

Is the human embryo legally defined and protected? Causes and consequences

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Abstract

"Everyone's right to life shall be protected by law", states the article 2 of the *European Convention of Human Rights* (1950). This article guarantees the protection of life of all persons. The human embryo, however, does not seem to be under the protection of this article, or, at least not always. The human embryo does not have a nature clearly defined and it is not considered always as person. The law protects only two categories by its ordinary regulations: things and persons. Our main objective is to find out if the human embryo is or not protected, according to the legal framework in Romania. The purpose of the paper is: (1) to familiarize professionals with current debate on the status of the human embryo; (2) to provide main legal standards and regulations concerning this specific area with examples from case reports; (3) to summarize causes and consequences of the human embryo legal interpretations. Our conclusion is that the human embryo is not protected by the law in force at this moment, with very few exceptions. It depends, most of time, on the parent's wishes. From ethical point of view, we are in front of an open and long debate. The law should regulate and define the human embryo in a clear way. Legal standards are extremely necessary for all involved, in the context of the development of the medicine. Embryo's issues have profound implications for medical practice.

Keywords: human embryo status, legal protection of embryo, unborn child rights.

☐ General considerations on the definition of the human embryo

Etymologically, the term *embryo* comes from the Greek noun *embryon*, which means *ingrow*. According to the *Stedman's Medical Dictionary* [1], the embryo is an organism in the early stages of development, from conception until the end of the eight week. The developmental stages from this time to birth are commonly designated as fetal. Until the 70's there was no real debate on the status and on the definition of the human embryo, of the person in becoming. The separation of the embryo from the person, as different subject of law and all debates on the topic, have occurred with the decriminalization of abortion. And researches on stem cells have relaunched and intensified debates, complaints and confusions. Therefore, in an essay on abortion from 1973, Mary Ann Warren argues that the unborn is not a person. "Merely being human – a creature with human DNA – is not sufficient for personhood. To qualify a person, an entity must possess certain intrinsically valuable traits". She identifies five traits central to personhood, such as: (1) conscientiousness and the capacity to feel pain; (2) reasoning; (3) self-motivated activity; (4) the capacity to communicate; (5) the presence of self-concepts, and self-awareness, either individual or racial or both. Any being that has none of these traits is surely not a person. An embryo or a fetus has none of them and is therefore not yet a person and "cannot coherently be said to have full moral rights" [2]. On the same line, but more nuanced, in 1989, Sebastiano Maffettone [3] indicates a separation between *person* and *human being*, showing that the two notions are not synonyms and do not have the same

content or, at least, not always. He considered that "not all *persons* are *human beings* and not all *human beings* are *persons* (...)". It is quite simple – even though not all agree – to find examples of human beings that are not persons, such as embryos, fetuses or people in serious comatose state. All these definitions are conceptual and philosophical points of view, but they have opened the way to many disputes and debates on the subject.

From the legal point of view, the embryo designates the product of the act of human reproduction. The expression "the legal status of the embryo" refers to the legal provisions related to the human embryo. However, there should be a body of coherent rules arising from defining its nature, not just few separate legal provisions, which refer to the topic [4]. As its nature is uncertain and is not defined as person or thing, there exist some definitions. They oscillate between naming the embryo "biological material" or "thing" and "person" (potential or not) [5].

There are three definitions given to the human embryo, such as:

(1) The embryo is a human person, having an inalienable right to life;

(2) The embryo is a heap of cells with the same moral status as the one of other cells and therefore, we behave toward it as it is a thing or a property;

(3) The embryo is not a person, owner of rights, but it has to be protected as it is a potential person or a special entity.

Depending on the adopted perspective, we will act differently in front of the human embryos: we will treat them as things or as persons.

☒ Embryo protection in domestic and international normative standards

In this paper, we refer through human embryo an expanded category regarding the human being, from conception to birth. When using the term *embryo* we refer also to the one of fetus, because, judicially speaking, the embryo and the fetus are treated together, aiming the unborn child.

In none of the present systems of law the status of the embryo and its legal nature are clearly defined. What certain states have regulated are only the conditions of the research on human embryos, as human stem cell research [6] or the access to the techniques of medically assisted reproduction.

Neither Romania has, in present, a body of specific laws in these two domains. There have been some legislative proposals in the past few years. Therefore, on 6 November 2013, the Senate adopted a legislative proposal on medically assisted human reproduction [7]. It was the fifth attempt to regulate the legislative medical reproduction, procedures that come to serve apparently infertile couples, but it has not yet become a law. Unfortunately, Romania is, in present, the only country from Europe which does not have a law to regulate this domain of medicine and research [8].

For a doctor or a researcher in this field, who exercises his/her profession in Romania, the question is: Which are the legislations and the normative standards we should take into account when we are dealing with human embryo?

Firstly, there are the internal legal norms, like: the penal norms, the civil ones, the special laws and the Medical Deontology Code.

Romanian legal framework related to embryo legal status

Romanian project of law on the medically assisted reproduction

The Romanian project of law on the medically assisted reproduction [7] defines the embryo as the organic assembly of cells, which, by development, may give birth to a human being [art. 4 lett. (d)]. The creation and use of the human embryos for research is prohibited [art. 8 lett. (d)]. This project of law does not refer to the possibility of research on embryos to procure the stem cells. But the law is not in force, yet.

The Criminal Code

The new Criminal Code (CC) adopted in 2009 [9], entered into force in 1 February 2014, protects only the fetus and not the embryo. The penal protection of the right to life starts only at the end of the process of birth, because the legislator chosen to protect the fetus as distinct passive subject, by criminalizing the injuring the fetus stated in art. 202 of CC [10]. If illegal abortion has a correspondent in the previous criminal legislation, the crime of injuring the fetus represents a novelty through which the legislator wanted to protect the becoming life [11]. The fetus enjoys judicial protection distinct from that of the mother, as it is a distinct subject of civil rights. According to the Criminal Code, there are three possibilities:

(a) The harm is committed during pregnancy and has as a subsequent result bodily injury of the woman or the death of the child [art. 201 align. (3)];

(b) Harming the fetus during birth leading bodily harm preventing ectopic life [art. 202 align. (1) and (2)];

(c) The harm is committed during birth by the mother in a state of mental disorder [art. 202 align. (4)].

Like most of the European legislations, neither the Romanian criminal law establishes a judicial protection of the embryo, but, by the interpretation of the provisions that regulate the crime of abortion, we can deduce that it enjoys protection only if the injury, which in the case of this crime it may consist only in abortion [12], is carried out without the consent of the pregnant woman.

The Civil Code

The new Civil Code adopted in 2009 [13] expressly states in the section *Rights to life, to health and to integrity of the individual*, the prohibition to create human embryos for research purposes, in art. 67. Same prohibition is stated also in art. 47 lett. (c) of the *Medical Deontology Code* [14] adopted in 2016, in force from January 2017.

In conclusion, what the domestic legal standards protect, to a certain extent, is only the fetus. It is prohibited to create embryos for research purpose and no reference is made to the legal nature of the human embryo.

International and European regulation related to the legal protection of embryos and fetuses

The Council of Europe is the main international institution which has adopted two legal standards obligatory to the member states, including Romania [15]. They are: (1) *Convention for the Protection of Human Rights and Fundamental Freedoms* (1950) and (2) *Convention on Human Rights and Biomedicine* (1997).

Convention for the Protection of Human Rights and Fundamental Freedoms

This Convention affirms, at the level of the principles, the acts that may violate the rights of any person. The articles that may protect, generally speaking, the human embryo are: art. 2, art. 3, and art. 8.

Article 2

Article 2 regulates the *Right to life*. This article prohibits, especially, the experiments deliberately mortal for man. It was invoked: (a) regarding the right of the children to be born; (b) the father refused to consent to the transfer of an embryo, but he agreed when the embryo *in vitro* was created.

(a) The right of the unborn child to life, *Case of Vo v. France* [16], judged by the European Court of Human Rights (ECHR) in 2004:

Mrs. Thi-Nho Vo, a French woman, of Vietnamese origin, pregnant in six months, came to the hospital for a routine medical visit. There was also another woman, Mrs. Thi Thanh Van Vo, waiting for the procedure of removing a sterilet. The gynecologist who should carry out this intervention has called from the waiting room « Mrs. Vo » and the pregnant woman went to the doctor. As the woman did not understand French well, she was not able to tell the doctor the

reason she was there. The doctor, without examining the patient has proceeded to the removing of the sterilet. The consequence was the abortion a few days later. The woman has filed a lawsuit, accusing the gynecologist as responsible for the loss of her child, at six months of pregnancy, as result of a medical error. Also, she claimed for violation of the art. 2 of ECHR. The physician was not incriminated, in French Courts, of committing manslaughter. ECHR did not consider the art. 2 was violated, estimating that “the life of the fetus is intimately connected to the life of the woman carrying it and it cannot be considered outside the life of the woman”. And “that it is not desirable, nor possible to answer now, in abstract, to the question if the unborn child is a person in the sense of the article 2 of the Convention”.

(b) The refusal of the consent in the transfer of an embryo, the *Case of Evans v. The United Kingdom* [17], in 2007:

In 2000, Natalie Evans was diagnosed with an ovarian tumor being recommended a surgical intervention to remove the ovaries. Before the intervention is carried out, she decides, by mutual agreement, with her partner to conceive, *in vitro*, an embryo that will be cryogened in view of its subsequent implantation. After that, the surgical intervention is carried out followed by the medical recommendation to wait at least two years for transferring the embryo into the uterus. The couple separates in the meantime and the former partner does not renew his consent to the transfer of the embryo. The British Courts rejected women’s claims, because the English legislation in matters does not authorize the implantation of the embryo only if both parts consent to the transfer. On 10 April 2007, Mrs. Evans addresses to ECHR, invoking the violation of the art. 2. As the English legislation does not recognize the quality of autonomous subject of an embryo, the art. 2 is not applicable, considers ECHR. Also, the Court decided to give to each member state the freedom to regulate these issues.

Article 3

Article 3 of the Convention prohibits the inhuman or degrading treatments: “No one shall be subjected to torture or to inhuman or degrading treatment or punishment”. To this article, it was referred the *Case of H. v. Norway* [18] in 1992:

Mr. H and his partner, both Norwegian citizens, wanted to get marry. The woman is pregnant and the couple decides to keep the baby. After a while, the woman changes her mind and decides to interrupt the pregnancy. The fetus already had more than 12 weeks when the request for abortion was made. In such situations, according to the Norwegian law, the abortion may not be practiced only if the mother can justify the special circumstances. After the woman exposed her reasons in front of a committee of physicians, her claim was allowed. When the intervention was carried out, the fetus had 14 weeks. Mr. H’s opinion, who was opposing to the intervention, has not been taken into consideration by physicians. After the procedure of abortion, he asked the right to bury the

remains of the fetus, but is refused. The Norwegian Court refused to give a Decision in this case. In front of ECHR, Mr. H. argued that the abortion suffered by his unborn child was an inhuman treatment, a torture. His claim was rejected by the Court, on the reason that no evidence of fetal suffering could not be provided.

Article 8

Article 8 of the Convention defends the right to respect for private and family life: “There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others”. It was referred to the violation of this article in a case where human embryos, which were no longer part of a parental project, could not be donated for research, the *Case of Parrillo v. Italy* [19], in 2015:

In 2002, Adelina Parillo, 48 years, resorted to the medically assisted reproduction techniques at a center of fertility from Rome, with her partner. As result of an *in vitro* fertilization procedure, five embryos were obtained, which will be cryopreserved. The partner of the woman has died the next year. After few years, the woman asked the director of the center her embryos, as she wishes to donate them for the research on stem cells. In Italy, however, the law prohibits the destruction of human embryos conceived *in vitro*, considered legal subjects, with the right to life. The judges of the ECHR, by vote of 16 to 1 considered that the Italian law does not violate the art. 8, the right to private life and of family, nor the right of ownership as this embryos cannot be considered as being in the possession of the mother.

From these decisions of the ECHR, results that the judges of the European Court intend to protect human rights to life and private life. But, the inclusion or not of the human embryo in the definition of the person is left at the appreciation of the member States. Therefore, the judicial status and the nature of the human embryo are still uncertain.

Convention on Human Rights and Biomedicine

This Convention was signed in 4 April 1997, in Oviedo (Spain) and it is the first mandatory international legal tool dedicated to the protection of the human being and of the dignity regarding the application of biology and medicine. This convention has been ratified by Romania in 2001 [20].

Article 18 of the Convention is a general provision concerning research on *in vitro* embryos. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo. The creation of human embryos for research purposes is prohibited.

The Convention was completed, later, with Additional Protocols, which prohibit the cloning of human beings (1998); it regulates the transplant of organs and of tissues of human origin (2002), the biomedical research (2005), genetic tests for medical purposes (2008).

There are no cases judged by the Court to be included under the incidence of the art. 18 of the Convention.

European Union

Charter of Fundamental Rights

Charter of Fundamental Rights was proclaimed in 2000. It has become legally binding on the EU with the entry into force of the Treaty of Lisbon, in December 2009. The Charter has the purpose to reunite in a single text the community *acquis* in matter of human rights. It has the same legal value as the European Union Treaty, obligatory for the member states [21].

Article 2 guarantees the *Right to life*: “Everyone has the right to life”. Article 3 refers to the integrity of the person, stating that “in the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law, the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings.”

Without referring directly to the human embryo, the Charter highlights the general principles of law of other legal standards.

European Union Court of Justice’s (EUCJ) Decisions

This Court is the only competent to make authentic the interpretation of the European Community treaties. The decisions of the Court are applied in all member states. On October 18, 2011, in the *Case of Oliver Brüstle v. Greenpeace* [22], the European Court of Justice ruled that “any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’ within the meaning of art. 6(2)(c) of the Directive [23] (§ 38):

Oliver Brüstle is a leading German stem cell scientist who holds a patent on neural cells produced from human embryonic stem cells. He introduced a patent application for using the stem cells to produce nerve cells. The German Federal Court of Justice refused Brüstle’s application because it would be contrary to ‘public order’ or morality and informed EUCJ to clarify this exception from patentability. The opinion of the general lawyer was mentioning that the destruction of the human embryos excludes the patentability because it is considered amoral by the law on patents. Also, the human embryo must not be defined restrictively, but it corresponds to a fertilized oocyte or found in the development stage, no matter in which stage is. In the end, the patentability of the cells obtained by the destruction of the human embryo should be excluded. Only the diagnostic and therapeutic applications useful to the human embryo are patentable. The Court decided, especially, ground on the art. 6 from the *European Biopatent Directive*, which specifies that “uses of human embryos for industrial or commercial purposes” cannot be patented [24]. The decision

of the Court is imposed in all member states of the Union.

These are the main legal standards and cases judged by the European Courts related to the human embryo and its legal definition and protection. It is obviously that we do not have clear regulations and unit legal definitions on human embryo issues so far.

▣ Possible explanations and consequences

Why the human embryo does not have a legal status?

The embryo cannot have a legal status, because it is not regulated the problem of its nature. In other words, the legislator does not know what a human embryo is and which its nature is. This is the reason for which the human embryo does not belong to a judicial category. The legal status and definition of the human embryo are the main issues when we are facing some important decisions, such as: abortion, pre-implantation diagnosis, *in vitro* fertilization, embryo research, therapeutic cloning. This is also the reason for which these themes are difficult to regulate and the legal standards are criticized as being restrictive or unsuitable to the evolutions of the science and medicine.

Is an embryo a person or a thing?

The persons are defined as subjects of law which have physical existence [25]. The things are designated by contrast, as everything that is not the person. The difference between things and persons is done by Immanuel Kant, affirming that a thing is, but it does not know that it is. The person knows that it is: what it is, what it is not, what it could be. It can dispose of herself (will-liberty-responsibility). It is not interchangeable (it is an “I” unique, unrepeatable) [26]. Between these two judicial categories, persons and things, there are no other intermediary categories, person only 80% or 120% [4]. The qualification of the human embryo as potential person, a project of person or human person in becoming does not clarify the ethical dilemmas, because it is not clear if the embryos should be treated either in the category of persons or things. There are some legal regulations where embryos are technically considered “property”, and in other like “persons”. Countries such as Australia, Great Britain, USA (Florida, Louisiana and New Hampshire) [27] treat the embryos as things when the cryogenized embryos are donated to other couples. When a transfer of ownership of embryos is done, it is mentioned that it is a “special” transfer, due to the potentiality of that embryo to become a human being [28]. Countries like Germany, Italy, and France consider human embryos as persons from the legal point of view; the cryopreserved embryos will be adopted in the same conditions as any child born. Also, the abandon of the cryogenized embryos is governed by the same provisions which are applicable to the traditional abandon. Thus, the abandoned embryos will be under the care of the state, which has the obligation to find them an adoptive family. This solution differs from the one applied in the states, which do not recognize the status of person of the human embryo.

Who should give the definition of a human embryo?

The legislator

The legislator does not define the embryo because he wants to be neutral. The right expects the science to progress and to give a definition to the embryo and the science cannot carry out researches on human embryos without respecting ethical and legal standards [4]. Therefore, how can be adopted a law with regard to the human embryo without knowing what it is? But this silence of the legislator and this neutrality is illusionary, inasmuch as, the law has a general principle according to which *what it is not expressly prohibited is allowed*. Therefore, even if there are now specific legislations, it does not mean that the science should expect the legal norms to be adopted. The regulations on these topics are extremely necessary in the context of the development of the medicine and of the actual progress of the biotechnologies and of research.

The judges

The judges do not pronounce on the status of the embryos, nor on the beginning of life, as we have noted in the decisions of ECHR, presented above. However, they indirectly qualify the embryo every time when applying or refusing to apply to the unborn child a text of law relative to the human being, to person or to the human person:

This is the case of a gynecologist who administered to a pregnant woman a drug unapproved neither in the European Union, nor in Romania (*n.r.*, Cytotec), to trigger the labor. The contractions provoked by this medicine were so powerful that led to lack of oxygen to the brain of the child and after led to irreversible neurological injuries. The judges of the Court of Appeal from Cluj (Romania), through a decision from June 2015 [29], have classified doctor's act as abuse in service and negligence at work, with no reference to the fetus or to the newborn in the quality of person with rights. Stating in this way, judges of the Court do not have qualified the unborn child as person of whose right to life should be protected, because the criminal regulations in act at the time do not protect the unborn child.

Parents

Parents, most of the time, are either those who decide if a human embryo has judicial protection or not. Even if the legislations do not apply the right to life of an embryo, this is not defined and treated always as it is a thing:

A decision of the Administrative Court of Appeal from Douai (France) [30] affirms that the embryos decryogenized by an error are neither human beings (persons), nor human products (things), concluding that the loss of the embryos, itself, does not cause prejudices. Only the existence of a paternal project will lead to obtain the compensation for damage, not directly for the loss of the embryo, but as result of the damage to parental project.

Another example is the one of Mrs. Knecht, in the *Case of Knecht v. Romania* [31]. In 2009, a fertility clinic

from Bucharest, which due to some legal problems of functioning was closed. The biological material was seized and moved to the "Mina Minovici" Forensic Institute in Bucharest. But, a mother, who was fertilized in the clinic, had another 16 cryogenic embryos and she asked to Romanian authorities to preserve her embryos because her intent is to give birth to another child through *in vitro* fertilization. She notified the ECHR, accusing Romania for the violation of the art. 8 (*Right to respect for private and family life*). The Court ruled on 22 February 2010, for the first time in Europe, the obligation of the Romanian state to take emergency measures in this case, in order to protect the right to life of the embryos belonging to Mrs. Knecht. Also, the Romanian authorities need to provide a solution and to return the 16 embryos by transferring them from the Forensic Institute to an authorized clinic. Only these 16 embryos and not all the cryogenized embryos existent in that clinic of fertility had a judicial protection. This is due to the existence of a parental project. The mother asked to be protected only her 16 embryos, unlike the other for which no legal protection was requested.

Concluding remarks

The unsecure legal status of the embryo, which is not considered neither person, nor thing leaves room to numerous debates and contradictions. Researchers and physicians are still facing a lot of questions and drifts. The point is if the science or the law should clarify these issues by giving a definition to the nature of the human embryo. The legislator cannot define the human embryo since he does not know what it is and the scientists cannot continue investigations since there are no clear standards based on which they carry out their researches. No matter what solution we use, the consequences were huge. Therefore, if recognizing to the human embryo the status of person, the interruption of pregnancy (abortion), no matter the conditions, would become murder and the researches on human embryos would become criminal acts, against the life of the person. On the other side, if the embryo would be considered a thing, it could be subject to marketing, sale, alienation, entering in the commercial circuit, as any other and the restrictions on the research on human embryos would have no sense. The existent laws are few and incoherent, leading to many complaints and confusions. Although desired a solution viable to all, we are far from this desideratum because of the existence of some viewpoints impossible to reconcile. Even if scientists need clear and precise framing, we are not close to a unitary viewpoint.

Conflict of interests

The authors declare that they have no conflict of interests.

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