguarding the legal rights of the embryo and pre-empting illicit practices, particularly those associated with commercialisation in this domain.

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