

THE JUDICIAL REGIME OF THE BIOMEDICAL PRACTICES, IN THE LIGHT OF THE NEW ROMANIAN CIVIL CODE

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ABSTRACT: *The article represents a commentary of the main alterations brought to the judicial regime of biomedical practices (curative and predictive medicine, organ procurement, exam of genetic characteristics, medically assisted reproduction) by the adoption of the Romanian New Civil Code. The new legislative framework is intended to protect vulnerable persons from biological exploitation, objectification of the human body or genetically based discrimination. The legislator's option for requiring the existence of an explicit, written, unequivocal, free and informed consent of the organ donor indicates without a doubt that, in the light of the new legislation applicable in the Romanian law since October 1st, 2011, organ procurement and transplantation is no longer authorized on the grounds of a tacit or presumed consent, the donor's written, express assent thus being required. The second major characteristics of the new legislation are related to the regulation over the donor's legal right of retract, exercisable by the donor in cases in which he or she intends to modify or revoke the prior consent to the organ procurement, before the initiation of the procurement procedure. In the field of the medically assisted human reproduction, the requirement of a parental project reverberates over the validity of the future parents' consent, so that the death, the divorce or the simple physical and patrimonial separation of the potential parents will be automatically followed by the inefficiency of their consent. The principle of the non-objectification of the human body justifies the legal prohibition of the scientific research on human embryos. The latter cannot be seen as merely material objects of scientific research, the present legislation prohibiting the creation of human embryos in the absence of a parental project and in the sole purpose of scientific research.*

KEYWORDS: *predictive medicine, respect due to human beings, bodily integrity, organ transplant, eugenic practices, cell research, gene therapy, New Romanian Civil Code*

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1. INTRODUCTION¹

The Romanian New Civil Code, applicable since October 1st, 2011, replaces an obsolete civil legislation which has been applied since 1865 and the obsolescent character of which was obvious mainly in the sphere of the person's right of decision on his or her body and the legal guaranties of the respect due to the human being.

The progress registered by the predictive medicine raised the question of establishing the measure in which the predictive capacities of the science may represent a threat to the principle of equality between the human beings. The medically assisted procreation (MAP) also raises questions over the medical realization of the infertile couples' intent of becoming parents, as well as on the ethical and juridical foundation of the notion of "the conceived child's best interest". All these recent interrogations on the mentioned principles of bioethics were meant to facilitate the establishment of legal rules representing a warranty of "legal protection", as well as "ethical guaranties". Establishing a general legal framework for the exercise of biomedical activities in the text of the New Civil Code is also important from the angle of the scientific research on genetic characteristics and interventions on the genetic characteristics, as being a field in which each individual or collective decision reverberates on the status of future generations. That is one of the reasons why the legislator's was preoccupied with the ethical content of principles such as the respect of the human dignity, freedom of choice, equality and solidarity between human beings. In the area of biomedical activities such as the eugenic practices, any moral ambiguity would prove to be unsatisfactory for the researchers and medical practitioners, as well as for each member of the society.

In the text of the articles 58-81, the authors of the Romanian New Civil Code intended to establish the premises of a legal protection meant to avoid the potential biological exploitation of vulnerable persons, as well as the objectification of the human body or discriminatory biomedical practices based on eugenic selection.

The ethical values attached to the human being are grounded on the principle of bodily integrity, as a facet of the human dignity the respect of which the rules of bioethics are meant to ensure. In the common sense of the term, the person's right to bodily integrity implies the legal prohibition of all non-consented biomedical interventions, excepting those representing medical emergencies in the therapeutic interest of third parties (for avoidance of an epidemic disaster, for example). In accordance with article 64 of the New Civil Code, "The human body is inviolable. Each person has a right to physical and psychical integrity. No intervention over the person's bodily integrity is conceivable outside the legal, exceptional limits". It is thus from this perspective that the future laws of bioethics are meant to generate a more explicit meaning for notions such as the "bodily integrity", "therapeutically necessity" or "legitimate interest of third persons".

In addition, the New Civil Code texts insist on the *altruistic, non-onerous character of the organ or blood donation*, by refusing to judicially allocate a patrimonial value to the human body and by condemning as illicit the utilitarian approaches to the human body. According to article 66 of the New Civil Code, "All contracts having as an object the patrimonial evaluation of the human body or of one element or product of the human body are absolutely void, with the exception of the judicial acts enumerated by law". The new regulation is meant to protect vulnerable persons from mercantile practices

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related to organ procurement, which have the potential of violating the integrity of the human body.

Nevertheless, there are practices which imply conciliating the principle of bodily integrity with the rule of saving lives, as in the case of certain transplants. Therefore, it is necessary to distinguish between the principles of bioethics representing *categorical ethical commandments*, which allow no exception (a) and the ethical principles representing *conjectural ethical rules*, the applicability of which depends on certain concrete features (b).

The therapeutic finality of a biomedical activity (palliative medical intervention over the human body, intervention on the genetic characteristics, and the exam of genetic characteristics) represents no justification in itself of the ethical or legal character of that practice. The therapeutic purpose (as opposed to the military or cosmetic purpose, for instance) may represent a condition of admissibility (of authorization) for the respective medical practice, while no ethical criterion may be extracted from it. The ethical principles of human dignity (a) and of non-objectification of the human body and the respect due to the diversity of the human species (c) are surpassing the importance of the strictly therapeutic finality of a biomedical practice, either palliative or curative.

2. THE NON-OBJECTIFICATION OF THE HUMAN BODY PRINCIPLE

2.1. Inviolability of the human body

While, before the entering into force, on October 1st, 2011, of the New Civil Code, the person's right of decision on his or her body was not expressly stated in the Romanian legislation which only made punctual application of the mentioned principle, the new regulation eliminates this lacunaria, also by enumerating in the text of article 60 the legal *limits* for the exercise of this right ("Each person has the right to decide on his or her body, while not violating other person's rights and freedom, the public order or the good morals"). The guaranties of the non-discriminatory exercise of the fundamental human rights are postulated in article 61, according to which "The life, health, physical and psychical integrity of each human being are equally protected by law". The second paragraph of the cited article is also important, as it stipulated that "The human being's best interest outrun the importance of the collective interest of society or science". The ethical rule postulated in article 61 is strongly correlated with a group of bioethical principles, such as the freedom of decision, the inviolability of the human body (expressly sustained in article 64, according to which "The human body is inviolable") and the principle of non-objectification of the human body.

The principle of non-objectification of the human body is thus postulated for the first time in the Romanian legislation, the New Civil Code also establishing the consequential rules derived from this ethical principle: (a) the scientific research over the human body (in the collective interest of society) cannot overcome the individual's interests; (b) the patient's refuse to be subjected to a research practice blocks its initiation as illicit; (c) the therapeutic finality of a biomedical act does not justify in itself the ethical character of the act, in the absence of the concerned person's consent. In accordance with article 67 of the New Civil Code, "No person will be submitted to scientific experiments, tests, organ procurement, medical treatments or other therapeutic or scientific interventions except in cases and under conditions fixed by law". One can observe, in the latest phrase of the cited legal text, the evocation of the necessity of adopting, in the Romanian law, of

future laws on bioethics, which would solve any left details on such biomedical practices. As long as the first desideratum is concerned, that of preserving life, it has been underlined in specialized literature that patient's right to self-determination – always personal and concrete – exceeds state's abstract interest in ensuring health care for its citizens and in preserving life.

2.2. Organ transplant and organ procurement from living donors

Organ transplant and organ procurement from living donors are regulated by article 68, according to which “(1) The organ transplant and organ, tissues and cells procurement from living donors may take place in the cases and under the conditions expressly established by law and under the donors' free, written and express consent after being informed on the risks of the intervention. In all cases, the donor has the right to retract his or her prior consent, before the initiation of the procurement procedure. (2) The organ, tissues and cells procurement from minors as donors or from mentally challenged persons, due to a mental handicap, a mental disease or other mental disturbance is forbidden, except in cases regulated by law.”

As opposed to the former legal attempts, the New Civil Code radically modifies the legal optics over the importance of the *donor's express consent*, the legislator thus renouncing at the idea of the tacit or presumed consent, grounded on the imperative of saving lives. The judicial and ethical consequences of the new regulation may be synthesized as follows: (a) the donor's written assent, expressly given, is necessary for organ procurement from living donors, while the verbal consent produces no legal effects; (b) the medical staff has the duty to thoroughly inform the donor on the risks of the intervention; (c) compliance to the mentioned duty to inform must take place with no infringement on the donor's free will; (d) *the donor's legal right of retract* may be exercised in any moment before the initiation of the organ procurement procedure; (e) the absence of the donor's veritable consent, in cases in which the donor's mental state does not allow him or her to fully understand the medical repercussions of the organ procurement, makes impossible the legal initiation of the procurement procedure. Thus, the organ procurement from living donors is legally excluded in the case of minors and mentally challenges persons.

The legislator's insistence on the necessity of the donor's *written, free, express and informed consent* unequivocally indicates that, starting from October 1st, 2011, on the Romanian law, organ procurement is no longer legal under a tacit or presumed consent, in the absence of the living donor's express and written consent. The second major characteristic of the new legislation is that of establishing a veritable *right of retract* allowing the donor to revoke his or her prior consent to the organ procurement, before the initiation of the medical procedure involved. The legal right of retract allocated to living donors is derived from the principle of the inviolability of the human body.

2.3. Prohibition of eugenic practices

Medicine is concerned with curing patients, not with eliminating them, as underlined by specialized literature². The New Civil Code expressly forbids eugenic

² See, for details on the legal issues raised by cell research, predictive medicine, gene therapy, surplus embryos usage and genetic choices, T.L. Beauchamp, J.F. Childress, *Principles of Biomedical Ethics*, 5th edition, Oxford

practices, by retaining in article 62 that “(1) No one is allowed to make an infringement over the human species. (2) All eugenic practices aiming to organize a selection of the human beings are forbidden”. The Romanian legislator was preoccupied of avoiding the potentially eugenic effects of the uncontrolled use of predictive medical practices (as the pre-implant diagnosis and the pre-natal diagnosis). The new regulation thus excludes the possibility of using the predictive medical techniques in other purposes than avoiding a malady (as, for instance, choosing the child’s hair or eyes color or choosing the child’s sex for other purposes than avoidance of a malady associated to the child’s sex).

In addition, it is excluded by law the use of genetic interventions as a meaning of eradicating the birth of persons suffering from certain maladies, as the eugenic use of the pre-natal diagnosis is illegal. *The principle of the diversity of the human species* is thus seen as a central bioethical rule, while admitting that neither the malady, nor the presence of a handicap alters our humanity.

2.4. Interventions on the genetic characteristics

The exam of the genetic characters of a person “may not be undertaken in purposes other than medical or for scientific research, under the conditions fixed by law. The identification of a person on the basis of his or her genetic prints may not be undertaken unless a civil or criminal judicial procedure has been initiated or, upon the case, for medical or scientific purposes, , under the conditions fixed by law” (art. 65 of the New Civil Code). After the entering into force of the new code, “(1) All medical interventions over the genetic characteristics of a persons on the purpose of modification of the person’s origins are forbidden, except in cases in which the prevention and treatment of genetic maladies is necessary. (2) All genetic interventions oriented towards the creation of a human being identical to another human being, deceased or alive, as well as creating human embryos in the sole purpose of scientific research are forbidden. (3) The use of the medically assisted reproduction techniques is forbidden when oriented towards choosing the sex of the conceived child, with the sole exception of preventing a serious hereditary malady associated to the child’s sex” (art. 63).

The main legal innovations brought to the judicial regime of the interventions on human genetics by adopting the New Civil Code may be resumed as follows: (a) the genetic modification of a person’s biological origins is forbidden by law, unless is oriented towards the prevention and treatment of genetic maladies; (b) the therapeutic finality of the genetic intervention, although not justifying in itself the ethical character of the medical act, represents a compulsory condition for the acceptance of the legal character of the biomedical practice. Two other important legal prohibitions postulated by article 63 are worth noting: (1) cloning of human beings is forbidden by law; (2) the creation of human embryos in the sole purpose of scientific research, without the existence of a “parental project”, is prohibited.

University Press, 2001, p. 88-116; A. Bugada, L. Grynbaum, C. Guettier, *Prevention des risques*, Presses Universitaires d’Aix-Marseille, 2006, p. 34-56; B. Gert, C. M. Culver, D. Clouser, *Bioethics: A Systematic Approach*, 2th edition, Oxford University Press, 2006, p. 112-143; A. Laude, D. Tabuteau, *Sécurité des patients, sécurité des consommateurs*, Presses Universitaires de France, Paris, 2009, p. 79-86; H. Widdows, *Localized Past, Globalized Future: Towards an Effective Bioethical Framework, Using Examples from Population Genetics*, “Bioethics”, Vol. 25(2), 2011; G. Rousset, *L’influence du droit de la consommation sur le droit de la santé*, L.G.D.J., Paris, 2009, p. 68-114; D. Tapinos, *Prévention, précaution et responsabilité civile*, L’Harmattan, Paris, 2008, p. 106-119.

It is also worth observing that the principle of non-objectification of human beings justifies the interdiction retained by the Romanian legislator in the text of article 63 of the New Civil Code, concerning the creation of human embryos. The latter may not, in any situation, be reduced at the stage of mere objects of study or scientific research, the present legislation thus refusing to authorize the creation of human embryos in scientific purposes. The existence of a parental project represents the sole case in which a genetic procedure of creating a human embryo may be legally initiated.

In the Romanian medical law, choosing the conceived child's sex by using predictive medical techniques is allowed only when oriented towards "the avoidance of a genetic malady associated to the child's sex" (art. 63, paragraph 3). The existence of the cited legal exception confirms the *conditional* character of the mentioned ethical principle, according to which no predictive medical technique may be used to choose the conceived child's sex. As opposed to the absolute bioethical principles, the conditionally applicable ethical rules may suffer exceptions, expressly enumerated by law. Obviously, ethical interrogations may persist over the question of conciliating these exceptions with the bioethical principle of diversity of human species (a) and with that of prohibiting eugenic practices (b). As for now, until the legal solving of these interrogations by adopting the future laws on bioethics (after the public debate of each legal project), it is worth concluding that, in the light of the New Civil Code, the eugenic biomedical practices are forbidden, while choosing the sex of the conceived child may be practiced not in an eugenic purpose, but for avoidance of a severe genetic malady associated to the child's sex. The therapeutic finality of a medical practice may represent an admissibility condition. In the case of interventions over the genetic characters oriented towards the choice on the child's sex, the therapeutic purpose (avoidance of a genetic malady associated to the child's sex) justifies its exclusion from the list of legally prohibited eugenic practices.

From the perspective of the bioethical principles, the use of predictive medical techniques raises several questions related to the potential violation of ethical commandments such as equality and solidarity between human beings. The development of the predictive capacities of the medical science may raise worries on the possibilities of anticipatory identification of persons potentially affected by certain maladies. Predictive medicine should not be a source of discrimination based on genetic characteristics. In addition, the protection of individual freedom represents a major ethical rule in terms of authorizing biomedical practices. Several ethical principles are derived from this bioethical imperative, such as freedom of requesting an genetic test (a), freedom of requesting to be informed on the results of a genetic test (b) and freedom of be subjected to a transplant based on genetic techniques (c).

The illicit character of the exam of genetic characters when oriented towards other purposes than the therapeutic or scientific one (a military or a cosmetic purpose, for instance), derives from the ethical issues involved. The scientific research on human embryos and on embryo cells is justified by the therapeutic finality of the respective biomedical practice.

There are two observations to be made: (1) the New Civil Code does not explicitly regulate on the issue of scientific research on human embryos, the sole legal stipulation referring in article 63 to the prohibition of the creating of human embryos in scientific purposes; (2) the protection of human embryos and of human beings in prenatal stage against their objectification as objects of scientific research is not completely solved by the New Civil Code, which merely postulates the alive person's right (no mention being made on the status of embryos or human beings in the prenatal stage) not to be subject to

scientific experiments, tests, organ procurement, medical treatment and other therapeutic or scientific interventions unless expressly authorized by law (art. 67). Several interrogations are thus kept unsolved, in the present legislative stage, as to the general ethical legitimacy of scientific research on human embryos as human beings who will be born; the ethical risk involved being that of objectification of human beings in their prenatal stage of life.

The Romanian legislator expressly retained the prohibition referring to the creating of human embryos in the sole purpose of scientific research and in the absence of a parental project. This kind of use of genetic practices would visibly contradict a series of bioethical principles, such as the non- objectification of human beings and the respect of human dignity³. The authors of the New Civil Code avoided though pronouncing on the issue of the legitimacy of scientific research on human embryos and thus on human beings in prenatal stage. This kind of research is authorized by the present legislation in therapeutic purposes only, as in the case of avoiding genetic maladies and without transforming them into eugenic practices. Several interrogations persist however concerning the use of human embryos that are to be born as an object of scientific experiment, which would contradict the non- objectification of the human being principle, no less respect may be shown for the human being in the prenatal stage as after the birth.

Nevertheless, it should be noted that the discussion refers to a conditionally applicable ethical principle and not to an absolute, imperatively applicable bioethical rule, so that this ethical questions on the legitimacy of the scientific research on human embryos have to be conciliated with the freedom of choice regarding the termination of pregnancy (which might be invoked in order to avoid a genetic malady). Most likely, it is the future Romanian law on bioethics that will solve these interrogations, as well as define the concept of “personal rights on prenatal stage” and establish legal limits for the use of predictive medical techniques in the prenatal stage.

2.5. The respect due to a person after death. Organ procurement from deceased donors

The issue of organ and tissue procurement from deceased donors recently raised numerous controversial discussions in the Romanian society, its members being concerned with the possibility that, in the absence of their explicit refuse, expressed when alive, of becoming organ donors after death, the organ procurement procedure would be automatically initiated. A rule according to which organ procurement becomes legally possible in the case of all patients who have not refuse to be donors during their life time, has the capacity of at least generate an contradictory rhetoric. One might exemplify with the case of young patients who become involved in car accidents or other types of tragic incidents and who would therefore be treated as potential donors when deceased, in the absence of their explicit refuse (expressed during their life times, usually in an official act instrumented by a notary public) to become donors, under the imperative of “saving lives”. One might also argue that, in such hypotheses, the organ procurement would take place

³ See, for further comments, S.N. Bute, I. Stoica, *Demnitatea și statutul embrionului uman din perspectiva teologiei ortodoxe*, “Revista Română de Bioetică” nr. 8 (1), 2010, p. 27-32; F. Crișmăreanu, *Statutul embrionului uman - importanța presupuzițiilor în soluționarea acestei probleme*, “Revista Română de Bioetică” nr. 8(4), 2010, p. 51-62; Șt. Iloaie, *Biotechnology and Faith. Relativism in the Postmodern Moral. A Christian-Orthodox Approach*, “Journal for the Study of Religions and Ideologies”, vol. 8, issue 22 (Spring 2009), p. 38-52; M. Leabu, *Christianity and Bioethics, Seeking Arguments for Stem Cell Research in Genesis*, “Journal for the Study of Religions and Ideologies”, vol. 11, issue 31 (Spring 2012), p. 72-87.

without the donor's veritable consent and with no certainty that the deceased person had been sufficiently reflected, when alive, on the implications of consenting or not to the use of his or her deceased body for organ procurement. Is thus presumable the existence of a judicial will the expressing of which never took place?

The New Civil Code solves the problem of organ procurement from deceased persons using a radically different approach and establishing that these practices may be initiated only on the basis of the *donor's written, free consent* expressed when alive, no presumption of the existence of such assent being admissible. According to article 81, "The organ, tissue and cell procurement from deceased persons may be initiated in the conditions stipulated by law, on the basis of the donor's free, written consent expressed when alive or, in the absence of such consent, on the bases of the free, written consent expressed, in order, by the surviving husband or wife or, in their absence, of the deceased's parents or descendents or, in their absence, of collateral relatives of maximum forth grade."

The second legal solution, applicable to persons who did not express their will while alive, is that the consent for the organ procurement would be delivered in writing by their family members, the authors of the New Civil Code insisting on the "free" character of the expressed will, unaffected by psychological pressures. In addition, the legislator established a clear legal hierarchy for the family members involved in the substitution of the deceased donor's agreement, as this is provided, according to the legal order, by the surviving husband or wife or, in their absence, of the deceased's parents or descendents (children or nephews of the deceased person). In their absence, it is the collateral relative of maximum forth grade that will provide the written consent (brothers and sisters, or nephews from the brothers and sisters of the deceased person).

The Romanian legislator's choice of abandoning the solution of the tacit consent to organ procurement (the presumed consent, in the absence of an explicit refuse) represents a consequence of the idea according to which the therapeutic finality of the organ procurement – as much important as it is from the perspective of lives saving – is no justification in itself for the ethical character of such practices. Much more important is considered to be the respect of the inviolability of the potential donor's body, the human solidarity between organ donors and beneficiaries being a voluntarily assumed choice.

It is also important to notice that the national registers of potential donors will suffer radical modifications as to their content, while replacing the primate of registering the refuse of becoming an organ donor after death with registering the consent to becoming a donor. Nevertheless, registrations on these national lists of potential donors produces judicially irrevocable effects at the moment of death only, during their life time, the potential donors being able to exercise their right of retract, according to article 68 of the New Civil Code.

The importance of these national registers of potential donors derives also from the individual's possibility of avoiding transferring the choice over the organ procurement to the family members.

The risk of organ rarity was not considered by the authors of the New Civil Code to represent a sufficiently strong argument for justifying the solution of the presumed consent, while the bioethical principle of saving lives cannot be seen as superior to the inviolability of the human body principle (a) or to the non-objectification of the human beings principle (b). In cases in which the existence of the donor's explicit consent cannot be proved, no initiation of the organ procurement procedure can take place.

From a statistical point of view, there is the risk that, at least in the next years after the entering into force of the New Civil Code, a small number of persons would join the

national list of potential donors. Nevertheless, a “solidarity gesture” such as the organ donation has to be a “voluntarily gesture” as well, any human solidarity being unconceivable in the presence of a forced consent, while postulating the respect of the individual’s right to physical integrity and the freedom of choice concerning medical interventions over his or her body.

The individuals’ awareness (through informative campaigns as well) of the benefits which their anticipatory consent to organ procurement could bring for their family members (whose lives may be saved with the help of other compatible donors) is preferred to a so-called “forced solidarity” as the one grounded on the donors’ presumed consent.

3. MEDICALLY ASSISTED HUMAN REPRODUCTION AND DONORS OF GENETIC MATERIAL

3.1. The requirement of a parental project

The medically assisted reproduction techniques are considered a palliative alternative for natural infertility, while applying the principle of non-discrimination between the potentially parenting couples. The New Civil Code texts allocated to the issue of medically assisted procreation do not solve all potential questions raised by these techniques, the legislator avoiding to expressly regulate the issue of revealing the donors of the genetic material’ identity upon the conceived child’s request for other reasons than therapeutic, related to the conceived person’s health or its descendents’ (a), and not for reasons attached to the individual’s right to be informed on his or her biological origins (b)⁴. The post-mortem transfer of genetic material also remains not regulated by the present legislation. The majority of the details related to the judicial regime of the medically assisted reproduction will be regulated through the means of a future special legislation; according to article 447 of the New Civil Code, “The medically assisted human reproduction, its judicial regime, the confidentiality rules and the exceptions from their applicability will be established by special law”.

The necessity of a *parental project*, implying at least the mother’s existence, as an admissibility condition for the medically assisted human reproduction is expressly mentioned in article 441, paragraph (3), according to which “The parents, in the legal sense, may be a couple formed by a man and a woman or a single woman”. The first two paragraphs of the cited article are concerned with the paternity issue, the law establishing that “(1) the medically assisted human reproduction implying a donor determines no liens of paternity between the conceived child and the donor. (2) In this case, a judicial action for establishing the donor’s civil liability is inadmissible”.

The compulsory character of the existence of a parental project is also stipulated in the second paragraph of article 442, according to which the death (a), the divorce (b) or the separation (c) of the future parents has as consequence the invalidity of their consent to the medically assisted reproduction.

⁴ See, for a detailed argumentation, A. Sutton, *Revisiting reproductive technology’s slippery slope in the light of the concepts of Imago Dei, co-creation, and stewardship*, “Ethics & Medicine: a Christian Perspective on Issues in Bioethics”, vol. 18(3), 2002, p. 145-154; L. Siep, *Normative aspects of the human body*, “Journal of Medicine and Philosophy”, vol. 28(2), 2003, p. 171-173; P. Comstock Cunningham, *Is it right or is it useful? Patenting of the human gene, Lockean property rights, and the erosion of the imago Dei*, “Ethics and Medicine”, vol. 19(2), 2003, p. 85-87.

The *medical* and *social finality* of the medically assisted procreation (as part of a parental project, while surpassing natural infertility) and the homo parenthood issue are implicitly regulated by the new legal text. The latter contains no explicit references to the issue of the legal prohibition, for homosexual couples, to have access to the medically assisted human reproduction. In article 447, the legislator explicitly refers to the fact that the authorization of the genetic procreation techniques depends on the existence of a request from a couple formed by a man and a woman (a) or a single woman (b). The interdiction referring to the access of homosexual couples to the medically assisted reproduction confirms the rule existing in the Romanian civil law according to which the marriage between homosexual persons is forbidden, with judicial consequences on the paternity issue, even if socially the living together of homosexual couples is permitted as an exercise of the fundamental freedom of choice.

3.2. Consenting to the medically assisted reproduction

The requirements for the legal consenting to the medically assisted human reproduction are established in article 442 from the New Civil Code, according to which “(1) The parents who, in order to procreate, wish to have access to the medically assisted reproduction techniques implying a donor have to express their consent in front of a notary public, in fully confidential conditions, benefiting from the notary’s counseling on the judicial consequences of their choice. (2) The future parents’ consent is judicially void in the case of their death, divorce or separation before the initiation of the medically assisted reproduction procedure. The parent’s consent is revocable at any moment, in written, including in front of the medical staff that ensures the medical assistance for the reproduction procedure”.

The major chances brought by the entering into force of the New Civil Code in the field of the medically assisted reproduction may be synthesized as follows: (a) the parents’ consent to the medically assisted reproduction has to be expressed in front of a notary public; (b) the information delivered by the medical staff are doubled by the notary public’s counseling on the judicial repercussions on the paternity regime; (c) *parents’ right of retract* after consenting to the medically assisted reproduction may be legally exercised at any moment before the initiation of the medical procedure; (d) parents’ right of retract is exercisable in written only (thus respecting the similarity of form principle, in the context in which the original consent has been delivered in written); (e) as opposed to the regime of the initial consent, and in order to ensure freedom of option (in accordance with the importance of the legal consequences of paternity), the retract of consent may take place in front of the medical staff involved in the reproduction process, in the absence of the notary public; (f) the legal cases of consent inefficiency are related to the death, divorce or the separation of the future parents, as in these situations the existence of the paternal project is presumed to have ceased.

3.3. Revealing the donors of genetic material’s identity

The New Civil Code texts on the admissibility of requests related to the revealing of the donors of genetic material’ identities, on one hand mark a significant *progress*, while presenting *lacunaria* on the other hand. The legal progress is represented by the express authorization, in article 445, of the cease of anonymity for medical reasons, concerning other persons’ health (a). The lacunaria are related to the inexistence of an explicit legal

text authorizing the revealing of the donor's identity, upon the conceived person's request, for reasons such as the individual's right to be informed on his or her biological origins or the access to the personal genetic history (b).

Thus, according to article 445, "(1) All information on the medically assisted human reproduction are confidential. (2) Nevertheless, in cases in which, in the absence of access to these information, there is the risk that the conceived person's, his or her descendents' or other persons' health is endangered, the judicial court may authorize the revealing of the genetic information, under a confidentiality status, to the medical staff or the competent authority. (3) Similarly, any descendent of the conceived person may invoke this right of access to information if there is a risk that his or her health or other persons' health is endangered".

A commentary on the new regulation would have to encompass at least the following ideas: (i) regarding the issue of the donors' of genetic material' identity, the legal rule is that of the anonymity (or of the confidentiality of this kind of information); (ii) the revealing of information is exceptionally admissible upon the conceived person's request (a) or his or her descendents' (b), for one reason only: the therapeutic risk attached for the conceived person's, his or her descendents' or other persons' health; (iii) the present legislation does not authorize the request of revealing the donor of genetic material's identity for other reasons, such as the individual's right to be informed on his or her biological origins, as an autonomous right unattached to the medical, therapeutic consequences.

The reason why the Romanian legislator maintained these legislative lacunaria is attached to the judicial status of the conceived child and the donor of the genetic material used in the reproduction process. Between the two persons, no legal status of paternity or maternal link is established according to law. All legal links of civil relationship – in the context of the parental project authorizing the medically assisted human reproduction – are established between the consenting parents and the conceived child. In accordance with article 446, "The father has the same rights and duties in relationship with the child conceived through the medically assisted reproduction implying a donor of genetic material as in the case of natural conception".

Contesting the paternity does not represent a legal reason for requesting the revealing of the donor of genetic material's identity⁵. As retained in article 443 of the New Civil Code, "(1) No one is allowed to contest the paternity of a child for reasons related to his or her artificial conception and nor is the medically assisted conceived child able to contest his or her paternity on such grounds. (2) Nevertheless, the mother's husband may contest the child's paternity, under the conditions fixed by law, in cases in which he did not consent to the medically assisted reproduction implying a donor of genetic material". Thus, patrimonial or inheritance reasons, for instance (the artificially conceived child's access to the patrimonial inheritance left by the deceased donor of genetic material) may not be invoked as legal reasons for the anonymity lift, as long as according to law the artificially conceived child is not considered to be the donor's descendent. There are however several legal uncertainties related to the potential delimitation, in a future legal text, of the "anonymity of the donor of genetic material" notion (where the confidentiality represent the general rule) and the "secret" on the modality of conception (the use of genetic practices), this information being revealed to the conceived person on the grounds of the individual's right to have access to information concerning his or her biological origins.

⁵ See also S. Guțan, *Reproducerea umană asistată medical și filiația*, Ed. Hamangiu, București, 2011, passim.

4. CONCLUSIONS

The legal progress represented by the regulation of the biomedical practices in the text of the New Civil Code set aside, a number of questions remain unanswered while waiting for the adoption of a set of laws on bioethics.

In what concerns the prenatal diagnosis, the persisting interrogations which require the adoption in the Romanian law of special legal norms on bioethics are related to the limits to be fixed for the biomedical practices predictive of certain genetic anomalies and the place reserved for handicapped persons in our society. From this perspective, the question remained unsolved is that of establishing the measure in which discovering genetic maladies in the prenatal stage should become compulsory for medical staff and future parents, in the name of the so-called social costs imposed by the disabled. It is an interrogation which the texts of the New Civil Code keep unanswered, in a context in which the new regulation is oriented towards the regulation of the persons' civil rights and duties, while not strictly focusing on the bioethical approach of medical practices.

In the field of implants and organ transplants, the pre-implant diagnosis would have to be regulated in the future laws on bioethics which, in the Romanian medical law, still wait to be adopted. The new legal norms would have to refer, for instance, to the question of the power of decision kept for specialists as to establish the eugenic risks implied by a certain genetically predictive practice as opposed to the financial benefits associated to handicap avoidance.

From the perspective of the technical progress registered by certain biomedical practices, two possible temptations are to be avoided: the one attached to eugenic choices and the one derived from the utilitarian treatment or the objectification of the human body. The New Civil Code postulates in imperative terms the prohibition of eugenic practices, which would undoubtedly deny the principle of human diversity. The research on the human embryos raises the question of the opposition between the humanitarian and the utilitarian approaches of the predictive medicine. Additionally, it is also a problem of accepting a biomedical practice such as the exam of genetic characteristics as legal as long as the risks involved do not interfere with the respect of the bioethical principles.

It is thus worth noting that article 63 of the New Civil Code establishes unequivocal legal limits for the interventions over human genetics, while forbidding those oriented towards *modifications of the person's biological origins*, except those concerning the prevention and treatment of genetic maladies (a) and forbidding *the creation of a human being identical to another human being, deceased or alive* and the creation of human embryos in the purpose of scientific research (b), as well as the use of genetics for *choosing the conceived child's sex* (c). However, it must be underlined that, after the adoption of the New Civil Code, in the Romanian medical law it is legally possible to choose the conceived child's sex by the means of genetic predictive medicine, as long as it is oriented towards "the avoidance or cure of a severe genetic disease associated to the child's sex" (art. 63, paragraph 3).

The New Civil Code maintains the principle of altruistic, non-onerous donation of human organs, while not establishing explicit rules in the field of the donors' anonymity. The anonymity principle is numbered in the group of the conditionally applicable bioethical principles, being incident in the case of organ procurement from deceased or alive donors, while being excepted in the case of the donors of genetic material, where the questions raised by the conceived person's paternity and identity (the person's rights to access to information on his or her biological origins) may justify the revealing of the donor's

identity. The text of the New Civil Code however does not contain specific rules applicable to the raise of the donor of genetic material's anonymity, in the case of requests based on the individual's intent of knowing his or her biological origins, thus remaining an object of regulation for the future laws on bioethics.

The question of artificial insemination of a bearing mother is not expressly regulated in the New Civil Code, as opposed to the subject of the medically assisted human reproduction and of donors of genetic material, thoroughly regulated in articles 441-447. It is thus worth concluding that by establishing the requirement of a parental project for the legal authorization of the medically assisted procreation and by establishing in article 447 that the requests of medical assistance for human reproduction may be initiated only by couples formed by a man and a woman or by a single woman, the legislator has indirectly postulated the illicit character of homo parenthood, while prohibiting it. The commented legal solution valorizes the social and medical finalities of the medically assisted human reproduction, as an alternative to the natural infertility.