

**PENAL PROTECTION OF THE HUMAN EMBRYO. NEW
CHALLENGES FOR ROMANIA**

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ABSTRACT: *The rapid developments in the last decades in the fields of biology and medicine raise important issues regarding the need to respect the human being both as an individual and in its membership in the human species. Medical acts performed both in research and in terms of curative work must be subordinated to a goal: the need to respect human dignity. In their desire to discover new treatments or just out of curiosity, biology and medicine can become instruments through an improper use, to endanger human dignity. At a global level it has been recognized that progress in biology and medicine should be used for the benefit of present and future generations, with different forms of international cooperation-oriented research and circumscribing the limits of human intervention. These generally accepted limits are guaranteeing human dignity regarded as the supreme social value, as well as the rights and freedoms of the individual.*

The advanced and increasingly accelerated recent scientific progress in biology and medicine - which, almost 40 years ago were considered simple topics of SF novels - have outlined a new area of research, namely sociological and legal Bioethics. Powered by joining two words of Greek origin - bios, life and ethos, ethics - Bioethics term would mean "moral of life".

The field of action of bioethics includes the beginning and end of life issues (abortion, euthanasia, assisted suicide, assisted reproduction), genetic manipulation, prenatal diagnosis, cloning, stem cell therapy, etc.. Bioethics takes a number of elements and principles from biology and medicine, from medical ethics, but also from other disciplines and fields such as philosophy, sociology, psychology, law, and, based on their principles, clarifies decisions and possible technical choices in biology, genetics and medicine.

Technology has created new ethical problems. Artificial insemination, in vitro fertilization, surrogate mother, and transplantation of human cells or tissues, genetic manipulation and cloning are all medical realities. There is no question WHETHER they can be made, but IF they must be made. In this study we take a peek of the historical perspective on the issue of the origin of life - birth / creation of human embryo - in Ancient Greece and Ancient Rome. Then we tackle the issue of the need for legal protection of the human embryo and appropriateness of using specific tools of criminal law

The legal protection of the human embryo is a complex and controversial topic that requires a foray into international documents - especially Oviedo Convention, a comparative analysis of the law of states that have played an important role in shaping the principles of

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modern bioethics - France and Italy - and an analysis of the Romanian law, especially in terms of adoption of the new Penal Code. Far from claiming the exhaustion of topics addressed, this study aims to scientific curiosity of discussing taboo subjects, asks uncomfortable questions and provides legal internal solutions regarding criminal protection of the human embryo.

KEYWORDS: *bioethics, human embryo, social value, life, human dignity, transplant, in vitro fertilization*

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1. BIOETHICS - FINAL FRONTIER FOR THE CRIMINAL LAW

Bioethics is a new science, defined as "a branch of applied ethics studying ethical issues arising from advances in medicine and biology" (Zanc, Lupu, 2001). It is widely accepted that modern multicultural, multi-religious and pluralistic Western societies recorded large discrepancies between individuals and between the ways in which they express their religious beliefs and moral (Wyatt, 2011). For this reason, the vision on social values that are the object of concern of bioethics and especially on how to protect them more efficient is a task of "evil", almost impossible.

Lately there has been a growing trend of liberal individualist approach to these issues, which is centered on individual human dignity. People have the right and moral responsibility to verify the truth of the fundamental questions that must and put them each in relation to the grounds and values of their lives. (Dworking, 1995). Individual autonomy is both the "lock" and the "key" to all bioethical disputes, its content limits being difficult to sketch. John Stuart Mill said "the only purpose for which power can be exercised judiciously over any member of a civilized community, against his will is to prevent harm to others. (...) On him, on his body and mind, the individual is sovereign." (Mill, 1864).

Theoretical and practical implications of bioethics are extremely complex. We believe that we cannot generalize individual autonomy to justify and legitimize various medical revolutionary procedures as the future of human evolution cannot be known at this stage of scientific development. Perhaps the acceptance of new medical procedures appear seductive and even necessary in some situations, but long-term implications are impossible to be anticipated, which is why bioethics is the new "playing field" of philosophers. The sketching task of fundamental problems of bioethics is far from complete, the scholars are, from our point of view, in great dilemma. In this theoretical and conceptual thicket, the issue of effective protection of the social values identified in the field of bioethics activity arises. Regarding the need to criminalize certain conduct which harms humans or jeopardizes social values that constitute the core of bioethics, there are currently two trends of opinion.

According to a first trend, certain areas of social life, such as that of human reproduction, should be exempt from state protection by means of criminal law. The arguments relate primarily to an overly strict and inflexible characteristic of criminal law, in the context of modern society where the change as a result of scientific progress is so rapid and surprising that the criminal law should not be an efficient tool in this regard. New medical technologies, particularly reproductive ones, generated and still generate

fierce controversy in society, and a non-criminal regulation is preferable to a criminal one would require unanimous agreement. (Caulfield, Knowles, Meslin, 2004) Recourse to criminal law could be considered as thoughtless and superficial, the evolution of human relations in society demonstrating that certain human behaviors were considered undesirable at some moment and have been criminalized, and were later accepted by the society and extracted from illicit criminal sphere (ex. homosexuality). The interference of criminal law in an area so new and fertile like medical sciences - medical assisted human reproduction, stem cells, organ transplants, etc. - should be carefully weighed. The legislature must provide objective evaluation criteria according to which human behavior can be classified as hazardous or advantageous to society, but such criteria are lacking at present, historical dispute between Darwinists and Creationists are even more intense at the moment. The adoption of a rule of law in general should consider the necessity and capacity that incorporates rule to meet the developmental stage of social relations at a time. The legislative process is however a formalistic cumbersome process, that fails to keep pace with new social realities created on the background of scientific progress. It was shown that the legal norms are trying to protect traditional situations, fear of innovation leading to a static vision on family. Consequently it is necessary to limit the criminality dynamism of modern society where more advantageous solution would be to employ disciplinary or civil liability. "Urging to legislate on bioethics is a symptom caused by fear of change of society." (Ball, 2000)

Repression of certain human behavior is the best way to act as long as the avoiding repression creates the danger of increasing divergent movements, which will be dealt with differently, non-unified criteria, leading to deviation of certain practices from their original purpose. In the same time, the lax attitude of competent forums will encourage the hope of legalization of acts whose antisocial nature cannot be denied – human body trade acts, trade of reproductive capacity, trade of the genetic profile, breaching of dignity and inviolability of the human species by creating embryos for use in cosmetics etc. (Huidu, 2010)

But the call to criminalization cannot be seen as a solution to the lack of other viable legislative options. Criminal laws are strict, inflexible, durable and unable to reflect the diversity and complexity of ethical theories present at some point in society. A non-criminal regulation is sufficiently flexible and efficient in balancing the relation between scientific development and rapidly changing social priorities. (Huidu, 2010)

The second trend points the need to criminalize such conduct in the field of bioethics, based on the idea that avoidance or lack of incrimination conveys a message of tolerance and encouragement of such behavior. The criminalization of behaviors indicates that a certain type of human conduct is of particular importance for society. In the same time criminal rules can be as flexible as non-criminal ones, without constituting an obstacle to scientific progress.

We have identified in the field of bioethics criminal certain values that need criminal protection: life, physical and mental integrity of the individual, personal and private life, consent, family, freedom, self-determination. These values are protected by criminal law in all European countries, by the new Romanian Penal Code - Law no. 286/2009 and by the European Convention on Human Rights and Fundamental Freedoms. Obviously, these values are summarized in fundamental human rights, seen as inherent attributes of human beings, with natural spring. (Bîrsan, 2005) The human person is considered a social value

itself by the school of natural law, which places it at the center of social life, recognizing attributes reflecting its autonomy. The *man*, as a human being is considered a distinct entity from the *citizen*, starting with the Declaration of the Rights of Man and of the Citizen of August 26th, 1789, the manifesto of the French Revolution. This observation is necessary as doctrinal disputes arising from bioethics and biotechnology point to the human being with all its inherent attributes and not to the citizen.

But the "special" documents in the field of protection of human beings against unethical practices are the Oviedo Convention - Convention on Human Rights and Biomedicine signed in Oviedo on 4th of April 1997 and the Additional Protocol to the European Convention for the Protection of Human Rights and Human Dignity to the Application of Biology and Medicine, on the Prohibition of Cloning, signed in Paris on 12th of January 1998, both ratified by Romania by Law no. 17/2001.

2. HUMAN EMBRYO - *RES OR PERSONA*

2.1. The human embryo. A historical approach

The issue of life before birth is a controversial topic, however old and new at the same time. Over time the explanations and answers to the question of the existence of life in the period between the moment of conception until birth were diverse and contradictory. Lately answers are different depending on the stage of temporal post-conception that records the development of the fertilized ovum. The human embryo was considered one of the most enigmatic creatures whose mysteries, far from being resolved, become deeper, as scientific knowledge in the field progresses. (D'Antuono, 2013)

The human embryo is different from any other living creature, challenging both medical science and the legal and sociological ones, and ethics in general. Science gives us a description of the biological identity of the embryo, of temporal aspects involved in its development; ethics states on its personal status and on other ways of assessing embryo.

In *The abortu procurato – The Declaration of Sacred Congregation on the Doctrine of the Faith* adopted by the Vatican in 1974, it is stated: it is not the biology's prerogative to issue a value judgment on philosophical or moral issues, such as when an individual human becomes a person or about the legitimacy of abortion. (http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19741118_declaration-abortion_en.html). "The danger of *biologyzation* of ethical discourse in the appeal to science as regulatory authority, has already caused in the past moral degradation and brought disgrace on human beings in a tragic experience of scientism" (D'Antuono, 2013). Since ancient times there was a concern about the origins of life and the birth (as an individual) of the human being. There were theses on late ensoulment of the embryo as there were opposing views that fostered the immediate acquisition of the soul from the moment of conception.

Hippocrates was the embryo's early advocate with a theory later called pre-formism, according to which the man is contained *in nuce* in a small and primitive life form (Hippocrates, *Corpus Hippocraticum*). This theory appears to Plato, in his *Timaeus*, where he asserts the existence of the soul before birth (Plato, *Timaeus*). Aristotle argued that there are three souls - vegetative, sensitive and rational - that succeed in embryonic

development in the theory of epigenesis. (Aristotle, *Generation Animalium*, II). With the establishment of Christianity there is an increased weight of the theological element over the gnosological one. It is launched the dramatic question about the origins of soul and on determining the exact moment when the soul becomes one with the body.

In the days of the Church Fathers, the issue of the origin of the human soul was to determine when the union of the soul with the body takes place, more precisely to determine when the insoulment of the embryo occurs. Tertullian launched the thesis that the soul, which is created directly by God, shares the same fate body from beginning to end. According to this, the original sin infects the soul and is transmitted per translate. That argument was rejected by the Church and regarded as heretical. (Tertullian, *De testimonio animae*).

Lactanius offered a different perspective on the issue of identity of the embryo: God creates the soul and man creates the flesh. Soul and body are united not by birth but from the moment of conception: *post conceptum protinus, cum ferum in utero necessitas divina formavit*. (Lactanius, *The opificio Dei*)

For Augustine life and the origin of life is placed before birth and abortion must be differently punished in his opinion as the fetus is formed or not. Mosaic Law does not define the fetus as a human being since there isn't any parallel between the sentence for abortion and the sentence for murder. (Augustine, *Enchiridion*)

Albertus Magnus, follower of the doctrine of the late insoulment shows that the soul is united to the body when the body is perfectly designed - on the 40th day for male fetuses and 90th day for female fetuses. Thomas d'Aquino states that the body is formed and ready to take the soul in successive stages. The soul enters the body in the 40th day after conception. The stages of development of the human being from the conception until birth are: *vivum* - living entity; *animal* - animal entity; *homo* - human entity, each of them corresponding a pattern of soul: vegetative soul, sensitive soul, and rational soul. (S. Thomas Aquinas, *Summa Theologica*).

These concepts have survived for centuries without major changes in philosophical thinking on the issue of the union of soul and body.

2.2. Philosophical and legal issues concerning the beginnings of life

The doctrine of epigenesis contrasts with preformism – that asserts differentiated development of embryonic phase. The doctrine of preformism outlined two different ways of interpreting – *animaculism* and *ovism*. The *ovism* focuses on the idea that the egg contains all the features and elements of the body and the sperm acts as a stimulator, triggering the fertilization process and embryonic development. The *animaculism* or *spermism* tilt the balance towards sperm which allegedly contains a tiny but fully formed animal - *animalculus* - called in case of humans - *homunculus*.

The non-born baby (embryo, fetus) is a paradox: it represents life without exceeded the birth. Not yet a "person" as not separated from the mother's body and not capable of self-determination. Therefore the embryo cannot be a person. (Sacchi, 2013). Paraphrasing a decision of the Italian Constitutional Court - Decision no. 438/2008 – the human embryo is not a person because cannot show self-determination cannot provide any written, informed, consciously manifest and present consent. <http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2008&numero=438>).

According to some theorists, the term *persona* – person, is synonymous with the individual seen as a rational human being and, consequently, capable of self-determination. Since the human embryo does not meet any of these goals, we would be tempted to view it as *res*. The Roman jurists considered the unborn child (hence the embryo) as *persona* (even if uncertain): "*Ac ne heres quidem potest institui postumus alienus; est enim incerta persona*". Gaius, when undertaking the classification of persons, including category includes non-borns (*qui in utero sunt*) attributes it to natural law: "*qui in utero sunt, in toto paene iure civili intelleguntur in rerum natura esse*".

Logical analysis involves *ab initio* an identification of the purpose of the two categories in which the embryo is likely to be placed: *res* or *persona*. The first category – *res* - includes goods, any object that can satisfy a human need. (Hamangiu et al., 1996) In a legal sense by goods we understand those things likely to be subject to individual or collective appropriation. May the human embryo be susceptible to be classified in this category? May it be appropriate in the legal sense? If we accept the non-individualistic thesis according to which the embryo is an extension of the mother's body, we see that the human embryo cannot be classified in this category as extensions and parts of the human body and are not susceptible of appropriation. Moreover, for the purposes of criminal law, the human body, its parts, organs, tissues and cells cannot constitute material object of the offense of theft. (Dongoroz, 1971 Dobrinou, 2011). If we insist on individualistic thesis, according to which a human embryo is a distinct entity (within the meaning of distinct life), the more we cannot include it into the *res* category. And how can we explain then the seizure measure on genetic material consisting of embryos that has been taken in a famous criminal trial? One of the women who used IVF techniques of a specialized clinic in Bucharest, heard from the media in July 2009 that the Prosecutor - DIICOT - Bucharest Territorial Service initiated a criminal investigation, ordered the closure of the medical clinic and seized all its genetic material found in the bank (Ordinance no. 143 / D / P / 2009). Subsequently, the plaintiff has obtained on 12th of November 2009 the return of genetic material in accordance with art. 169 (1) Criminal Procedure Code. ("If the prosecutor or the court finds out that things picked up from the accused or defendant, or from any person who has received to keep them, are owned by the injured person or have been wrongfully picked up, orders the return of such things to the injured person. Any other person claiming a right on high things may, in accordance with Art. 168, claim for their restitution"). The seizure measure ordered during prosecution phase bears the goods and is necessary in order to repair the damage caused by the offense. Behold, unwittingly DIICOT managed to give rise to a debate of great magnitude whose stake is the status of the embryo – *res* or *persona*. May this legal precedent be an indication of the direction to go of the current debate on legal and philosophical foundation of human embryo status?

Italian Court of Cassation managed to trigger a revolution by one of its decisions (Corte di cassation sez.III Decision no. 16754 of 02/10/2012) stating in a context related to the recognition of the right on not to give birth of women, that the embryo is part of the mother's body and must be protected as a guarantee of the right to health of the woman. Not recognizing the unborn child as a subject of law, but recognizing the right to legal protection deriving from the obligation to ensure and protect the health of the mother, the unborn child is qualified *portio rei*, but yet as a subject of legal protection. (Palma, 2013 http://www.unifr.ch/dpr/images/stories/File/Compilation_final_29_1_13.pdf)

3.LEGAL PROTECTION OF HUMAN EMBRYOS

3.1. The Oviedo Convention and other relevant documents

The Oviedo Convention - Convention on Human Rights and Biomedicine signed in Oviedo on 4th of April 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 of Human Beings signed in Paris on 12th of January 1998, both ratified by Romania by Law no. 17/2001 are, as already stated, the main international instruments in the field of bioethics.

According to art. 18 of the Oviedo Convention, when research on embryos *in vitro* is allowed by law, it shall ensure adequate protection of the embryo. The creation of human embryos for research purposes is being absolutely banned. The Convention also notes, in its Preamble, the implications of rapid developments in the field of biology and medicine, and points to the need to respect the human being both as an individual and in his membership in the human species, and the importance to respect the human dignity. Misuse of biology and medicine is likely to endanger human dignity, so the progress of biology and medicine should be used for the benefit of present and future generations. Furthermore Additional Protocol prohibits *in extenso* the cloning of human beings pointing that the instrumentalisation of human beings by the deliberate creation of genetically identical human beings is contrary to human dignity and constitutes a misuse of biology and medicine. Such a bioethical procedure involves for the people created like this, great medical, psychological and social difficulties.

Other international instruments relevant for the protection of human embryo impact are:

- UN Resolution no. 59-280 on human cloning (adopted 8th of March 2005)
- Universal Declaration on the Human Genome and Human Rights (adopted by UNESCO)
- Universal Declaration on Bioethics and Human Rights (adopted by UNESCO on 19th of October 2005)
- Council of Europe Recommendation no. 1046/1986 on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes
- Council of Europe Recommendation no. 1100/1989 on the use of human embryos and fetuses in scientific research
- Council of Europe Recommendation no. R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and genetic counseling adopted on 21st of June 1990
- Council of Europe Recommendation no. 1512 of 2001 on the protection of the human genome
- European Parliament resolution no. A2-327 / 1988 on the ethical and legal problems of genetic engineering
- European Parliament resolution no. 1352/2003 on research on stem cells derived from humans.

The UNESCO Universal Declaration on the Human Genome and Human Rights, underlines the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, the human genome is the heritage of humanity (art. 1 of the Declaration).

Recommendation 1046/1986 on the use of human embryos and fetuses for therapeutic, scientific, industrial and commercial purposes comprises, in addition to a set of proposals submitted by the Parliamentary Assembly, a set of regulations on the use of human embryos and fetuses and on prelevating tissues for diagnostic and therapeutic purposes. According to this document, it is emphasized that the progress of medical science has led a very precarious legal position of the human embryo and fetus and that their status was not defined by any law until that moment, thus there are no legal provisions to regulate their use. In addition, it is considered that the human embryo and fetus must in all circumstances be treated with due respect for human dignity and the use of tissues must be strictly limited and regulated to achieve therapeutic goals only (see paragraph 10 of the Recommendation). It strongly affirms the need for European cooperation in this field, as only isolated national legislation would have no effect, because any work in this area could easily be transferred and exercised in another country, as the legal provisions are missing (paragraph 12).

Recommendation 1100/1989 covering the use of human embryos and fetuses in scientific research starts from the observation that science and technology, especially in the field of biomedical sciences continues to advance and develop as an expression of human creativity and freedom of action. This scientific research cannot be arbitrarily limited, but only based on professional, legal, ethical, social and cultural principles, and for the purpose of protecting human rights and human dignity (paragraph 1). Thus, it is considered appropriate to protect by legal instruments the human being from the moment of, following the same rules as set out in Recommendation 1046 / 1986.

Universal Declaration on Bioethics and Human Rights (adopted by UNESCO on 19th of October 2005) is the latest document, adopted by the General Conference of UNESCO at the 33th session. This is an international document seen as a development of the international Bio-law and human rights. Even if, like other statements, this Declaration is a soft legal instrument (having the authority of a treaty), its strength and value, especially as regards the concept of dignity, are most important.

3.2. The French Debate

The French society confronted a revolution in the field of bioethics in the year of 1994, by adopting a set of laws on assisted human reproduction, human cloning, embryonic stem cell research (Law 94-630 of 25th of July 1994 on the protection of individuals involved in biomedical research, Law 94-653 of 29th of July 1994 on the respect of human body, Law 94-654 of 29th of July 1994 concerning the donation and use of elements and products of the human body in health care and treatment for procreation and prenatal diagnosis, Law 94- 548 of 1st of July 1994 on the nominal data used in health research field). This set of rules is more important since the supranational European Oviedo Convention was to be adopted three years later. The rules governing the conduct in the field of biomedical research were found in French law before 1994: French Civil Code, Public Health Code, Family Code, Criminal Code, French Administrative Code.

The 1994 set of laws reaches punctual issues in the field of bioethics, such as ensuring the integrity of the individual, human dignity, ensuring respect for human life since its conception (art. 16 of the French Civil Code, Law 94-653). Such principles do not conflict with the "Veil" Law - Law 75-17 of 17th of January 1975 on the voluntary interruption of pregnancy, legislation allowing abortion up to 12 weeks. A woman can get an abortion not

exceeding 12 weeks of pregnancy if justifies a simply financial or psychological problem. More, abortions are allowed in case of advanced pregnancies for medical reasons. According to the Veil Law, if a woman chooses to terminate her pregnancy, is her right because her financial or psychological problems prevail over the right to life from conception of the fetus or embryo.

The set of laws from 1994 were also mandating the principle of inviolability of the human body. Parts or components of the human body cannot, for any reason, be exploited in scientific or commercial purpose (Law 94-653, art. 16-3 French Civil Code). Although the human body is not assimilated to a person, it is considered that this right belongs to the private sphere of individual rights. Elements of the human body are not alienable property. Consequently a person cannot alienate or sell body parts or gametes, no woman can become a surrogate mother, even without remuneration. (Merchant, 2005)

Moreover, in the 1994 version, assisted human reproduction was legally possible only as a form of treatment for couples with infertility diagnosis. Only heterosexual couples could benefit from such treatment subsidized by the French state and only if they were married or lived together for at least 2 years. (art. L. 152. 3 of the French Public Health Code). Single women, post-menopausal women or lesbian couples did not have access to this treatment (art. L. 152. 3 FPHC). Post mortem insemination was also prohibited (art. L. 152. 3 FPHC), as well as artificial insemination with sperm from a donor (art. L.673-2 FPHC). Donation of eggs, sperm or embryo was allowed in certain circumstances, and only after obtaining written informed consent from both the donor and the recipient couple (art. L.673-2 FPHC).

The couple who donates an embryo should have already procreated, a man who donates sperm must already have a child, while women who donate eggs must meet two conditions: to have a child and be married or living with a man. All donations of this kind must be authorized by a judicial authority (art. L.673-2 FPHC) must remain anonymous (art. L.665-14 FPHC) and any violation of anonymity clause constitutes an offense punishable by imprisonment and a criminal fine a significant amount (art. L.675-11 FPHC). Double gamete donations are prohibited, in other words it is imperative that future child to be genetically related to one of the couple donee (art. L. 152-3 FPHC).

In 1995 experiments on embryos were banned and embryos could not be created for experimental purposes, criminal penalties were provided in such cases by both the FPHC (art. L. 152-8) and the French Criminal Code in force at that time (art. L. 511-18). In exceptional cases however, the couple could agree to studies on embryo, if the consent was given in writing, the studies had an experimental purpose and not harming the embryo (art. L. 152-8).

France became the first country to have a permanent national advisory committee on bioethical issues. Thus, by signing a decree on February 23rd, 1983, the French President Francois Mitterrand, was prefiguring the creation of the French National Consultative Committee on Ethics, Health and Life Sciences, subsequently enacted by adopting the set of laws in 1994. The mission of this committee was to produce views on ethical and social problems due to scientific progress in the fields of biology, medicine and health. (www.ccne-ethique.fr)

After the year 1994, in following 10 years, the French society faced an extensive debate on specific medical practices, which also led to the late adoption of the Law 2004-800 of 6th of August 2004 on bioethics.

Law 2004-800 of 6th of August 2004 on bioethics criminalizes human cloning, which is also defined as a crime against the human species punishable by 20 years in prison and a criminal fine in the amount of 7.5 million euros (art. 28 and 29 of Title VI). This provision will apply to French citizens even if the offense is committed abroad. The law also prohibits therapeutic cloning and research on human embryos. Notwithstanding, however, for a limited period of 5 years from the adoption of the law the research on embryos created *in vitro* is allowed under specific procedures, if the research is to be conducted on the surplus of frozen embryos that are no longer required to procreation, and both members of the couple who created the embryos give their explicit consent. Research in such cases should focus on achieving major therapeutic benefits that could not be obtained by an alternative procedure (Title VI).

Under the new law it was created a new institution, the Biomedicine Agency (l'Agence de la Biomedecine) approving and overseeing research on human embryos, organ donation, authorizing the screening of embryos created for *in vitro* fertilization which will become "saviour siblings" (perfectly compatible with a living child suffering from a serious illness, and once become children will have to donate, by the will of parents, tissues or organs). The Agency also advises ministries for approval or rejection of specific scientific research.

It is widely accepted that an important role in the adoption and revision of French legislation in the field of bioethics and biomedical sciences was played by the French civil society, and especially by interest groups (communities of scientists) that provided a constant pressing on French legislature and on the authorities and institutions presented.

3.3. Italian Experience

The need to ensure adequate protection of constitutional rights – starting with the rights of the conceived and ending with the right to identity and genetic uniqueness of the individual - led in time to principles governing assisted human reproduction techniques. The Italian society has experienced a dramatic debate in this area. Appropriate legislation in Italy has been hindered by a rigid and sterile opposition between a laic outlook on Bioethics (inspired by a "liberal profession of faith") and a religious vision expressed by the the Head of the Catholic Church. (Canestrari, 2012)

In Italy extreme proposals were made: on the one hand the extension of the right to benefit from assisted human reproduction techniques to single women or homosexual couples; on the other hand, the absolute prohibition of heterogeneous fertilization because is contrary to the model of procreation in a normal couple. The Italian Parliament had to find a solution in bridging ideological conflict that characterized the Italian debate on assisted human reproduction and find a balance between certain rights protected at the constitutional level, but that are in constant conflict: the integrity of the embryo, women's health, the right of unborn to double parental figure, freedom of scientific research. Law no. 40 of 19th of February 2004 relating to assisted human reproduction (published in Gazzetta Ufficiale nr. 45 of 24th of February 2004) involved the assumption of "absolute ethical goals" (Berger, Zijderveld, 2011) and provided a useful scheme of techniques used in reproductive field. The law makes a distinction between *in vivo* and *in vitro* human

fertilization. On the other hand it distinguishes between homogeneous and heterogeneous artificial fertilization. If case of *in vivo* fertilization the embryo develops in the human body. Per a contrario, the *in vitro* procedure involves the removal of oocytes, their fertilization in the test tube (in vitro) and then transferring the embryos developed in the laboratory inside the womb. Both types of fertilization - *in vivo* and *in vitro* - can be homogeneous and heterogeneous as male or female gametes come from the couple, or a third donor. Regarding the purpose of the act of procreation, the distinction between surrogate mother and carrying mother appears necessary. Analysis of the Italian legislation in the field of assisted human reproduction involves three research goals: the nature and essential characteristics of the methods of assisted human reproduction; the level of protection of the embryo; the protection of the human genome – interdependent goals that do not overlap.

3.3.1. Italian criminal regulation of assisted human reproductive technologies

By using a highly plastic metaphor, the doctrine pointed that criminal sanctions provided by the Italian legislature in the field of assisted human reproduction can be viewed as the product of a heterogeneous fertilization: the seed of criminal law is introduced into the body of administrative law. (Canestrari, 2012)

Art. 4 of. 1 of Law no. 40/2004 provides that the use of assisted reproductive techniques is only allowed when the impossibility of eliminating the causes which constitute impediments to procreation has been determined, and in any case limited to cases of infertility or sterility established and certified by a medical act. This legal provision sets preconditions need to be met in order for someone to benefit from assisted human reproduction techniques, namely pathological and physiological assumptions that qualifies the applicant for this procedure. But the problem is far from being as simple as Italian law does not establish clearly the definition of sterility and infertility, and in Italian literature there are many different opinions on the subject. Moreover, art. 1. 2 of the law expressly establishes the criteria of subordination of assisted human reproduction techniques to natural procreation without providing punitive sanctions for ignoring it.

Art. 12 of the law entitled *Prohibitions and penalties* establishes a set of administrative and criminal penalties in case of breach of the law on assisted human reproduction techniques. The incrimination rules ban under a criminal sanction the following conducts: a) production, organization or advertising relating to the sale of gametes or embryos or surrogate services; penalty: imprisonment from three months to two years and a criminal fine of 600,000 to a million euro. b) a procedure that aims to create a human being who descended from a single cell of origin, possibly identical with regard to nuclear genetic heritage, coming from another human being, alive or dead; penalty: imprisonment from ten to twenty years and a fine of 600,000 to a million euro.

The prohibitive-sanctioning model proposed by the Italian legislature is somehow bizarre. One author says: "Deceit label" (Truffa delle etichette) is witnessing a heterogeneous fertilization of the broader category of punitive law: criminal law seed is introduced into the body of administrative law. Genetic heritage of the two branches of law is not altered, but the administrative liability arises highly afflictions - an abnormality inherited from the "parents". (Canestrari, 2012)

The absolute prohibition of heterogeneous fertilization is based on the concept of the Italian legislator that the separation of biological filiation from social filiation causes unacceptable damage of family rights and relevant damage to the psychological development of the child. But Italian literature does not agree with this explanation. The statement that a "rift" between biological and social dimension would jeopardize the physical and emotional of the future child conceived heterogeneously was not confirmed by pedagogical science. In fact studies have shown the importance of a double parental figure for the child's balanced formation of personality, regardless of genetic relatedness. In the absence of a united and coherent position of the scientific community regarding the possible gaps in the mental development of the child conceived heterogeneously the use of the precautionary principle to absolutely prohibit such procedures is excessive is incorrect.

3.3.2. Prohibition under criminal sanction of surrogate motherhood

Surrogate motherhood is characterized by the obligation of a woman to carry a pregnancy to term and give the child to a contractor couple. In Italian literature were analyzed two types of surrogate motherhood: the first involves the husband, who, with the consent of his wife, fertilizes the eggs directly into the woman's uterus that will bring her own genetic contribution to creating the future child. The second type involves in vitro creation of an embryo based on genetic material from the beneficiary couple, that will be subsequently implanted into the uterus of a surrogate mother, in which case she will have no genetic contribution to the creation of future child. The issue of legal acceptance of such a procedure is based on the conflict between technique in question and the value of human dignity that comes in contradiction. Italian doctrine accepted such a technique based on the idea of human solidarity and the gratuity of benefit provided by surrogate mother (Moccia, 1998) but, in spite of all favorable echoes, the Italian legislator opted in 2004 for a total ban criminal sanction of surrogate motherhood conventions (penalty is imprisonment from 3 months to 2 years and a criminal fine of from 600,000 to 1,000,000 Euro). Such a radical solution affected all subjects involved in various surrogate practices (social mother, uterine mother, biological father) instead of referring only to brokering activities or facilitation agreements on surrogate motherhood.

3.3.3. Measures of legal protection of the embryo

Law on assisted human reproduction had to satisfy two requirements of fundamental importance: complete ensuring of women's health and adequate protection of the human embryo. The human embryo is a value under protection of Italian Constitution, the case law, special laws and international documents of the European institutions. For this reason in Italian legislation there are many offenses that can be divided into two groups: a group that includes cases of criminality which are founded on general principles, the expression of fundamental values, deeply rooted in the very pluralistic society today. The second group is composed of criminal illegal acts, in order to safeguard the integrity of the human embryo in various procedures of assisted human reproduction.

Criminalizing provisions contained in the first group aim to prevent those behaviors that are not compatible with the idea of recognizing the humanity of the embryo. In this regard, paragraph 3 of art. 13 of the Law no. 40/2004 bans the creation of human embryos

for research purposes or for purposes that infringe the legal provisions. This offense is punishable with imprisonment from 2 to 6 years and a fine of 50,000 to 150,000 Euro.

The law also prohibits under criminal penalty other conducts that could affect the embryo, as envisaged by art. 12 par. 6. This criminal rule punishes with imprisonment from 3 months to 2 years achieving, organizing or advertising any form of commercialization of gametes or human embryos. This text is in full compliance with art. 21 of the Oviedo Convention which provides that the human body or its parts cannot become sources of profit in any way.

Another extremely important criminal rule which belongs to the first group analyzed is provided by art. 13 par. 3 letter b which prohibits unlawful alteration of the genetic patrimony of the embryo.

It is forbidden any conduct which occurs through selection, manipulation or any other techniques of artificial intervention on the embryo in order to alterate the genetic patrimony of the embryo or gamete and predetermine its genetic characteristics, except for those techniques used for diagnostic and therapeutic purpose. Art. 14 par. 6, bans under the criminal penalty up to 3 years of imprisonment and fine of 50,000 to 150,000 Euro creating and preserving a larger number of embryos than necessary in assisted reproductive procedure. Such provision ends up compromising the effectiveness of current assisted human reproduction methods. In the same law, article 14 prohibits the practice of embryo cryopreservation. This while the law prohibits the creation of more embryos than required for an implant and in any event not more than 3! This legal text ignores medical practice according to which in the woman's uterus may not be transferred more than 2 embryos once in order to avoid multiple pregnancies and disregards the need for repeated use of the techniques in case of successive failures. Limiting the number of oocytes to 3 to be used in the insemination process, without any possibility of derogation, does not take into account neither the biological diversity of individuals nor the doctor's obligation to choose the optimal treatment for each patient. It happens that, in case of some couples, none of oocytes collected would turn into embryo. As in case of others, all three oocytes successfully transform into embryos and are successfully transferred in the womb, increasing the risk of premature births and perinatal mortality due to immaturity. These cases present risks to both women's health and embryo, and legitimize the physician to refuse to provide assisted procreation under art. 6 par. 4 of the law. Finally, for most couples more treatment cycles and several successive inseminations are needed to produce a viable pregnancy. So the prohibitions provided by Italian law are founded solely on safeguarding the value of the embryo. Women's Health (which is, according to Italian doctrine, a superior value than embryo) does not enjoy adequate legal protection.

Spanish legislation on assisted human reproduction - Law (Ley) 35/1998 of 22nd of November 1998 is more efficient. Art. 4 par. 3 of this legal act clearly provides: there will be a maximum of three fertilized oocytes to be transferred to the woman in the same cycle, unless this is prevented by the basic pathology of the parents. Pathophysiological typologies of these cases allow fertilization of a greater number of oocytes whenever the couple accepted in their reproductive project, which will be specified in a protocol developed by the Spanish Ministry of Health and Consumption and with the prior approval of the National Commission on assisted human reproduction.

The experiments on embryos are prohibited, although freedom of scientific research is guaranteed by the Italian Constitution (art. 9 and art. 33). However, in this case Italian

doctrine provides a hierarchy of social values enshrined in constitutional level and notes that scientific freedom is a social value less important than the value of human life, even in its early stages of development. (Canestrari, 2012) Art. 13 par. 1 of the Law bans experiments on embryos and any collection of stem cells from embryos that cannot be implanted anymore.

The only statutory exception on scientific research in such cases is provided by art. 14 par. 1 according to which it is allowed to undertake studies or observational and non invasive intervention for diagnostic and therapeutic purposes in order to protect the health and the development of the embryo itself, and only if there are no alternatives. Any type of research that results in suppression of the embryo it is absolutely prohibited.

3.3.4. Legal protection of humanity and irrepeatability of human genome.

Italian law provides two incrimination rules that aim an efficient protection of irrepeatability and humanity characteristics of the human genome. Art. 13 expressly prohibits research on human embryos. Clinical and experimental research on a human embryo is allowed provided that they pursue diagnostic and therapeutic purposes exclusively related to it to protect the health and development of the embryo itself, and where there is no alternative. It is absolutely forbidden:

a) production of human embryos for research or experimentation or for purposes other than those provided by law;

b) any form of selection of embryos and gametes on eugenic purposes or any intervention by the selection techniques, manipulation or artificial processes, intended to modify the genetic heritage of the embryo or gamete or to predetermine the genetic characteristics, except interventions diagnostic and therapeutic purposes;

c) cloning interventions by the nuclear transfer or by early scission of the embryo or by early ectogenesis conducted both on reproductive or research purposes;

d) fertilization of a human gamete with a gamete belonging to a different species and the production of hybrids or chimeras.

In the event of such acts, the penalty is imprisonment from two to six years and a fine of 50,000 to 150,000 Euro.

3.4. Romanian Challenges

The status of the human embryo was not the object of concern for Romanian legislator. Although Law 301/2004 - former New Romanian Criminal Code criminalized a series of conducts prohibiting, under criminal sanction, in Title I of the Special Part, Cap. IV - *Crimes and offenses relating to genetic manipulation*: alteration of human genotype (art.193), dangerous use of genetic engineering (art. 194), the illegal creation of human embryos and cloning (art. 195), this act was never put into force, being expressly repealed by the enactment of Law no. 286/2009 on the Romanian Criminal Code (art. 446 al. 2).

The first rules applicable in Romania which underlined the issue of creating and handling the human embryos, but not their status, were set by Law no. 95/2006 on health reform. This act regulates the activity of procurement and transplantation of organs, tissues and cells for therapeutic purposes (Title VI of the Act), but does not refer expressly to the embryos, which cannot be enrolled neither in the concept of organ nor in that of cell, or human tissue. Because it doesn't refer expressly to embryos, we can say that the

law as a whole, and therefore its criminal rules do not apply to embryos, so the human embryos do not enjoy any legal protection in general or any criminal protection in special!

Given this legal vacuum, Romanian legislator attempted to adopt in 2005 a law on reproductive health and medically assisted human reproduction, covering legal unregulated situations faced by practitioners in reproductive medicine. The reasons for taking such a project were different: from the legal vacuum to the need to combat demographic decline or the necessity to align national legislation with the legislations of other European countries. ([Http://www.senat.ro/legis/PDF%5C2013%5C13L453EM.pdf](http://www.senat.ro/legis/PDF%5C2013%5C13L453EM.pdf)).

Despite many positive social echoes, by Decision no. 418 of 18th of July 2005 published in the Official Monitor no. 664 - July the 26th, 2005, Romanian Constitutional Court declared unconstitutional the majority of articles of the Law on reproductive health and medically assisted human reproduction. This decision was criticized by the doctrine. (Streteanu, 2006)

There was a new attempt by the Draft law no. 63/2012 on medically assisted human reproduction with a third party donor (http://www.cdep.ro/pls/proiecte/upl_pck.proiect?cam=2&idp=12651) but the draft does not bring into question the concept of embryo, but only that of gamete. This draft is regulating only the situation of persons involved in such proceedings, although, as a result of medically assisted human reproduction techniques may result embryos that would be implanted in the woman's body. (<http://www.cdep.ro/proiecte/2012/000/60/3/se99.pdf>)

Art. 201 par. 2 of the Criminal Code - Law no. 286/2009 provides a very limited protection of the embryo by criminalizing termination of the pregnancy, performed under any circumstances without the consent of the pregnant woman. Since the paragraph 1 letter c of the same article stipulates that is criminalized, inter alia, an abortion if the pregnancy has exceeded 14 weeks of age, any interruption of a pregnancy, even less than 14 weeks without the consent of the pregnant woman constitutes an offense. Or, from the 14th day after conception until the third month of pregnancy (12-14 weeks), the conceived human entity is embryonic. So in these conditions the embryo enjoys some legal protection from criminal point of view. In addition we do not believe that the legislator thought so far, since the act of interruption of pregnancy is classified as an offense against the fetus. Intention of the law was to protect fetal life (product of conception after the third month of pregnancy) and not the embryo!

The new Criminal Code, Law no. 286/2009 does not cover the vacuum created by the previous legislative gaps, so that is why the legal status of the embryo in Romania is uncertain and the legal protection of human life forms before birth we can say is almost absent. Therefore we would like to propose *de lege ferenda*, for the purposes of completing the new Criminal Code, or at least the Law no. 95/2006, the incrimination of conducts involving the creation and improper use, contrary to international standards mentioned throughout this study, of the human embryos.

4.CONCLUSIONS

The human embryo is a human being because it meets three conditions: it lives (alive), belongs to human species and has individuality. (Huidu, 2010). The development of medical technologies raises the profile of the embryo as a separate entity from the mother's body, the conceived entity is considered the second patient, in addition to the

pregnant woman. Whether we embrace individualist current, or, on the contrary, the opposite current according to which the embryo and the mother form an indivisible entity, we all agree that it is only a matter of time before science will reveal its new secret. As regards human genome as depositary of the heritage of humanity, the human embryo must enjoy appropriate legal protection, which, as we have seen, was achieved at an international level and in the laws of most European countries. Romania is once again left behind in the chapter of modernizing its legislation, which is unacceptable given that we claim to be a modern European state. Legal protection and in particular the criminal protection of the human embryo is even more necessary as the human embryo is subject to medical procedures that continue to develop. An inappropriate use of these procedures may lead to irreparable consequences on humanity. We look forward to see signs of modernization of Romanian criminal law in the field of biomedical sciences.

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