

Private Law**Legal Limitations of Researching and Using
the Stem Cells****Rustin-Petru CIASC¹**

Abstract: The importance of research in view of using stem cells for scientific and medical purposes must be regulated in a clear and, to the degree possible, single manner, at European and world level. Beginning with this obvious necessity, this article attempts to review the relevant provisions in the domestic legislation, while supplying the required appreciations and criticism. In the end, it reaches the idea, also upon replying on some compared law elements, that not only some legislative modifications or adaptations are imposed, in connection to the normative acts in force, but particularly the creation of a complete and complex legislative framework. It must cover the existence of all practical situations and regulate the scientific research activity in this domain, without ignoring at any time the inviolability of human dignity and acknowledging the right of integrity of the person's body and mind.

Keywords: tissue; personality right; harvesting; transplant; cloning

In a global manner, practically all multicellular organisms have stem cells. A stem cell is an undifferentiated cell characterized by its ability to generate specialized cells that would differentiate themselves; its multiplication ability is practically endless, mainly in the growth media. The animal stem cells and particularly the human stem cells are subject matter of numerous researches, mainly in medicine in order to regenerate tissues and even to create some pieces of tissues and bodies (the latter being the objective pursued by cell therapy). The origin of stem cells used in research also raises ethical issues: it is true, most of them come from embryos, although recently it was discovered the possibility to use other sources, such as blood cells from the umbilical cord or the stem cells in the adipose tissue. When researching the stem cells is allowed, the international legal norms included in the

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legislations that provision that procedure limit it to the cells coming from supernumerary embryos derived from medically assisted reproduction procedures, especially prohibiting the creation of embryos just for research purposes. More, given the potential advantages that they seem to bring, the therapeutic cloning experiments were developed for leading to their production in higher quantities.

Right now, the researches on embryo stem cells are not extremely advanced, the ethical and legal reasons decisively contributing to this fact. The research connected to human embryo stem cells is controversial due to destruction an embryo. The risk of organ incompatibility in the case of persons that went through a transplant could be avoided by preparing stem cells from “embryos” created by nuclear transfer (transfer of a nucleus from the patient’s own cells). Some researchers within the Kyoto University named this procedure “therapeutic cloning”; an example for applying research in this area is the uncontrolled proliferation of transplanted cells or transmitting infectious agents. As well, the research made on embryo stem cells could cause revolutions in several branches of medicine by the possible discovering of treatments for several conditions that are now mostly incurable. The so-called “direct reprogramming” provides such an example that implies genetic modifications by rearranging the DNA of some adult cells in order to create stem cells. While developing this method, the researchers from pilot universities, the Kyoto University and the Wisconsin-Madison University are using cells harvested from the foreskin of a newborn baby and skin cells harvested from an adult woman.

In the case of nervous system diseases, such as Parkinson’s, Alzheimer’s, multiple sclerosis, as well as other neurodegenerative diseases, the solution might come by replacing the lost or damaged nervous cells by tissues developed in laboratory, derived from embryo stem cell lines. Transplanting neurons that would enter the brain or produce various missing neurotransmitters might be possible. As well, it would be possible to transplant glial cells. In clinics, the treatment of patients suffering of Parkinson’s was made on a limited scale, by transplanting cells from the fetal brain. The heart muscle cells destroyed during a heart attack might be replaced by smooth muscle cells produced by in vitro differentiation of embryo stem cells.

For the bone and cartilage diseases, such as osteoarthritis, they might be rectified by inserting cells that could repair the damaged portion. As well, the missing bone (as consequence of trauma or surgical interventions) might be replaced by newly generated bone cells. For cancer treatment, the bone marrow, which is now used

for transplanting blood and cells playing a part in immunity (part of the cancer treatment that allows the more intensive use of cytotoxic medicines), might be efficiently replaced by hematopoietic stem cell injections derived from embryo stem cells with defined immunogenetic potential or autologous to the patients. This method having direct benefic effects on immunity could also be extremely useful for treating immunodeficiency disorders such as AIDS or immune disease, such as **systemic lupus erythematosus** or multiple sclerosis.

In Romania, in some definitions included in article 142 of Law no. 95/ April 14, 2006 on reform in the health area, according to which the cell is the anatomic and functional elementary unit of living matter, the term referring thus to individual human cell or a collection of human cells, which are not united by any intracellular substance form, and the tissue is seen as representing the differentiated cell group joined by the amorphous intercellular substance, which make up together a topographic and functional association, it can be found that the distinction between the two formations is obvious. More, the next provisions of the same normative act differentiate those notions, thus that article 144 refers practically to harvesting human tissues, organs or cells from the live donor. The future law on medically assisted reproduction expressly provisions the possibility to perform researches on embryos in order to obtain stem cells, an aspect I believe useful considering that every national legal system is bound to decide on ethical matters it is facing, including as regards the researches made on embryo stem cells.

The main penal norms regulating the penal liability in the area of harvesting and transplanting (implicitly of handling) human tissues, organs and cells (including stem cells) are included in the legal provisions on the reform in the health area. Such norms are found also in the draft law on medically assisted reproduction but they can only be, at least for the time being, subject matter of some theoretical discussions, thus being maintained the legislative insufficiency in the area of medically assisted reproduction, of liability for committing illegal deeds on abusively producing and developing embryos, altering the human genome and genetic selection, surrogacy contract, donation, chimeras and hybrids, selling gametes and embryos, harvesting and using them, breaching confidentiality, false statements on the medically assisted reproduction activity, achieving the medically assisted reproduction techniques and procedures, and scientific research developed by medical centers and laboratories, as well as the storing activity.

Law no. 95/ 2006 on reform in the health area incriminates the deeds that are felonies concerning the activity of organizing and performing the human origin

organs, tissues and cell harvesting. Performing the harvesting and transplanting of human organs, tissues and cells for therapeutic purpose is regulated by Title VI of this law, the regulations complying with Directive 231/2004/ EC of the European Parliament and Council of March 31, 2004 on setting out quality and safety standards concerning the donation, acquiring, testing, processing, preserving, storing and distributing human tissues and cells. As well, Law no. 95/2006 provisions in article 141 the obligation for harvesting human cells (the anatomic and functional elementary unit or a collection of human cells, which are not united by any intracellular substance form), next to harvesting tissues and organs to be made for therapeutic purposes.

Harvesting is defined as the activity of taking human healthy organs and / or tissues and/or cells from a functional and morphological point of view in order to achieve a transplant (article 142 letter d of Law no. 95/2006). Practically, the activity of harvesting human organs and /or tissues and /or cells has a double meaning; it helps save the receiver's life and it must not affect or harm the live donor or the physiognomy of the deceased person from whom the harvesting was made. The regulations in force (Law no. 95/ 2006 and the new provisions of the New Civil Code, mainly article 68) do not differentiate between various types of cells that can be harvested or transplanted, but is limited to using the general term of human origin cells, thus including the ova and stem cells in this category. Thus, I believe that as long as the Parliament did not understand that it should explicitly exclude certain cell categories from the activity of organizing and performing the harvesting and transplanting, the only condition for them to be subject matter of these harvesting or transplanting activities is to represent an anatomic and functional elementary unit or a collection of human cells, which are not joined by any intracellular substance form.

Referring once more to the legislation in force at this time it can be noticed that, in general, the subject matter of legal penal protection in the case of felonies provisioned by Law no. 95/ 2006 is the social relations on protecting the life and public health, more precisely the social relations concerning the harvesting and transplanting of human tissues and organs in other conditions than those provisioned by law.

In another special meaning, the legal subject matter of the felonies provisioned by Law no. 95/2006 is the social relations concerning the attributes indissolubly connected to the human existence and human being's personality, to protecting the integrity, health and existence of the human species (Pitulescu, 2006, p. 170). The

material object of these felonies is, as applicable, the body of the traumatized persons, the tissues and organs, which were taken from or brought to Romania, were means for acquiring some financial benefits or contributed to compromising a forensic medical examination.

The new regulations provisioned by the Civil Code in chapter II “Respect owed to the human being and her inherent rights” broaden the subject matter of legal penal protection in the case of illegally harvesting and manipulating the organs, tissues and cells, in general, and implicitly of ova and stem cells, as it is indicated until now by the provisions of the special law. Thus, this subject matter became now much more complex and vast. Thus, article 58 of the New Civil Code confirms, for the first time in the Romanian legislation, the personality right, which belongs to each individual by the simple fact of being a human being, thus being inherent to her. The approach coming from the provisions of the New Civil Code refers to present day matters imposed by the scientific evolution on genetic selection, examining the genetic traits, harvesting and transplanting tissues, cells and organs, human cloning, genetic fingerprint identification, and medically assisted reproduction.

According to the definition supplied by article 58, the person should be seen as an ensemble of notions referring to the biological and the psychological and social existence of the individual. More precisely, the personality rights refers to two large right categories, on one hand the rights concerning the human body protection (right to life, health, and physical and psychic integrity), and on the other hand the rights protecting the moral values (dignity, honor, privacy, and own image).

In the first category of rights that make up the personality right, the right on „inviolability of human body” (article 64 of the New Civil Code) is included also, understanding by it the fact that no person will be constrained to accept any harming of her body. The exact understanding of the inviolability of human body right leads to the distinction between human body as ensemble of organs and components (tissues and organs) and its products, as result of scientific evolution and progresses (which can be seen as “things”, due to the possibility to detach them from the body, but without them becoming subject matter of any patrimony right). Thus, it could be said that the provisions of the New Civil Code on the inviolability of human body complete and practically adapt the Romanian legislation on the principles that govern the human body protection, beginning of course with the

provisions of articles 22 and 26 of the Constitution and continuing with the provisions of the special law.

On its turn, the right of the person to dispose of herself (article 60 of the New Civil Code) refers to the bodily, physical freedom, the right to dispose of one's body, but also to the psychic and moral implications, being one of the most natural, inalienable and imprescriptible human rights. This right comprises also the right to donate organs and tissues for transplantation or other medical and genetic engineering experiments (Constantinescu et al., 2004, p. 50), that including the harvesting of ova or stem cells as transplant manner. The human body is the biological support of person thus that by protecting it the subject of law is defended. The human body cannot be subject to commerce, which complies with the legal nature of personality rights. The partial freedom the law acknowledges to the human being on her body, which includes her right to agree to performing some surgical interventions or to harvesting tissues or organs, is not an aspect of the right to dispose on oneself, seen as attribute of the ownership right, but a manifestation of the personality rights, which are limited by public order and morals (Cercel, 2009, pp. 8-9).

In principle, medical care is granted only according to the free informed written consent, according to article 144 of Law no. 95/ 2006 (it can be withdrawn anytime until the time for harvesting), thus being excluded any forced treatment. Continuing this idea, Law no. 95/ 2006 forbids harvesting organs and tissues from a live donor that is mentally unable to decide. As a rule, the underage child cannot be subject to organs or tissues harvesting, exception to this being the harvesting of stem cells for therapeutic purpose. In the case when the donor is an underage child aged over 14 years, harvesting organs and tissues can be made only with her and her legal representative's consent (parent or guardian) - article 145 of Law no. 95/ 2006 and article 68 of the New Civil Code. Thus, the conclusion is that harvesting or transplanting organs, tissues or cells without the donor's consent is prohibited (article 155 of the law mentioned above), and such activities must be performed only for therapeutic purpose and according to the law (articles 141, 149, and 157 of Law no. 95/2006).

Performing the activity of harvesting and transplanting human organs, tissues or cells, in other conditions than those imposed by law and mentioned above, commits, as applicable, the civil, disciplinary, patrimony or penal legal liability. This liability is legally provisioned by articles 642 through 643 of Law no. 95/2006 and articles 1381 through 1395 of the New Civil Code, articles 442 through 451 of

Law no. 95/2006, articles 271 through 273 of the Labor Code (Law no. 53/2003 published in the Official Bulletin of Romania, Part I, no. 72 of February 5, 2003, completed and modified) and articles 155 through 159 of Law no. 95/ 2006 (penal liability).

Article 144 letter f) of Law no. 95/2006 provisions that the doctor commits a misdemeanor as regards his civil liability in connection to the damages caused at the time of harvesting and transplanting human origin organs, tissues and / or cells, these activities not being subject matter of some legal deeds and acts. The conclusion is implicitly that the doctor's liability for the damages caused at the time of performing such procedures leads also to a liability for misdemeanor. This liability must rely on his own fault that will be set out by considering, on one hand, the risk involved by his activity, and on the other hand, the failure of which he cannot always be guilty.

As regards the disciplinary liability of the medical staff and doctors, I will only emphasize that it is included in the Labor Code, Title XII "Exercising the physician profession. Organization and operation of the Romanian College of Physicians", Section VI "Disciplinary liability", articles 442 through 451 of Law no. 95/2006. As well, for the financial damages caused to the employer by the physicians or other employees during the activity of harvesting and transplanting human origin organs, tissues and cells, the patrimony liability will be included within the limits of the present legislative framework set out for employees.

Finally, according to article 154 of Law no. 95/2006: "Organizing and performing the harvesting and / or transplanting of human origin organs, tissues and cells in other conditions than those provisioned by this title is a felony and punished according to the law" (Chapter V- Punishments).

As it can be seen, these provisions were included in the punishments chapter that sets out, according to the specialty literature (Diaconescu et al., 2009, pp. 208-209), the dangerous deeds that the law stipulated as felonies, but comprised no orders concerning the severity, such a general norm contradicting the incrimination practice by special laws. As well, it is found that according to the latest modification of Law no. 95/2006, namely the text in force on July 6, 2013, this article 154 would be rescinded on February 1, 2014 (the date when Law no. 286/2009 on the Penal Code will enter in force), practically making reference to the future Penal Code – general penal law in this matter. At least at this time, it does not provision incriminating such deeds, which will lead to creating a legislative

void concerning this matter, because Law no. 95/2006, being a special law on the reform in the health area with some penal provisions, cannot be deemed penal law to which references can be made.

As indicated already, the terminology used by the legislation now in force refers to the activity of organizing and harvesting human origin organs, tissues and cells, including in these activities their subject matter and the operations that follow to be made with it. From the present day formulation of the law text, the conclusion is that the terminology used can lead to various interpretations at least in connection to the operations developed during the harvesting procedures for transplant purposes, as well as those made with the harvested material, which is not transplanted. Thus, the law clarifies the harvesting activity as procedure of taking human origin organs and / or tissues and / or cells, which are morphologically and functionally healthy (except for the self-transplant of hematopoietic stem cells) in order to implant them in the body of a patient, without stating anything in connection to the activity of handling the organs, tissues or cells (implicitly ova and stem cells). That is although this activity is obvious and inherent (more, it is emphasized in the service contracts concluded between medical commercial companies, which are service suppliers, and the beneficiary persons). More, no express clarification is made in connection to the activities developed after the harvesting takes place, when the transplanting of human organs, tissues or cells does not occur, or as regards the possible (penal) liability of those involved in such operations (physicians, medical staff, companies, and organ, tissue or cell banks).

I believe that, although when first analyzing the law, it seems not to cover these operations, still from corroborating and extensively single-handedly interpreting the texts concerning this matter without special laws, such as New Civil Code, Penal Code, the conclusion is that they are also regulated, at least for the situation of harvesting and transplanting human organs, tissues or cells (article 154 of Law no. 95/2006). However, *de lege ferenda*, it would be imposed, for avoiding any interpretation and eliminating any doubts, to state the text in article 154 of the law mentioned above, in the meaning of emphasizing also the activities of “handling” the material harvested, as well as underlining these provisions in the New Civil Code. As well, it would be required to regulate expressly the penal liability of the depository (organ, tissue or cell banks, and medical societies acting in this domain) for destroying or compromising the harvested stem cells, considering its intent or fault, as well as the express clauses in the civil contracts concluded, by incriminating the illegal activities in this domain.

In the European Union, the European Group on Ethics in Science and New Technologies issued in November 2000 an opinion on the ethical aspects of research on human stem cells and using them, believing that each state must allow or forbid such researches. That opinion categorically prohibited human cloning for therapeutic purpose and believed that the clinical trials with stem cells other than embryo ones (made in the case of some patients with severe diseases) can lead to ethics problems, more as creating human embryos for research purposes is expressly prohibited by the Oviedo Convention. Nevertheless, the European Union is in favor of researches on embryo stem cells; in November 2011, the European parliament allotted several billion Euros for this purpose.

Also within the European Union, the member states had various stands on regulating the research on stem cells, these regulations showing the diversity of ethical, philosophical and religious beliefs in Europe. Thus, in Great Britain research on human embryos is only authorized for certain objectives, such as promoting the improvements in the infertility treatment, enhancing the knowledge on false tissue causes, developing more effective birth control techniques, developing some methods that would allow identifying the presence of genetic or chronic disorders, broadening the knowledge on embryo development, enhancing the knowledge on some severe diseases, and allowing the application of such scientific knowledge for developing treatments. The authorized research can only use in vitro embryos, being allowed on embryos whose age does not surpass fourteen days. The human reproductive cloning is illegal on the territory of United Kingdom, as is the nuclear transfer technique or any other procedure meant to create a cloned baby.

The French law of bioethics adopted in 1994 prohibited research on human embryos and embryo stem cells, and its revision from 2004 confirmed this interdiction while issuing five-year derogation. The biomedicine agency was made in charge with applying this derogation to specific cases “susceptible to allow major therapeutic progress” and provided that no alternative method with comparable efficiency existed. This legal regime of France that is single in the world allowed mainly granting some time to think in order to understand better the possibility provided by this type of research without rendering it legal *ipso facto*. Within the revision of the bioethics law, the Council of State issued in May 2009 an opinion foreseeing the authorization of research on human embryo stem cells, while acknowledging that they pose a therapeutic interest, even if other promising alternatives were developing. If the temporary moratorium forecasted according to

the previous norms seemed to be an obstacle at scientific level, the Council of State forecasted the preservation of the same authorization regime, not allowing that the research on stem cells coming from supernumerary embryos surpass the purpose of allowing major therapeutic progress.

On December 4, 2012, the French Senate adopted a legislative proposal that authorized research on human embryos and human embryo stem cells provided certain conditions were met. The National Assembly (lower chamber of French Parliament) will discuss this legislative proposal submitted by the Parliament members close to the present government during 2013. That legislative proposal allows altering some aspects comprised by the bioethics law adopted in 2011, as well as going from a principle interdiction of research on human embryos and human stem cells to an authorization under the strict control of national Biomedicine Agency. Those researches refer to supernumerary embryos conceived by in vitro fertilization that are no longer subject matter of a parental project, after previously informing the couple in question and acquiring their consent, being strictly included at the same time in the meaning of pursuing a medical purpose. That law will allow conciliating the ethics and research freedom, clarifying at the same time the legal framework of research made on human embryos and human stem cells in France. It also represents a significant advance expected for over 20 years by researchers in this domain. The potential legislative modification generates, at the same time, numerous expectations on the medical progress, with the possibility for partnerships between French and international researcher teams be created (<http://www.enseignementsup-recherche.gouv.fr>).

As a conclusion, given that the European diversity led to animated debates when the financing for research based on stem cells determined the involvement of some countries in order to fund certain projects, according to the limitations of legislative proposals, while other European partners refused to become involved calling upon mainly the legislative void or ethics aspects (being found out, still, that the general trend is in favor of the research on embryo stem cells), it can be stated that the present day Romanian legislation, mainly the penal one, requires some future incriminations, modifications, clarifications, and completions. They must be made provided all operations developed in connection to the activity of organizing and performing the harvesting of human organs, tissues and/or cells (in the meaning indicated above) for transplant purposes are mentioned expressly, as well as the period when the harvested material can be used and the liability of all factors involved in these harvesting, collecting, transporting, processing, qualifying, and

storing activities (right now, they are only subject matter of service contracts concluded between supplier and beneficiary, which leads only to civil liability). In addition, it is required that the law of medically assisted reproduction enters in force as soon as possible, in order for a complete and complex legislative framework be created that would cover all practical situations and regulate the activity of scientific research in this area.

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