MEDICÍNSKA ETIKA & BIOETIKA

MEDICAL ETHICS & BIOETHICS

ČASOPIS PRE MEDICÍNSKU ETIKU A BIOETIKU

■

JOURNAL FOR MEDICAL ETHICS AND BIOETHICS

ISSN 1335-0560

BRATISLAVA, SLOVAK REPUBLIC
Spring – Summer 2014 Vol. 21 No. 1 – 2

OBSAH / CONTENTS

CITÁTY / QUOTATIONS[1]

Helsinki Declaration (2013)

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed. When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

[1]Taken from the World Medical Association web page at http://www.wma.net/en/30publications/10policies/b3/

OBJECT OF PROPERTY OR HUMAN BEING? THE STATUS OF THE HUMAN EMBRYO BEFORE THE GRAND CHAMBER OF THE EUROPEAN COURT OF HUMAN RIGHTS (Case Parillo v. Italy)

Marina Casini[2], Carlo Casini[1], Joseph Meaney[2], Mária Šuleková[2, 3], Antonio G. Spagnolo[2]

[1]European Parliament, Committee on Constitutional Affairs, [2]Institute of Bioethics, Faculty of Medicine, Catholic University of the Sacred Heart, Rome, Italy, [3]Faculty of Education, Trnava University, Trnava, Slovakia

The case before the European Court of Human Rights (ECHR)

The Grand Chamber of the European Court of Human Rights (hereinafter ECHR) is to rule soon on the matter of the status of the human embryo in the case of Adelina Parrillo v. Italy (Application n. 46470/11). Are human embryos property, or do they have human rights? This is the dilemma that is soon to be faced by the seventeen judges of the Grand Chamber.

In 2002 after Adelina Parrillo, a 48-year-old Italian woman and her partner, opted to have children by means of *in vitro* fertilization (hereinafter IVF). The woman suffered from endometriosis, a condition where tissue similar to the endometrial lining of the womb is found outside the womb. This causes discomfort during menstruation, pain in the pelvis and other areas, and can cause infertility. Five embryos were created for this purpose, stored and frozen for implantation at a later date. In 2003, her partner died and she gave up the pursuit of the implantation of the embryos.

In 2004, the Italian Law n. 40 of 19 February 2004 passed, whose Art. 13 prohibits experimentation on human embryos, even for the purposes of scientific research.

The applicant wished to donate the embryos for scientific research. However Italian law prohibited her from donating her embryos for this purpose, obliging her to keep them in a state of cryopreservation until they will no longer be viable. So in 2011 (July 26) the applicant applied directly to the ECHR, without exhausting national remedies, alleging that Art. 1 of Protocol n. 1 of European Convention for the Protection of Human Rights and Fundamental Freedoms [1] (hereinafter Convention), Art. 10 and Art. 8 of Convention, were breached by this law that banned her from making her embryos available for destructive scientific research. In other words the applicant claims: 1) her right of "property" over the five frozen embryos, 2) the right of freedom of expression, a fundamental aspect of which is freedom to do scientific research; 3) her right to respect for her private life.

The Second Section of the ECHR ruled on 28 May 2013 rejecting the alleged violation of Article 10 of the Convention (absence of the applicants' quality as victims [2]), but declaring the other two issues admissible [3].

The case is very significant and alarming, because it is the first time that the legal status of the human embryo is challenged in such a drastic way [4]. According to the applicant, the human embryo is a mere thing that can be owned, used, or destroyed, as an object of her property. It is true that Mrs. Parrillo invokes also Art. 8 of the Convention, but the argument of privacy is very tied to that regarding the value of the embryo. Indeed, if a right to property of the applicant doesn't exist, neither is there a violation of her private and family life. In this case-law the applicant doesn't want, as in other cases-law before the ECHR, to have children by means of medical assistance and to raise them [5]. She is in fact not raising an issue regarding family life or private life. A breach of Art. 8 could be assumed for the right to manage one's own property, but only if the human embryo is a thing, and so the claim of a violation of privacy would be a consequence of a claim of the right to property.

Experimentation on human embryos in the Oviedo Convention

In order to rule favourably to the Italian law, it is sufficient to consider Art. 18 (*"Research on embryos in vitro"*) of the Oviedo Convention on Human Rights and Biomedicine of 4 April 1997 [6] (hereinafter Oviedo Convention), which states: *"Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo."* This means that the experimentation on human embryos can be allowed or banned by Member States.

So it is not possible to assert that the Italian ban breaches human rights, because the same Convention on Human Rights and Biomedicine recognizes the right to prohibit the killing of embryos. In other words, the Oviedo Convention permits Member States to allow or prohibit research on embryos *in vitro*. The Italian law chose prohibition, so the appellant cannot demand that the five embryos be used for scientific aims.

Art. 18 adds further: *"The creation of human embryos for research purposes is prohibited."* This clear ban wouldn't have meaning if the principal aim was to promote research. Vice versa, the whole of Art. 18 goes in the direction of restricting research on human embryos: even where it is allowed by domestic law, the law *"shall ensure adequate protection of the embryo"*. Although the criterion to evaluate the adequateness is not very clear, it is sure that some limits are compulsory.

From within Art. 18, there is clearly an unfavourable, rather than favourable attitude regarding the legality of experimentation on embryos. The general rule is that protection exists for embryos even in the earliest phases of their existence and the prohibition on experimentation is rigorously enforced. The lawfulness of experimentation is an exception.

The Convention of Oviedo put forward three recommendations to the Parliamentary Assembly of the Council of Europe 934 (1982) *on genetic engineering* [7]; 1046 (1986) *on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes* [8] and 1100 (1989) *on the use of human embryos and foetuses in scientific research* [9].

The content of these recommendations is very vast. One is reminded only of the request *"to forbid any creation of human embryos by in vitro fertilisation for the purposes of research"* [10] the ban on experimentation using living human embryos, whether viable or not [11], the statement that *"No intervention for diagnostic purposes, other than those already authorized under national legislation, on the living embryo in vitro [...] shall be permitted, unless its object is the well-being of the child to be born and the promotion of its development [...] that is, to facilitate its development and birth"* [12].

Recommendation 1100 (1989), section B, specifically dedicated to scientific research and/or experiments on live preimplanted embryos (zygotes), clearly distinguishes between living and non-living embryos. It recommends that research on living embryos should be prohibited particularly *"if the embryo is viable"* and *"if it is possible to use an animal model"*.

Consistent trends in this direction emerge also from the European Parliament resolutions of 16 March 1989 [13], Direc-

tive 98/44 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [14], and the European Court of Justice's decision in the case Brüstle v. Greenpeace (*Case C-34/10*, 18 October 2011) [15].

Following Art. 18 of the Oviedo Convention, the full legitimacy of Art. 13 of the Italian Law 40/2004, which bans any experimentation on human embryos, is clearly supported.

The case of Parrillo v. Italy clearly has no merit after consulting article 18 of the Convention of Oviedo. The Parrillo case is connected, however, to these three other questions of great judicial relevance. These regard:

a) the principle of the wide margin of appreciation of States in questions of bioethics,

b) the legal status of the human embryo in the European Law,

c) the compatibility and coherence of Law 40/04 with the European Law.

The margin of appreciation doctrine in the ECHR's jurisprudence on bioethics case-law

The principle of the wide margin of appreciation given to States has the effect of preventing the ECHR from pronouncing a censure on certain domestic laws. It is advisable to individualize the grounding, the limits, and conditions of this principle as resulting from some decisions in the field of bioethics.

The case of Fretté v. France (Application n. 36515/97; issued 2 February 2002) [16] concerned the legitimacy of prohibiting homosexual marriage and the adoption of a minor by a homosexual person: *"the Contracting States enjoy a certain margin of appreciation in assessing whether and to what extent differences in otherwise similar situations justify a different treatment in law. The scope of the margin of appreciation will vary according to the circumstances, the subject matter and the background; in this respect, one of the relevant factors may be the existence or non-existence of common ground between the laws of the Contracting States"* (n. 40); "*By reason of their direct and continuous contact with the vital forces of their countries, the national authorities are in principle better placed than an international court to evaluate local needs and conditions. Since the delicate issues raised in the case, therefore, touch on areas where there is little common ground amongst the member States of the Council of Europe and, generally speaking, the law appears to be in a transitional stage, a wide margin of appreciation must be left to the authorities of each State"* (n. 41); *"If account is taken of the broad margin of appreciation to be left to States in this area and the need to protect children's best interests to achieve the desired balance, the refusal to authorize adoption did not infringe the principle of proportionality"* (n. 42).

In the case of Christine Goodwin v. United Kingdom (Application n. 28957/95; ruling of 11 July 2002) [17] regarding the refusal to accept the marriage of a transsexual who changed sex from male to female the Court affirmed: *"In accordance with the principle of subsidiarity, it is indeed primarily for the Contracting States to decide on the measures necessary to secure Convention rights within their jurisdiction and, in resolving within their domestic legal systems the practical problems created by the legal recognition of post-operative gender status, the Contracting States must enjoy a wide margin of appreciation"* (n. 85).

In the ruling of 5 September 2002 in the case of G. Boso v. Italy (Application n. 50490/99) [18], the plaintiff sought compensation for the infringement of his right as a father and of the unborn child's right to life. His wife, who was pregnant, decided to have an abortion despite his opposition according to Art. 5 of Law n. 194 of 1978, by which she alone had the right to decide whether to undergo an abortion. The ECHR responded that: *"In the Court's opinion, such provision strikes a fair balance between, on the one hand, the need to ensure protection of the foetus and, on the other, the woman's interests. Having regard to the conditions required for the termination of pregnancy and to the particular circumstances of the case, the Court does not find that the respondent State has gone beyond its discretion in such a sensitive area"* (The Law, n. 1).

Regarding the wide appreciation afforded to States in certain cases by the ECHR, the case of Vo v. France (Application n. 53924/00), 8 July 2004 is particularly significant [19]. Mrs. Thi-Nho Vo went to a hospital for a medical examination scheduled during the sixth month of pregnancy, but the doctor believed she was there to have an intrauterine device removed. The doctor pierced the amniotic sac causing the loss of a substantial amount of amniotic fluid. In French law there was no legislation for manslaughter through abortion, however the plaintiff Thi-Nho Vo, whose doctor caused the miscarriage of her six-month pregnancy, obtained from the Appeals Court in Lyon a sentence of manslaughter by abortion. However, the sentence was annulled by the Court of Cassation and Thi-Nho Vo appealed to the ECHR invoking article 2 of the Convention to defend the unborn child's right to life. The Court responded that *"the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere, notwithstanding an evolutive interpretation of which must be interpreted in the light of present-day conditions"* (n. 82). The ECHR, therefore, recognizes (no. 84) that human embryos are members of the human species, and this can be regarded as a common denominator in the legislations of European States ("At best, it may be regarded as common ground between States that the embryo/foetus belongs to the human race"). They further declare that: *"the Court has stated on a number of occasions that an effective judicial system, as required by Article 2, may, and under certain circumstances must, include recourse to the criminal law. However, if the infringement of the right to life or to physical integrity is not caused intentionally, the positive obligation imposed by Article 2 to set up an effective judicial system does not necessarily require the provision of a criminal-law remedy in every case"* (n. 90).

The ruling in Vo v. France was cited by the ECHR in deciding on the case of Evans v. United Kingdom (Application n. 6339/05), by the Grand Chamber on 10 April, 2007 [20]. This decision pays particular attention to the definition of the content and the meaning of the "margin of appreciation", regarding both the interpretation of Article 2, and of Article 8 of the Convention.

Mrs. Evans had serious pre-cancerous tumours in both ovaries necessitating their removal. Before undergoing the operation to remove her ovaries the applicant and her husband, commenced treatment for IVF. She was told that she should wait two years before attempting to implant any of the embryos in her uterus. Mrs. Evans with the full consent with her husband had their six embryos frozen while she waited for the procedure to transfer them to her uterus. However the relationship broke down. After the separation of the couple, the woman requested the transfer of the embryos which her partner opposed. Mrs. Evans appealed first to the law courts of the United Kingdom and then to the ECHR, citing her embryos' right to life (Art. 2) and for herself, the right of private and family choice (Art. 8). Both the First Section and the Grand Chamber rejected her plea. On the right to life the Grand Chamber confirmed what had been decided in the case of Vo v. France, repeating also from the First Section that: *"in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within*

the margin of appreciation which the Court generally considers that States should enjoy in this sphere" (n. 54).

On the question of respect of private life the ECHR wrote: *"A number of factors must be taken into account when determining the breadth of the margin of appreciation to be enjoyed by the State in any case under Article 8. Where a particularly important facet of an individual's existence or identity is at stake, the margin allowed to the State will be restricted"* (n. 77); *"The issues raised by the present case are undoubtedly of a morally and ethically delicate nature"* (n. 78); *"In conclusion, therefore, since the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the case touch on areas where there is no clear common ground amongst the member States, the Court considers that the margin of appreciation to be afforded to the respondent State must be a wide one"* (n. 81); *"The Grand Chamber, like the Chamber, considers that the above margin must in principle extend both to the State's decision whether or not to enact legislation governing the use of IVF treatment and, having intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests"* (n. 82).

One particular aspect is gained from the sentence of 4 December 2007 in the case of Dickson v. United Kingdom (Application n. 44362/04) [21]: *"Accordingly, where a particularly important facet of an individual's existence or identity is at stake (such as the choice to become a genetic parent), the margin of appreciation accorded to a State will in general be restricted. Where, however, there is no consensus within the member States of the Council of Europe either as to the relative importance of the interest at stake or as to how best to protect it, the margin will be wider. This is particularly so where the case raises complex issues and choices of social strategy: the authorities' direct knowledge of their society and its needs means that they are in principle better placed than the international judge to appreciate what is in the public interest. In such a case, the Court would generally respect the legislature's policy choice unless it is "manifestly without reasonable foundation." There will also usually be a wide margin accorded if the State is required to strike a balance between competing private and public interests or Convention rights"* (n. 78).

More recently, the principle of the wide margin of appreciation was used by the ECHR to sustain both Irish legislation on abortion (case A.B.C. v. Ireland, Application n. 25579/05; Grand Chamber's decision of 16 December, 2010) [22], and the prohibition of heterologous medically assisted procreation (having recourse to gametes external to the couple) in Austria (case of S.H and others v. Austria, Application n. 57813/00; Grand Chamber's decision of 3 November, 2011) [23]. In the first sentence the wide margin of appreciation was connected to the ethical feelings of the Irish people *"the Court does not consider that the prohibition in Ireland of abortion for health and well-being reasons, based as it is on the profound moral views of the Irish people as to the nature of life and as to the consequent protection to be accorded to the right to life of the unborn, exceeds the margin of appreciation accorded in that respect to the Irish State. In such circumstances, the Court finds that the impugned prohibition in Ireland struck a fair balance between the right of the first and second applicants to respect for their private lives and the rights invoked on behalf of the unborn"* (n. 241).

Also in the case of S.H. v. Austria, the request to condemn the Austrian law was founded on article 8 of the Convention: *"Where a particularly important facet of an individual's existence or identity is at stake, the margin allowed to the State will normally be restricted. Where, however, there is no consensus within the member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider. By reason of their direct and continuous contact with the vital forces of their countries, the State authorities are, in principle, in a better position than the international judge to give an opinion, not only on the exact content of the requirements of morals in their country, but also on the necessity of a restriction intended to meet them. There will usually be a wide margin of appreciation accorded if the State is required to strike a balance between competing private and public interests or Convention rights"* (n. 94).

Even more recently, the second section of the ECHR in the case of Costa and Pavan v. Italy (Application n. 54270/10; decision of 28 August, 2012) [24] confirmed the principle of the wide margin of appreciation, but condemned the provision of the Italian Law 40/04, which does not allow genetic testing before implantation (DGP) and so conflicts with the Law 194/78 that consents to abortion in the case of observed handicaps of the unborn child. This issue is addressed in greater detail below. The ruling, which the authors consider highly problematic, is mentioned here only because it confirms the principle of the broad margin of appreciation.

Finally, in the case of Knecht v. Romania (Application no. 10048/10; decision of 2 October, 2012) [25], the court recognized a broad margin of state discretion regarding both the *"an"* as well as the "quomodo" of the regulation of legislation, such as is present in questions characterized by the constant development of medicine and science, which are particularly sensitive to the ethical perspective. *"The Court's task is not to substitute itself for the competent national authorities in determining the most appropriate policy for regulating matters of artificial procreation, in respect mainly of procedures to be followed or authorities to be involved and to what extent, especially since the use of IVF treatment gave rise then and continues to give rise today to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments. It is why in such a context the Court considered that the margin of appreciation to be afforded to the respondent State is a wide one. The State's margin in principle extends both to its decision to intervene in the area and, once it has intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests"* (n. 59).

This paragraph makes reference to, apart from the first two cases indicated, the ethical decisions regarding the beginning of human life. That is, both the majority of decisions, as well as the subject of this contribution focus on the status of the human embryo.

In addition, regarding "end of life" issues the doctrine of a wide margin of appreciation is also applied. In the case of Haas vs. Switzerland (Application n. 31322/07) regarding assisted suicide (ruling of 20 January 2011) [26], *"the Court observed that the Council of Europe member States were far from having reached a consensus as regards the right of an individual to choose how and when to end his life. The Court concluded that the States had a wide margin of discretion in that respect. Considering that the risk of abuse inherent in a system which facilitated assisted suicide could not be underestimated, the Court agreed with the Swiss Government's argument that the restriction on access to sodium pentobarbital was intended to protect health and public safety and to prevent crime. Therefore there had been no violation of Article 8".*

The basis and the wider or narrower extent of the margin of appreciation. The difference between Art. 2 and Art. 8 of the European Convention of Human Rights

This long sequence of quotations from ECHR rulings shows the solid features of the wide margin of appreciation doctrine. The ECHR justifies its recourse to the above-mentioned principle when there exists one or more of the following

conditions: a) lack of a general consensus between States or within society; b) the necessity to respect the largely well-established and widespread ethical vision of a particular population; c) the complexity of the subject matter with the consequent difficulty of choosing the best means to resolve a problem (distinction between the ends and the means); d) proximity of the national parliaments and the local institutions to the problems of the people and the consequent presumption of their more likely adherence to the reality of local needs than a supranational court.

Regarding bioethics the principle of the wide margin of appreciation is applied with reference to the interpretation of two fundamental human rights: the right to life, guaranteed by Article 2 of the Convention, and the right to self-determination of the individual in the private sphere, guaranteed by Article 8 of the Convention. There is however, a great difference between the ways the principle of the margin of appreciation is applied in the two cases. In fact, regarding Article 2, there is the problem of determining the possession of human rights. The diversity of views regarding the beginning of life and the concept of legal personhood and status of the human embryo, justifies – according to the Court – different domestic choices. Instead, applied in Article 8, the principle goes into an objective difference between the rights and interests of the public and private, which intersect. This is demonstrated well in the content of Article 8, which – after having claimed the right of respect for private and family life – admits that there can (and sometimes should) be legal limitations for the protection of democracy, public security and national welfare, as well as for economic wellbeing, health, morals and the rights and freedoms of others. These problems can become quite complex when there is a conflict of rights.

Around the wider or narrower margin of appreciation many times the Court has declared that the margin of appreciation accorded to the competent national authorities will vary in accordance with the nature of the issues and the importance of the interests at stake. Where a particularly important facet of an individual's existence or identity is at stake, the margin of appreciation accorded to a State will, in general, be restricted. *Vice versa,* where there is no consensus within the Member States, either as to the relative importance of the interest at stake or as to the best way to protect it, the margin will be wider.

That being so, it is questionable, if the first criterion, that of a general consensus, is compatible with the idea of universal human rights.

Historical memory recalls situations, in which totalitarian regimes trampled on human dignity but enjoyed a large consensus and sometimes, in virtue of that consensus they gained power. The Universal Declaration of Human Rights and all the covenants and declarations derived from it, aimed at establishing some values that take precedence over positive laws, in order to counter extreme Legal Positivism or "Might makes Right".

Now, when the means are at stake in order to reach these objectives, it is right to recognize the principle of the broad margin of appreciation of States. The reason is already written in Article 8 of the Convention, and, rightly so, the ECHR recalls that national authorities have the best understanding of the problems and the possible solutions at a local level. They are also closer to the common people and are more sensitive to moral, cultural and ethical issues, which shape the population's identity. So, national authorities are more competent than the ECHR in determining the most appropriate policy in creating regulations.

The distinction between the ends and the means is essential, but naturally a Court called to judge with respect to human rights cannot accept that an important value (end) is directly attacked.

We have already underlined the difference between Articles 2 and 8 of the Convention and we have recalled that the rule according to the margin of appreciation is reduced when one debates "the existence and identity of individuals". Now, those who invoke Article 2 to defend the right to life of the unborn claim precisely this: that human identity and therefore the lives of human beings is recognized since their first coming into existence. Can this question be avoided? May it be left to the variability of opinions? If human rights are only a general view of what is expected and what happens, and therefore not constant and universal in thought and action, what remains of the project inaugurated in 1948, celebrated each year, and cited in many national constitutions? Ultimately, it comes down to recognizing that all human beings have rights from conception, otherwise the grounding of all these rights is gravely flawed.

And yet, in the current cultural context, to appear wise the criterion of the broad margin of appreciation is used, not only regarding means (as in Article 8 of the Convention), but also with reference to ends like the right to life (Article 2). The different opinions on this matter are well known and not only at the level of the national judicial system. The Council of Europe has tried many times to reach consensus on this issue without success. The day after the signing of the Treaty of Oviedo, four Committees worked on additions to the Protocols. One of these should have defined the status of the human embryo. The meetings did not achieve any results, because within the delegated committee, the disagreements remained insurmountable, and the only agreement reached was regarding a meticulous description of the various positions [27].

However, there is a statement that formed a consensus, this statement is already written in the quoted ruling on the case of Vo. v. France, n. 84: the human embryo is a part of the human species. Subsequently, it is not a thing. Certainly, it is not a thing under European law, as the following will demonstrate. And so, what is it? This is a question that justifiably troubles legal scholars, legislators and judges. Their modern culture, their idea of justice, is founded on the principle of equality, sacred in the same international and national acts on human rights. Because an individual is a part of the human species – as science confirms [28] – should they not also be covered under the principle of equality? Despite the many different interpretative positions, doubts can remain, but a judge needs to remember the precautionary principle, continuously applied in the field of ecology. Why should not it suggest practical behaviour in the case of doubt regarding the existence and identity of human beings?

The difficulty of the organs of justice are understandable, but at least, it is reasonable that the principle of the margin of appreciation be as wide as possible and not narrower, when in the complex area described in Article 8 of the Convention, the protection of conception plays a very important role. In fact, among the indicated boundaries to the principle of self-determination there are the "rights of others". The principles of equality and the precautionary principle assert that it is reasonable to look at the embryo at least "as if" it were "another". Because it certainly cannot be considered as a thing, it is not a thing.

The evaluation of human embryo in the European law (human embryo is not a thing)

It is not necessary, at this time, to establish whether the embryo is or is not a "person". It is sufficient to realize that certainly, on the basis of general consensus and European positive law, the human embryo is not considered as a thing, or as an object to be owned. We have already considered Art. 18 of the Convention of Oviedo and underlined the relevance of the criterion of adequacy that the domestic laws have to maintain and to follow in the protection of embryos.

Art. 18 proposes that the embryo is not a thing, but a very important reality, qualitatively different from mere things. As we have seen, the general ban on producing human embryos for research purposes argues in favour of this view. *"Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine"* (art. 1). It proclaims that *"The interests and welfare of the human being shall prevail over the sole interest of society or science"* (art. 2 *Primacy of the human being*). The fact that article 1 implicitly seems to propose a distinction, notoriously present in the bioethical debate, between "human beings" (worthy of protection) and "persons" (entitled to rights that must be guaranteed) is not fundamental to this case, as it is sufficient to observe that the "protection" article 18 refers to evidently recalls the concept of human being, as an entity which is not a "thing", but something different, of greater value.

This perspective is confirmed by the case-law of the ECHR previously mentioned in reference to the States' margin of appreciation. In this jurisprudence it is continuously stated that: *"A broad margin was specifically accorded to determining what persons were protected by Article 2 of the Convention ... there was no European scientific or legal definition of the beginning of life so that the question of the legal protection of the right to life fell within the States' margin of appreciation"* [29]. Note that the doubt relates to the concept of person, but there is no claim that the embryo is a "thing".

The confirmation that the human embryo is not to be considered a "thing" comes from some already quoted documents. Council of Europe's recommendations 934 (1982), 1046 (1986), and 1100 (1989) recognize the dignity and the right to life of the embryo as a human being. In 1046 (1986), for example, it is stated: *"human life develops continuously from the moment of fertilization, therefore it is not possible to distinguish during the first phases (embryonic) of its development in which "the embryo or the human foetus should benefit from the respect due to human dignity"* (point 5).

A similar refusal to consider the embryo as a "thing" stems from the documents of the European Parliament, especially from the resolutions of 16 March 1989 on the ethical and legal problems of genetic engineering [30] and artificial insemination "in vivo" and "in vitro"[31] and from the resolutions on human cloning (1993, 1997, 1998, 2000) [32]. Moreover, in the context of the European Union (hereinafter EU), Directive 44/98 on the legal protection of biotechnical inventions (1998) should be kept in mind [33]. From these documents it really seems that the embryo is not a thing, but rather a human individual. In particular, it has been recognized that the embryo has a right to life, to family (right to an existential-psychological identity), and to a genetic identity. Regarding experimentation, the same rules should apply to human embryos as those established for born human beings; the declared duty to protect the embryo implies the concrete safeguard of his life, or better, as it is said, his right to life. The prohibition on preimplantation diagnosis implies the application of the principle of equality as applied to every human being. Only on things is it right and admissible to apply quality control measures.

Particularly significant is the refusal to distinguish between therapeutic cloning and reproductive cloning. Regarding this distinction, the European Parliament claimed that *"an attempt at linguistic sleight of hand is being used to erode the moral significance of human cloning": "there is no distinction between cloning for therapeutic purposes and cloning for the purposes of reproduction [...] any relaxation of the present ban will lead to pressure for further developments in embryo production and usage"* [34].

However, the document which deserves the greatest attention is the aforementioned sentence produced by the Court of Justice of the EU 18 October, 2011 from case C-634/10 *Oliver Brüstle v. Greenpeace eV*. With this decision the Court excluded in a categorical way that the embryo could be considered a "thing" even when he lies in a test tube. Considering that the Court of Justice interprets the law of the EU so that it can be applied in a uniform way in the 28 countries of the EU, the important ruling of 18 October 2011 establishes a firm and positive point, within the communal law, about the question of the status of the human embryo. The main positive result of the sentence of 18 October, 2011 is the discarding of the "preembryo" theory, which has no scientific basis [35]. It aimed at "downgrading" the phase of development of the human embryo within 14 days after fertilization. The notion of embryo, affirms the Court, *"must be understood in a wide sense" because it is anchored to "the respect needed for human dignity"* (n. 34). That is, *"any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a human embryo"* (n. 38, but also points 35 and 36). While interpreting article 6 of the European Directive 44/98 on the legal protection of biotechnical inventions, the Court *"excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos"* (n. 52). The reason for the ban of patentability indicated by the Court was *"to respect the fundamental principles safeguarding the dignity and integrity of the person"* (n. 32).

The associations that intervened in support of the appellant wanted to restrict the scope of the ruling only to patentability, but this goes against what was explicitly decided by the Court regarding the unity of European law. The wide interpretation of the concept of the embryo is affirmed as "unitary and European" on the basis of the principle of equality (n. 25), which is not a concept born from patent law, but rather precedes patent law and can be found outside of it. The reason for non patentability consists, therefore, in an ethical evaluation that cannot be ignored outside of the patent field. The motivation and the decision establish significant premises for a reflection that can be extended to other industrial and commercial fields. This is demonstrated by having placed the destruction of human embryos in the context of public order and, above all, by the connection between the ban on patentability and human dignity, which has an inherent value to the existence of each human being and is founded on the principle of equality, according to a correct interpretation of the Universal Declaration of Human Rights of 1948 and the following international pacts of 1966.

The sentence, on the basis of Article 6 of Directive 44/98, indicates also public order or morality as a reason for non-patentability (n. 33), notions which imply a particular seriousness of the fact. Such seriousness consists in the destruction of human embryos. The third part of the decision provides a very clear evidence of it: the patent cannot be conceived *"where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos"* (n. 52). The confirmation comes from the reasoning summarized in n. 48. The cells extracted from the blastocyst (embryos that have already reached a certain level of development) are no longer totipotent. Therefore, they cannot be considered "embryos" because they are not the beginning of a human body. Their extraction from

the blastocyst, however, implies the destruction of the blastocyst. Consequently, patentability must be refused even to the use of the cells extracted from the blastocyst. It is obvious that the affront to human dignity and the infringement to public order are the result of the blastocyst' destruction, not specifically the use of extracted material. The Lawyer Bot clearly and efficiently states in his opinion [36]: *"Nevertheless, it is not possible to ignore the origin of this pluripotent cell. It is not a problem, in itself, that it comes from some stage in the development of the human body, provided only that its removal does not result in the destruction of that human body at the stage of its development at which the removal is carried out. The pluripotent stem cell in the present case is removed from the blastocyst which, as I have previously defined, constitutes itself an embryo, that is to say one of the stages in the formation and development of the human body which the removal will destroy. The argument put forward to the Court at the hearing, that the problem of patentability which hinges on the removed cell, the way in which it has been removed and the consequences of such removal do not have to be taken into account seems unacceptable, in my view, for reasons connected with public order and morality. A simple example will illustrate my remarks. The current judicial activity of the International Criminal Tribunal for the former Yugoslavia shows us, obviously subject to the presumption of innocence, that in the course of those events prisoners were killed in order to remove organs for trafficking. If, rather than trafficking, there were experiments which resulted in 'inventions' within the meaning of the term in patent law, would they have had to have been recognised as patentable on the ground that the way in which they were obtained was outside the scope of the technical claim in the patent?"* (nn. 103, 104, 105, 106).

Thus it is evident therefore, that the embryo is not a group of cells, nor it is a thing. The patent is not excluded if the invention implies, for example, the destruction of some blood, or of a small piece of skin. Consequently, that which is against public order is the destruction of the embryo. So the embryo cannot be considered a thing.

Rigor in the protection of the embryo does not contrast necessarily with the legalization of abortion, because the very particular situation of pregnancy implies, according to the logic of the laws, also the safeguarding of the woman and the protective measures for the embryo that necessarily need the mother's cooperation.

The scientist Brüstle had underlined the scientific importance of the requested patent, as well as the large prospective of therapeutic and diagnostic benefits of his invention that is focused on the healing of serious and widespread illnesses, such as Parkinson's disease. Nevertheless, the Court responded that *"the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes also covers use for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable"* (n. 46). It is evident from this claim that the embryo must not to be destroyed. In the ruling of the Court, the importance of the human dignity of the human embryo and the consequent negation of its destruction is more important than scientific research aimed at safeguarding the heath of human beings already born.

At the level of domestic regulations the human embryo is not explicitly considered as an object of ownership. This can be gathered from the same laws that allow abortion and in vitro fertilization. The legal will to introduce or maintain more or less ample margins for abortion (according to the various legal systems: system of time limits, of special circumstances or a mix of the aforementioned), and for *in vitro* fertilization (even in the most manipulative or dissociative practices) is never accompanied by an explicit denial of the humanity of the unborn or by an explicit statement that the human embryo is a "thing".

Furthermore, in some cases, as in the Kansas state law approved April 19, 2013 (in force since July 1) [37], it is stated that *"The life of each human being begins at fertilization"; "Fertilization" means the fusion of a human spermatozoon with a human ovum"; "Unborn children or unborn child shall include all unborn children or the offspring of human beings from the moment of fertilization until birth at every stage of biological development"*.

A look at the interventions of Constitutional Courts proves that, even when a decision on the beginning of human life is avoided, there are no decisions that significantly qualify the human embryo as a "thing." On the contrary, there are decisions that define the human embryo as *"a living individual belonging to the human species,"* and that acknowledge its right to life. Exemplary in this regard are the authoritative German constitutional judgments (25 February 1975, 4 August 1992, and 28 May 28 1993) and the judgment of the Polish Constitutional Court dated May 28, 1997 [38]. The German Constitutional ruling dated 1975 states that *"everyone in the sense of Article 2 of the Constitution* ["everyone has the right to life"] *means every living, in other words, every human individual who possesses life, therefore 'everyone' means also the human being just conceived"*. These words have not been contradicted by the decisions of 1992 and 1993. In the ruling dated 1993, in fact, the Court states that *"in reference to the conceived, we are faced with an individual life, already determined in its genetic identity and therefore in its uniqueness and distinctiveness, that in the process of growing and developing itself not only evolves into a human being, but also as a human being."*

The Polish decision dated 1997 is an interesting reference to the principle of equality in order to claim that the human embryo is not a thing, *"lacking sufficiently precise and built criteria to allow such discrimination in relation to human development"*.

The qualification of the human embryo as a human being – and not as a "thing" – can be also found in the Hungarian constitutional ruling n. 64 dated 17 December 1991 [39]: *"It cannot be proved [...] by evidences of principle why the embryo should be acknowledged as a human being only from a given time, and not before";* this is even clearer in the Portuguese Constitutional judgment n. 25/84, dated 19 March 1984 [40], concerning humanity of the embryo, which states: *"the progress of science, particularly genetics and embryology, is so very well known nowadays as to dispense us from having to provide further information or demonstrations."* In this respect, the judges reported a quote from Prof. Bigotte Chorao that recognizes the human embryo as a "real human being".

The last two decisions – Hungarian and Portuguese – do not hesitate in affirming the opportunity of acknowledging the legal capacity of the conceived: *"The idea of the legal capacity of the unborn child loses its shocking aspect when it comes into consideration that the unborn is already a living human being and as such, is deserving of protection"* (Portuguese ruling), *"the embryo plays an increasing role in society [...] for its physical reality and even more for its individual characteristics. The advancement of medical technology and the use of technical tools allow a deeper understanding of the embryo [...] It cannot be proved [...] why the conceived from a given moment, and not before is recognized as a man [...] The question arises from the fact that the legal position of the human being should be updated [...] the legal concept of the human being should be extended to the prenatal stage, starting from conception. The nature and scope of such an extension could be compared only to the abolition of slavery, or rather it would be even more significant because the legal subjectivity of man would reach its extreme*

limits and its possible perfection: the various concepts of man could coincide" (Hungarian ruling).

The well-known ruling of the U.S. Supreme Court Roe v. Wade, January 22, 1973 [41] that legalized abortion nationwide, refers to the growing dangers for the health of the mother in indicating a criterion for each trimester in the legalization of abortion, but it does not dare to describe the embryo as a "thing" even in the first trimester. Moreover, the same U.S. Supreme Court has declared the acknowledgement of the right to life from conception in a state to not be in conflict with the Federal Constitution.

The investigation carried out shows that there are no documents affirming the human embryo belongs to the realm of things. Instead, what emerges is an elusive attitude, which, however, does not coincide with the denial of the humanity of the unborn and with its "objectification". In this regard, the embarrassment is universal and it is evident also in the 1989 UN Convention on the Rights of the Child (1989) ratified by Italy in 1991 [42]. In the Preamble of the Convention it is only stated that *"The child [...] needs special safeguards and care, including appropriate legal protection before and after birth"* and art. 1 defines a child as *"every human being below the eighteenth year"*. The final term is clear, but where does the initial term start? Of course, at the starting point of the human being. But when does the child of a man and woman become a human being? The silence of the Convention does not authorize us to identify such beginning in a moment following the fertilization of the ovum by the sperm.

To support the *"in vitro* embryo as a thing" theory the claimant uses the argument that *"it is certainly not a living being, meaning an individual with unity, identity and independence"* (no. 23) and that *" it would only be a set of cells as big as less than half of the tip of a needle"* (No. 25). But, the criterion of size doesn't need any answer, while the dependence on the mother is countered by the fact that we are talking about embryos that survive in the test-tube and that the newborn baby does not survive for long without assistance.

In any case, many committees of scientists appointed by governments and parliaments have expressed their thoughts on the nature of the embryo: they have never concluded that the embryo, is a "thing" not even in the moment of its the fertilization. [43]

Even the committee chaired by Lady Mary Warnock, who in 1984 established the basis of the concept of "pre-embryo", acknowledged *"the unity, identity and independence"* of the embryo.

If in the final report the experimentation on embryos is allowed, it is merely and exclusively for practical uses. Chapter n. 11, paragraph 11.19, reads, in fact: *"once the process has begun, there is no particular part of the developmental process that is more important than another, all are part of a continuous process, and unless each stage takes place normally, at the correct time, and in the correct sequence, further development will cease. Thus biologically there is no one single identifiable stage in the development of the embryo beyond which the in vitro embryo should not be kept alive. However we agreed that this was an area in which some precise decision must be taken, in order to allay public anxiety"*. As a consequence, *"despite our division on this point, a majority of us recommend that the legislation should provide that research may be carried out on any embryo resulting from in vitro fertilisation, whatever its provenance, up to the end of the fourteenth day after fertilization"* (n. 11.30). [44] From the aforementioned it becomes clear that the "pre-embryo" theory, suggested within the Warnock Committee, was believed by many to be a way of supporting the possibility of experimenting on embryos. At the end, the word in itself lost its original attraction [45].

Many other bioethics committees have recognized the nature of the embryo as a human being" [46]. In addition to the National Bioethics Committee (NBC) of Italy, several opinions of which will be discussed in the next section, it is necessary to recall the Avis n. 8 and Avis n. 112 of the *Comité National d'Éthique Consultatif pour les Sciences de la Vie et de la Santé* (France). In the first opinion, dated 15 December 1986 [47], the *Comité* claims that *"the human embryo from fertilization belongs to the order of being and not having, of the person and not a thing or an animal" and that "respect for human dignity must guide the development of knowledge and the limits or rules that research must observe"*.

The statement contained in a second opinion, dated 21 October 2010, according to which the human embryo should be respected "as a potential human person", does not deny the humanity of the unborn, but confirms it by refusing to treat the embryo as a "thing".

The intervention by associations in support of the appellant brings up the ruling of the Inter-American Court of Human Rights, dated November 28, 2012 [48]. This ruling refers, however, to the Covenant of San José of Costa Rica (1969) that covers the American States, while for the European point of reference is European law, which is defined by the Convention dated 1950, by the Oviedo Convention dated 1997 and by the rulings of the European Courts.

This case concerned the across-the-board ban on the practice of IVF in Costa Rica [49]. The Inter-American Court ensured this ban exactly because of its absolute nature. There is no mention of the limitations that may be used to protect the dignity of the embryo in a system that allows IVF. Indeed, precisely these limits, including those regarding the creation of supernumerary embryos, destruction, freezing and experimentation, are implicitly regarded as lawful by the Court (i.e. n. 306).

Certainly the American judgment follows the thinking of those who believe that the life of an embryo does not require "absolute" protection, but it should be noted, however, that to deny an "excess" of protection does not mean to exclude "any" protection for the embryo or to believe that the embryo is a thing. The ruling states that the embryo cannot be considered a person, but this questionable conclusion is not relevant in this case, where what is to be decided is whether the embryo is a "thing", and therefore, an object of property.

Three aspects are instead relevant for this purpose. First, the American judgment presumes that there is a conflict between the rights and interests: on one side there is the embryo, on the other side there is the right of adults to privacy and to forming a family (n. 274-275). Well, the conflict and the balance also assume the embryo to be of value and certainly not a thing. Instead, in the Parrillo case the conflict is completely absent.

Secondly, the Inter-American Court was faced on one hand with the claim of some infertile couples to have a child, while on the one hand the law absolutely prohibited IVF. Instead, in the Parrillo case this conflict does not exist. Nor is the plaintiff authorized to represent the supposed interests of "science", as stated by the ECHR itself in its decision dated May 28, 2013.

Third, the Inter-American Court reached its conclusion after a summary of the opposing theories regarding the beginning of human life and the status of the embryo. It resulted that the thesis that the embryo is a living human individual is scientifically significant. Therefore, the lack of unanimous consent is confirmed by the ruling of Inter-American Court and this further supports the principle of the wide margin of appreciation which must be granted to States.

The Italian Law n. 40/2004 in the European context. The human embryo as a subject under the Italian law

The Parrillo's appeal is part of a long series of attacks against the February 19, 2004 n. 40 Law [50], which have given rise

to various legal proceedings and have involved the Italian people in four referendums held on 12-13 June, 2005. Recalling this popular referendum is appropriate for two reasons. First of all: the appeal to the ECHR of the associations "Luca Coscioni", "Amica cicogna", "Cerco un bimbo" and "L'altra cicogna" attempted to manipulate the historical and numerical data with the absurd claim of proving the popular rejection of the law, which in fact was upheld by the voters who rejected the abrogative requests; secondly because – on the contrary – the results of those referendums constitute a strong element to include the Law 40/04 in the wide margin of appreciation justified by the ECHR as referring to the culture and ethical beliefs of a people. In fact, a referendum demonstrates in a clear and indisputable way the sentiments of a population. It would be very important that the ECHR know the following facts: the defence of the Law n. 40 of 2004 was implemented through the advocacy of abstention from voting, not only as a technical way to defend the law, but also as a protest against the misleading way in which the referendum questions were formulated and the attempt to erase from memory the long, open, passionate, scientific and legal debate that preceded the law. Therefore, abstention was not a manifestation of uncertainty or lack of interest, but a strong way to repel the attack [51].

This is demonstrated by the slogan promoted in thousands of meetings, and in millions of posters: "On life you do not vote"; this is demonstrated by the public appeals of *"Scienza e Vita"*, thousands of doctors, lawyers and women, to support abstention from voting on the basis of scientific and legal requirements. Among 49,794,704 citizens registered to vote, 37,065,225 abstained and 1,463,027 declared in the vote their opposition to the abrogation. So there were a total of 38,528,252 citizens who would not repeal any of the measures which had the support of only 22 percent of voters.

It is necessary to point out that compliance with the margin of appreciation which allows states to defend and promote the values that characterize their cultural identity, historical and constitutional sensitivity and the ethical convictions of a population, must also take into account the widespread adhesion of Italian citizens to the European citizens' initiative called "One of Us", promoted in the 28 EU countries [52]. Italian citizens made up 631,024 of the total of 1,891,406 signatories of the European Citizen's Initiative [53]. With this initiative the EU institutions are called upon to recognize the full humanity of human embryos (more precisely, the human dignity and the consequent right to life) and as a consequence not to fund destructive research on human embryos.

The new attack on Law 40/04 can and should be dismissed – as we have seen – simply by referring to the Oviedo Convention, but the reflections that we proposed on the principle of the margin of appreciation must also be applied to the solutions adopted by Italy in Law 40/04, especially as the cornerstone of the whole law is: Article 1, wherein the embryo in a test tube is described as a "subject" entitled to rights [54].

We have seen that the ECHR applies the principle of the wide margin of appreciation also to the various possible interpretations of Article 2 of the Convention. Article 1 of Law 40/04 is just one of the positions mentioned in the judgements of the ECHR as not inconsistent with Article 2 of the Convention.

Art. 1 of Law 40/2004 did not come as a complete novelty. Its content is supported by an impressive body of regulations. We have already mentioned the documents of the Council of Europe that recognize the full human dignity of the embryo (recommendations 934 (1982), 1046 (1986), 1100 (1989)) and the two resolutions of the European Parliament of 1989, which Law 40/2004 widely referred to. It is worth remembering now the opinions of the National Committee for Bioethics (Italy) *Identity and status of the human embryo* (June 22, 1996) [55] *and Opinion on research using human embryos and stem cells* (April 11, 2003) [56], confirmed after Law 40 from the opinions on the so-called "ootides" (July 15, 2005) [57] and on "adoption for birth" (November 12, 2005) [58].

Article 1 of Law 40 seems to be the final echo of the statement contained in the first opinion, where – from the question: *"is the unborn a human being or a thing?"* – it concludes as follows: *"The Committee has unanimously come to recognize the moral duty to treat the human embryo, since fertilization, according to criteria of respect and protection that must be adopted towards human beings who are recognized as persons"*. This conclusion has been confirmed several times and never contradicted in all subsequent opinions relating to the human embryo: in particular that of 11 April 2003 on "Research using human embryos and stem cells" states that *"human embryos are fully human lives" and that there is "a moral duty to always respect them and always protect them in their right to life regardless of the manner in which they were generated and regardless of the fact that some of them could be qualified – with a questionable expression as having no ontological value – supernumerary"*.

Behind Art. 1 of Law 40, there are also two important rulings of the Italian Constitutional Court. Sentence no. 27 of 18 February 1975 [59], which annulled the provisions of the Penal Code punishing voluntary abortion, wrote that: *"the protection of the unborn child has a constitutional basis, namely Art. 2 of the Constitution, which recognizes and guarantees the inviolable human rights, among which the legal position of the unborn shall be included"*. Therefore, the embryo is not a thing; he/she is the beneficiary of protection related to human rights. In this direction ruling n. 27 of 18 February 1975 was interpreted by sentence n. 35 of the same court on February 10, 1997 [60], where the right to life of the unborn is repeatedly affirmed. The point is: the legal possibility to destroy embryos is accepted, but without denying their quality as human beings. The logic followed is that of the conflict between the right to life of the child and the mother's health. In essence, it is – according to the Court – attempting to balance the rights of different subjects. Note that the Constitutional Court (ruling n. 324 of December 11, 2013) [61] recently confirmed the constitutional basis of the unborn's protection recalling both earlier decisions (27/1975 and 35/1997).

Law 40 of 2004 in comparison with the Law 194 of 1978

The ruling of the ECHR (Second Section) in the Costa and Pavan v. Italy case has ignored the principle of the margin of appreciation that Member States enjoy in the most controversial bioethical issues. Instead, it has preferred to argue that there is contradiction between the Law 40 of 2004 on assisted reproduction and the Law 194 of 1978 on abortion: while, on one hand, Italy prohibits pre-implantation genetic diagnosis (hereinafter PGD), which implies discarding embryos deemed to be affected by genetic defects, according to Law 40/2004, on the other hand, it permits the abortion in cases of illness of the unborn child, according to the Law 194/1978.

Actually, the conclusion is incorrect, because the comparison between the two laws must take into account many factors that the Court did not consider. Firstly, the Law 194/1978 does not provide for the child's anomalies as a justification of an abortion, but always regarding the risk to the health of the mother. That means, therefore, that conceptually the context authorizing the elimination of the embryo is the balancing between opposing both constitutionally guaranteed rights. It has not accepted the logic of eugenic selection, as it often happens in the field of assisted reproduction techniques. It is also noteworthy that the PGD (which neither heals nor treats), involves the death of many embryos,

not – and possibly only – of just one as in the case of prenatal diagnosis. Above all, we must consider the great difference between the natural and the artificial generation and the consequent need for different rules.

But in the Parrillo case, it must be assessed whether the alleged qualification of the embryo as a "thing" may find a place in the discipline of abortion. In fact, pregnancy is a very special and unique condition in which a human body lives and grows inside another human body. This implies specific consequences with regard to the means of protection, but does not justify the assumption that the embryo is a "thing". Indeed, no law authorizing abortion is based on the assumption that the embryo is a "thing". Rather on the contrary, the State's commitment is to protect life. This rule is declared, though often betrayed. Not surprisingly, the Italian Law on abortion states in Art. 1: "The Republic protects human life from its very beginning" and Art. 2 requires the institutions to do everything possible to avoid an interruption of pregnancy. The judgment of balance between opposing rights is well shown by the Italian Constitutional Court. It is therefore not correct to evoke Law 194/78 to qualify the human embryo as a "thing" and to justify the direct and voluntary destruction of the embryo *"in vitro"*, outside the mother's body.

In Law 40/04 Art. 1 qualifies the embryo as a "subject" – not a thing, not an object – which has rights in the same way as the other subjects. The logic of the law is to allow IVF but without unnecessary sacrifice of human embryonic life beyond the risks inherent to the IVF technique. For this reason, in contrast to what is allowed in the very special situations of pregnancy the wilful destruction of embryos in the test tube is forbidden. Direct killing of human embryos through destructive experimentation or PGD with the consequent rejection and killing of certain embryos is prohibited. Freezing, since it adds great risk to embryonic life, is allowed only when it is absolutely necessary to save the life of the embryo.

Ultimately, the tendency of the law is to reconcile as far as possible the aspiration of sterile adults to have a child with the protection of the subject-embryo. This line takes into account the fact that even in natural fertilization some embryos do not survive the complicated process of implantation in the endometrium. While death rates from failed implantation with IVF are much higher than in natural pregnancies, Law 40/04 at least provides a chance for life to each embryo. The law allows IVF but at the same time tries to avoid to the maximum extent possible the death of embryos outside the womb.

In conclusion, there is an internal consistency in the law, whose provisions are consequences of the principle laid down in its first article, which in turn is provided for by Art. 2 of the Convention, and which is in accordance with the principle of the margin of appreciation.

The accumulation of surplus embryos and the claim of the "gift to science"

It is true that ruling 151/2009 of the Italian Constitutional Court removed the maximum limit of three embryos which can be generated in a single cycle and transferred into the uterus at the same time, as prescribed in Article 14 of Law 40/04. This norm aimed also to safeguard the life of the embryo endangered by the freezing of supernumerary embryos, which are not immediately transferred into the uterus. The Court nevertheless maintained the rule that IVF must be practiced within the limits of the "strictly necessary" and the procreation of supernumerary embryos can be allowed only in reference to the need to preserve the woman's health. Therefore, the generation of "spare" embryos should remain an exception. However, it enlarged the possibility of an accumulation of frozen embryos because of the end of the parental project that led to their existence. This raises the question of making a "gift to science" that the appellant claims to be implemented in the name of her alleged property right resulting from a reduction of the embryo to a "thing." In fact, if the embryo is not a thing, but a human being (i.e. a person), the treatment reserved for it cannot be different from that concerning any other living human being. The donation of organs from a living donor is not lawful in any country of the world if the organ's removal results in the death of the donor. Special precautions are also foreseen for the legal removal of organs from cadavers. Death must be absolutely certain. Yet, an organ transplant could save the life of another person, but the scientific or therapeutic purpose never justifies putting a human being to death.

The fact that in the current state of knowledge only death is expected at the end of a prolonged freezing does not justify the voluntary anticipation of death. In fact, in the case of patients whose death is now certain and imminent the anticipation of death is not allowed in order to remove organs. Nor can it be ruled out that new scientific discoveries can make ascertainable the natural death of a frozen embryo.

There are other practical reasons that support the consistency of the Italian system. It is clear that the prohibition of destruction and then to the "gift to science", even in the case of parental project's relinquishment, contradicts the requirement of generating the strictly necessary number of embryos. Otherwise generating supernumerary embryos would be encouraged and would be circumvented by the same prohibition of generating embryos for experimental purposes.

As part of the ethical evaluation and policy left to the free appreciation of States, it must also be considered that, as is well known, research on embryonic stem cells has not led to any positive result for therapeutic purposes [62]. On the contrary, adult stem cells extracted from human body parts already differentiated, have a practical use for the treatment of certain diseases and studies on them have opened up prospects of a solid therapeutic use [63]. Moreover, the recent Nobel Prize for science to awarded to the Japanese Yamanaka for his discovery of methods that rejuvenate multipotent adult stem cells, shows that it is not necessary to conduct research on embryonic stem cells as adult stem cells are devoid of any up to date and useful perspective burdened with heavy ethical difficulties. The decision to direct resources towards research on adult stem cells instead of embryonic cells is reasonable to everyone, but especially for States that qualify the embryo as a "subject."

Certainly the storage of frozen human embryos is a serious problem. At present, the only way to ascertain when their death would occur is by thawing them. But if they are still living they cannot be frozen again. Their only faint hope of life is transfer into a uterus. This is the reason why the possibility of some sort of prenatal adoption has been proposed, whose consistency with Law 40/04 has already been declared by the CNB in its opinion of 18 November 2005. In this regard, there are legislative proposals in Italy. We must not overlook the ethical difficulties of embryo adoption, but they could perhaps be overcome, if the generating of supernumerary embryos was absolutely forbidden. The adoption of minors in Italy presupposes the abandonment of a child by the biological parents and it is certainly a commendable and positive solution, but the abandonment in itself remains a negative fact to be countered. It is not ethical to produce abandoned embryos in order to facilitate adoption, but at the same time it is right to promote adoption as a remedy to abandonment. To conclude this paragraph it is very appropriate to mention again Article 2 of the Oviedo Convention under the title "Primacy of the human being" which states: "the interest and welfare of the human must prevail over the sole interest of society or science".

Conclusion

These observations show that Parrillo's appeal should fail both with reference to the right to property, and to the right to respect for private and family life. If the human embryo is a human being, that is "someone" (and not "something", or a "moral opinion"), it is clear that the freedom of parents is limited by the very existence of this "someone", of this "other". The second paragraph of Art. 8 of the Convention moves exactly in this direction: it establishes the lawfulness of a limit imposed by the public authority not only for the protection of morals, but also for the protection of the rights and freedoms of "others".

Casini M., Casini C., Meaney J., Šuleková M., Spagnolo A.G.: Object of Property or Human Being? The Status of the Human Embryo before the Grand Chamber of the European Court of Human Rights (Case Parrillo v. Italy). / Predmet vlastníctva alebo ľudská bytosť? Status ľudského embrya pred Veľkou komorou Európskeho súdu pre ľudské práva (prípad Parillo vs. Taliansko). Med. Etika Bioet., Vol. 21, 2014, No. 1 – 2, p. 2 – 13.

Abstract

After the European Court of Human Rights (EHCR) (Second Section, 28 May 2013) declared partly admissible the case Parrillo v. Italy (Application n. 46470/11), the Grand Chamber will soon rule on this case, which has serious implications for the question of the legal status enjoyed by the human embryo. The appellant claimed that Article 13 of the Italian Law n. 40/2004 on medically assisted procreation, which bans the destruction of human embryos (including through scientific research), violated her "property rights" over the frozen embryos under the Article 1 of the Protocol 1 of the European Convention for the Protection of Human Rights and Fundamental Freedoms and her "right to private life" under Article 8 of the same Convention. Are the embryos just pieces of property or are they human beings? This is obviously the core of the case discussed.

The authors of this paper argue that in the light of scientific and legal bases the embryos originated from male and female gametes should be recognized as human beings. The analysis is conducted reviewing numerous dispositions, first of all the Article 18 of the Oviedo Convention on Human Rights and Biomedicine. Much space is given to the bioethics case-law of the ECHR regarding the doctrine of the margin of appreciation, which should be applied also to defend Italy in the case examined. Besides, it is showed in the paper, how the Italian Law n. 40/2004, which recognizes the embryo as a subject holder of rights (Article 1), is backed by an important normative complex. Thus the thesis of the inconsistency between the Law n. 40/2004 and Law n. 194/178 is clearly rejected. The authors also argue that it makes a well established scientific, ethical and legal sense to encourage science to focus rather on the research using human adult stem cells instead of human embryonic stem cells. Ultimately, what is written in the Article 2 (*"Primacy of the Human Being"*) of the Oviedo Convention *("The interests and welfare of the human being shall prevail over the sole interest of society or science"*) should be set great store.

Key words: human embryo, scientific research, medically assisted procreation, Italian Law n. 40 of 2004, European Convention for the Protection of Human Rights and Fundamental Freedoms, Oviedo Convention on Human Rights and Biomedicine, European Court of Human Rights, margin of appreciation of States, biolaw

Abstrakt

Potom, čo Európsky súd pre ľudské práva (EHCR) (Druhá sekcia, 28. mája 2013) označil za čiastočne prijateľný prípad Parrillo verzus Taliansko (Podanie č. 46470/11), Veľká komora tohto súdu čoskoro vynesie rozsudok, ktorý bude mať závažné dôsledky pre otázku právneho statusu ľudského embrya. Sťažovateľka tvrdí, že článok 13 talianskeho zákona č. 40/2004 o medicínsky asistovanej prokreácii, ktorý zakazuje deštrukciu ľudských embryo (vrátane prostredníctvom vedeckého výskumu), narušilo jej "vlastnícke práva" voči zmrazeným embryám podľa článku 1 Protokolu 1 Európskeho dohovoru o ochrane ľudských práv a základných slobôd a jej "právo na súkromie" podľa článku 8 toho istého Dohovoru. Sú embryo iba časti majetku, ale sú ľudskými bytosťami? To je zrejmé jadro diskutovaného prípadu.

Autori článku argumentujú, že vo svetle vedeckých a právnych skutočností embryá pochádzajúce z mužských a ženských gamét je nutné považovať za ľudské bytosti. Vykonali podrobnú analýzu na základe celého radu významných dokumentov, predovšetkým článku 18 Dohovoru z Ovieda o ľudských právach a biomedicíne. Veľký priestor v článku dostala bioetická judikatúra ECHR, ktorá sa týka doktríny "margin of appreciation", ktorú je potrebné aplikovať aj v prípade obrany Talianska v aktuálnom prípade. Okrem toho článok ukazuje, ako taliansky zákon č. 40/2004, ktorý uznáva embryo ako subjekt a držiteľa práv (čl. 1), je založený na významnom normatívnom systéme. Tým je jasne odmietnutá téza o nekonzistentnosti zákona č. 40/2004 a zákona č. 194/178. Autori zároveň argumentujú, že z vedeckých, etických a právnych dôvodov má skôr zmysel zameranie na výskum s využitím ľudských somatických kmeňových buniek oproti výskumu na ľudských embryonálnych kmeňových bunkách. Napokon, je potrebné plne rešpektovať ustanovenie uvedené v čl. 2 (*"Primát ľudskej bytosti"*) Dohovoru z Ovieda (*"záujem a dobro ľudskej bytosti musia mať prednosť pred záujmom vedy alebo spoločnosti"*).

Kľúčové slová: ľudské embryo, vedecký výskum, medicínsky asistovaná reprodukcia, taliansky zákon č. 40/ 2004, Európsky dohovor o ochrane ľudských práv a základných slobôd, Dohovor z Ovieda o ľudských právach a biomedicíne, Európsky súdny dvor pre ľudské práva, doktrína "margin of appreciation", bioprávo

---

Correspondence to: Dr. Marina Casini, Institute of Bioethics, Faculty of Medicine, Catholic University of the Sacred Heart, Largo F. Vitto 1, 00168 Rome, Italy
e-mail: marina.casini@rm. unicatt.it

Notes and References

[1] Council of Europe. Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No. 11, Accessed Feb. 10, 2014. Available at: http://conventions.coe.int/Treaty/en/Treaties/Html/009.htm. **[2]** The application was also inadmissible *ratione materiae* under Article 10, since the applicant's complaint – that the prohibition of embryo donation amounted to a breach of freedom of expression, a fundamental aspect of which was freedom of scientific research – concerned a right which was not vested in her directly, but rather in those operating in the sector in question, namely researchers and scientists. Mrs. Parrillo concerned a right which was not vested in her directly, but rather in those operating in the sector in question, namely researchers and scientists. **[3]** European Court of Human Rights. *Adelina Parrillo vs. Italy* (Application no. 43028/05) Second section -17 November 2005. Accessed Feb. 10, 2014. Available at: http:// hu doc.echr.coe.int/sites/fra/pages/search.aspx?i=001-126930. **[4]** The European Centre for Law and Justice (ECLJ) has been authorised to submit an amicus brief in the case in favour to Italian Government. See: *The European Court on Human Rights to rule on the status of the human embryo* (Accessed Feb. 10, 2014. Available at: http://eclj.org/Releases/Read.aspx?GUID=4d63713f-2153-442c-90fb-c436342

33aa4&s=eur. **[5]** *Dickson v. United Kingdom* (Application n. 44362/04) C Fourth Section - 18 April 2006 GC - 4 December 2007; *Evans v. United Kingdom* (Application n. 6339/05) C Fourth Section – 7 March 2006, GC – 10 April 2007; S.H. *and Others v. Austria* (Application n. 57813/00) C First Section – 1 April 2010, GC – 3 November 2011; *Costa and Pavan v. Italy* (Application n. 54270/10) C Second Section - 28 August 2012, GC - 11 February 2013; *Knecht v. Roumanie* (Application no. 10048/10) C Third Section 11 February 2013. **[6]** Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997. Accessed Feb. 10, 2014. Available at: http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm **[7]** Council of Europe. Parliamentary assembly. Recommendation 934 (1982) on genetic engineering Accessed Feb. 10, 2014. Available at: http://assembly.coe.int/Main.asp?link=/Documents/AdoptedText/ta82/EREC934.htm **[8]** Council of Europe. Parliamentary assembly. Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes. Accessed Feb. 10, 2014. Available at: http://www.assembly.coe.int//Main.asp?link=http://www.assembly.coe.int/Documents/AdoptedText/ta86/erec1046.htm#1 **[9]** Council of Europe. Parliamentary assembly. Recommendation 1100 (1989) *on the use of human embryos and foetuses in scientific research.* Accessed Feb. 10, 2014. Available at: http://assembly.coe.int/Main.asp?link=/Documents/AdoptedText/ta89/EREC1100.htm **[10]** Council of Europe. Parliamentary assembly. Recommendation 1046 (1986) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes. Accessed Feb. 10, 2014. Available at: http://www.assembly.coe.int//Main.asp?link=http://www.assembly.coe.int/Documents/AdoptedText/ta86/erec1046.htm#1 Point n. III **[11]** Ibid. Point n. IV. **[12]** Ibid. Attached A point I and attached B point I. **[13]** European Parliament. Resolution on the ethical and legal problems of genetic engineering and artificial insemination (A2-372/88 and A2-327/88). Accessed Feb. 10, 2014. Available at: file:///C:/Documents%20and%20Settings/Maria%20Sulek/Dokumenty/Downloads/AX5789645ENC_001.pdf **[14]** Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Official Journal L 213, 30.07.1998. Accessed Feb. 10, 2014, 2014. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML **[15]** Available at: http://curia.europa.eu/juris/document/document.jsf?text=&docid=111402&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=401440 **[16]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-60168# {"itemid": ["001-60168"]} **[17]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/fra/pages/search.aspx?i=001-60596#{"itemid":["001-60596"]} **[18]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-43821# {"itemid": ["001-43821"]} **[19]** Accessed Jan. 15, 2 Feb. 10, 2014014. Available at: http://hudoc.echr.coe.int/sites/eng-press/pages/search.aspx#{"itemid":["001-66445"]} **[20]** Accessed Jan. 15, 2014. Available at: http://hudoc.echr.coe.int/sites/fra/pages/search.aspx#{"itemid":["001-80036"]} **[21]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/fra/pages/search.aspx?i=001-83791# {"itemid": ["001-83791"]}. **[22]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/fra/pages/search.aspx?i=001-102332#{"itemid":["001-102332"]}. **[23]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-107325# {"itemid": ["001-107325"]}. **[24]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-112992#{"itemid":["001-112992"]}. **[25]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx#{"itemid":["001-113291"]}. **[26]** Accessed Feb. 10, 2014. Available at: http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-102940# {"itemid": ["001-102940"]}. **[27]** Steering Committee on Bioethics (CDBI). The Protection of the Human embryo in vitro. Report by the Working Party on the Protection of the Human Embryo and the Foetus (CDBI – CO – GT3, 2003, 13). Strasbourg, 19 June 2003. Accessed Feb. 10, 2014. Available at: http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-CO-GT3 (2003)13E.pdf **[28]** The following references illustrate the fact that a new human embryo, the starting point for a human life, comes into existence with the formation of the one-celled zygote: Pansky, B. *Review of Medical Embryology*. 1982. USA: Macmillan: New York, Lejeune J. *The concentration can: when does human life begin? An eminent geneticist testifies*. 1992. San Francisco: Ignatius Press. O'Rahilly R., Müller F. *Human Embryology and Teratology*, 3rd edition. 2001. New York: Wiley-Liss. Serra A. *L'uomo embrione. Questo misconosciuto*. 2003. Cantagalli: Siena. Moore K.L. *The Developing Human: Clinically Oriented Embryology*. 2003. Moore K.L. *Before We Are Born: Essentials of Embryology*, 7th edition. 2008. Sadler T.W. *Langman's Medical Embryology*, 11th edition. 2010 Lippincott Williams & Wilkins: Philadephia. See also: England M.A. *Life Before Birth*. 2nd edition. 1996. England: Mosby-Wolfe, p. 31 ("Development of the embryo begins at Stage 1 when a sperm fertilizes an oocyte and together they form a zygote."). Moore, K.L. *Essentials of Human Embryology*. 1988 Toronto: B.C. Decker Inc,, p.2 ("Human development begins after the union of male and female gametes or germ cells during a process known as *fertilization* (conception). [...] Fertilization is a sequence of events that begins with the contact of a *sperm* (spermatozoon) with a *secondary oocyte* (ovum) and ends with the fusion of their *pronuclei* (the haploid nuclei of the sperm and ovum) and the mingling of their chromosomes to form a new cell. This fertilized ovum, known as a *zygote*, is a large diploid cell that is the beginning, or *primordium, of a human being."*). Dox, I.G., Melloni B.J., Eisner G, Melloni J. *The Harper Collins Illustrated Medical Dictionary*. 1993. New York: Harper Perennial, p. 146 ("Embryo: An organism in the earliest stage of development; in a man, from the time of conception to the end of the second month in the uterus."). Walters, W. and Singer, P (eds.). *Test-Tube Babies*. 1982. Melbourne: Oxford University Press, p. 160 ("Embryo: The early developing fertilized egg that is growing into another individual of the species. In man the term 'embryo' is usually restricted to the period of development from fertilization until the end of the eighth week of pregnancy."). Langman, *J. Medical Embryology*. 3rd edition. 1975. Baltimore: Williams and Wilkins, p. 3 ("The development of a human being begins with fertilization, a process by which two highly specialized cells, the *spermatozoon* from the male and the oocyte from the female, unite to give rise to a new organism, the *zygote*."). Considine, D (ed.). *Van Nostrand's Scientific Encyclopedia*. 5th edition. 1976. New York: Van Nostrand Reinhold Company, p. 943 ("Embryo: The developing individual between the union of the germ cells and the completion of the organs which characterize its body when it becomes a separate organism. [...] At the moment the sperm cell of the human male meets the ovum of the female and the union results in a fertilized ovum (zygote), a new life has begun. [...]The term embryo covers the several stages of early development from conception to the ninth or tenth week of life."). Moore, K.L. and Persaud, T.V.N. *Before We Are Born: Essentials of Embryology and Birth Defects*. 4th edition. 1993. Philadelphia: W.B. Saunders Company, p. 1 ("Zygote. This cell, formed by the union of an ovum and a sperm (Gr. zyg tos, yoked together), represents the *beginning of a human being*. The common expression 'fertilized ovum' refers to the zygote."). Larsen, W. J. *Human Embryology*. 2nd edition. 1997. New York: Churchill Livingstone, p. 17 ("The chromosomes of the oocyte and sperm are...respectively enclosed within *female* and *male pronuclei*. These pronuclei fuse with each other to produce the single, diploid, 2N nucleus of the fertilized zygote. This moment of zygote formation may be taken as the beginning or zero time point of embryonic development."). Carlson, B.M. *Patten's Foundations of Embryology*. 6th edition. 1996. New York: McGraw-Hill, p. 3 ("Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote). [...] The time of fertilization represents the starting point in the life history, or ontogeny, of the individual."). **[29]** Case of *A, B and C v. Ireland* (Application no. 25579/05), Grand Chamber, judgment 16th December 2010 n.185. Also: Thi-Nho *Vo v. Francia*, July 8, 2004; *Evans v. United Kingdom* April 10, 2007; *Tisyac v. Poland* March 20, 2007. **[30]** Official Journal C 96, 17.04.1989, p. 165. **[31]** Official Journal C 96, 17.04.1989, p. 171. **[32]** Official Journal C 315, 22.11.1993, p. 224 (res. 28.10.1993); Official Journal C 115, 14.04.1997, p. 92 (res. 12.03.1997); Official Journal C 34, 22.02, 1998, p. 164 (res. 15. 01. 1998); Official Journal C 378, 29.12, 2000 p. 20 (res. 30.03.2000); Official Journal C135, 7.05.2001, p. 263 (res. 7.09.2000). **[33]** Official Journal L 213, 30.07. 1998, p. 13. **[34]** European Parliament. Resolution on human cloning, 7 September 2000. Accessed Feb. 10, 2014. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2001:135:0263:0264:EN:PDF. **[35]** O'Rahilly, R. and Muller, F. *Human Embryology & Teratology*. 2nd edition. 1996. New York: Wiley-Liss, pp. 8, 29. This textbook lists "pre-embryo" among "discarded and replaced terms" in modern embryology, describing it as "ill-defined and inaccurate" (p. 12). The Author also writes: "Although life is a continuous process, fertilization is a critical landmark because, under ordinary circumstances, a new, genetically distinct human organism is thereby formed. [...] The combination of

23 chromosomes present in each pronucleus results in 46 chromosomes in the zygote. Thus the diploid number is restored and the embryonic genome is formed. The embryo now exists as a genetic unity." Silver, L.M. *Remaking Eden: Cloning and Beyond in a Brave New World.* 1997. New York: Avon Books, , p. 39 ("[A]nimal biologists use the term *embryo* to describe the single cell stage, the two-cell stage, and all subsequent stages up until a time when recognizable humanlike limbs and facial features begin to appear between six to eight weeks after fertilization. [...][A] number of specialists working in the field of human reproduction has suggested that we stop using the word *embryo* to describe the developing entity that exists for the first two weeks after fertilization. In its place, they proposed the term *pre-embryo* [...]" [...]The term pre-embryo has been embraced wholeheartedly by IVF practitioners for reasons that are political, not scientific. The new term is used to provide the illusion that there is something profoundly different between what we nonmedical biologists still call a six-day-old embryo and what we and everyone else call a sixteen-day-old embryo. [...]The term pre-embryo is useful in the political arena – where decisions are made about whether to allow early embryo (now called pre-embryo) experimentation – as well as in the confines of a doctor's office, where it can be used to allay moral concerns that might be expressed by IVF patients."). **[36]** Opinion of advocate general Bot, delivered on 10 March 2011. *Brüstle v. Greenpeace e.V. Case* C-34/10. Feb. 10, 2014, 2014. Accessed: Feb. 10, 2014, 2014. Available at: http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d0f130d66eb00e508a3043eca38fc38fa0518371.e34KaxiLc3eQc40LaxqMbN4OaxuNe0?text=&docid=81836&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=197076 **[37]** Abortion Restrictions and Declaration that Life Begins at Fertilization. HB 2253. Accessed: Feb. 10, 2014. Available at: http://www.kslegislature.org/li/b2013_14/measures/hb2253/ **[38]** The references are taken from: Casini, M. Il diritto alla vita del concepito nella giurisprudenza europea, Le decisioni delle Corti Cosituzionali e degli organi sovranazionali di giustizia, Cedam, Padova: 2001, **[39]** Brunner, G., Sólyom, L. Verfassungsgerichtsbarkeit in Ungarn, Baden Baden, Nomos Verlagsgesellschaft: 1997, p. 256-279. **[40]** Diario da Republica. II s_rie, n. 143 de Junho de 1985. **[41]** U.S. Supreme Court Roe v. Wade, 410 U.S. 113 (1973) 410 U.S. 113 Roe et Al. v. Wade, District Attorney of Dallas County Appeal from the United States District Court for the Northern District of Texas No. 70-18. Argued December 13, 1971 Reargued October 11, 1972 Decided January 22, 1973. Accessed: Feb. 10, 2014, 2014. Available at: http://www.foxnews.com/projects/pdf/roevwade.pdf. **[42]** Legge 27. 5. 1991 n. 176. Ratifica ed esecuzione della Convenzione sui diritti del fanciullo (New York 20. 11. 1989), Gazzetta Ufficiale, 11. 6. 1991, n. 135 serie ordinaria. **[43]** For example, in Italy: "Santosuosso Commitee", "Guzzanti Commitee", "Busnelli Commitee"; in Spain: "Palacios Commitee"; in Germany "Benda Commitee"; in France: "Lenoir Commitee"; in United Kingdom: "Warnock Commitee". **[44]** Warnock, M. A question of life. The Warnock Report on human fertilisation and embryology, Oxford Basil Blackwell: 1985. Available also at: www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into Human_Fertilisation_and_Embryology_1984.pdf. **[45]** "The story of this word resembles the brief lifetime of a shooting star, which, after a brief moment of splendour, disappears and is not seen again". Colomer, M.F, Pastor L.M. The pre-embryo's short lifetime. The history of a word, Cuad. Bioét. XXIII (2012/3_), p. 667-694. **[46]** Corsetti, L.B, Bompiani A., Chieffi G.,Dalla Torre G., Danesino V., Donati P., Fiori A., Isidori A., Leocata A., Manni C., Pinkus L., Preziosi P., Romanini C., Rossi Sciumé G., Sgreccia E., Silvestrini B. Additional Declaration of the Identity and Status of The Human Embryo, Opinion by the Italian National Bioethics Committee, Rome, 22nd of June 1996. Accessed Feb. 10, 2014.Available at: http://www.palazzochigi.it/bioetica/eng/pdf/human_embryo_19960622.pdf **[47]** Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé. Avis relatif aux recherches et utilisation des embryons humains in vitro _ des fins médicales et scientifiques, n. 8 dated 15. 12.1986. Accessed Feb. 10, 2014. Available at: http://www.ccne-ethique.fr/fr/publications/avis-relatif-aux-recherches-et-utilisation-des-embryons-humains-vitro-des-fins **[48]** Inter-American Court of Human Rights. Murillo et al. (*"in vitro fertilization"*) v. *Costa Rica.* November 28, 2012. Accessed Feb. 10, 2014, 2014. Available at: http://www.worldcourts.com/iacthr/eng/decisions/2012.11.28_Murillo_v_Costa_Rica.pdf **[49]** *Decreto Ejecutivo 24029-S Reglamento para las Técnicas de Reproducción Asistida* del 3 febbraio 1995 n. 24029-S1; Sala Constitucional Corte Suprema De Justicia Costa Rica, *Sentencia n. 2000-02306 de 15 de marzo de 2000.* Accessed Feb. 10, 2014, 2014. Available at: http://es.scribd.com/doc/36185708/12-Sentencia-2000-02306-Costa-Rica **[50]** Gazzetta Ufficiale n. 45 del 24 febbraio 2004. Accessed Feb. 10, 2014. Available at: http://www.camera.it/parlam/leggi/04040l.htm **[51]** Casini, C. Il dibattito in bioetica, Le ragioni del non voto. *Medicina e Morale*, 2 (2005), p. 409-428. **[52]** Accessed Feb. 10, 2014. Available at: www.oneofus.eu **[53]** Accessed Feb. 10, 2014. Available at: http://www.mpv.org/uno_di_noi/00018255_Home.html **[54]** Art. 1, paragraph 1, of 40/2004 law: *"In order to facilitate the solution of problems arising from human reproductive sterility or infertility recourse to medically assisted procreation is allowed, under the conditions and in the manner prescribed by this Act, which ensures the rights of all parties involved, including the unborn."* **[55]** Italian National Bioethics Committee, Identity and Status of the Human Embryo, 22nd of June 1996. Accessed Feb. 10, 2014. Available at: http://www.palazzochigi.it/bioetica/eng/pdf/human_embryo_19960622.pdf **[56]** Id. Parere su Ricerche utilizzanti embrioni umani e cellule staminali, 11 aprile 2003. *Medicina e Morale* 4 (2003), p. 725 – 726. **[57]** Id. Bioethical remarks on the so-called "ootide", 15th July 2005 Accessed Feb. 10, 2014 Available at: http://www.palazzochigi.it/bioetica/eng/pdf/BIOETHICAL_15062005.pdf **[58]** Id. Adoption for the birth of cryopreserved and residual embryos obtained by medically assisted procreation MAP, 18th November 2005. Accessed Feb. 10, 2014 Available at: http://www.palazzochigi.it/bioetica/eng/pdf/ADOPTION_18112005.pdf **[59]** Accessed Feb. 10, 2014. Available at: http://www.giurcost.org/decisioni/1975/0027s-75.html **[60]** Accessed Feb. 10, 2014. Available at: http://www.giurcost.org/decisioni/1997/0035s-97.htm **[61]** Gazzetta Ufficiale, 1a Serie Speciale, 2-1-2014. Accessed: Feb. 10, 2014 Available at: http://www.giurcost.org/decisioni/2013/0324o-13.html **[62]** "[T]he controlled expansion and differentiation to specific cell types is an area where considerable research will be required before cell transplantation becomes clinical practice." de Wert G., Mummery C. Human embryonic stem cells: research, ethics and policy. *Human Reproduction.* 18:4 (2003), p. 672-682. For review see: Passier R., Mummery C. Origin and use of embryonic and adult stem cells in differentiation and tissue repair. *Cardiovasc Res.* 58:2 (2003), 324-35. **[63]** Daniela, F., Vescovi, A.L., Bottai, D. The stem cells as a potential treatment for neurodegeneration. *Methods Mol Biol.* (2007), 399: 199-213, doi: 10.1007/978-1-59745-504-6 14. Galli, R., Gritti, A., Vescovi, AL. Adult neural stem cells. *Methods Mol Biol.* (2008), 438: 67-84. doi: 10.1007/978-1-59745-133-8_7. Gritti, A., Vescovi, A.L. Galli, R. Adult neural stem cells: plasticity and developmental potential. *Journal of Physiology-Paris* 96 (1), 81-90. Smith, A.R., Wagner, J.E. Alternative haematopoietic stem cell sources for transplantation: place of umbilical cord blood. *Br J Haematol.* (2009), 147(2): 246-61, doi: 10.1111/j.1365-2141.2009.07828.x., Harris, D.T. Non-haematological uses of cord blood stem cells. *Br J Haematol.* (2009) 147(2):177-84, doi: 10.1111/j.1365-2141.2009.07767.x. Gluckman, E. Ten years of cord blood transplantation: from bench to bedside. Br J Hae-matol. (2009), 147(2): 192-9, doi: 10.1111/j.1365-2141.2009.07780. x. Monti, M., Perotti, C., Del Fante C., Cervio M., Redi C.A., Fondazione IRCCS Policlinico San Matteo, Pavia (Italia). Stem cells: sources and therapies. *Biol Res.* 45:3 (2012), 207-14, doi: 10.4067/S0716 - 97602012000300002. van de Ven, C., Collins, D., Bradley, M.B., Morris E., Cairo M.S., The potential of umbilical cord blood multipotent stem cells for nonhematopoietic tissue and cell regeneration. *Exp Hematol.* 35:12 (2007), 1753-65. Lee, M.W., Jang, I.K., Yoo, K.H., Sung, K.W., Koo, H.H. Stem and progenitor cells in human umbilical cord blood. *Int J Hematol.* 92:1 (2010), 45-51, doi: 10.1007/s12185-010-0619-4. Epub 2010 Jun 25.

Memorandum of the International Conference "Stem Cell Technologies: Clinical, Scientific, Legal and Ethical Aspects in the European Union", Kaunas, Lithuania, 10.–11. X. 2013

We, the participants of the conference, together with experts in biomedicine, ethics and law, gathered in Kaunas, Lithuania, on October 10 – 11, 2013, at the conference entitled ***"Stem Cell Technologies: Clinical, Scientific, Legal and Ethical Aspects in the European Union"*** have agreed by consensus the following:

1. We acknowledge that stem cell research must be carried out in accordance with the principle of human dignity as enshrined in the Charter of Fundamental Rights;
2. We recognize the great potential of cell-based therapies for the treatment of a wide range of difficult or previously untreatable conditions and the progress achieved in haematopoietic stem cell and other adult cell therapies;
3. We acknowledge that sensitive ethical questions continue to arise with regard to embryonic stem cell research and that embryonic stem cell research is illegal in a number of the EU Member States;
4. We express concern that some cell products are outside the Advanced Therapy Medicinal Products Regulation and that unproven cell medicinal products are being offered to Europeans within and outside the EU.

We conclude that there is a need:

to ask for greater cooperation between EU Member States, the scientific community, industry and other partners in developing safe and effective cell-based therapy medicinal products;

to note that the Court of Justice of the European Union has ruled that "any human ovum must, as soon as fertilised, be regarded as a human embryo if that fertilisation is such as to commence the process of development of a human being," and that this ruling has serious ethical implications for our society, for research and for industry;

to reaffirm that protection of patients is at the core of medical practice and urge EU Member States to develop an adequate control mechanism of advanced therapeutic medicinal products;

to raise awareness and improve access of patients to existing clinically safe and proven cell-based treatments;

to encourage EU institutions to consider their respective policies.

Adopted 11. X. 2013.

Consensus Framework for Ethical Collaboration between Patients' Organisations, Healthcare Professionals and the Pharmaceutical Industry

A Consensus Framework established for ethical collaboration between patients' organisations, healthcare professionals and the pharmaceutical industry, in support of high quality patient care. This Consensus Framework and the accompanying resources are intended to serve as a toolkit for those associations, groups and alliances who wish to develop their own policies. It neither aims to be comprehensive nor does it constitute a single common policy of the organisations involved. The individual policies of the participating organisations set out each organisation's detailed commitments and offer more diverse and in depth information and guidance.

Preamble

As developed and developing countries strive to address pressing health challenges in the complex and fast-evolving healthcare environment, collaboration between all partners is essential in ensuring proper delivery of the most appropriate care for patients worldwide.

In the 1980s international codes and guidelines were approved including the first IFPMA Code of Pharmaceutical Marketing Practices in 1981 and the WHO Ethical Criteria for Medicinal Drug Promotion in 1985. Since then progress has been made to ensure appropriate interactions and ethical promotion of medicines globally, including through self-regulatory and voluntary mechanisms such as codes of conduct and principles. These highlight the need for patients' organisations, healthcare professionals, and the pharmaceutical industry to work together for the benefit of patients, while recognizing each other's professional role in the context of the healthcare value delivery chain and maintaining their professional independence.

There is an important link between patients, healthcare professionals, the pharmaceutical industry and their organisations in providing best solutions to patients' health needs and each partner has a unique role and responsibility in ensuring that patients receive the most appropriate care. Patients must be informed and empowered to, along with their caregivers, decide on the most appropriate treatment options for their individual health needs and to participate responsibly in use of health resources and managing their own health. In this respect, healthcare professionals must ensure that the treatment options they offer to patients are appropriate. In turn, the pharmaceutical industry has a duty to provide accurate, fair, and scientifically grounded information for their products, so that the responsible use of medicines can be facilitated.

The Consensus **Framework for Ethical Collaboration** is characterized by four overarching principles: Put Patients First; Support Ethical Research and Innovation; Ensure Independence and Ethical Conduct; and Promote Transparency and Accountability. The Consensus Framework outlines some of the key areas that should be considered by all partners to help guide ethical collaborations at the individual and organisational levels [1], and is based on the common elements within the documents listed in the Tools and Resources section of the Framework. It encompasses a shared commitment of organisations representing patients, healthcare professionals, and the pharmaceutical industry to continually improve global health and ensure, in collaboration with other stakeholders, that all patients receive appropriate treatment. This Framework aims to complement the various national, regional and global codes and guidelines and serve as a model for similar joint initiatives between patient organisations, healthcare professionals and pharmaceutical industry associations at the national level.

The Consensus Framework is currently supported by IAPO [2], ICN [3], IFPMA[4], FIP[5] and WMA[6], as all partners have a mutual interest in ensuring that the relationship between patients, healthcare professionals, the pharmaceutical sector, and their organisations, is based on ethical and responsible decision making.

---

[1] The Joint Framework is based on the common elements within the documents listed in the Tools & Resources section. [2] International Alliance of Patients' Organizations (IAPO)[3] International Council of Nurses (ICN) [4] International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) [5] International Pharmaceutical Federation (FIP) [6] World Medical Association (WMA)

The Consensus Framework is a living document and is open to other key partners working in life-sciences and healthcare delivery, which are welcome to endorse it and comment upon it.

Consensus Framework Principles

Put Patients First

Patients are our priority.

For example:

1 Optimal Care for All - Working as partners, at both the individual and organization level, to ensure that collaboration between patients, healthcare professionals, and pharmaceutical companies support patients and their caregivers in making the best decision regarding their treatment.

2 Partnerships – All partners working in healthcare have a right and responsibility to collaborate to improve healthcare access and delivery. Establishing partnerships will aim to deliver greater patient benefits.

Support Ethical Research and Innovation

Partners encourage clinical and related research conducted to generate new knowledge about effective and appropriate use of health treatments.

For example:

3 Clinical Research – Continuing to advocate and support the principle that all human subject research must have a legitimate scientific purpose, aims to improve health outcomes, and be ethically conducted, including that participants are appropriately informed as to the nature and purpose of the research.

4 Objective Clinical Results – Continuing to ensure that compensation for research is appropriate and does not compromise objective clinical results of the research.

Ensure Independence and Ethical Conduct

Interactions are at all times ethical, appropriate and professional.

For example:

5 Gifts – Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence. No financial benefit or benefit in kind should be sought, offered, provided or accepted in exchange for prescribing, recommending, dispensing or administering medicines.

6 Sponsorship – Continuing to advocate that the purpose and focus of all symposia, congresses, scientific or professional meetings (an "Event") for healthcare professionals and patient organisations should be to provide scientific or educational information. The primary purpose of an event must be to advance knowledge and all materials and content must be balanced and objective. All events must be held in an appropriate venue. Moderate and reasonable refreshments and/or meals incidental to the main purpose of the event can be provided to participants of the event.

7 Affiliation – Business arrangements and professional relationships between partners should not inappropriately influence their practice, compromise their professional integrity or their obligations to patients. Business arrangements and relationships should respect professional integrity and should be transparent.

Promote Transparency and Accountability

Partners support transparency and accountability in their individual and collaborative activities.

For example:

8 Fees for Services – Working together to ensure that all arrangements requiring financial compensation for services, such as consultancy or clinical research, have a legitimate purpose and a written contract or agreement in place in advance of the commencement of services. Remuneration for services rendered should not exceed that which is commensurate with the services provided.

9 Clinical Research Transparency – Continuing to support the premise that both the positive and negative outcomes of research evaluating medicines, other products and services should be disclosed. Clinical research in patients and related results should be transparent while respecting patient privacy.

Implementation, Monitoring and Reporting Mechanism

Partners are encouraged to develop their own self-regulatory codes and principles for ethical collaboration and interactions and ensure their effective implementation. Systems to monitor and report breaches of the set standards should be established to support ethical practices and ensure accountability both at the institutional and individual levels. These may include, for example, public statements detailing collaborative agreements and external review mechanisms.

Tools and Resources

- WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2013)

http://www.wma.net/en/30publications/10policies/b3/

- IAPO Healthcare Industry Partners Framework (2012)

http://www.patientsorganizations.org/partners

- FIP Rules of Procedure – Guidelines for Sponsorship (2012) (internal document)
- IFPMA Code of Practice (established in 1981; last revision 2012)

http://www.ifpma.org/ethics/ifpma-code-of-practice/ifpma-code-of-practice.html

- ICN Code of Ethics for Nurses (2012)

http://www.icn.ch/about-icn/code-of-ethics-for-nurses/

- WMA Statement Concerning the Relationships b/w Physicians and Commercial Enterprises (2009)

http://www.wma.net/en/30publications/10policies/r2/

- ICN Position Statement: Informed Patients (2008)

http://www.icn.ch/images/stories/documents/publications/position_statements/E06_Informed_Patients.pdf

- FIP/WHO Developing pharmacy practice – a focus on patient care (2006); Chapter II-3: Information management and the use of evidence.

http://www.fip.org/good_pharmacy_practice

- ICN Position Statement: Nurse Industry Relations (2006)

http://www.icn.ch/images/stories/documents/publications/position_statements/E09_Nurse_Industry_Relations.pdf

- IAPO Organizational Values (2005)

http://www.patientsorganizations.org/attach.pl/700/278/IAPO7s0Organizational0Values.pdf

- FIP Statement on Professional Standards – Code of Ethics for Pharmacists (2004)

www.fip.org/statements

- WHO Ethical Criteria for Medicinal Drug Promotion (1985) http://archives.who.int/tbs/promo/whozip08e.pdf

---

Text taken from the web page of the World Medical Association at www.wma.net

6. konsenzný workshop – Klinické skúšanie produktov a liekov v SR v roku 2014 MZ SR, 2. 4. 2014

Dňa 2. apríla 2014 sa v konferenčných priestoroch Ministerstva zdravotníctva v Bratislave uskutočnil tradičný konsenzný workshop venovaný aktualitám z oblasti klinického skúšania a Správnej klinickej praxe v celoštátnom a v medzinárodnom kontexte. Konal sa pod odbornou garanciou Ústavu farmakológie, klinickej a experimentálnej farmakológie LF a Ústavu zdravotníckej etiky FOaZOŠ Slovenskej zdravotníckej univerzity a Slovenskej spoločnosti klinickej farmakológie, o. z. SLS (SSKF), za aktívnej účasti predstaviteľov MZSR, ŠÚKL, zástupcov zadávateľov a organizátorov klinických skúšaní, členov etických komisií a skúšajúcich (spolu 120 registrovaných účastníkov). Súčasťou programu bolo aj **16. celoštátne stretnutie etických komisií v SR**.

Workshop prebiehal v troch odborných sekciách. Prvá bola venovaná novému *Nariadeniu Európskeho parlamentu a Rady o klinickom skúšaní liekov nahrádzajúcemu Smernicu 2001/20/EK* a jeho dôsledkom pre príslušnú legislatívu SR z pohľadu MZSR (J. Slaný) a ŠÚKL (P. Gibala), z hľadiska zadávateľov a organizátorov klinických skúšaní (H. Mrázová, M. Noskovičová, N. Farkašová), ako aj s ohľadom na nové požiadavky na prácu, kvalifikáciu a odborné kompetencie etických komisií (J. Glasa). Ide o novú medzinárodnú právnu normu pre oblasť klinických skúšaní a Správnej klinickej praxe, ktorá má priamy účinok vo všetkých členských krajinách Európskej únie a vyžiada si prijatie viacerých závažných opatrení aj na území SR.

Nasledujúca odborná sekcia sa zaoberala obsahom a praktickým významom nedávnej novely Helsinskej deklarácie (SAL/WMA 1964/2013) pre oblasť biomedicínskeho výskumu a klinického skúšania v SR (T. Krčméryová), a to osobitne z hľadiska práce a zodpovednosti skúšajúceho lekára (H. Glasová), ako aj z pohľadu jeho zadávateľa a organizátora (A. Lengyelová, K. Kováčová).

Osobitná sekcia bola venovaná problematike klinického skúšania nových očkovacích látok a jeho významu pre národný program očkovania v SR (H. Hudečková), z pohľadu zadávateľa a organizátora klinických skúšaní (P. Rupčíková) a z pohľadu očkujúceho pediatra (K. Šimovičová).

Výstupom rokovania je konsenzný odborný materiál – *Závery workshopu a odporúčania pre prax* (viď nižšie), ktorý účastníci prostredníctvom organizátorov zaslali príslušným štátnym inštitúciám (MZ SR, ŠÚKL) s ponukou odbornej spolupráce pri príprave a implementácii potrebných opatrení, ktoré bude v pomerne krátkom čase nevyhnutné na Slovensku realizovať.

Prof. MUDr. Jozef Glasa, prezident SSKF SLS

Závery workshopu – odporúčania pre prax

A. Prijatie nového nariadenia Európskej únie (EÚ) o klinickom skúšaní a Správnej klinickej praxi[1] prináša závažné zmeny pre vykonávanie a právne prostredie klinického skúšania v EÚ a v Slovenskej republike (SR). Ide o nový, záväzný odborný, právny a etický štandard. Vyžaduje:

1. zosúladenie legislatívneho prostredia v SR s týmto novým štandardom (novela príslušných zákonov);

2. spresnenie vnútroštátnych postupov a štandardov posudzovania a povoľovania klinických skúšaní v SR, vrátane činnosti, úloh a zodpovednosti etických komisií (vyhláška /odborné usmernenie; registrácia / akreditácia / certifikácia);

3. aktívnu a systematickú edukáciu všetkých subjektov, ktoré sa zúčastňujú na klinickom skúšaní, vrátane zodpovedných skúšajúcich, pacientov i laickej verejnosti (certifikácia / akreditácia);

4. zabezpečenie informovanosti skúšajúcich, odbornej i laickej verejnosti o požiadavkách novelizovanej Helsinskej deklarácie Svetovej asociácie lekárov (2013) a ich dôslednú implementáciu v oblasti klinických skúšaní a biomedicínskeho výskumu v SR (oficiálny preklad, edukácia, popularizácia; zlepšenie prostredia a vnímania klinického skúšania a biomedicínskeho výskumu; aktivity EUPATI; úlohy, zodpovednosť a aktivity MZ SR, SZU, SSKF, SLS, ŠÚKL a i.)

B. Klinické skúšanie nových vakcín zabezpečuje overenie ich účinnosti a bezpečnosti po predchádzajúcom predklinickom skúšaní. Jeho podpora, pri rešpektovaní príslušných odborných a etických štandardov, je žiaduca aj v podmienkach SR.

[1] Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (prijaté Európskym parlamentom 2. 4. 2014)

Medicínska etika & bioetika - Medical Ethics & Bioethics. Medzinárodný, dvojjazyčný, vedecko-odborný časopis pre otázky medicínskej etiky a bioetiky. Je určený najširšej medicínskej a zdravotníckej verejnosti v Slovenskej republike a v zahraničí, zvlášť členom etických komisií. Má za cieľ napomáhať medzinárodnú výmenu informácií a dialóg na poli medicínskej etiky a bioetiky. Prináša informácie o aktuálnych podujatiach a udalostiach v oblasti medicínskej etiky a bioetiky, pôvodné práce, prehľady, významné materiály a dokumenty, kurz pre členov etických komisií, listy redakcii a recenzie. Pôvodné vedecké a odborné práce publikované v časopise sú recenzované a musia zodpovedať obvyklým medzinárodným kritériám. Založený v roku 1994 Nadáciou Ústav medicínskej etiky a bioetiky. Počas prvých rokov existencie tvorba časopisu nadväzovala na vedecko-odborné aktivity Ústavu medicínskej etiky a bioetiky, spoločného pracoviska Inštitútu pre ďalšie vzdelávanie zdravotníckych pracovníkov (IVZ) a Lekárskej fakulty Univerzity Komenského (LF UK) v Bratislave.

Medicínska etika & bioetika - Medical Ethics & Bioethics. International, bilingual, scientific – professional journal for medical ethics and bioethics. It is devoted to the broadest medical and health care professional public in the Slovak Republic and abroad. Journal pays special attention to the informational and educational needs of ethics committees' members. It aims to foster international exchange of information and dialogue in the field of medical ethics and bioethics. The journal publishes information on actual activities and events in the field of medical ethics and bioethics, original papers, review articles, important materials and documents, continuous course for ethics committees' members, letters to the editor and book reviews. Original research and review papers published in the journal are peer-reviewed and they must abide to the usual international standards. The journal was founded in 1994 by the Institute of Medical Ethics and Bioethics Foundation. During the early years of its existence, editing of the journal was related to the scientific and professional activities of the Institute of Medical Ethics and Bioethics, the joint centre of the Institute for Postgraduate Education of Health Care Professionals (IPEHCP) and the Faculty of Medicine of the Comenius University (FM CU) in Bratislava.

ISSN 1335-0560

Included into Medline ™ and Bibliographia medica slovaca
www.bioetika.sk, www. bioethics.sk

PRINTED IN SLOVAKIA