A reality outside the law: an ethical-legal analysis of the 30 years of deontological regulation of assisted reproduction technologies in Brazil

Manuel Camelo Ferreira da Silva Netto, Carlos Henrique Félix Dantas*

ABSTRACT: For more than four decades, assisted reproduction technology (ART) techniques have enabled the design of parenting projects in cases where infertility and sterility are obstacles to having children. In Brazil, for example, the first "test tube baby" was born in the early 1980s, and the use of ART has since expanded in the country. However, the normative reality does not show such a feat, since, so far, there is no specific law that regulates the matter, a situation that ended up generating a great appreciation of the deontological Resolutions edited by the Federal Council of Medicine (CFM), which, despite not being law in a formal sense, end up establishing guidelines for the use of these procedures. In this way, the problem arises: what are the main contributions brought by the CFM Resolutions to the regulation of ART in Brazil and what is its role in the face of the Brazilian regulatory framework? With this, it was found that these Resolutions have been updated, over time, in order to accompany the advances of ART technologies, but they still lack the cogent force that only a law in the formal sense would have the power to make possible, leaving to the judiciary and its administrative bodies, in most cases, the role of overcoming this absence. For that, it was used the method of analytical-deductive reasoning, through bibliographic and documental research with a qualitative approach.

KEYWORDS: Bioethics; biolaw; medical ethics; reproductive biotechnology; assisted reproduction technology

* *Manuel Camelo Ferreira da Silva Netto, Doctoral student in Civil Law at the Universidade do Estado do Rio de Janeiro (UERJ), Brazil. Master in Private Law at the Universidade Federal de Pernambuco (UFPE), Brazil. Researcher With a scholarship from the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES). Mail: manuelcamelo2012@hotmail.com; Carlos Henrique Félix Dantas, Doctoral student in Civil Law at the Universidade do Estado do Rio de Janeiro (UERJ), Brazil. Master in Private Law at the Universidade Federal de Pernambuco (UFPE), Brazil. Researcher With a scholarship from the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES). Mail: carloshenriquefd@hotmail.com.* *The article was subject to a double-bind peer review process.*

ISSN 2284-4503

Diagnosis – 2.9. *Post Mortem* ARTs and Surrogacy – 3. Critiques on the Nature of the Tool: can the CFM (alone) regulate the ARTs in Brazil? – 4. Final Considerations.

1. Introduction

Infertility has always presented itself as a health issue with significant social consequences, which were mitigated when, in the 20th century, the so-called assisted reproduction technologies (ARTs) emerged, providing an opportunity to remedy those problems. In 1978, the first "test tube baby" in the world was born, the English Louise Brown, as a result of the application of the *in vitro* fertilization (IVF) technique and resulting from the efforts of embryologist Robert Edwards and gynecologist Patrick Steptoe. In Brazil, in its turn, it did not take long for this technique to be successful, and in 1984, Ana Paula Caldeira, the first Brazilian "test tube baby", was born, due to the work of gynecologist Milton Nakamura.

Ever since, reproductive biotechnology has advanced and continues to advance in ways never before imagined, bringing with it necessary reflections and impacts, especially in the legal field. However, curiously, after almost 40 years of this achievement, Brazil still lacks specific legislation capable of comprehensively regulating the use of the ARTs, to the extent that no bill has been passed to date.[1] It was in this context that the deontological guidelines, prepared by the Federal Council of Medicine (CFM)[2] – administrative body responsible for inspecting and regulating medical activity –, through its Resolutions, gained great importance on the subject, because, although they do not have the nature of law in a formal sense, they correspond to the main parameters for regulating these techniques in the country.

In view of this, the following problem was raised: what are the main contributions brought by the CFM Resolutions to the regulation of ARTs in Brazil and what is its role in the Brazilian regulatory framework? Therefore, the present study aims to conduct a comparative study between the CFM Resolutions on the matter, in order to investigate the ethical guidelines established for their application and the role they play in the Brazilian legal system. In addition, it proposes to investigate the position of Brazilian courts in face of the ethical guidelines established by the CFM Resolutions in the country.

To do so, it was used the analytical-deductive reasoning method, with a qualitative approach, by applying the techniques of literature review and documentary research. In this sense, we sought to provide a theoretical-legal basis for understanding ARTs techniques and to what extent their deontological regulation was/is being sufficient to establish ethical guidelines in the absence of legislation on the subject in the country.

[1] From the verification of data collected until april 19th, 2022, it appears that there are 24 bills being processed in the Brazilian National Congress and that they are willing to regulate to some extent the use of ART's in Brazil. However, so far, none of them has been approved, which is why the CFM's (Conselho Federal de Medicina, in free translation: Federal Council of Medicine) deontological Resolutions still play an important role in establishing guidelines for their use. For further details, see M. C. F. DA SILVA NETTO, *A reprodução humana assistida e as dificuldades na sua regulamentação jurídica no Brasil: uma análise dos vinte e quatro projetos de lei que tramitam no Congresso Nacional*, in M. EHRHARDT JÚNIOR, M. CATALAN, P. MALHEIROS (coord.), *Direito Civil e tecnología,* 2. ed., T. II, Belo Horizonte: Fórum, 2022.

[2] From the acronym in Portuguese: Conselho Federal de Medicina.

ISSN 2284-4503

2. The Deontological Regulation of the ARTs in Brazil

Currently, in Brazil, there is no specific legislation that regulates the exercise of ARTs. At most, there are clauses III, IV and V of article 1.597 of the Civil Code of 2002 (CC/02),[3] which is restricted to the attribution of presumptions of parenthood and, even so, brings an approach still very insufficient when compared to the real complexity of the matter.[4] However, it can be said that such resources are not totally apart from regulation, only that such regulation does not occur through formal legislation, since the CFM, by adopting some Resolutions of deontological nature[5] – normative that impose ethical conducts, binding only the acts adopted by doctors when applying reproductive procedures –, cannot restrict or extend rights in the legal order.

In any case, there is no lack of minimum ethical parameters for the use of ARTs, since the CFM has already edited eight Resolutions on the subject: (i) n. 1.358/1992;[6] (ii) n. 1.957/2010;[7] (iii) n. 2.013/2013;[8] (iv) n. 2.121/2015;[9] (v) n. 2. 168/2017;[10] (vi) n. 2.283/2020[11] (which only made a minor wording change to 2.168/2017); (vii) n. 2.294/2021;[12] and, (viii) the recent n. 2.320/2022,[13] currently in effect, as the Resolutions were drafted sequentially in an attempt to improve their provisions; thus, revoking their predecessors. In light of this, we will now analyze, in a comparative manner, the main provisions and the changes that have been implemented over these 30 years of discipline, highlighting the main changes and how the Brazilian courts have behaved in this matter.

[3] Civil Code of 2002, our translation: *"Art. 1.597. Children are presumed to have been conceived during marriage: [...] III - produced by homologous artificial fertilisation, even if the husband is deceased; [...] IV - produced at any time, when surplus embryos are involved, resulting from homologous artificial conception; [...] V - produced by heterologous artificial insemination, as long as the husband's prior consent is obtained".*

[4] On the subject, see C.H.F. DANTAS, M.C.F. DA SILVA NETTO, *O "abismo" normativo no trato das famílias ectogenéticas: a insuficiência do art. 1597 (incisos III, IV e V) em matéria de reprodução humana assistida homóloga e heteróloga nos 20 anos do Código Civil*, in H.H. BARBOZA, G. TEPEDINO, C.E.D.R. MONTEIRO FILHO (Coords.). *Direito Civil: o futuro do direito*, Rio de Janeiro, 2022.

[5] Normative that impose ethical conducts, binding only the acts adopted by doctors when applying reproductive procedures.

[6] Conselho Federal de Medicina, *Resolução CFM nº 1.358/1992*, de 19 de novembro de 1992. Available at: http://www.portalmedico.org.br/resolucoes/CFM/1992/1358_1992.htm, accessed on: 13 jun. 2022.

[7] Conselho Federal de Medicina, *Resolução CFM nº 1.957/2010*, de 06 de janeiro de 2011. Available at: http://www.portalmedico.org.br/resolucoes/CFM/2010/1957_2010.htm, accessed on: 13 jun. 2022.

[8] Conselho Federal de Medicina, *Resolução* CFM nº 2.013/2013, de 09 de maio de 2013. Available at: http://www.portalmedico.org.br/resolucoes/CFM/2013/2013_2013.pdf, accessed on: 13 jun. 2022.

[9] Conselho Federal de Medicina, *Resolução nº 2.121/2015,* de 24 de setembro de 2015. Available at: https://sistemas.cfm.org.br/normas/arquivos/resolucoes/BR/2015/2121_2015.pdf, accessed on: 13 jun. 2022.

[10] Conselho Federal de Medicina, *Resolução CFM nº 2.168/2017*, de 10 de novembro de 2017. Available at: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2017/2168, accessed on: 13 jun. 2022.

[11] Conselho Federal de Medicina, *Resolução CFM nº 2.283/2020*, de 1 de outubro de 2020. Available at: https://sistemas.cfm.org.br/normas/arquivos/resolucoes/BR/2020/2283_2020.pdf, accessed on: 13 jun. 2022.

[12] Conselho Federal de Medicina, *Resolução CFM nº 2.294/2021*, de 15 de junho de 2021. Available at: https://sistemas.cfm.org.br/normas/arquivos/resolucoes/BR/2021/2294_2021.pdf, accessed on: 13 jun. 2022.

[13] Conselho Federal de Medicina, *Resolução CFM nº 2.320/2022*, de 20 de setembro de 2022. Available at: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2022/2320, accessed on: 14 oct. 2022.

2.1 General Principles and Beneficiaries

All Resolutions, without exception, predicted the use of ARTs in order to facilitate the process of procreation, assisting in solving problems of human infertility, as long as there is probability of success and there is no health risk for the patient or possible offspring. Thus, initially, the Resolution n. 1.358/1992 brought as beneficiaries only capable women, requiring the authorization of the spouse or partner, if they were married or in a common-law marriage.[14] However, as of Resolution n. 1.957/2010, the beneficiaries became all adults and capable[15] people, as long as they were agreed and informed.
As for the extension of such rights to homoaffective[16] couples and single persons, the action of the Federal Supreme Court (Supremo Tribunal Federal – STF), in 2011, in recognizing the family nature of homoaffective unions,[17] had repercussions in Resolutions 2.013/2013, 2.121/2015, and 2.168/2017 that established this possibility, with the exception of the doctor's right to conscientious objection. It should be noted, however, that in 2020, an alteration was made to the Resolution n. 2.168/2017, through Resolution n. 2.283/2020, which gave a new wording to its Item II-2 – which had been maintained in Resolution 2.294/2021 –, expressly including as beneficiaries, besides homosexual people, those who are transgender (CFM, 2013, 2015, 2017, 2020, 2021).[18]

[14] In this article, we have opted for translating the Portuguese expression *"união estável"* as *"common-law marriage"*, considering that it is an informal union established by the cohabitation between the partners in a public, lasting, continuous, and intentional manner, in the terms of article 1.723 of the CC/02, similar to the aforementioned US institute.

[15] The notion of "capacity", in the terms established in the Resolutions, follows the viewpoint of the civil capacity system set forth in the CC/02, considering every person over 18 years of age – the age chosen by the legislator as the civil age of majority in the country – to be fully capable in the terms of article 5th of the referred law. On the other hand, regarding incapacities, we have: a) in article 3rd, absolute incapacity: people who are not fully able to perform the acts of civil life, requiring, for this purpose, the assistance of a legal representative (parents or guardian). This is the case of minors under 16 years of age; and, b) in the article 4th, relative incapacity: consisting of those persons who are not yet fully able to perform the acts of civil life, but who can do so with the help of a legal assistant (parents, guardian or curator). This is the case of those over 16 and under 18 years of age, habitual drunks, drug addicts, prodigals, and persons who, for temporary or permanent reasons, are unable to express their will.

[16] The term homoaffectivity has become popular in Brazilian legal doctrine since its use by the jurist Maria Berenice Dias, who, in an attempt to destigmatize relationships of same sex couples, which were commonly related to abnormality and promiscuity, chose to emphasize the affection and love present in these relationships, highlighting them through the neologism [homo]affectivity.

[17] In 2011, in the judgment of the Ação Direta de Inconstitucionalidade (ADI) n. 4.277/DF and the Arguição de Descrumprimento de Preceito Fundamental (ADPF) n. 132, the STF recognized the family nature of homoaffective unions and equated them to the common-law marriage, conditioning its configuration to the requirements contained in Article 1.723 of CC/02.

[18] The wording brought by resolution n. 2.283/2020 and maintained by resolution n. 2.294/2021 brought the following: *"2. The use of AR techniques is allowed for heterosexuals, homoaffective and transgenders"*, replacing the previous text, which read: *"2. The use of AR techniques is allowed for homoaffective relationships and single people, respecting the doctor's right to conscientious objection"* (CFM, 2017, 2020, 2021, our translation). Regarding this change, despite its clear intention to consolidate the amplitude of access to the techniques, some issues must be pondered: a) when the CFM brings this wording ("heterosexuals, homoaffective and transgenders"), it sins in the terminological choice, because when talking about expression of sexuality/sexual orientation, one has the figure of "heterosexual" and "homosexual", while the terminology "homoaffective" would not fit to designate the person itself, but the relationship in which it is inserted, in a way that bisexual

Nevertheless, resolution 2.320/2022, currently in effect, removed this express mention that qualified LGBTQIAP+ people as beneficiaries of the ART's (CFM, 2022), which does not prevent such an interpretation from remaining implicitly, since these resolutions cannot restrict or extend rights due to their deontological nature.

Furthermore, as of Resolution n. 2.121/2015, the possibility of co-IVF by a lesbian couple was also mentioned, which was also reproduced in all subsequent resolutions (Item II-3 or II-2). (CFM, 2015, 2017, 2021, 2022).

2.2. Maximum Age of Beneficiaries

Regarding the maximum age, there was some variation, since Resolutions n. 1.358/1992 and 1.957/2010 did not stipulate any age limit for patients, while Resolution n. 2.013/2013 determined a maximum age of 50 years (Item I-2) for pregnancy candidates and Resolution n. 2.121/2015, even having established the maximum age of 50 years, also admitted exceptions to this age limit by determination of the responsible doctor, as long as for technical scientific reasons, after clarification of the risks involved (Item I-3).

Resolution n. 2.168/2017, in its turn, maintained the maximum age of 50 years and also presented the possibility of exceptions, based on technical-scientific reasons, related to the absence of comorbidities of the woman, and on the autonomy of the patients after they were informed about the risks of such interventions, both for the pregnant woman and the future offspring (Item I-3, §§1 and 2), which was maintained in Resolutions n. 2.294/2021 and 2.320/2022 (Item I-3.1 and 3.2). (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

people can also come to compose homoaffective relationships, for example; b) it is equally important to emphasize that sexual and gender diversity is not restricted to a hetero/homo, cis/trans binarism, embracing, in the same way, the figures of bisexuality, pansexuality, asexuality, non-binarity, intersexuality, etc. For this reason, it is believed that the following wording would be more adequate: "The use of AR techniques is allowed regardless of the sexual orientation/expression of sexuality or gender identity of the beneficiaries, also not mattering, for purposes of its application, the format of the family entity in which they are inserted". It is noteworthy that the right to conscientious objection remained, in an implicit form, at the resolutions 2.283/2020 and 2.294/2021 to the extent that, in its explanatory statement for the change of the wording, this possibility was admitted, based on the "General Principles" of the Code of Medical Ethics. This alternative concerns the fact that these professionals can refuse to perform the AR process when this application is against their *Freedom of Conscience*. In any case, one cannot fail to mention that the Code of Medical Ethics brings some limits to the exercise of this right, by excepting the cases: a) of absence of another doctor; b) urgency or emergency; and, c) in which the refusal can bring harm to the patient's health. Furthermore, it is important to highlight that, in 2019, the Ação Direta de Inconstitucionalidade por Omissão (ADO) n. 26 and the Writ of Injunction (Mandado de Injunção – MI) n. 4.733 were judged by the STF, which placed homo-transphobia, whatever its form of manifestation, within the crimes contained in Law n. 7,716/89 (Law for the Crime of Racism), based on the social understanding of racism, until autonomous legislation edited by the National Congress comes along, also making it impossible to refuse the treatment for this reason. (For more details see M.C.F DA SILVA NETTO, *Planejamento Familiar nas Famílias LGBT*: desafios sociais e jurídicos do recurso à reprodução humana assistida no Brasil, Belo Horizonte: Fórum, 2021; M.C.F DA SILVA NETTO, C.H.F. DANTAS, *"Nossas vidas importam?" Vulnerabilidade sociojurídica da população LGBTI+ no Brasil: debates em torno do Estatuto da Diversidade Sexual e de Gênero e da sua atual pertinência*, in M. EHRHARDT JÚNIOR, F. LÔBO (Orgs.), *Vulnerabilidade e sua compreensão no direito brasileiro*, Indaiatuba, 2021).

2.3. Maximum Number of Embryos to be Transferred and Embryo Reductions

As for the maximum number of embryos or oocytes to be transferred, there were also some modifications. Resolution n. 1.358/1992 only determined that they could not be more than 4 (Item I-6). The following Resolutions divided into categories, while n. 1.957/2010 determined that up to 2 embryos should be transferred for patients up to 35 years old, up to 3 for patients between 36 and 39 years old, and up to 4 for patients over 40 years old (Item I-6), the three subsequent ones changed only the last category: a) n. 2.013/2013 determined up to 4 embryos for women between 40 and 50 years old (Item I-6); b) n. 2.121/2015 resumes the prediction of up to 4 embryos for patients over 40 years old; and, c) Resolution n. 2.168/2017 (Item I-7) replicated this age stipulation (patients over 40 years old), which is justified because the maximum age of 50 years old, in these last two Resolutions, can be set aside in certain hypotheses, as had been highlighted earlier.

Resolutions n. 2.294/2021 and 2.320/2022, in its turn, reformulated these age categories – with the justification that technological advances and improvements in pregnancy rates authorize a reduction in the number of embryos transferred – and included the following possibilities: a) up to 2 embryos for women up to 37 years old; b) up to 3 embryos for women over 37 years old; and, c) up to 2 embryos in cases of euploid[19] embryos for genetic diagnosis (Item I-7).

Moreover, all Resolutions prohibited the possibility of embryo reduction, which is nothing more than the removal of embryos in order to avoid multiple pregnancies (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022). This is due to the fact that, in practice, such technique resembles abortion, which, in its turn, is expressly forbidden by the Brazilian legal system (articles 123, 124, 125 and 126 of the Penal Code - CP), except in the legal (rape and mother's life risk) and judicial (case of anencephalic fetuses) hypotheses provided.

2.4. Informed Consent

All Resolutions establish the informed consent as mandatory, and it must contain the medical aspects in detail and the results obtained in that treatment unit with the suggested technique (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022). The only difference in this topic, however, was regarding the elaboration of the informed consent form, to which, in Resolution n. 2.121/2015, it was added the need to be formulated by a bilateral discussion among those involved, being this idea resumed in following Resolutions (Item 1-4), which reveals a greater concern with the patient autonomy. (CFM, 2015, 2017, 2021, 2022).

2.5. Sex or Other Biological Characteristics Selection and Genetic Material Preservation

Regarding sex selection or any other biological characteristic of the future child, all Resolutions were unanimous in forbidding its possibility, except to avoid diseases in the child that will be born. As for

[19] Euploid embryos are those that have 46 chromosomes, presenting higher chances of successful pregnancy (See Genomika – Hospital Albert Einstein (s.d). *Triagem genética pré-implantação: saiba como aumentar as chances de uma gravidez bem-sucedida*, 2022. Available at: https://genomika.einstein.br/medicina-fetal/, accessed on: 18 jun. 2022.).

ISSN 2284-4503

the purpose of ARTs, they all determine that it must always be procreative, and that any other purpose different from this is forbidden (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

An important innovation brought by Resolution nº 2.168/2017 regarding the general principles of the use of ARTs is in the provision of the possibility of social or oncological preservation of sexual gametes, embryos or germinative tissues (Item I-2),[20] what was manteined by the following Resolutions, n. 2.294/2021 and 2.320/2022, applicable to medical and non-medical reasons (Item I-2). (CFM, 2017, 2021).[21]

2.6. Gamete or Embryo Donation

Regarding gamete donation, all Resolutions determine that it should be free of charge, being forbidden to doctors, employees and other members of the multidisciplinary team of the clinics, units or services. However, as of Resolution n. 2.013/2013, a maximum age for gamete donation was established: 35 years for women and 50 years for men. This provision was repeated in Resolutions n. 2.121/2015 and 2.168/2017 (Item IV-3), being changed to 37 years for women and 45 years for men in Resolutions 2.294/2021 and 2.320/2022, admitting exceptions in cases of previously frozen oocytes or embryos donation, provided the recipients are informed about the risks (Item IV-3 and 3.1). (CFM, 2012, 2015, 2017, 2021, 2022).

In this continuity, it is noted that all the Resolutions determined donor confidentiality, in a model of absolute anonymity[22] of the donations, where neither the donors nor the recipients could know each other's identities, and, exceptionally, in case of medical motivation, information about the donors could be provided exclusively to doctors, safeguarding their civil identity (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

This stipulation was maintained in Resolution n. 2.294/2021, but an exception to this rule was admitted: gamete donation by relatives up to the 4th degree of kinship of the recipient(s), "provided they are not consanguineous" (Item IV-2 and 4).[23] This relativization of absolute anonymity – as can be in-

[20] This provision was very important because patients undergoing oncologic treatment may have infertility as a side effect, and it is important to offer this alternative. Moreover, it gave other patients – those who have not been diagnosed with infertility or those undergoing other types of treatments or affected by diseases that cause infertility – the option of preserving their sexual gametes, in order to have a future parental project.

[21] It should be noted, however, that there is no specific provision regarding the possibility of its preservation in the case of trans patients who wish to undergo the transsexualizing process. It is obvious that this provision may be interpreted in favor of these people, adapting to the notion of social preservation (non-medical reasons). However, it would be opportune to bring, in a specific way, this alternative, both in Resolution n. 2.320/2022 and in Resolution n. 2.265/2019 (which regulates medical follow-up to trans people), as one of the steps of the gender affirmation process, in order to give visibility to the preservation of the reproductive rights of these people. (CFM, 2019, 2022); (M.C.F DA SILVA NETTO, *Planejamento Familiar nas Famílias LGBT: desafios sociais e jurídicos do recurso à reprodução humana assistida no Brasil*, Belo Horizonte: Fórum, 2021).

[22] A.C.B. DE B.C. FERRAZ, *Reprodução humana assistida e suas consequências nas relações de família: a filiação e a origem genética sob a perspectiva da repersonalização*, 2. ed., Curitiba: Juruá, 2016.

[23] Note, however, that, contrary to the normative provision of the CFM, the Federal Regional Court of the 3rd Region in São Paulo, for example, decided on the expansion of the understanding to allow anonymous donors of gametes and human embryos to also be known persons beyond the restriction of up to the 4th collateral degree, reinforcing the doctrine of socio-affectivity present in Brazilian law. See (Brazil. Tribunal Regional Federal da 3ª

ISSN 2284-4503

ferred from the Resolution's own explanatory statement – was due to the high number of court decisions in favor of gamete donations between relatives, which is justified on several grounds, such as: a) the fundamental right to the exercise of free family planning (art. 226, §7 of the Federal Constitution of 1988); b) the absence of express legal prohibition; c) the consolidation of socio-affective kinship[24] (adoption, possession of offspring status, "Brazilian adoption"[25] and heterologous ART)[26] in Brazilian legislation, doctrine and case law; d) the solidification of the distinction between the right to know

Região (TRF3). 2ª Vara Cível Federal da Seção Judiciária de São Paulo. *Case n. unavailable*. Reporting Judge: Rosana Ferri, Date of decision: 05/2022. Available at: https://ibdfam.org.br/jurisprudencia/13909 . Accessed on: 13 jun. 2022.). Furthermore, it should be emphasized that, despite the somewhat confusing wording regarding the indication of non-consanguinity in these known donations, it should be understood that the CFM was concerned with prohibiting the performance of fertilization procedures with gametes from persons of the same family. This, in turn, must be observed both in cases of consanguineous kinship and in cases of civil (adoption) and socio-affective kinship (possession of offspring status, "Brazilian adoption" and heterologous ART), observing the rules that prohibit incest and grounds marriage impediments based on the kinship (Art. 1.521, I to V and Art. 1.723, §1º of CC/02): *"Art. 1.521. The following cannot marry: [...] I - ascendants and descendants, whether by natural or civil kinship; [...] II - kin in a direct line; [...] III - the adopter and whoever was the spouse of the adopted and the adopted with whoever was the spouse of the adopter; [...] IV - brothers and sisters, unilateral or bilateral, and other collaterals, up to the third degree; [...] V - the adopted with the child of the adopter; [...] Art. 1.723. [...] §1º The common law marriage shall not be constituted if the impediments of art. 1.521 occur; not applying the incidence of clause VI in case the married person is in fact or judicially separated"* (Brasil. Civil Code, 2002, our translation).

[24] Such debates had as a precursor João Baptista Villela who, in his famous text "De-Biologization of Paternity" (1979), already attributed to paternity – which here can be understood in a broader sense, also encompassing the idea of maternity – an element much more cultural than natural. After all, in the words of the mentioned author, "[...] to be father or mother is not so much in the fact of generating as in the circumstance of loving and serving" (See J.B. VILLELA, *Desbiologização da paternidade,* in *Revista da Faculdade de Direito da Universidade Federal de Minas Gerais*, 21, 1979, 400-418, 408, our translation). Furthermore, according to Carlos Dantas, there is no question here of multiparentality (attribution of more than two parenting bonds to the same person), since the biological origin and the civil identity of the donor are known, once the socio-affective parenthood, in Brazilian Law, is much more comprehensive than a mere criterion based on pure biologism. C.H.F. DANTAS, *Aprimoramento genético em embriões humanos: limites ético-jurídicos ao planejamento familiar na tutela da deficiência como diversidade biológica humana*, Belo Horizonte: Fórum, 2022, 136.

[25] It must be emphasized that the expression we have chosen to translate here as "Brazilian Adoption", in Portuguese, is called "adoção à brasileira", meaning an adoption made "Brazilian style", due to the fact that it has been a widespread practice in the country, but that, with time, it has been tried to be discouraged, because it is understood that the due legal process of adoption better respects the idea of the best interest of the child.

[26] In short synthesis a) the adoption corresponds to the civil kinship, in view of being a form of establishing filiation in the parameters stipulated by law, through the due process of adoption; b) the possession of offspring status is established when someone assumes the role of father or mother, regardless of having biological links, configuring a paternal-maternal-filial bond through coexistence; c) the "Brazilian adoption" occurs from the false affixation, in the birth register, of the quality of father or mother of a child born from another woman, married or not, without observing the legal requirements of adoption. In such cases, although it constitutes a crime (article 242 of the Penal Code), the case law has been admitting the recognition of the filiation, provided that the coexistence has been consolidated for many years through the possession of offspring status; and d) the heterologous ART occurs when the performance of the ART procedure happens with the authorized use of donated genetic material, attributing parenthood to those persons who consented to the procedure, in the terms of article 1.597, V of CC/02. In the same sense, see (P. LÔBO, *Direito ao estado de filiação e direito à origem genética: uma distinção necessária*, in *Revista Brasileira de Direito de Família*, 1, 1, 1999, 133-156).

ISSN 2284-4503

one's genetic ancestry and filial status in heterologous ARTs;[27] and, e) the possibility of the pregnant woman being known in surrogate pregnancy, etc.

Still on donations, the Resolutions attributed the choice of donors to the units, responsible for ensuring maximum phenotypic similarity and maximum compatibility with the recipient, with Resolutions n. 2.013/2013, 2.121/2015 and 2.168/2017 innovating by admitting the possibility of shared oocyte donation (Item IV-9). Resolutions 2.294/2021 and 2.320/2022, on the other hand, maintained the possibility of shared donation, attributing to the doctor, only in this case, the responsibility for the choice of donors – selecting, as far as possible, those with the maximum phenotypic similarity and compatibility with the recipient(s) (Item IV-8 and 9) – while, in the case of gametes or embryos banks resource, attributing exclusively to the users the responsibility for the selection of donors (Item IV-10) (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

Regarding the use of genetic material from the same donor in more than one pregnancy, some changes were added to the text of the Resolutions throughout time: a) in Resolution n. 1. 358/1992 – it was imposed that the fact of, in the region where the unit is located, a donor producing more than 2 pregnancies of different genders in an area of one million inhabitants be avoided; b) in Resolution n. 1.957/2010 – this number was reduced to 1 pregnancy of a child of different genders in an area of one million inhabitants; c) in Resolutions n. 2.013/2013 and 2.121/2015 - the number was again raised to 2 pregnancies of children of different genders in an area of one million inhabitants; and, d) in Resolutions 2.168/2017, 2.294/2021 and 2.320/2022 - the number of 2 pregnancies of children of different genders in an area of one million inhabitants was maintained, but the same donor was allowed to contribute with as many pregnancies as desired, as long as in the same family (Item IV-6), demonstrating, once again, the concern with the prohibition of incest, established in law by the legislator (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

2.7. Surplus Embryos

Regarding surplus embryos, the Resolutions have opted for the possibility of their cryopreservation, and the last four have added the possibility of cryopreserving gonadic tissues as well, in addition to spermatozoa and eggs, also contained in the first two Resolutions. Moreover, according to the current provision of Resolution n. 2.320/2022, it was revoked the previous provision of Resolution 2.294/2021, in wich the total number of embryos to be generated in laboratories could not exceed 8, and there is no longer such limitation (Item V-2) (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

At the moment of cryopreservation, patients must express their will, in writing, as to the destiny of these embryos in case of divorce, dissolution of common-law marriage, or death, of one or both, and when they wish to donate them (Item V-3).[28]

[27] For further information on the theme, see (P. LÔBO, *Direito ao estado de filiação e direito à origem genética: uma distinção necessária,* in *Revista Brasileira de Direito de Família*, 1, 1, 1999, 133-156).

[28] Although there is the need to establish the will regarding the destination of human biological material at the time of contracting the service, by determination of the Resolution, the Brazilian case law has been reinforcing that, at any time, this decision may be modified. This is because: a) the Fourth Panel of the Superior Tribunal de Justiça – STJ (2021), in the Recurso Especial (REsp) n. 1.918. 421-SP determined, by majority vote, that even if there is previous manifestation of will in a term of informed consent, regarding surplus embryos to be implanted after death, a more specific document will be required, such as express authorization via will, rejecting the ex-

The deadline for the disposal of embryos was changed over the course of the regulations, since, in Resolutions n. 2.013/2013 and 2.121/2015, it was established that embryos cryopreserved for more than 5 years could be discarded or used for research with stem cells in the terms of the article 5th of the Biosafety Law (Law n. 11.105/2005),[29] respecting the patients' will. In resolutions 2.168/2017 and 2.294/2021, this deadline was lowered to 3 years, while in resolution 2.320/2022 nothing was stated about the deadline; therefore, the 3 years stipulated in article 5th of the Biosafety Law should be considered[30] (CFM, 2013, 2015, 2017, 2021, 2022).

wife's claim to implant them (Brazil. Superior Tribunal de Justiça (2021). *Recurso Especial n. 1.918.421-SP*. Rapporteur: Minister Marco Buzzi. Rapporteur for the Judgment: Minister Luis Felipe Solomon. Date of Judgment: 06/08/2021. Available at: https://bit.ly/3ST7YeA, accessed on: 13 jun. 2022); and, b) the Fifth Panel of the Tribunal de Justiça do Distrito Federal e Territórios – TJDFT (2021) determined that, even if the destination of the cryoconserved embryo is established when the service is contracted, after divorce, the ex-spouse may change his or her mind, even to request disposal of the human biological material. (Brazil. Tribunal de Justiça do Distrito Federal e dos Territórios. Quinta Turma. *Case n. 0702501-17.2019.8.07.0011*. Rapporteur: Judge Maria Ivatônia, Fifth Civil Panel. Date of publication: 12/13/2021. Available at: https://www.tjdft.jus.br/consultas/jurisprudencia/decisoes-em-evidencia/19-1-2022-2013-descarte-de-embrioes-criopreservados-2013-divorcio-2013-tjdft, accessed on: 13. jun. 2022).

[29] Biosafety Law (nº 11.105/05): *"Article 5. The use of embryonic stem cells obtained from human embryos produced by in vitro fertilization and not used in the procedure for research and therapy purposes is permitted subject to the following conditions: I - are unfeasible embryos; or II - are embryos frozen for 3 (three) years or more, on the date of publication of this Law, or that, already frozen on the date of publication of this Law, after completing 3 (three) years, counted from the date of freezing. […] § 1st In any case, the consent of the parents is required. […] § 2nd Research institutions and health services that conduct research or therapy with human embryonic stem cells should submit their projects for consideration and approval by the respective research ethics committees. […] § 3rd The marketing of biological material referred to in this article is prohibited and its practice implies the crime typified in art. 15 of Law nº 9.434, of February 4, 1997".* The Attorney General's Office (Procuradoria Geral da República – PGR), in 2008, through ADI n. 3.510/DF, plead the full unconstitutionality of article 5th of the Biosafety Law on the grounds that human life would start from conception, to protect the criopreserved embryo. When the case was judged, the rapporteur minister Celso de Mello understood that the device is endowed with constitutionality and the human life of the cryopreserved embryo, in a restricted way, would not be linked to conception, depending on other factors, such as live birth and implantation in the uterus. As a result of the judgment, it was also not possible to determine the legal nature of these surplus embryos, a fact that still raises doubts today, as it becomes untenable to classify them within the classic dichotomy of civil law: thing or person. (See C.H.F. DANTAS, *Aprimoramento genético em embriões humanos: limites ético-jurídicos ao planejamento familiar na tutela da deficiência como diversidade biológica humana*, Belo Horizonte: Fórum, 2022).

[30] In 2017, Resolution n. 2.168/2017 reduced the deadline for disposal, according to the will of the beneficiaries, to 3 years; also authorizing the possibility of disposal, regardless of the patients' will, when the embryos were abandoned by them, considering abandoned those embryos whose guardians failed to comply with the pre-established contract with the clinic and were not found by it (Item V-5), silencing with respect to its destination for scientific research purposes. Such a device was quite problematic, as it contradicted the express provision of the Biosafety Law (art. 5, §1), in which it was established that, in any event, the disposal can only be carried out with the consent of the parents, which implied in a review of this provision by the CFM in Resolution n. 2.294/2021, which established the need for judicial authorization for the disposal in all cases, both for embryos cryopreserved for more than 3 years, and those said "abandoned" (Item V-4 and 5). Resolution 2.320/2022, on the other hand, did not make any provision regarding the deadline for disposal, nor the need for a court decision to do so.

ISSN 2284-4503

2.8. Preimplantation Genetic Diagnosis

In terms of pre-implantation genetic diagnosis, Resolutions n. 1.358/1992 and 1.957/2010 allowed it only for the purposes of prevention and treatment of genetic or hereditary diseases,[31] when perfectly indicated and with sufficient guarantees of diagnosis and therapy (CFM, 1992, 2010).
In its turn, Resolutions n. 2.013/2013 and 2.121/2015 also allowed the previous diagnosis, but this time for two other purposes: a) selection of embryos with genetic alterations that cause diseases; and b) embryo's Human Leukocyte Antigen (HLA) typing, to verify HLA-compatible embryos with the child of the couple already affected by the disease, whose effective treatment is with stem cells, enabling the technique known as "savior sibling"[32] (CFM, 2013, 2015).
In the rest, Resolution n. 2.168/2017 only brought, as a requirement for carrying out this diagnosis, the existence of a specific informed consent term regarding this technique (Item IV-1), Resolution n. 2.294/2021 added that, in the genetic evaluation report, to avoid social sexing, it is only allowed to inform whether the embryo is male or female in case of sex-linked diseases or sex chromosome aneuploidies[33] (Item VI-1), which was revoked in the later resolution, 2.320/2022 (CFM, 2017, 2021, 2022).

2.9. *Post Mortem* ARTs and Surrogacy

In the case of *post mortem* ARTs, that is, those when the technique is applied after the death of one of the original beneficiaries (article 1.597, III, of CC/02), Resolution n. 1.358/1992 did not provide anything for the respect, while all the others allowed it to be carried out, provided that there was specific prior authorization from the deceased for the use of genetic material, in accordance with current legislation. It should be noted that this provision, despite some controversies regarding the inheritance

[31] On the subject, it is emphasized that the tool, when used to read the individual genetic heritage of future offspring, must use as a parameter the necessary distinction between disease and disability, insofar as the latter refers to a limitation of physical, sensory or intellectual order while the other determines the absence of quality of life and health. Therefore, disability should not be interpreted as a synonym of disease, so that it does not incur in a discriminatory way in family planning, especially when it is combined with new available tools, such as the CRISPR-Cas9 gene editing technique, which must be used with therapeutic and non-eugenic purposes. (C.H.F. DANTAS, *Aprimoramento genético em embriões humanos: limites ético-jurídicos ao planejamento familiar na tutela da deficiência como diversidade biológica humana,* Belo Horizonte: Fórum, 2022).

[32] Claudia Aparecida Costa Lopes and Pedro Henrique Sanches explain that the conception of the "savior sibling" begins with the collection of eggs and sperm from the parents for IVF. During the process, embryos are formed, which will undergo pre-implantation genetic diagnosis, in which a deep analysis of their genetic characteristics is carried out, in order to exclude the possibility of that child developing the hereditary disease in question. The diagnosis is made from the removal of cells from the embryo (called, at that time, blastomere) when it has 6 to 8 cells. Embryos that do not have the disease and that are compatible with the sibling who is affected by the disease are then selected. Finally, at birth, umbilical cord stem cells are collected and frozen. C.A.C. LOPES, P. H. SANCHES, *Do bebê medicamento: "instrumento" de dignidade familiar*, in *Encontro Nacional da CONPEDI: A Humanização do Direito e a Horizontalizarão da Justiça no Século XXI*, 23, 2014, João Pessoa. *Anais Direito de Família II.* Florianópolis: CONPEDI, 2014.

[33] Aneuploids are embryos that do not have the correct number of chromosomes (46 chromosomes), not being recommended for transfer, as they have very low chances of producing a successful pregnancy (Cf. Genomika – Hospital Albert Einstein (s.d). *Triagem genética pré-implantação: saiba como aumentar as chances de uma gravidez bem-sucedida,* 2022. Available at: https://genomika.einstein.br/medicina-fetal/, accessed on: 18 jun. 2022.).

right of these children,[34] is fully compatible with the provisions of art. 1.597, III and IV of CC/02, which authorizes the homologous ART even after the death of one of the parents.

Finally, with regard to surrogacy, all Resolutions admitted it, free of charge, in cases of medical problems that prevented or contraindicated pregnancy in the genetic donor.

However, some issues have changed over time:

a) in Resolutions n. 1.358/1992 and 1.957/2010 – only women belonging to the family of the genetic donor, in consanguineous kinship, up to the 2nd degree were admitted as surrogate mothers;

b) Resolutions n. 2.013/2013 and 2.121/2015 – allowed women in the family of any of the beneficiaries, in consanguineous kinship, up to the 4th degree (1st degree – mother; 2nd degree – sister and grandmother; 3rd degree – aunt; 4th degree – cousin), could appear in the position of surrogate mother, including in cases of same-sex couples;

c) in Resolution n. 2.168/2017 – the limitation of kinship in the 4th degree, consanguineous, was maintained, with expansion of the hypotheses (1st degree – mother and daughter; 2nd degree – sister and grandmother; 3rd degree – aunt and niece; 4th degree – cousin), and the possibility of the practice was also extended to single people; and,

d) in Resolution n. 2.294/2021– the limitation of kinship in the 4th degree by consanguineous kinship and the possibility of its use for same-sex couples and single people was maintained, requiring, now, that the surrogate has at least one child alive. In addition, exceptionally, pregnant women who do not have kinship criteria can be admitted, provided that there is a prior opinion from the CRM authorizing the practice of those cases;

e) in Resolution n. 2.320/2022 – the limitation to the 4th degree of kinship was maintained (1st degree – parents and children; 2nd degree – grandparents and siblings; 3rd degree – uncles and nephews; 4th degree – cousins[35]) and the need for the surrogate to have at least one living child, removing the express mention previously present as to the possibility of its use by single people and same-sex couples. Nevertheless, this does not mean that this is no longer a possibility since, in the resolution's explanatory statement, express mention is made of cases of homosexual male couples using surrogacy in order to clarify that "the doctor must know the male genetic material that gave rise to the implanted embryo – mixing the spermatozoa of both partners is forbidden, making it difficult to know the genetic origin […]" (CFM, 1992, 2010, 2013, 2015, 2017, 2021, 2022).

[34] The controversy arises because of article 1.798 of CC/02 that establish that only those born or conceived at the time of the opening of the succession, that is, the death, are entitled to succeed, which could represent a limitation on the inheritance right of those conceived *post mortem*. For more details, see (C. H F. Dantas; M. C. F. da Silva Netto. O "abismo" normativo no trato das famílias ectogenéticas: a insuficiência do art. 1597 (incisos III, IV e V) em matéria de reprodução humana assistida homóloga e heteróloga nos 20 anos do Código Civil, in H.H. Barboza, G. Tepedino, C.E.D.R. Monteiro Filho (Coords.), *Direito Civil: o futuro do direito*, Rio de Janeiro, 2022.).

[35] Note that, although nothing is mentioned about this in the Resolution, the use of expressions tending toward gender neutrality in specifying the surrogate's kinship to the beneficiaries raises the possibility that, also, trans men may self-determine to be a surrogate in favor of another's parental project. On the topic of transmasculine pregnancies, see (M.C.F. da Silva Netto, *Uma (re)leitura da presunção mater semper certa est frente à viabilidade de gravidezes masculinas: qual a solução jurídica para atribuição da paternidade de homens trans que gestam seus próprios filhos?*, in *Revista Brasileira de Direito Civil*, 31, 1, 2022, 255-273, 2022. Available at: https://rbdcivil.ibdcivil.org.br/rbdc/article/view/562, accessed on: 30 dec. 2022).

Thus, it can be noted that there is a great restriction on the use of this technique, as the administrative guidelines established by the CFM end up restricting some accesses, which, *a priori*, would not be excluded by the legislation itself. For example, it is the case of civil or socio-affective kinships, which, by law, presents similar dignity when compared to consanguineous (article 1.596 of CC/02), but which is outside the *rol* listed by the CFM for the use of the surrogacy, being necessary, in practice, the opinion of the Regional Council of Medicine (CRM)[36] of the state in which the technique will be performed to overcome this requirement.

In this case, it is understood that such deontological provisions of this class council do not have the power to rule out equality in kinship, which represents a fundamental legal achievement, enshrined both in the constitutional and infraconstitutional fields. For this reason, the use of surrogacy may be linked to any form of kinship, and no discrimination can be established regarding any of the possible links, when duly proven. In this way, what must be investigated is the autonomy of the surrogate, through her/his effective informed consent, so that the necessary legitimacy is given to the procedure, not being essential, for the case in question, the opinion of the CRM, even though, in practice, it is commonly requested.

3. Critiques on the Nature of the Tool: can the CFM (alone) regulate the ARTs in Brazil?

Finally, it should be noted, once again, that, despite the existence of these deontological norms, the legislator cannot be exempted from its role of enacting specific laws in this matter. This is because, as Olga Jubert Krell[37] (our translation) rightly points out: "The constitutional principle of 'law reserve' must be respected, which requires a decision by the democratically legitimized parliamentary legislator on matters that directly involve fundamental rights, that directly involve the freedom of persons". After all, these Resolutions only configure "paralegal" rules applicable to doctors and whose breach only implies the initiation of disciplinary administrative proceedings, within the scope of the specific professional council, in the face of those professionals who do not observe the precepts brought in the Resolutions, not causing any state common sanctions.

For this reason, attention is drawn to the urgency of regularizing this issue, which can no longer go unnoticed by the Legislative, which has not yet consolidated a law that regulates its procedures. However, despite the lack of such laws, one cannot avoid pointing out that there are several bills (PLs), twenty-four in total, in progress in the National Congress. In this sense, the bills can be divided into two larger groups: a) the bills with more extensive regulation proposals – being present in this group those bills, six in total (PL nº 2.855/1997, PL nº 1.135/2003, PL nº 1.184/2003, PL nº 2.061/2003, PL nº 4. 892/2012 and PL nº 115/2015), which aim to create a true legal system for legalizing the use of ARTs in Brazil, some of them inspired in the guidelines brought by the CFM resolutions; and b) the bills with specific proposals for regulation – placing, in this category, the bills, eighteen in total (PL nº 4.664/2001, PL nº 4.665/2001, PL nº 6.296/2002, PL nº 120/2003, PL nº 4.686/2004, PL nº 4.889/2005, PL nº 5.624/2005, PL nº 3.067/2008, PL nº 7.701/2010, PL nº 3.977/2012, PL nº 7.591/2.017, PL nº

[36] From the Portuguese acronym for Conselho Regional de Medicina. Within the CFM structure, the CRMs are regional bodies, present in each of the 26 states and in the federal district.

[37] O.J.G. KRELL, *Reprodução humana assistida e filiação civil*: *princípios éticos e jurídicos*, Curitiba: Juruá, 2006, 37.

9.403/2017, PL nº 5.768/2019, PL nº 1.218/2020, PL nº 4.178/2020, PL nº 299/2021, PL nº 3.461/2021 and PL nº 3.996/2021), that intend to regulate only some specific issues related to ARTs, such as the establishment of inheritance rights for children born from the use of *post mortem* ARTs, stem cell research, establishment of criteria for the operation of ART clinics, etc.

However, while such regulation is still pending, one cannot fail to consider that the medical field plays an important role in the establishment of parameters for the application of ARTs, especially when one observes the importance of the use of bioethical postulates. This is because innovations in the scientific field have singularities that cannot be disregarded – providing improvements in the quality of life and in human development – but, at the same time, implying ethical-legal repercussions that cannot be forgotten.

In this sense, Bioethics unveils itself in an attempt to understand and study the possible repercussions to be generated by biotechnological advances, creating a kind of guideline for the attitudes of biomedical professionals, in order to preserve ethics in actions and the Dignity of those involved. It is through it, as an autonomous field of knowledge, that the ethicality and legitimacy of certain treatments undertaken in the doctor-patient relationship can be assessed. For this, it uses its own postulates that should guide the conduct of professionals in the biomedical field, finding in the Principialist Theory, improved by James Childress and Tom Beauchamp in their book "Principles of Biomedical Ethics" (1979), perhaps one of its main guiding landmarks.[38]

In it, four basic principles are listed: a) *Autonomy* – determined by the respect for the patient's self-determination regarding the treatments implemented in him/her, and must always be preceded by free and informed consent; b) *Beneficence* – prioritizing that the health professional always promote benefits to his/her patients; c) *Non-Maleficence* – based on the motto *"primum non nocere"*, which imposes on these same professionals the duty of not causing harm to patients; and d) *Justice* – which presupposes an equitable distribution of biotechnological resources.[39]

It is said, then, that supported by these various principles, Bioethics seeks to preserve respect for living beings in the face of advances in science and new technologies, being crucial to the promotion of human protection in biomedical relations. On the other hand, it is worth mentioning the ponderation made by Heloisa Helena Barboza[40] when she calls attention to the fact that it is imperative that external control models be clarified, and that one cannot rely solely on the autonomous self-restrictions of the ethical field. Thus, we speak of understanding a Biolaw that is formed by the intersection between the legal field and Bioethics, considering that the former is endowed with adequate means to enforce respect for the basic assumptions that compose it.

For this, it is crucial the respect and the observance of the fundamental principles and guarantees, printed in the Federal Constitution – among which we can mention: (i) the *Dignity of the Human Person* (art. 1º, III); (ii) the *Solidarity* (art. 3º, I); (iii) the *Family Freedom*, specially the one focused on a free family planning (art. 226, §7º); (iv) the *Family Equality* (art. 226 caput and §5º and art. 227, §6º); (v)

[38] D. Diniz, D. Guilhem, *O que é bioética*, São Paulo: Brasiliense, 2012, 38-39.

[39] M.C.C. Brauner, *Direito, sexualidade e reprodução humana: conquistas médicas e o debate bioético*, Rio de Janeiro: Renovar, 2003; A. M. Soares; W. E. Piñero, *Bioética e Biodireito*: uma introdução, 2. ed., São Paulo: Edições Loyola, 2006.

[40] H.H. Barboza, *Princípios da bioética e do biodireito*, in *Revista de Bioética*, 8, 2, 2000, 209-216, 212-213.

ISSN 2284-4503

the *Prohibition of Any Form of Discrimination* (art. 3, IV);[41] and, (vi) the *Protection of the Genetic Heritage* (art. 225, §1, II)[42] –, so that CFM's Resolutions cannot oppose or restrict the rights enshrined in such precepts.

In this sense, it is now necessary to analyze the application of ARTs from the ethical-legal dictates of these areas of knowledge. To this end, the Principialist Theory of Beauchamp and Childress will be adopted. Furthermore, knowing that this is not an exclusively Bioethical approach, but also a legal one, the application of Fundamental Rights in the private sphere and its protection against the advances in biotechnology will also be taken into consideration.

Regarding the principles of *Beneficence* and *Non-Maleficence*, it is expected that the professionals who are part of the staff of the Clinics, Centers or Services of application of the ARTs always take into consideration the welfare of all people involved in the procedure, whether they are the beneficiaries, the surrogate mother or the child to be conceived. Therefore, it is important that there is due attention to all biopsychosocial and technical criteria that involve this process, such as age limits, the risks of the procedure, care to avoid the occurrence of multiple pregnancies, control of infectious and contagious diseases, the pregnant woman's health status and prenatal care, the suggestion to use the most appropriate techniques for each specific case, respecting the patients' autonomy, etc.

Regarding the principle of *Autonomy*, it is important to say that, given the multiplicity of existing techniques, it is important that the Clinics, Centers or Treatment Services take due care to provide their customers with clear and understandable information, and must make their professionals available to them to answer any questions about the efficiency and appropriateness of the techniques indicated, including information on the results obtained with that specific technique in that unit, focusing not only on the advantages of the techniques, but also emphasizing the risks.

Regarding the principle of *Justice*, when dealing with ARTs, it is necessary to call attention to the high costs of these techniques, a reason that hinders their diffusion in the most varied social layers. Currently, there is an offer of some of these services in the Brazilian public health system, free of charge, but even so, it does not cover all regions of the country, nor the wide range of techniques available today. Moreover, although it is important to implement this model of public policy, numerous barriers present themselves as obstacles to the expansion of its effectiveness. Among them, the State's ability to pay for these treatments, one could say, is the main one.

Finally, it is important to emphasize that the use of these principles does not occur in isolation, on the contrary, there must be a harmonization in their application, in order for the ethical interests to be best envisioned. Furthermore, as said before, the Biolaw cannot be based only on the incidence of

[41] For more detail on the scope of these principles, see M.C.F. DA SILVA NETTO, *Planejamento Familiar nas Famílias LGBT: desafios sociais e jurídicos do recurso à reprodução humana assistida no Brasil*, Belo Horizonte: Fórum, 2021.

[42] While a specific beacon in Family Planning, one can incur in the interpretation of the protection of diversity in the human genetic heritage, from the joint interpretation of this device with art. 2 of the Convention on Biological Diversity of 1992 in order to establish limitation to the procreative autonomy in face of the disruptive advancement of ARTs in the field of genetics, when looking at editing techniques such as CRISPR-Cas9 (See, C.H.F. DANTAS *Aprimoramento genético em embriões humanos: limites ético-jurídicos ao planejamento familiar na tutela da deficiência como diversidade biológica humana*, Belo Horizonte: Fórum, 2022).

Bioethics on biomedical relations, so it is necessary to combine its use with the respect for the fundamental rights stamped on the Constitution. Therefore, as we are talking about freedom in the performance of the parental project and in the formation of family entities, all those principles that guide Family Law today – with emphasis on the Principle of Dignity of the Human Person – as well as the guidelines that guide the exercise of Family Planning also apply to these cases, namely: a) the human dignity itself (of those who plan the parental project and the future child) and responsible parenthood as limits; and b) the freedom of the beneficiaries as the north of its exercise, meaning they should be free to choose whether or not to have children, how many children they wish to have, what is the time spacing between these children and in what way they will have them (whether through natural human reproduction, any of the modalities of socio-affective parenthood or through the use of ARTs), forbidden any forms of state coercion in this decision-making.

4. Final Considerations

A comparative analysis of these Resolutions was made (being 8, in total, so far). In view of this study, it was realized that, despite the CFM creates ethical guidelines and minimum parameters for the use of ARTs, these criteria do not always show observance of rights and guarantees that have already been achieved in legislation or case law on the Brazilian family law. In this sense, the following stand out:

(A) the right to access these procedures was assured, in the Resolutions, to heterosexual people, homosexual people, especially after the decision of the STF, and transgender people, not requiring a particular marital status and also being admitted its post mortem realization, provided there is express authorization of the owner of the genetic material in this sense;

(B) the maximum age of the candidate for pregnancy is 50 years old, with exceptions justified by the attending doctor and respecting the patient's autonomy;

(C) the need for the joint construction of a term of informed consent, explained in detail, and resulting from a bilateral discussion between the medical team and the patient;

(D) the prohibition of sexing and the choice of any other biological characteristic of the child, except to avoid diseases in the offspring;

(E) the establishment of a maximum number of embryos to be transferred, according to the age range of the recipient or the characteristic of the embryo: a) up to two for patients up to 37 years of age; b) up to three, when they are over 37 years of age; and c) up to 2, when these embryos are euploid, embryo reduction being expressly forbidden;

(F) regulation of the anonymity of sexual gamete donations – except in cases of donors related up to the 4th degree to at least one of the recipients –, with revelation of the donor's civil identity not being authorized in other cases, leaving the choice to the users, when resorting to gametes or embryos banks, and to the doctor, when making shared donations, observing the phenotypic characteristics of the recipients, and establishing a maximum limit of 2 pregnancies of children of opposite sexes in an area of one million inhabitants. Furthermore, the maximum age for making this donation is 37 for women and 45 for men, and the practice of shared oocyte gestation is admitted, as well as the cryoconservation of gametes and embryos;

(G) pre-implantation genetic diagnosis is allowed in order to: a) identify genetic alterations causing diseases; or b) to establish the HLA-compatible system typing for the realization of the "savior sibling" technique;

(H) the recognition of the possibility of using the practice of surrogacy, provided that it is free of charge and that the surrogate mother – having at least one living child – belongs to the family of one of the beneficiaries, in consanguineous kinship up to the 4th degree (mother, daughter, grandmother, sister, aunt, niece, cousin), with the observation that the restriction to this type of kinship does not apply, in view of the equality established by the Constitution and the Civil Code. In addition, exceptionally, pregnant women who do not fit the kinship criteria can be admitted, provided there is a prior opinion from the CRM authorizing it.

Such regulation, therefore, is still very incipient, because it is merely deontological rules aimed at directing the professional conduct of doctors in the use of ARTs, never having legal force capable of assigning filiation to couples submitted to them. In light of this, there is a need to resort to the fundamental principles and guarantees listed in the Federal Constitution in order to preserve the respect for the legal order and its postulates of protection of the human beings and their Dignity.

ISSN 2284-4503