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**MEDICALLY ASSISTED HUMAN
REPRODUCTION - LEGAL AND MEDICAL
CHALLENGES IN THE CONTEMPORARY
SOCIETY**

- DOCTORAL THESIS (*summary*) –

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In a society that supports and protects democratic values, the human being is manifested above all, so that people and their vocation of having, over time, a blood relation with their parental origins, as the foundation of family unity and stability, represents a source of order and justice in the entire social life, the ultimate goal of social order. For this reason, the society needs to have an open and permanently evolving moral shield, justified by the complete human freedom which generates the full responsibility of their actions and makes what is moral to be also legal and what is legal to be presumably also moral.

Medically assisted human reproduction is one of the extravagances of scientific research, which launches interdisciplinary challenges for the contemporary society that bring together - in terms of the debate and decision - the medical community, supporters of ethics and religion, of social and human sciences, in a framework that cannot, and especially must not ignore the rule of law.

Addressing the theme of medically assisted human reproduction from a strictly legal point of view is not possible, and this paper aims to build on the bioethical context, taking into consideration the theological reflections on the current reality, but without ignoring the medical details that make it possible to understand the necessity for regulations to provide the person with the guarantees of their being and of the individual or couple manifestation, in line with their life beliefs, religious affiliation and complete freedom of will.

Assisted human procreation and the conception of a child ensure the observance of the exclusive and inalienable human right to become a mother and father through each other, but also by resorting to safe medical procedures, which exclude risks. The current biomedical techniques complement the natural procreation act by a heterologous fertilization process that respects the rights of the child and ensures the parentage relationship necessary for the development of their personal identity. The origin of a human person is the result of an act of giving, and the child conceived through the intervention of medical and biological techniques is not equivalent to reducing it to an object of scientific technology, since it remains the fruit of the parents' love, who only recourse to technical efficiency conditions.

The legal regulation of the medically assisted human reproduction and of the dignity of

procreation, with the underlying principles of equality between people and respect for every person, is the goal of just laws.

The research is structured into four chapters, including several subchapters and sections, grouped around the information that we considered useful in understanding the reality that the contemporary society is facing when discussing the medically assisted human procreation act.

Chapter I - Medically Assisted Human Reproduction, is dedicated to general notions concerning this reproduction medical therapy, covering basic concepts, definitions, indicating the medical techniques known and practiced in connection with medically assisted human reproduction, without ignoring the controversy that these biomedical developments has generated in society.

Infertility was defined as “*the inability of a couple to conceive after one year of intercourse without contraception, or otherwise, as a reduced ability to conceive compared to the general population.*” As a result, a distinction between infertility and sterility is required; *sterility* is the inability to procreate, while *infertility* is the inability to give birth to children, i.e. to maintain pregnancy and give birth to a living child. The role of the medical reproduction act was, since the beginning, one of remedy against sterility or infertility or to avoid the transmission of severe or genetic diseases and has become, in recent years, besides adoption, an alternative to having children. The development of medically assisted reproduction techniques is justified, on the one hand by the progress of biotechnology, and on the other hand, by the increasing interest of persons unable to conceive naturally, to whom this “artificial” solution offered the opportunity to be the beneficiaries of guaranteed own parental biological material, of at least one of the couple partners, sometimes of both partners.

The temptation to resort to these medical techniques at the expense of the adoption process often reflects a couple’s desire to have their own children, but here cannot be ignored either of the following: the cumbersome adoption procedure, the small number of the children available for adoption in relation to that of the requests for adoption, issues of non-compliance with the conditions of adoptive family certification, etc.

Among the various definitions that were given to this medical procedure, we noted the one issued by the French Law (Law no. 94-654 of July 29, 1994 on the donation and use of human body products, medically assisted procreation and prenatal diagnosis), the concept of “*medically assisted human reproduction*” (*MAHR*), combining “*the totality of clinical and biological gestures that allow in vitro fertilization, embryo transfer and artificial insemination or*

other equivalent techniques, allowing the procreation outside of a natural process.”

The enumeration of the medical techniques, with a brief presentation of their characteristics, was intended for informational purposes on several medical terms to be mentioned later in the paper.

To understand, in a much more applied manner, the impact of scientific and medical research results on individuals and society, we considered necessary to review those medical terms that may lead to the understanding of reason in discerning the consequences that each person could be confronted with. Of course, the existence and application of these medical procedures, which are centered on the human being, were not exempted from controversy, particularly due to the lack of a clear legal protection, which led, as any pioneering act, to a debate on the pros and cons.

The establishment of criteria for the selection of implementing rules on medical reproduction techniques should be in line with both the rights of individuals participating in the medical act and the rights of the unborn person. As a result, the options of the applicants comprise the following:

- 1.) *Techniques to facilitate the in vivo fertilization* - inside the woman's body -, such as: a) the technique of artificial insemination by: intracervical insemination, intrauterine insemination, intraperitoneal insemination and intratubal insemination; b) gamete intrafallopian transfer technique and c) intravaginal culture;
- 2.) *In vitro fertilization techniques* - outside the woman's body -, such as: a) the technique of *in vitro* fertilization with embryo transfer and b) techniques with equivalent effect to *in vitro* fertilization: zygote intrafallopian transfer technique, the tubal embryo transfer technique, intracytoplasmic sperm injection, subzonal sperm insertion and the peritoneal transfer of ovum-sperm;
- 3.) *Other reproductive methods and techniques* such as: *in vitro* maturation, blastocyst transfer and ooplasmic transfer.

It is necessary to note that medically assisted human reproduction techniques can use the genetic material of the couple (intra-marital medically assisted reproduction techniques) or the genetic material of a donor (extramarital medically assisted reproduction techniques).

The implementation of IVF techniques raises a number of issues, dilemmas and debates, from those related to the biological sciences to those related to ethics, sociology and law. Among the topics that have attracted the public attention by invoking the undermining of the traditional

family values and which generated the most controversy, we noted the following: the origin of gametes, the dehumanization and medicalization of the reproduction health process, the fate and number of embryos, the embryo and parental statute, the statute and implications of using surrogate mothers, the risk of confusion on sperm donors when using genetic material that was donated and stored in sperm banks, the selection of the semen, posthumous children, financial consequences, sexual orientation of the parents, maternal age, experiments on embryos.

Reaffirming the view that the progress of genetics, biotechnology and of current medical techniques tend to give humans the immediate and uncontrolled power of management and manipulation of the biological individuality, we support the need for a multidisciplinary and cross-cultural dialogue, having as starting point the observance of the ethical criteria. Only moral rules may constitute the solid grounds to remove opinions according to which the reproduction without sexuality generates the risk of turning the human being into an object. The scope of any regulation cannot ignore the protection of the individual constitutional rights and the legislation regarding the medical research and its impact on the human being, is required to be issued in a responsible manner and based on the exhaustive knowledge and acknowledgement of the principles of bioethics.

The examining of the most important ethical issues raised by the impact of new human reproduction technologies took into consideration that casuistry that generated the strongest debate and, to determine what is moral or immoral, what is legal or illegal in this field, the views of all those involved must be considered, because the truth can be determined only as a result of a dialogue between the multidisciplinary specialists involved.

Any analysis in this area should not ignore the principle according to which the evolution of the scientific world has as the main beneficiary the human being, and precisely in compliance with this principle, it is necessary that the public opinion should be informed. The correct information of society brings it closer, by each of its members, to controlled results and uncompromised ethics. The reality of the last decades has shown us that the evolution of medical techniques and biotechnology has been highly dynamic and it determined new approaches and concepts related to the human body and its parts. At the same time, individual freedom must be protected against any form of biomedical abuse, and biosciences should not substitute natural acts, they should not intervene by irresponsibly modifying the human reproduction process. Therefore, we share the view that the promotion of bioethics is to fill in any legal void and to accelerate the issuance of regulations in the field of medical research.

Bearing in mind the certainty that bioethical issues cannot be completely covered by the presentation in our research, we consistently support the opinion that ethics remains the bridge between the subjectivity and objectivity of the field discussed, in a manner which would allow it to capitalize the human aspect of the scientific truth.

Although the initial fundamental thesis of the applicability of these techniques concerned their use only in situations where conventional treatments - medication or surgery - did not work, the religious communities qualify these acts as being substitutive and manipulating, by which the human being is pushed to overcome the natural order. The birth of a human being remains a unique and unrepeatable event and the international scientific community as a whole does not aim to overcome certain natural limits or to transform the procreation act into an act of human being prefabrication. Cutting-edge biotechnology with a more extensive influence of genetic engineering creates for the people the prerequisites for true "orders" of life, disregarding human dignity, so that the two basic elements of the human being - the life and dignity of the person - remain starting points for the different religious communities that watched with interest these scientific facts and supported reasoned opinions based on biblical concepts.

But the law cannot interfere by ignoring traditions and religious beliefs, as the respect for woman and man, as well as the child that is born cannot be limited to practices and norms that exclude the spiritual relationships between human beings.

Although varying from one religion to another, the theological positions on medically assisted human reproduction, but also on all actions that precede or follow it, are mostly in agreement when they do not consent to the artificial intervention in the human reproduction act, because Life is a gift from God, not a manufactured product. Considering that the love between a man and a woman is always an intimate aspect of the Christian life, theologians rejected the medical techniques which depersonalize procreation and supported individual accountability.

Reviewing the positions expressed by the major religious communities (Judaism, Islam, Hinduism, Protestantism, Anglicanism, etc.) we decided to take a deeper view on the Christian position.

Undoubtedly, the Catholic Church has a well-developed position regarding the medical facts and, in terms of medically assisted human reproduction, the position is of a firm rejection of any procedures of this kind. Ever since 1956, the Vatican, through the authorized voice (Pope Pius XII) declared medically assisted reproduction - MAR - as immoral and illegal because it separates the human procreation from the intimate communion of life partners. From this point,

the opinion of the representatives of the Catholic clergy has not become more flexible, arguing that this type of biotechnology, called even “biotechnology adventure”, cannot inspire confidence and the Catholic teaching is concerned about the uncontrolled development of these methods. Last but not least, the attitude of rejection of these medical practices was motivated also by the existence of huge economic interests (medical, pharmaceutical, technological, etc.) that might be behind these medical developments and the pressure of commercial interests would prevent real and honest information of the interested people.

As we belong to a people who have an Orthodox majority, the Orthodox theology attitude is the one that should be of interest both for the individual and the community, as well as for the multidisciplinary specialists. And because between bioethics and theological reflection there should be no unreasonable divisions, the interest raised by bioethical issues was also reflected at the level of the Holy Council of the Romanian Orthodox Church. Although in 1992, it was decided to establish an advisory committee to make proposals to the Council on the issue of the Church’s attitude towards the issues raised by the bioethical reality, this committee was never established, and medical interventions claiming the morality of the medical act remained unattended on the agenda of the Council. By 2004-2005, the only documents issued by the highest authority of the Romanian Orthodox Church were related to three themes: organ transplantation, abortion and euthanasia, while topics such as medically assisted procreation, contraception and cloning have not yet determined a position of the Holy Council. From the text of the documents issued by the Holy Council of the Romanian Orthodox Church on the bioethical issues analyzed, is to be noted the Christian attitude towards people, substantiating the notion of “human dignity” on the spiritual values.

Although these synodical views are purely for spiritual guidance for the persons in a position to decide on bioethical issues, the lack of their existence for the topics discussed above reveals an insufficient involvement on behalf of the representatives of the Orthodox Church, with the consequence of increased suspicions and uncertainties, whose estimation was overcome by reality facts. Equally, the representatives of the Orthodox clergy believe that the Christian morality has the inner strength to meet the new challenges of bioethics, although the analysis of situations and drawing conclusions have become more complicated than before. This is precisely because the Christian principles of moral attitudes towards the fellow people and ourselves remained the same and they will not change, as the spiritual mission remains the same: the salvation of people, regardless of the age in which they live and its challenges, but without

forgetting that the Orthodoxy also proclaims: “When a woman gives birth, she touches God’s hands!”

The social and psychological implications accompanying the access to these medical reproduction techniques cannot be ignored, so that the regulations concerning this field should establish rules on advising and informing people about any type of risk, including psychological, social, economic, legal, etc. risks. Only under these circumstances will be the psychological comfort provided that is necessary for an objective option with regards to medically assisted reproduction.

Regarded as a psychological entity, the infertile couple can become the holder of feelings of inferiority, helplessness, guilt, frustration and even isolation, these often leading to a wrong self-evaluation by each partner of the couple, whereas the decline of self-esteem allows for depression. Therefore, psychology experts have legitimately proposed the psychological testing of the partners in sterile couples, with the priority purpose of investigating their potential for parenthood, as it was found that sometimes infertility may be due to a fear of becoming a parent, of assuming the parental responsibilities. For a complete health assessment, in which mental health is a priority, the clinics in the field have a duty to perform a psychological evaluation of the beneficiaries, with the inclusion of a document agreed by them under the form of a psychological consent. Precisely because resorting to medically assisted reproduction techniques creates so strong hope in solving infertility issues for the partners, the use of these should occur after effective and efficient information of both partners, and the psychological counseling should include both the procedures to be performed but also the risks and success rates.

It is necessary, therefore, that those who face infertility problems to seek the benefit of specialized psychological counseling and be advised to participate in information programs related to medically assisted human reproduction. Certainly, the current communication possibilities, the advertising and forums launched on the internet in inventive formulations can easily influence the people interested in the matters of medically assisted reproduction, but specialized communication is preferable to any informal discussion.

Chapter II - Medically Assisted Human Reproduction with Third Party Donors, presents the characteristics of the donation, as legal act and act of liberality and the concept of third party donor with medical references to the donation of genetic material, and analyzes the current regulations of the Romanian legislation regarding the medically assisted human reproduction with third party donors.

This presentation on the legal act of donation was aimed at understanding precisely those elements that are required for the validity of the donation in general, and to determine the legal attributes according to which an act of donation of genetic material is compliant with these requirements.

In our opinion, the donation of genetic material must be contained in a legal document called donation agreement that the donating person must be aware of and understand, and the agreement of will should be expressed following the correct information on the legal consequences arising from this. Therefore, the rigor of this type of contract must be included in such an agreement, in terms of the essential elements of the donation, but should also meet the conditions of validity. Regarding the mandatory condition that validates the donation contract in terms of the beneficiary of the liberality designated by the donor, we believe that it must observe the condition of anonymity, so that, given the “subject” of donation, it can no longer be regarded as mandatory condition, subject to the sanctioning of the agreement by nullity, so the provisions of Article 989, paragraph 3 of the New Civil Code no longer apply. In the same respect, we believe that the provisions of Article 1011, paragraph 1 of the New Civil Code cannot affect this agreement, the condition of authentic form should be one derogating from the peremptory norm of this type of contract. Establishing the fulfillment of the validity and the evidence conditions should be sufficient by signing a document between the donor and the duly authorized medical facility, and the donor’s manifestation of consent should lead to full irrevocability of the action.

Obviously, in agreement with the principle of confidentiality of these medical techniques, such a contract would not be made public and the medical unit would report these agreements to the competent authority. We appreciate that this authority would have the direct responsibility of establishing the terms of such an agreement, which should reconcile the reality of facts with the legal reality. Having regulatory powers, the competent authority that would be recognized by special law, would be able to provide this type of donation (which concerns the elements of the human body) with the legal requirements to protect the donors’ privacy and family life. Therefore, it is necessary that a donation agreement to be properly delimited by the general conditions of a contract of donation and to include those legal elements that validate the factual reality.

The medical options available for reproduction with third party donors offer nowadays the possibility for many couples to become parents. The development of these reproduction techniques, in which resorting to a third party donor is no longer an exception, but tends to be a

therapeutic normality, still requires a better understanding of the medical, ethics and legal issues concerning the persons involved. In this reality, the ultimate goal of the medical world and of the legal community is to allow these reproductive techniques to advance more and to bring joy and satisfaction for all parties involved in ensuring the conception and birth of a healthy child, with a legal status provided by well-defined rules.

Collecting the paternal genetic material by medical and technical means and its transfer to the mother's body for the purpose of fertilization can be considered a form of transplantation of human cells, which also explains why, at this moment, the performing of these therapeutic acts in the Romanian medical clinics obey the regulations of Law No. 95/2006 on Health Reform - Title VI - The harvesting and transplantation of organs, tissues and cells of human origin for therapeutic purposes.

The social realities and medical progress made by the Romanian society has generated many concerns to create a legal framework for medically assisted human reproduction techniques, given that enough eager people or specialists were attracted to find solutions by improvising within the existing regulatory framework.

With the entry into force of the New Romanian Civil Code (October 1, 2011) - Title III - Kinship, Chapter II - Parentage, Section 2 - it is also created the general regulation on medically assisted human reproduction with third party donors (Articles 441-447). Therefore, this regulation covers only those situations that apply to a person outside the parental infertile couple, the donor of reproductive cells, and aims to avoid any negative impact on family relationships without neglecting society in general. The recognition of the right of reproduction for infertile people should be analyzed with a legal judgment applied to all persons involved in the *act of procreation*, when medically assisted human reproduction with third party donor is performed.

Undoubtedly, since the purpose of resorting to these methods of reproduction is the child, its legal status is to be protected and well established so that the participants in the medical reproduction technology to have a clear view of the rights and obligations arising from this medical act and on the safety of subsequent social and family relations.

By "parents", the new Romanian civil regulation understands: "*a man and a woman or a single woman*" (Article 441, paragraph (3) of the New Civil Code). Therefore, the rule of law currently in force does not require the parental couple marriage, making no distinction between married and unmarried persons, reasoning sustained by the possibility of a single woman to become a parent. When the legislature referred - as a potential parent - to the "single woman", the

following situations were considered: the female person is unmarried, or not in a relationship with a life partner, or is even married but applies on her own to the procedure of medically assisted procreation.

The confirmation of this reasoning comes from Article 443, paragraph (2) of the New Romanian Civil Code which states that: “... *the mother’s husband may deny paternity of the child, under the law, unless consented to medically assisted reproduction performed by using a third party donor.*” Therefore, performing a medically assisted human reproduction technique for the women expressing their unequivocal consent, and under the law, is undoubtedly possible and allowed. What causes possible consequences, such as denial of paternity for the child conceived and born in this manner, is the lack of valid consent of the mother’s husband. Therefore, *the consent* of the persons resorting to assisted procreation is the foundation for performing these medical techniques, and also for the legal consequences of these therapeutic procedures. The essential condition regarding the consent must be satisfied by each of the parents, namely the parental couple - married or unmarried - or the single woman who wants to become a mother.

Therefore, the regulatory framework of the condition of consent is extremely rigorous, ensuring also the complete legal freedom of participants in medically assisted reproduction with third party donors, especially since Article 442, paragraph (2) section II of the New Civil Code recognizes to the future parents the validity of revocation of their manifestation of will up to the last moment preceding the moment of conception, even if declared in front of the doctor who provides the specialized care.

Valid consent but also revocation or the ineffectiveness of this manifestation of will have to take place, mandatorily, prior to any therapeutic steps aimed at performing any medically assisted human reproduction technique.

The legal guarantee of a therapeutic procedure performed under full observance of the law is the very purpose which the legislature had in mind when they regulated explicitly and expressly the fulfillment of the essential consent condition, but also its revocation or its ineffectiveness as a fundamental freedom of the individual.

We note that, based on the consent of the participants, the provisions of section 2 of the New Romanian Civil Code, establish the following:

- *The legal relationship between the child and the third party donor;*
- *The legal relationships between the third party donor and parents / parent;*
- *The relationships between parents / parent and child.*

The analysis of the possibility of establishing paternity and paternity denial leads to what the new civil regulation establishes: *the liability of the father*.

The liability of the father is determined by judicial action, for the situations in which the mother's partner, who consented to the medically assisted conception with third party donor, refuses to acknowledge paternity of the child born in this manner. The legal norm indicates the father's liability both to the mother and to the child. Regarding the child, the liability arises from the possibility of establishing paternity by judicial action and leads to all legal effects that such action produces about parental liability, including financial child support.

To the mother, the liability is that provided for in Article 428 of the New Civil Code, relating to the establishment of economic obligations to be paid by the father. The mother's right to compensation is dependent on the legal action to establish paternity, which in practice will become the main claim and the claim for compensation will become subsidiary. The admission of such legal action will decide both on the legal status of the child born through assisted procreation, but can also regulate the relations of obligation arising from the establishing of this statute, involving the child and the persons whose parentage was established in relation to the child.

Chapter III - Issues of Privacy in the Medically Assisted Human Reproduction System debates the notion of "personality rights" in agreement with the concept of "private life", provides a summary of the evolution of the statutory individual privacy rights and aims to discuss the issues of the beginning of life.

The private life, beyond concept and regulation, must be regarded as central to the legal protection of the individual, and the analysis of its aspects related to medically assisted human reproduction was considered to be appropriate. From the desire to overcome the legal concept of civil rights and obligations holder, the analysis of the concept of human being as a complex reality that combines the law with biology, considered the moment of the beginning of life and the boundaries between which the legal protection can be manifested. The observance of the privacy and dignity of the person are rights that have been harnessed by explicit rules and have found the legislative support required in many international regulation frameworks.

Until the coming into force of the New Civil Code (2011), the regulation of personality rights was included in several acts, such as the Constitution, Decree no. 31/1954, the Family Code, Law no. 95/2006 on Health Reform - Title VI - The harvesting and transplantation of organs, tissues and cells of human origin for therapeutic purposes; Law no. 46/2003 regarding the

patient rights, as well as in international sources of Civil Law, such as the Convention on the Rights of the Child, ratified by Romania by Law no. 18/1990, the International Covenant on Civil and Political Human Rights, ratified by Romania by Decree no. 212/1974, the Convention for the Protection of Human Rights and fundamental Freedoms, ratified by Romania by Law no. 30/1994 and, last but not least, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Convention on Human Rights and Biomedicine signed in Oviedo on April 4, 1997 and the Additional Protocol to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the prohibition of cloning human beings, signed in Paris on January 12, 1998 and ratified by Romania by Law no. 17/2001.

The observance of the private life and dignity of the person are rights enhanced by the explicit inclusion in the new regulation, noting that, in the matter of the harvesting of organs, tissues and cells, as part of the provisions of the New Civil Code, there are no new additions.

The legal regime in which the statute of the human body does not remain a mere legal fiction includes the moment of beginning of life, respectively the human embryo. Knowing the moment, at which a human being can be considered, constituted mainly the concern of those who were interested in the technical medical procedures involving human embryos and genetic manipulation. With the development of medical procedures and scientific research there was also outlined the need for legal protection of the human embryo.

Topics such as permissiveness of abortion and manipulating human embryos proved to be of permanent interest, with associative trends trying to militate in any way considered effective to impose their opinion. These multiple approaches, which are maintained by controversial medical cases, have not yet been outlined into sufficient arguments to support the emergence of clear regulations. Moreover, the requests for intervention of domestic and international supreme courts led to extremely conservative views, which often left in silence many of the expected answers. It is clear and understandable that a single point of view on human life before birth cannot be imposed, but the existing rules need to be interpreted in a positive way for the benefit of life and human beings. Currently, in the Romanian law, the right to life can be considered only at the moment of birth, when the intrauterine life ends, but any other concerns for the potential abuse of biomedical technologies from the moment of conception until the moment of birth, do not reflect the preoccupation to protect life in its early forms.

The rights and obligations of the participants in the medically assisted reproduction act,

but also the rights of child born through this therapeutic procedure, are aspects of privacy that should generate effective legislative concerns and the health of the person cannot be ignored.

Chapter IV - The Legislation on Medically Assisted Human Reproduction in the Romanian Legal System - Current State and Necessity covers the current regulations in this field, but also the legislative efforts that did not result in sufficient and specific regulation, and analyzes several existing regulatory models in the law of other states. The final part of this chapter contains a proposal for a new law to establish specific rules for such proceedings.

Up to the moment of this analysis there is no special law to supplement the general framework provided by the New Civil Code, but the social, medical and legal reality demands a serious preoccupation not to let the Title VI of the Law no. 95/2006 be the only regulation in the field of MAHR, and the medically assisted human reproduction with third party donor must find a detailed legal certainty, especially since the existence of these few articles creates a sufficiently grounded reference point for a serious and applied debate.

Due to the fact that the only medically assisted human reproduction procedures that were developed in the accredited facilities in our country are the *in vitro* fertilization and the artificial insemination, the legal framework under which the authorized medical facilities currently operate is extremely precarious.

Regulations in the field have succeeded one another as follows:

- 1998, when the first modern law on transplant was introduced in Romania - Law no. 2/1998 on the harvesting and transplantation of human organs and tissues, where all the conditions for the procurement and transplantation of organs and tissues were established;
- 2004, when Law no. 588/2004 appears, establishing the National Transplant Agency;
- 2006, when Law no. 2/1998 was replaced by Title VI "Performing the harvesting and transplantation of organs, tissues and cells of human origin for therapeutic purposes" of the Law no. 95/2006 on health reform, including a more detail chapter on the transplantation of cells and tissues. In 2009, when there was a legislative intervention on this legal norm (represented by the Ministry of Health Order no. 1156/September 23, 2009 to repeal Article 6 of the Methodological Norms approved by Order of the Ministry of Health no. 1290/2006) which incriminated the performing of any medically assisted human reproduction techniques aimed at obtaining profit and recognized the full effectiveness of the provisions of Article 158, paragraph (1) as follows: *"the organization and / or the harvesting of organ and / or tissues and / or cells of human origin for transplantation in order to obtain a material benefit for the donor or organizer, constitutes*

the crime of trafficking organs and / or tissues and / or cells of human origin and is punishable by imprisonment for 3-10 years.”

The only legal framework that refers more specifically to medically assisted human reproduction activities is the Health Ministry Order no. 1763 of October 12, 2007 establishing the technical requirements for the donation, harvesting, testing, processing, preservation, distribution, encoding and traceability of tissues and cells of human origin used for therapeutic purposes, as well as the reporting of serious adverse incidents and serious adverse reactions occurred during their transplantation. Being an activity subordinated to the National Transplant Agency (NTA), the procedure of harvesting human reproductive cells for therapeutic purposes is subject to the regulation mentioned above, in line with the European directives in the field of the donation, harvesting, testing and distribution of human tissues and cells, although often by references of exclusion from the general framework for harvesting and transplantation of cells, tissues and organs mentioned above. As a result, only the norms in Annex III of this order entitled *ANNEX III to the Technical Requirements - SELECTION CRITERIA and Laboratory Tests Mandatory for the Donors of Reproductive Cells* are intended exclusively for reproductive cells.

With regards to the legislative efforts concerning this field, there were two projects:

- the first Romanian legislative initiative was the subject of the Draft Law on reproduction health and medically assisted human reproduction, submitted to the Romanian Senate for debate under no. 334/May 3, 2004, and which was challenged in terms of constitutionality of several articles of the proposed law, and the Constitutional Court (July 2005) found that 27 out of the 36 articles of the proposed law were unconstitutional, which led to the rejection of the bill (February 2006);

- the second legislative initiative occurred in connection with the entry into force of the New Romanian Civil Code, when the Ministry of Health experts developed and submitted to public debate (in 2011) the Draft Law on medically assisted human reproduction with third party donors, but this project was unsuccessful because during the proceedings, the law was adopted by the Romanian Senate (on April 2, 2012) following the expiry of the period for adoption, and at the notification of the Chamber of Deputies the project was sent for discussion and approval to several parliamentary committees, including the Commission for Human Rights, Cults and National Minorities which granted, by majority, a negative vote.

Reviewing the legislation in several countries that we considered of interest, we tried to produce short summaries of the regulations in medically assisted human reproduction, noting that

the concern for this field does not always resonate with the state's economic development stage, that existing legislation creates a rather restrictive framework, but these rules do not neglect the medical reality or the interest that the members of these societies have shown for solving the problems of infertility. The demographic issues of each state are reflected in the social policies of each government program, but the State, through regulation and control, should not allow that, under the cover of topics of public policy, the procreative freedom be manifested in an unstable and obscure manner.

The final part of the paper was devoted to a legislative proposal, divided into five chapters, by which we tried to draw attention to the need for a specific regulation of these medically assisted reproduction techniques. The proliferation of artificial conception in recent years is the best clue by which the civil and the medical society could draw the attention of the legislative body in our country, and the indulgence of certain procedures - by the interpretation that they are not expressly prohibited by a legal text - must cease.

Of course, it is preferable that individual freedom should contain explicitly the right to access the medically assisted conception and this recognition be guided by specific legal provisions not only by interpretations of a regulatory framework created strictly for the medical field, interpretations that are either positive or negative and that can lead to consequences having a fragile legal coverage and can generate confusion.

The concerns regarding the Revision of the Romanian Constitution would be useful in connection with the medically assisted human reproduction, in the context in which infertility is one of the major problems that people have to face.

A possible constitutional regulation could be supplemented by a special law that should be intended solely for the field of medically assisted human reproduction.

We appreciate that the *first chapter* should contain only general provisions, which are subject to further provisions. From the beginning of the special law it should be specified its subject and the regulation principles that govern the law, establishing the purpose for such special law, in line with the fundamental rights and freedoms guaranteed by the national constitution, as well as it would prove necessary to establish an authority subordinated to the Ministry of Health, following the National Transplant Agency model, having the role of coordination, supervision, approval and implementation of any provisions relating to medically assisted human reproduction and that could be explicitly named The National Agency for Medically Assisted Human Reproduction.

Chapter II of the special law, we think, should be dedicated, in a more generous approach, to the medically assisted human reproduction technique, and the provisions should be presented in a configuration enabling a coherent regulation. For this purpose, we propose two sections: *Section I* to establish the general principles and *Section II* to establish the imperative conditions for authorization regarding the performing of these reproduction techniques.

In the category of general principles, based on the principle of the welfare of the child, it is necessary that the law establishes the individuals with access to these medical therapies by indicating the medical criteria, as well as the criteria of age, marital status, etc., and by mentioning explicitly which are the prohibited techniques. The conditions relating to information, counseling, consent and confidentiality are basic rules for performing any medical procedure, therefore, we think their inclusion in the general principles should not require a detailed explanation.

The specificity of this medical information and the consent required compel to strict rules because they represent the fundamental legal elements, and the legal consequences are essential, both for the beneficiaries as well as for the practitioners.

The second section is devoted to the authorization necessary to perform these medical techniques, both regarding specialized personnel and medical units, by providing strict sanctions for non-compliance. Certainly, the competent recognized authority in this field would have the responsibility of developing the explicit norms required for the authorization, procedures for approval and withdrawal of approval, possibilities for renewal and monitoring of these licenses, as well as sanctions/penalties.

With regard to the anonymity of the identity data and of the medical information belonging to persons participating in such medical reproduction techniques, we believe that the authority whose jurisdiction should be recognized in the field would be able to establish the specific terms and conditions of access to such information, based on own organization and operation criteria. What is desired from the special law is to establish the principle of guaranteeing confidentiality, as the anonymity cannot be protected against those who justify a legitimate interest in connection with a serious health condition, affecting them or their descendants.

Chapter III is devoted to activities involving the use of genetic heritage, establishing the mandatory provisions aimed at eliminating all forms of abuse of gametes or human embryos. Thus, any activity involving human genetic heritage is censured by the validity of the consent of

the person to whom it belongs, and the purpose of such use is solely for reproduction. The establishing of a time limit for the storage of gametes and conservation of embryos should be in line with the other provisions on the age of participants subject to the various artificial reproduction procedures.

Chapter IV sets out the general conditions which should govern any act of donation of the genetic material and the part dedicated to the donation of sperm reconfirms the permissiveness granted by the law to this type of donation, at this moment. Certainly, the biomedical developments that will find application in our country will require the supplementing of this framework regarding the donation of reproduction material, but we think that a special law, which would find its first consecration by the legislature, should not create a sense of procreative freedom in any conditions, the citizens would need a framework which should provide sufficient guarantees against abuse.

Chapter V is devoted to the prohibited practices, being a legislative assembly which explains those acts and facts that (especially practitioners) should control without reservation and whose gravity, by the medical and legal consequences they could generate, should be sanctioned by criminal law. We consider that the establishment of criminal sanctions, of prohibiting certain rights or regarding the application of severe financial penalties, in a combined or individual form, could be done also by means of the criminal law.

The final chapter brings into highlight the recognition of the role of the National Agency for Medically Assisted Human Reproduction as competent authority in the field of medically assisted reproduction, subordinated to the Ministry of Health, which would be empowered to develop the rules governing the organization and the activity of this institution.

Certainly, the topic of medically assisted human reproduction can benefit from multiple approaches, but this analysis has attempted to draw attention to the need for debate.

Undoubtedly, it is difficult to write about evolving facts and thus be subject to a risk of superficiality, especially since the analysis tools in the field of medically assisted human reproduction are quite limited at this point. The transfer of concepts and research methods from one field to another and combining them in an approach that aims at the normative regulation of the phenomena analyzed constituted the preoccupation of the present research, considering that it could contribute to the development of future approaches to the medical progress and regulations in the field, subject to review whenever required by adequacy and mentality changes.

What remains after all this is defined by one word: CHALLENGE.

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