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PRIVATE AUTONOMY AND BIOLEGAL SELF- REGULATION: CHAL- LENGES IN THE CHOICE OF HUMAN GAMETES IN THE INTERNATIONAL ASSISTED REPRODUC- TION MARKET¹

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Abstract: The importation of germline genetic material into Brazil, as an alternative for choosing donors, provokes a confrontation between individual autonomy in planning parental projects and the deontological norms of the Federal Council of Medicine (CFM), which regulate secrecy and altruism in donation procedures. This practice highlights legal and contractual challenges that go beyond the Brazilian legal system, encompassing bio-legal and economic transactions arising from the transnationality of human gametes. This study aims to analyse the legality of contractual relationships and possible regulatory conflicts in heterologous assisted human reproduction, especially with regard to the commercialization of gametes and the applicable biolegal regulations. The dilemmas arise in relation to state protection over the import of gametes, associated with the issue of private autonomy. The progress of transnational exchange, supported by Anvisa's RDC 771/2022 and 81/2008, reveals a fine line between reproductive autonomy and ethical limits, highlighting the risk of pricing genetic material. However, human dignity and bodily autonomy legitimize the use of gametes for family planning, as long as ethical and legal principles are fully respected.

Keywords: human gametes. biolegal transnationality. market

INTRODUCTION

Biolegal transnationality in assisted human reproduction practices has gained prominence in contemporary times, especially in the context of importing human gametes. Globalization, advances in reproductive technologies and the growing demand for fertility treatments have led to discussions about the intersection between local regulations and international practices.

The importation of germinal genetic material, as an autonomous choice of donors, reveals the altruistic and confidential nature of the donation, as determined by the deontological norms of the Federal Council of Medicine in Brazil. The justification for this practice lies in the self-determination of the family planning process. On the other hand, a series of legal and contractual issues arise that go beyond the Brazilian legal system, involving the application of private law in international contexts.

The existence of a reproductive right, based on the right to health - especially reproductive health - supports the right to privacy and autonomy in individual choices, as well as the right to start a family, as regulated by family planning. In this context, a biological-market circle is established, involving commercial contracts for the transfer of human gametes in a free market (as is the case in the United States), compensation contracts for donors (common practice in some European countries, such as Portugal) or even sharing without legally clear criteria, either through the import and export of this germinal material, disregarding the legislative restrictions of each legal system, or through practices that run parallel to legal and ethical determinations, such as home inseminations.

The aim of this work is to analyze the legality of contractual legal relationships and identify possible regulatory conflicts in the provision of the service of importing human germ genetic material used in heterologous assisted human reproduction in Brazil. To this end, we will use the bibliographical, legislative and normative research method of the Federal Council of Medicine, referring to assisted human reproduction in Brazil; studies of the legal nature of the commodification of human gametes, through transaction and opportunity costs; involving the contractualization of the importation of germinal genetic material.

In the preliminary hypotheses, the question arises as to whether, legally, the importation of germinal genetic material into Brazil should be subject to state protection, as it is a matter of public and collective order, which transcends individual responsibility; or whether, as it is an expression of private autonomy, it should be recognized as a right reserved for the intimacy of family life, without state intervention; or whether the legal business of importing human germ cells would be invalid. It can be seen that there is a fine line separating the autonomy of private life from ethical limits and the integrity of the human being, which, given the possibility of market profitability, entails the imminent risk of the unrestricted objectification of human germinal genetic material.

In this scenario, the progress of transnational exchange in the import of human gametes is evident, especially from European countries, based on pseudo-operational regulations in RDC/Anvisa No. 771/2022 and No. 81/2008, which regulate the entire procedure for importing this germinative genetic material.

SELF-REGULATION OF THE HUMAN REPRODUCTIVE MARKET

The assisted human reproduction market is marked by a complex intersection of bio-legal, economic and ethical transactions, which are intertwined in regulated assisted reproduction practices. Regulations relating to the use and storage of semen and eggs directly influence the costs and operation of fertility centers. In addition, the ethical and business rules governing the transfer and donation of gametes shape the economic dynamics of this market. Contracts between patients and clinics, as well as between clinics and donors, are fundamental to defining the ownership of gametes, donor compensation and the responsibilities of each party. In this context, the term gamete

donation refers exclusively to the act of physical transfer, rather than the strict application of the definition of a donation contract.

The importation of human gametes is a common practice in the European Union and the United States, usually regulated by laws that allow pricing through assignment or compensation, encouraging the recruitment of donors. However, when this germinal material is received by countries such as Brazil, often through formalized legal transactions, doubts arise as to whether it complies with the national legal system (OLIVEIRA, 2021).

From a marketing point of view, there are two fundamental conditions for the transfer of gametes in Brazil. The first refers to demand, which can be driven by an individual's infertility or the desire for a parental project. The second concerns supply, which is restricted by the altruistic attitude of donors, whether through semen banks or family donors, or even egg donation programs (BERLINGUER; GARRAFA, 2001).

One of the main challenges facing this market is the growing imbalance between demand and supply. This imbalance occurs, on the one hand, due to the deontological barrier created by medical rules that superimpose the choice of donors on medical activity, based on the catalog of phenotypic and genotypic characteristics determined by patients. On the other hand, the lack of mutual advantages between contractors and donors also contributes to the imbalance. In this context, it is important to distinguish between the will of the individual when giving away their genetic material: donation, which is purely in solidarity, and commercialization, which is based on exchange for currency or other forms of remuneration.

Berlinguer and Garrafa point to two factors driving the international reproductive market: scientific advances and self-regulating market laws. The trade in human body fragments can be supported by legal arguments about the

right to ownership of gametes, by economic motives based on utilitarianism and, finally, by theological considerations (BERLINGUER; GARRAFA, 2001).

Between 2016 and 2019, Brazil saw a significant increase in imports of germ cells and tissues, with the number of samples rising from 1,378 in 2016 to 4,010 in 2019, representing a growth of more than 290%. In 2020, due to restrictions imposed by the COVID-19 pandemic, the number fell to 2,053 samples. The majority of seminal samples come from three North American banks - Fairfax Cryobank, Seattle Sperm Bank and California Cryobank - all private, locally licensed and registered by the FDA (Food and Drug Administration). In contrast, egg (oocyte) imports have seen an alarming rise, from 36 samples in 2011 to 3,087 in 2019, an increase of over 8,000%.

This reality calls into question the biomaterial logic of the transnational marketing of human gametes. This occurs through international service contracts for the acquisition of gametes, with the aim of realizing a parenthood project, within the scope of the rights to freedom of contract and free disposal of the body. Assisted reproduction, or artificial fertilization, emerged as a solution to sterility; however, soon after the emergence of techniques and donations, the globalized market entered the scene, creating a network of market and existential relationships that respond to a parental project, allowing the transition from donation to the sale of semen and, later, human eggs.

The inequality between supply and demand is one of the factors driving this transformation. In many countries, the supply of gametes for donation is not enough to meet local demand, which leads doctors and patients to seek gametes in regions where the supply is more abundant. Variability in laws and regulations also plays a crucial role in this transnational flow of gametes, since countries that prohibit anonymous donation end up se-

eing their citizens turn to places where anonymity is allowed. In addition, differences in the costs of fertility treatments and compensation for donors/providers make importing gametes an attractive option for clinics and patients (BERLINGUER; GARRAFA, 2001).

The human gamete market is structured around gamete banks and specialized clinics that act as intermediaries, offering gamete storage, screening and sales services. The commercial structure of this market can vary according to the degree of regulation in each country. In places with stricter regulations, the market tends to be more controlled; in countries with more flexible rules, marketing tends to be more lucrative and less regulated, generating a diversity of business models and market practices. Gamete prices, which vary according to demand, the quality of the genetic material and local regulations, can influence access to fertility treatments and encourage imports and domestic trade.

Gamete donors play a crucial role in this context. Rigorous donor screening is essential to ensure that gametes are of high quality and free of genetic diseases, thus protecting the health of future children and meeting the standards of fertility clinics. The financial compensation offered to donors can encourage donation, especially in countries where this represents a form of additional income. In places where compensation is low or non-existent, the motivation to donate may be more altruistic. Detailed screening, including genetic and medical evaluations, helps to ensure that donors meet the necessary requirements.

In the United States, the absence of strict legislation has contributed to the proliferation of assisted reproduction clinics and a market worth more than two billion dollars, stimulating the expansion of reproductive techniques and the urgent need for international standards (BERLINGUER; GARRAFA, 2001).

It is essential to highlight the regulatory diversity to which assisted reproduction is subject, both by laws and guidelines, in the most varied cultural contexts. This diversity has consequences for the implementation of treatments in a world of fluid borders. Not all legal systems, for example, allow the donation of female and male gametes. In Germany, Austria, Switzerland and Norway, for example, egg donation is prohibited, allowing only semen donation. The reasoning behind this ban is the attempt to avoid the dissociation of motherhood and the risk of favoring late pregnancies through egg donation. On the other hand, most countries, such as Brazil, Portugal, Spain, France, Belgium, Greece, the United Kingdom and the United States, allow the donation of both gametes.

In the United States, egg donors are routinely compensated for their participation, usually between \$5,000 and \$10,000 per completed cycle. Paying donors for services rendered has been common practice since 1984, although the adequacy of this remuneration is constantly questioned.

Freedom of self-determination in assisted reproduction transcends borders, allowing patients to choose the best resources available globally. However, this freedom is limited by national regulations, which prioritize altruism and anonymity in gamete donation. Biolegal contracts play a central role in gamete importation, formalizing the obligations between patients, clinics and gamete banks. They include clauses on informed consent, confidentiality and responsibility for the imported material, seeking to align international practices with Brazilian ethical requirements and ensuring legal certainty for those involved.

One of the main ethical challenges in importing gametes is the possibility of eugenic practices, especially when patients choose donors based on phenotypic characteristics

(MEIRELLES, 2005). Although the choice can be justified by the search for genetic compatibility, it can also reinforce social prejudices and inequalities. In Brazil, the lack of incentives for local donors contributes to the scarcity of gametes and dependence on the international market. An ethical and sustainable solution requires a balance between patient autonomy and protection against discriminatory practices, ensuring that gamete selection respects human dignity.

Given the challenges identified, we propose a set of regulatory measures for the import of human gametes in Brazil: establish specific federal legislation governing all stages of assisted reproduction, including the import, storage, distribution and use of gametes, with clear criteria to ensure ethical and legal compliance; create mechanisms to encourage local donation, such as awareness programs and fair compensation for donors, in line with the principles of altruism and human dignity; harmonize Brazilian regulations with international standards, promoting regulatory compatibility and legal certainty in transnational transactions; implement policies that guarantee the affordability of assisted reproduction treatments, offering subsidies or tax benefits for low-income populations; and invest in the bioethical education of professionals and in raising awareness in society, reinforcing the importance of the balance between individual autonomy and the ethical limits necessary to avoid the indiscriminate commercialization of gametes and preserve human dignity.

THE MARKET INTERACTIONS OF HUMAN GAMETES

The power that comes from biotechnological knowledge, from the expansion of reproductive technologies, ignites motivations that are intrinsically linked to both the increase in the supply of services linked to assisted reproduction (such as the search for profit, both on the part of the companies involved, doctors, researchers and even intermediaries) and the demand for these same services, human desire working as an engine for the search for happiness, the search for a “quality of life that is increasingly emphasized by the media, and which translates into an almost absolute respect for the relativity of personal choices”. (LEWICKI, 2001)

From this perspective, the Brazilian reproductive market is an ecosystem involving a dynamic and multifaceted sector, characterized by a complex interaction of supply and demand, in the analysis of production factors, opportunity costs and transaction costs, ethical regulations, as well as media performance in the spectacularization of medically assisted life. Assisted human reproduction clinics play a central role in this market, offering a wide range of services from artificial insemination to *in vitro* fertilization (IVF), gamete donation and fertility preservation.

In this movement, “business conglomerates offering fertility” (CATALAN, 2020) emerge through a portfolio of “services such as the sale of medication, (LAUREANO, 2022) psychological and genetic counseling, some exams, genetic tests using artificial intelligence, a bank of male and female gametes, financing, etc. within the patient’s reach.

THE BRAZILIAN DEONTOLOGICAL SCENARIO OF ASSISTED HUMAN REPRODUCTION

Freedom of self-determination is at the heart of reproductive choices. This principle, enshrined in civil law and the principle of autonomy of will, legitimizes the search for gametes outside Brazil when the domestic market does not meet patients’ needs. However, this freedom is limited by ethical standards and the right to the integrity of the human body.

The Brazilian reproductive market faces a significant legislative gap when it comes to regulating the commercialization of human gametes. Although Article 199 of the Federal Constitution prohibits the commercialization of human substances, the rule does not specifically deal with gametes, which are essential elements for assisted reproduction.

Infra-constitutional legislation, such as Law No. 9.434/1997, which regulates the removal of human organs and tissues, also omits gametes, restricting itself to transplants. Law 11.105/2005 (the Biosafety Law) prohibits the commercialization of embryonic stem cells, but again does not address the issue of human gametes. Even the Civil Code, in establishing people’s rights and duties in the civil order, does not fill this gap, although it does influence contracts related to assisted reproduction, such as those for gamete donation. In fact, this legislative omission leaves the market vulnerable, especially in the face of growing demand and a shortage of local donors. There is no clear constitutional command prohibiting the commercialization of gametes, and broad interpretations of “human substances” could generate undesirable practical consequences.

Given the lack of federal regulation, the deontological standards of the Federal Council of Medicine (CFM) have served as supplementary guidelines, guaranteeing a minimum of ethics and control.

In Brazil, the absence of specific federal legislative regulation on assisted human reproduction - especially with regard to heterologous donation, donor anonymity and the possible pricing of gametes - highlights a legal anomie in the sector. The practical regulation of the subject is centered on the deontological norms of the Federal Council of Medicine (CFM), which has issued eight resolutions over thirty years, culminating in Resolution 2,320/2022.

These resolutions prohibit the commercialization of gametes and base donation on altruism, based on the bioethical principles of justice, beneficence and autonomy. Justice prevents undue profit, beneficence prevents the commodification of the human body and autonomy guarantees free decisions, protecting vulnerable populations.

Despite the quest to democratize assisted reproduction, the sector faces challenges due to the “verticalization” of services” (LAUREANO, 2022), which centralizes activities and increases costs. In this context, there is a need to harmonize commercial practices with ethical standards, promoting debates on biolegal contracts and transaction costs in the reproductive market.

However, it is essential that the legal framework evolves to include clear and comprehensive rules on the marketing of gametes, protecting both the rights of individuals and the integrity of the reproductive market.

The ethical standards established by the Federal Council of Medicine (CFM) strictly regulate medical activity, although in some cases these standards seem to conflict with market advances in reproductive technologies. These guidelines include the selection and screening of donors, the maximum number of embryos to be transferred, the preservation and disposal of embryos, as well as ensuring transparency in the embryological practices offered by clinics. The CFM also addresses fundamental ethical issues, protecting patients’ rights and prohibiting the commercialization of human gametes.

In addition to deontological regulations, the biolegal contracts that exist in doctor-patient-clinic relationships are fundamental for establishing the rights and duties of the parties involved in assisted reproduction treatments, as well as for establishing free and informed consent about the consequences and responsibilities of choosing reproductive techniques. These contracts cover aspects such as the ownership and destination of cryopreserved gametes, financial responsibility, the rights of donors and recipients, ensuring legal certainty and clarity in procedures.

The Brazilian reproductive market, therefore, is an arena where technological advances, bio-legal discussions and economic analysis of the law meet, emerging from medical needs, ethical issues and legal challenges. This requires a careful and informed approach to ensure that everyone involved can exercise their rights safely and responsibly.

BIOLEGAL AND ECONOMIC REPRODUCTIVE TRANSACTIONS

Reproductive technologies have emerged as a significant sector in the market relations surrounding medical practice, with complex economic transactions and market structures that require detailed analysis. The economic transaction is seen “as the instruments by which economic agents seek to interact in order to obtain maximum efficiency in the production or allocation of available goods and services and thus maximize their own interests” (PIMENTA, 2024). In the reproductive market, this involves not only the application of advanced technologies, but also economic dynamics, the expansion of new agents, the allocation of goods, the verticalization of services, the “commoditization of medicines” and “democratization mechanisms” (LAUREANO, 2022).

Therefore, in order to understand bio-legal - economic transactions in the field of assisted human reproduction, it is necessary to detail their factors of production (production costs), the opportunity costs and transaction costs in the structure and operation of assisted reproduction services, which contribute to satisfying the reproductive needs of individuals and society.

The factors of production, also known as production resources, are defined by Eduardo Goulart (2024) as “gifts of nature (land factor), the economically mobilizable population (labor factor), the different categories of capital (capital factor) and technological (technology factor) and entrepreneurial capacities (entrepreneurship or organization factor)”.

Thus, the land factor represents the physical infrastructure where the services are provided: clinics and laboratories specializing in procedures such as *in vitro* fertilization (IVF), artificial insemination, and other reproductive techniques, the BCTG Germ Cell and Tissue Banks (BCTGs) and diagnostic laboratories. These facilities must meet the technical and health requirements to guarantee adequate safety and quality conditions, both in the process of preparing and handling germinative genetic materials, such as gametes and embryos. They must be equipped with environments that allow for the following activities: administrative, laboratory, semen collection, oocyte collection, processing of germ cells, germ tissues and human embryos and storage of this germ material.²

The work factor involves a workforce specialized in reproductive technologies, with employees who are qualified, trained and undergoing constant training, compatible with the activities carried out. This includes a diverse team made up of legal guardians, health technicians with training in human reproduction, those responsible for quality assurance actions, doctors specializing in reproduction,

2. This is determined by article 64 of Collegiate Board Resolution-RDC no. 771, of December 26, 2022.

embryologists responsible for processing semen, eggs and embryos, those responsible for bio-surveillance actions, as well as nurses, laboratory technicians and other health professionals (LAUREANO, 2022).

The capital factor refers to the financial resources and investments needed to operate assisted reproduction clinics. These centers must have equipment and instruments according to their complexity and demand. This includes the costs associated with acquiring equipment such as incubators, microtomes and cryopreservation systems, as well as investment in advanced technologies for diagnostics and treatments, both domestic and imported, which must be regularized with Anvisa, in accordance with Collegiate Board Resolution - RDC No. 185, of October 22, 2001, which provides for the registration of medical products, or with Resolution RDC No. 40, of August 26, 2015, which provides for the registration requirements of medical products.

The technology factor is essential in assisted reproduction, involving the use of advanced techniques and specialized equipment to optimize treatment results. This includes technologies such as *in vitro* fertilization (IVF), intrafallopian transfer (GIFT), gamete and embryo cryopreservation techniques, the use of artificial intelligence in gamete selection, embryo and egg quality assessment and outcome prediction. Continuous technological innovation allows for improvements in procedures, increasing success rates and offering new solutions to infertility problems. A clinic's ability to integrate and update its technologies is fundamental to its competitiveness and effectiveness. (IBRRA, 2024)

Finally, the entrepreneurial or organizational factor refers to the ability to manage and organize the resources and operations of an assisted reproduction clinic efficiently. This includes strategic management, coordination of activities and the ability to innovate and

adapt to market changes and patient needs. Under ANVISA Resolution RDC 771/2022, the management of a CRHA must involve maintaining ethical and quality standards, implementing a quality management system that establishes policies for good practices in cells, germ tissues and embryos, document management and compliance with biosafety and hygiene standards.

Transaction costs in the Brazilian reproductive market are significant and vary according to the treatment. For example, an IVF cycle can cost between R\$15,000 and R\$25,000, not counting additional expenses for medication, consultations and ancillary procedures. These costs represent a barrier for many couples seeking treatment, reflecting the need for access to clear and precise information, as well as multiple consultations and authorizations that add emotional and bureaucratic costs.

In the economic context of assisted human reproduction, production resources are fundamental to the effective operation of the services offered. The appropriate combination and interaction of these factors - land, labor, capital, technology and entrepreneurship - results in care that aims to satisfy the reproductive needs of patients, contributing to safety in the qualification and validation of the activities carried out. Efficient management and strategic mobilization of these resources are essential for the success and quality of assisted reproduction services.

Opportunity costs are a critical aspect of assisted human reproduction (AHR), referring to the costs associated with the choices made when allocating resources for their specific use. Decisions about the allocation of financial and human resources in fertility treatments have significant implications for both clinics and patients. For example, investments in more advanced technologies may result in better success rates, but they also increase operating costs. For clinics, choosing between

offering a wide range of services or specializing in specific techniques can influence their profitability and position in the market. (LAUREANO, 2022)

The demand for reproductive treatments related to infertility is high, as a significant portion of the population faces difficulties conceiving. In addition, reproductive techniques have become a “product to be consumed” (CATALAN, 2020) in order to fulfill the autonomy of procreative planning. Treatment options vary according to the underlying cause of infertility and demand, ranging from drugs to stimulate ovulation to surgical procedures, with a view to assisted reproduction techniques, as discussed in the previous chapter.

Therefore, in the context of an assisted human reproduction contract, the factors of production involve the essential resources to offer the services, such as facilities, professionals, technology and capital. Opportunity costs are associated with choices to allocate resources that could be used in other areas. Transaction costs refer to expenditures related to the management and implementation of legal and operational relationships, such as contracts and compliance. Understanding these concepts is crucial to analyzing the efficiency and economic viability of assisted reproduction services in the Brazilian market.

In Brazil, gamete donation is anonymous and altruistic, and although payment for donation is prohibited, donors end up being reimbursed for expenses associated with the process or are included in egg donation programs, expanding economic rationality in the practice of medicine.

Thus, in the construction of the bio-legal contractual relationship that is formed around the relationships arising from assisted human reproduction, the operational costs with the cataloging of “genetic and phenotypic profiles of gamete suppliers” (CATALAN, 2020), from germ cell and tissue banks, essential for the

functioning of the reproductive market and to meet the demand for procreative purposes, are evident. This process, however, remains overshadowed by the deontological norms of the Federal Council of Medicine, and there is a concrete legislative anomie on the subject.

CONCLUSION

The ever-expanding Brazilian reproductive market reflects not only the growing demand for gametes, but also the complexity of the bio-legal transactions involved, which involve an intersection between ethical norms, regulations and the commodification of these essential human resources for assisted reproduction. The transnationality of this market adds an additional layer of complexity, since national regulations need to be reconciled with international norms, creating a challenging scenario for the protection of procreative and ethical rights in a globalized context.

Self-regulation, which arises in the absence of a uniform regulatory system, is a central aspect in understanding contemporary reproductive practices. The multiplicity of practices and standards, often influenced by market pressures and legislative gaps, makes it difficult to create an effective and cohesive system. In this scenario, freedom of self-determination becomes a fundamental principle, supporting the right of individuals to seek out the reproductive resources necessary for family planning. However, this freedom requires clear regulations that align international practices with local ethical and legal values.

This study revealed, through a critical analysis of assisted reproduction practices in Brazil, that the interaction between patient-recipients, donors and the institutions involved is crucial, as it reflects the tensions between the objectification of gametes and the comple-

xity of bio-legal contractual relationships. In addition, consideration of production factors - such as facilities, professionals, technology and opportunity costs - is essential to understanding the economic viability of assisted reproduction services in Brazil.

Bodily and procreative autonomy, which guarantees individuals the power to control their bodies and their genetic elements, as long as human dignity is respected, is the basis that legitimizes the objectification of human gametes in the family planning process. However, this process must be carefully regulated to avoid the transformation of gametes into commodities devoid of an ethical context.

In the international context, the search for gametes in a globalized market presents additional challenges. The creation of a "catalog" of donors - or "assignors", as they are called in this study, due to the pricing of gametes - raises questions about transaction costs and the ethics of choosing a donor. Transnationality, combined with the commercialization of gametes, exposes the weaknesses of the current regulatory system, which urgently needs a more cohesive and integrated approach, capable of balancing reproductive freedom with the ethical norms that govern human dignity.

Thus, the conclusion of this study points to the urgent need for clearer and more comprehensive federal regulations, which harmonize internal and external standards and guarantee the protection of reproductive rights, without compromising the fundamental principles of bioethics. Only with a balance between autonomy, ethical regulation and economic efficiency will Brazil be able to position itself as a benchmark in the global reproductive market, promoting a practice of assisted reproduction that is fair, accessible and respectful of human rights.

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