

## THE ROLE OF THE LEGAL NORM IN BIOETHICS

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**ABSTRACT:** *In 2001, Romania ratified the European 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, known as the Oviedo Convention and its Additional Protocol, time when their provisions were transposed into the national law having the binding force of the regulatory acts.*

*After this time, taking the example of other European countries such as France, Romania required the adoption of a law devoted to bioethics that should translate the principles of the Convention, by adapting them to the specificity of our realities, by establishing the rules of conduct and the institutional framework for compliance with these principles, including sanctions for their violation.*

*This paper aims that, starting from the review of the relationship between bioethics and law, to state the need to adopt a law on bioethics in Romania that should bring together all the specific regulations in this area, penalizing their violation. We consider that the debate on this topic in the medical world, but also in the legal world, could constitute a signal for the country's legislative body to lean responsibly on these so important issues, which could influence each of our lives.*

**KEYWORDS:** *Oviedo Convention; bioethics; law; law on Bioethics*

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### 1. INTRODUCTORY CONSIDERATIONS

Nearly a century ago (1919) in a metaphorical revealing expression, the poet and philosopher Lucian Blaga anticipated the profound implications of the scientific knowledge on each of our lives, "*I do not crush the world's corolla of wonders*". The author invoked two types of human knowledge: *the scientific knowledge*, exemplified by the line "*the light of others*", but also the Luciferic, "*paradisiac knowledge*", invoked in the phrase "I, with my light". The mystery symbols are *the life, the mirror of the soul, love and death*, but that cannot be deciphered, as the poetic message suggestively says "*crush*", "*I do not kill with my mind/the mysteries that I meet/on my way*"\*\* (Lucian Blaga, *Poemele luminii* [Poems of Light], 1919).

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The evolution of scientific knowledge confirmed these philosophical visions so that, in addition to the benefits that they have brought to the peoples' lives and health, they have triggered a series of ethical dilemmas: *Do we have a right to be born? Do we have the right to decide over death? Is it ethical to harvest organs from brain-dead persons for transplantation into the body of another person, thus saving his/her life? When is the beginning and end of life of a human being? Is the human embryo an animated being or just a property that can be destroyed? What are the ethical and legal conditions in which people can do science experiments on people?*

Bioethics, as a branch of the normative ethics, emerged in the decade VII of the past century, as a universal, interdisciplinary research of the ethical issues in medicine and biological sciences, namely euthanasia, abortion, organ transplantation, genetic manipulation, cloning, medical research on humans, physicians' liability towards their patients, etc. As stated in the legal doctrine, the *Bioethics is neither a science nor new ethics but a multidisciplinary concern bordering with philosophy, theology and law* (Gh. Scripcaru). On these guidelines, bioethics is a response to the challenges of scientific knowledge to draw attention and to sanction the abuses that can endanger human being itself, the existence of the future generations. The crimes committed by the Nazis in the name of biomedical "research" with experiments on people, during the Second World War, led to the adoption of the Nuremberg Code, the first synthetic regulation of the ethical standards regarding the medical scientific research. Facing the growing dangers posed by the scientific and technological progress for the human being, bioethics brings hope of respect for the human dignity, being a guarantee for the human dignity protection from conception until death.

Grasping the impact the accelerating developments in biology and medicine have on the rights of the human being, on 4 April 1997, the European states have adopted the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, known as the *Oviedo Convention*. The main objective of the convention was the respect for the human being, both as a person and as a member of the human species by acknowledging its dignity.

In 2001, Romania ratified the *European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, known as the *Oviedo Convention* and its *Additional Protocol*, time when its provisions were transposed into the national law having the binding force of the regulatory acts. This remarkable event represented a plenary acknowledgement of the need to respect the human being, facing the hazards that may arise in the context of knowledge development of the biomedical science. The Convention established as a fundamental principle the protection of the *dignity and identity of all human beings, being guaranteed, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine*. (Article 1) Therefore, each state covenantor of the Convention must ensure *equitable access to health care of appropriate quality*. (Article 3). It has been expressly stated that, in order to ensure effective protection for patients, *any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards*. The *rules on obtaining the patient's informed consent* were regulated in the contents of Article 4 of Chapter I of the Convention.

After this time, taking the example of other European countries such as France, Romania required the adoption of a law devoted to bioethics that should translate the principles of the Convention, adapting them to the specificity of our realities, establishing rules of conduct and the institutional framework for compliance with these principles, including sanctions for their violation. The issues are of paramount importance if we consider that in the medical and biomedical research new ethical problems arise whose solution depends on the content of such normative regulations. Moreover, there is the need of a review from a National Committee of Bioethics on all the measures taken in the society regarding life sciences. Any endeavor in the medical activities which ignores these fundamental principles is nothing but *an affront to ethics* (V. Astărăstoae, interview) and may cause damage, often incommensurable and irreducible, which involve civil and criminal liability. (L.R. Boilă, 2009)

Thus, rightly to be noted is that *Romania is the only country in the European Union that does not own a national institution for bioethics. In Romania, an effective ethical review in the medical activity whose main objective is the human being, seems undesirable... In a society where the debates are more on pragmatism than morals, a Romanian committee of ethics is perceived negatively by politicians, by the opinion leaders and sometimes even by media.* (V. Astărăstoae).

Based on these reflections, in this study we intend to analyze the relationship between bioethics and law, to advocate in favor of the initiative for adopting a *law on bioethics* in Romania, that should bring together all the specific regulations in this area, sanctioning their violation. We consider that the debate on this topic in the medical world, but also in the legal world, could constitute a signal for the country's legislative body to lean responsibly on these such important issues, that could influence each of our lives.

## II. *The relationship between Bioethics and Law.*

The normative component of Bioethics regards the protection of fundamental human rights on his body, inalienable, universal and sacred rights, known in the legal world through the phrase *the rights of human personality*. (E. Chelaru, 2012, I. Reghini, Ș. Diaconescu, 2009) Being intimately attached to the individual, the personality rights express the quintessence of the human being itself, referring to "*all or the universality of the patrimonial rights and obligations belonging to a person*" (L. Pop, L.-M. Harosa, 2006). Conventionally, these rights belong to the moral heritage being an extension of the individual's personality. (C. Jugastru, 2009).

In an interdisciplinary approach on contemporary issues raised by Bioethics, the law provides the basic legal information by regulating the human rights that embody legal protection of the human being. The legal norm ensures the capitalization of scientific progress benefits and the prevention of the risks that they incur. The law ensures equitable access to new treatments such as organ or genetic material donation, any negotiations or patrimonial acts being prohibited and criminalizing organ trafficking. The positive law, inspired by the fundamental human rights, establishes the legal framework for biomedical practices, according to its historical and cultural heritage of each State.

Within the complexity of social issues addressed, bioethical approach supports the idea of rebuilding the morality of law in order to ensure a balance between the legal protection of the individual and the community health. The Bioethics of the scientific world provides the law with ethical axiomatic arguments likely to determine to what extent the juridical law reflects the moral law established in society, whether the values of

the human being are really protected or, on the contrary, whether the concepts of justice and truth display an ethical and relative content, while being dominated by economic or political interests. If, from the scientific point of view, the human being is an object of research, from the ethical and legal point of view, the man is sovereign over his own body, being the only one in the position to take a decision regarding his life and health, after a preliminary and correct medical information. This poses new challenges for engaging legal liability in the activity of biomedical research and medical care. (Fl. Mangu, 2010, pp. 251-260; L.R. Boilă, A.C. Boilă, 2009, p. 88.)

The current level of scientific research in the field of Biomedicine and the pulse of recording new progress have led to the development of a set of legal rules intended for the regulation of the medical applications, according to the development of modern biotechnology. But the evolution of science in recent decades has become extremely fast, which led to the need for new legal regulations or the improvement of existing ones. The legislative process has proved to be much more slowly - a few months, often years, sometimes even decades for the adoption of a law or an international convention that could lead to severe dysfunctionalities. Precisely because of that, the Law must be in a continuous transformation, improvement, harmonization according to the scientific research progresses. This involves the legal definition of new *concepts*, the establishment of new *legal institutions*, the establishment of *preventive measures and sanctions*, all enhanced with a constant objective, hardened in time: *the idea of human dignity*.

The intervention of the legislator within an essentially scientific, medical field, may seem like a *blasphemy*, all the more so as the approached themes are of ethical, psychological, philosophical, sociological, theological, economic nature, with a strong impact on the human being. However, the regulatory classification of medical practices is not new, being nearly as old as the medicine itself. The Hippocratic Oath written in 5<sup>th</sup> century BC is recognized as a veritable Code of ethics of the medical profession. Over the centuries, the principles of the Code surprise us by its simplicity, concision and the depth of thoughts, stating with honesty and accuracy the obligations of the physician towards his patient. Over time, all these rules have been transposed into national laws and international conventions, representing the legal framework where the medical professions and scientific research develop in this area.

This led to the need for a legislative classification of the biomedical practices against potential hazards to protect the individuals by prohibiting or conditioning them to follow certain rules. Thus, medical research on human embryo and on embryonic stem cells or assisted medical procreation can not be analyzed only in scientific terms. The legislator, as a representative of the national sovereignty, establishes the rules of the researches by respecting the cultural, legal and medical values.

## 2. DEBATES ON THE MORALITY OF LAW

*The legal norm* is a rule of conduct of general and impersonal character, issued by the competent state authorities, whose compliance with may be provided by pressure. The foundation of any legal rule is represented by the moral principles settled in society that reflect the cultural values of a nation. More by token, the law can only exist within the framework of the established moral rules in society over time. Based on these ethical coordinates, the issue of protecting the *common good* by legal rules acquires new and

deeper meanings in the analysis of the axiomatic foundations of law. That is, if we consider the fact that the new scientific conquests from the biomedical area bring up the inviolable human values, respectively the defense of life by legal rules that should guide the human behavior and penalize any deviation.

The analysis of the relationship between bioethics and law, reveals the traditional controversies between the *ethical relativism* and *juridical positivism*, with the aim of adopting moral legal rules. Therefore, lately, in the legal doctrine, we witness the debates on the *amorality of law*, considering that the law is the emanation of the political interests that do not reflect – in all situations – the social need regarding the protection of the common good. It is stated that “the vision of postmodernism is one of the ethical minimalism” (A. Sandu, 2012), which is considered that it falls within the “*twilight of duty*” and within post-moralism (G. Lipovetsky, 2006). These guidelines give voice to the moral doctrine only within the boundaries where the absolute primacy of law is acknowledged, being modeled on the legal principles, universally accepted and enshrined by the International Human Rights declarations. Other authors consider that it does not depend in any way on the *truth* but is confined solely to the normative will of the one who governs.

Unquestionably such approaches have repercussions on the legal framework given the fact that it influences the dilution of the ethical contents of law. This becomes just *a tool* at the hands of the political governance, in the search for *consensus*, without regarding the fact that the law must be built on truth so as to ensure the commonwealth of all the members of society. The democratic system instead of being at the service of defending the rights of each individual, it becomes the purpose that must be followed to safeguard the interests of majority. However, we must not forget that in a democratic society, the rule of law ensures *respect for individual rights and defends human dignity*. (Ciuc, 2010) The essential moral and universal human values of a truly democratic society consider the human being itself, which ought to be protected, promoted and respected. The main objective of the law, whose content is ennobled by profound moral meanings, is discovering these values and their consecration by generally binding legal rules.

On these lines, the creation process of the rule of law must take into account the requirements of human life in society, imposing rules of conduct liable to protect life, physical integrity and human health, eliminating the danger of abusive or arbitrary solutions that is likely to impair the ideal of justice and truth. By ensuring a normative content to the civil law we assert the *truth of law*, being respected the requirements of the objective moral law which incriminates any violence on human life.

Bioethics and progress of medical science have brought new horizons regarding the issue of *liability for medical malpractice*. The discussion is more about the need to *ensure the risks* of investigations, treatments or interventions, known or undiscovered, to ensure the compensation of victims of medical accidents. The involvement of insurers in the repair mechanism, is one of the effective ways to ensure prompt resolution of disputes arising from the production of bodily harm in the medical practice. On the other hand, bioethics offers a new perspective for the objective substantiation of medical staff liability on the idea of risk, with landmarks like the ethical-legal values and criteria such as *empowerment of the person or providing individual and social benefit* by minimizing risk and maximizing benefits. This is a guarantee for the respect for fundamental principles of fundamental human rights, namely the primacy of the individual, the respect for dignity,

inviolability and the unavailability of the human beings. (C. Jugastru, 2009). On the other hand, assessing the conduct of the medical staff in case for claiming abuses, has the same bioethical criteria, providing lawyers with ethical arguments likely to determine whether the medical act is a *professional error* that could lead to civil, disciplinary or criminal liability. (Fl. Mangu, 2010 L.R. Boilă, 2009)

### 3. HIGHLIGHTS REGARDING THE ROLE OF LEGAL NORMS IN BIOETHICS

Bioethical issues on medical research and practice influence the content, interpretation and implementation of legal norms designed to protect the human being.

A. In the first place, *the civil law is the one that sets the conditions of the accomplishment of the medical act, imposing certain restrictions, of which violation is likely to attract legal liability.*

The implementation of the law is achieved by the coercive force of the state, which means that, in relation to bioethics, the law is binding and is of strict enforcement. The question is to know if these legal regulations imposed by the legislator to the members of society comply also with the moral imperatives. In hospitals, research centers and laboratories, the bioethics committees are consulted when taking decisions, but the recommendations must be consistent with the positive law, next with the patients' will.

For example, in the case of active euthanasia or assisted suicide, from the ethical point of view, the patient's desire must be respected, but legally, the committed act is a criminal act, the perpetrator being liable to be convicted. A patient with end-stage disease, faced with great physical and mental suffering, even if he has consented to be prescribed a lethal injection, the law obliges the physician to stop from acting in that direction because that would mean – killing a human being, which is a crime.

B. Secondly, *Bioethics is an area of social life being governed by legal rules.* In this sense, Bioethics contribute to the development of legislation designed to protect the human being facing the hazards posed by the biological and medical research, aiming at making sure regulations in medicine and biology area are moral. The progress of the biomedical research in the recent decades imposed with necessity the adoption of a new legislation, namely harmonizing existing ones to suit the new social realities. The new medical and biological technologies raise a number of legal issues, becoming gradually more complex, for the solution of which the company is obliged to adopt new rules of behavior, such as to ensure the legal relationships.

In this respect, the national bioethics committees in some European countries and the US serve to indicate the ethical, medical and social issues, to provide ethical solutions concerning the professional conduct and to advise the state bodies in drafting of normative bioethical issues. Among the discussed bioethics issues that raised the subject of the need to adopt new legislation rules we recall those concerning the status of the human embryo, assisted reproductive technology, surrogate motherhood, gay parenthood, embryo donation, donation of gametes, abortion. They have raised live disputes among the public opinion, with supporters or opponents, but they have also contributed to the adoption of new regulations which considered the bioethics guidelines.

In the case of abortion there is an ethical dilemma: it is unacceptable ethically, but it is permitted in some countries, in certain circumstances, from the legal point of view.

Thus, abortion is considered *a crime* which is likely to involve liability but can also be interpreted as a right of a woman to decide over her own body, namely the moment when she would become a mother. However, to what extent the law has a moral content? The two approaches must, however, coincide because the law must have primarily a moral content. (Beuchamp / Childress, 1994, p. 10).

We note that new medical technologies are in constant transformation and progress, which assumes that the laws must be adapted to new scientific challenges. We assist to permanent changes regarding people's attitude towards them, which contributes to the shaping of new legal guidelines. An example of this is the *reproductive cloning of human beings*, initially unknown, but which, at every decade, was tackled by international laws and policy documents that established prohibitions which emphasized the need to respect and protect human uniqueness, the human's dignity.

Moreover, regarding the much debated *brain death*, a concept that was first proposed by the famous "Ad Hoc Committee of the Harvard Medical School" in 1968, has been adopted by almost every country. The protocols adopted to determine some scientific, medical guidelines, are essentially of bioethics nature. The concept of *person* is a legal one, so that the decision to declare a patient brain dead to be able to harvest organs for transplantation is a decision primarily legal, but must comply with the ethical requirements.

C. Viewed from another perspective, in its relation to the law, *Bioethics rules on the principles and guidelines on how to interpret and apply the law in force*.

Thus, the regulation of transplantation, euthanasia, abortion, genetics requires specific legal approaches, but also ethical. The existence of a legal framework is not enough if compared to the case under judgment, it raises issues of interpretation. The ethical debates regard, in the first place, the need to respect people's fundamental rights and autonomy. Judicial solutions adopted, reflect these new scientific approaches, such as to strengthen the legal arguments on the issue of health in question.

In this regard, the trials have become famous in US which raised a number of controversies on *euthanasia and assisted suicide* – *Quinlan in re* (1976), and *Cruzan v. Director, Missouri Department of Health* (1990), *Vacco v. Quill* (1997). In these cases, the courts were invested to solve bioethical issues of paramount importance and serious consequences to the accused persons. Analyzed in terms of constitutional and legal provisions, the prohibition of assisted suicidal constitutes a restriction on the freedom of individual action, so it is considered unlawful. On the other hand, the act of the physician to prescribe the lethal drug, to cause its patient's death, is considered illegal. A doctor violates his patient's rights if he acts against his will in such a way that it causes death. If the patient does not want to die, every predictable act which may lead to death, has a distinct moral and legal status, they are likely to incur the physician's liability. Therefore, a physician is not permitted to end a patient's life in order to use his organs to save another. Likewise, it is considered impermissible for a doctor to refuse the administration of antibiotics to a patient with pneumonia, if he seeks organs available for transplantation. Quite different is the situation in which several patients need organ transplants, and the doctor refuses a patient, even if he dies, to give the organ to another patient, then his gesture is considered moral.

#### 4. THE CURRENT LEGAL FRAMEWORK IN ROMANIA ON BIOETHICS ISSUES

In the Romanian post-revolutionary regulatory landscape the adoption of legal rules governing some of the current problems of Bioethics was achieved very late either amid the political controversy that led to unacceptable delays, or by taking over certain European regulations imposed by the European bodies.

At this point in our legislation, the provisions concerning current bioethical issues are included in several acts, mainly in the Law no.95 / 2006 (Title VI – Effecting removal and transplantation of organs, tissues and cells of human origin for therapeutic purposes, Title XV – Liability of the healthcare professionals and providers of medical goods and services, health care and pharmaceuticals).

As an innovative element in our civil legislation, the Civil Code in force from 1 October 2011, introduced a series of regulations aimed at protecting life, integrity, health and dignity in Book One, Title II – The individual, Chapter II - Respect for the human being and its inherent rights. The editors of the Civil Code text have considered it necessary to incorporate in this context, provisions of principle on the rights of human personality with reference to current concerns of Bioethics facing the hazards posed by the biomedical scientific research. The scientific endeavor was considered to be a doctrinal response put into practice by the legislator, towards the external jurisprudence concerning the necessity of such legislation (E. Chelaru 2012, pp. 62-63).

Taking the experience of other European codes, such as the French Civil Code, the Civil Code inserted human rights enshrined in Chapter II “*Respect for the human being and its inherent rights*” in the following structure: “*Common provisions*” (Articles 58-60), “*The individual’s rights to life, health and integrity*” (Articles 61-69), “*Privacy and dignity of the human being*” (Articles 70-77) and “*Respect owed to the human being even after his death*” (Articles 78-81).

According to Article 58 of the New Civil Code, *any person has the right to life, health, physical and mental integrity, dignity, self-image, to privacy and other rights also recognized by the law*. All these rights are considered to be inherent to the human being in the sense that they last throughout its life, being nontransferable, being strictly related to the quality of the human being. The personality rights aim at protecting the physical and moral features, the uniqueness and personality of the human being. For good reason, the doctrine highlighted that the personality rights are confined to the sphere of moral values of the human as they belong to the moral heritage and constitute the extension of the individual’s personality. (C. Jugastru, 2010)

The New Civil Code makes a clear distinction between *the human personality*, the man being analyzed as a subject of rights and obligations and *the human being*, in its biological materiality of its existence, with reference to its right to life, physical integrity and health. In the category of “*personality rights*” governed by Article 58 paragraph (1) were included “*the right to life, health, physical and psychological integrity, honor and reputation, the right to privacy and the right to one’s own image*”. Paragraph (2) expressly stated that “*these rights are not transferable*”, being “*inherent*” rights to every human being. These provisions corroborate those of paragraph (1) of Article 61, devoted to *ensuring human rights: “life, health and physical and mental integrity of every person are guaranteed and protected equally by the law.”*

We note that paragraph (2) of this Article establishes the principle value that the “*the interest and welfare of the human being shall prevail over the sole interest of society or science*”. This rule summarizes the ethical-legal meanings on the development of scientific research whose main objective will be “*the interest and welfare of the human being*” and not just the expansion of knowledge in medical perspectives.

The principle of inviolability of the human body has been enshrined in the Article 64 of the new Civil Code, being established a rule according to which “no one can harm the integrity of the human being, except in conditions and cases expressly and exhaustively prescribed by law”. We appreciate that “harming” refers to those actions circumscribed to the medical act by which, in scientifically or therapeutically experiments, they intervene on the body of a person, a situation where, if the damage occurred, civil liability may be engaged.

In connection with these provisions the conditions under which medical interventions can be effected, were expressly regulated in Article 67: “*No person may be subjected to experiments, tests, samples, treatments or other interventions for therapeutic purposes or for purposes of scientific research except in cases and conditions expressly and exhaustively provided by law*”. The aggressive actions on the human body can be achieved by various methods, from experience, testing, treatment application, and surgery. Any intervention must be carried out only in compliance with the law.

The provisions of Article 66 of the New Civil Code established the sanction of absolute nullity for “any acts which confer property values to a human body, its elements or products” except for the cases expressly provided by law. The rule, according to which the human body can not be the subject of patrimonial legal acts, given that the donation of some elements of the human body is essentially altruistic, with the purpose of saving a patient’s life, is confirmed.

The special conditions in which the harvest and transplantation of organs, tissues and cells of human origin from living donors may be achieved, were established by the provisions of Article 68 of the New Civil Code, thus being reiterated the European Convention for the Protection of Human Rights and Dignity of the Human Being to the Application of Biology and Medicine at Oviedo in 1997, ratified by Romania by Law no.17/2001. It is said that these activities may be carried out *exclusively in the cases and conditions provided by law*, which implies strict compliance to the rules applicable to this area, the harvest and transplant of organs in situations other than those expressly regulated or which take place under conditions other than those required by the applicable law being forbidden. The actions that violate these provisions engage legal liability of the persons involved which can be civil, disciplinary or even criminal liability.

The mandatory legal requirement by law is that of obtaining the *written consent freely, prior and express of the donor, and only after the donor was informed in advance about the risks of the intervention*. We note that the future regulation elected the informed consent, despite the discussions that were held on the possibility of changing the rules by introducing presumed consent.

In connection with the requirements of an expressed consent of the donor, the legal text establishes requirements for content and form: it should be *freely* in the sense that it was not obtained by error, fraud or violence and *express* with clear, unambiguous reference, on the donating activity to which the donor will subject. Accurate and complete, prior information is required for the donors particularly with regard to the risks

they are subject to having effected that intervention. The legal text requires the *written form* of the legal act whose content expresses the consent. It is not specified to whom they must submit such a statement, whether it must be dated or whether it needs countersigning by witnesses. Importantly, however, in our assessment, is the certification of such a document in order to be sure about the person's identity, date, signature and that he had a sound mind at the time of signing the statement.

Specifically the second thesis of the article quoted states that "*the donor can return upon the consent given until the moment of the organ harvesting*". It is the exclusive attribute of that person to freely dispose of his body, which justifies the possibility to return to a decision taken, whenever desired, without this return to entail his liability or cause any other consequences. This means that the consent may be expressed until the last moment of organ harvesting.

Minors and people with mental disabilities can not consent to the removal of organs, tissues and cells of human origin, according to paragraph (2). This rule is explained by the lack of mental maturity of the donor who, because of age or poor status of mental health does not have the ability to take a decision in full knowledge. Act of donation with its special importance, involves the full knowledge of the consequences, especially of the dangers to which the donor is exposed. The causes of lack of discernment to adult can be "mental handicap or a serious mental disorder or another similar reason".

According to Article 78 of the New Civil Code "*the deceased is owed respect in regard to his memory as well as his body*". These provisions are applicable in cases where donations can be made, from scientifically point of view, from the deceased person, but even in such cases the consent of the donor must be obtained while he is alive or of the representatives, expressly mentioned in the legal text.

Articles 80-81 set the conditions for expressing the consent to organ donation, tissues and cells donation "after death" based on "the written consent, expressed during the life of the deceased or, in its failing, by a "written consent, free, prior and expressly given, in this order by the surviving spouse, parents, offspring or, finally, the collateral relatives up to the fourth degree inclusive". It stresses that the removal is carried out solely for therapeutic or scientific purpose. The donor's desire may be achieved after his death, also by the *universal legatees or by the order of the mayor of the village, town, city or district of Bucharest in whose jurisdiction the death occurred*.

Article 69 of the New Civil Code establishes rules on the "*referral of the court*" whenever it alleges "*unlawful harm affecting the integrity of the human body*". The referral can be performed by an "*interested person*", without specifying whether this involves a certain quality or relationship with the victim. Given the seriousness of such acts, in our assessment, the referral could be made by *any person* who can provide court with the necessary information, likely to form a belief as to the existence of a state of danger or the occurrence of the victim's body harm as a consequence of a medical accident. The purpose of promoting such actions consists in taking all the necessary measures to prevent or to stop illicit actions but also to rule compensation, in accordance with Articles 252-256, for the material and moral damages suffered.

## 5. DO WE NEED A LAW ON BIOETHICS?

The General Theory of State and Law enshrines the *Law* as being the main source of law containing generally binding rules issued by public authority bodies that are competent to issue such documents. (Gh. Boboș, C. Buzdugan, V. Rebreanu 2009, pp.261-262) The ensemble of the normative acts in force forms the positive law which, according to Mircea Djuvara, they represent the emission of a nation's conscience. (M. Djuvara, *Drept rațional. Izvoare și drept pozitiv*, Bucharest, Editura Socec).

Currently, in Romania, we do not dispose of a normative act that should be devoted exclusively to the current problems of Bioethics, although they concern the protection of our lives and our health even our future generations. The ethical debates in the medical field and that of the biomedical research are becoming more numerous, with profound implications, continuously amplified by the evolution of the scientific knowledge, without a unified legal, harmonious and coherent framework. The provisions existing at this moment in our legal system prove to be inadequate, incomplete, scattered facing the many ethical and legal dilemmas the medical and scientific world deal with.

The solutions chosen in practice relate to international or the constitutional provisions, with no articulated system of legal rules that should cover the most important issues of bioethics, structured on the impact of biotechnology on human, the interventions on the human body and the effects of research on the environment. More than ever, we need legal regulations intended to establish conditions under which certain activities may be carried like medical or biomedical research, establishing sanctions for the violation of the rules. However, it is necessary to establish an institutional framework to oversee the compliance with the legal, well established procedural rules, having the power to intervene and order the competent authorities to apply sanctions.

In these circumstances, we believe that we need a Law on bioethics which, starting with the establishment of the two fundamental principles regarding *the dignity of the human being* and *the unavailability of the human body*, to regulate *the patients' rights, the conditions governing the medical activities and of scientific research in the field, the institutional system* empowered to observe on the enforcement of these provisions and the civil, criminal sanctions of these offenses that can be applied for their violation.

Romania offers a contrasting situation. There is no law to regulate the assisted human reproduction, there is no surrogacy law (which is otherwise permitted), there is no law regarding research on human embryos. There have been attempts to create a legislative framework (between 2004-2005), but the law on human reproduction was rejected by the Constitutional Court and thus not promulgated. A bill was introduced in Parliament, but it has received a large number of negative recommendations from the Government and the legal commission. Also, we do not have legal provisions on the rights of patients at end of their life, on the protection of vulnerable persons and on the scientific experiments on human subjects.

Taking the example of other countries such as France, we support the initiative of adopting a bill regarding the law on bioethics as a prerequisite for legal regulation of these problems by training the coercive force of the state bodies to ensure compliance with the legal rules.

## 6. CONCLUSIONS

There is a daily, abundant information in the medical world that raises bioethical questions, some of them of high seriousness (such as those from the area of organ transplantation, the issue of lack of donors, to the detriment of patients on the waiting lists debates about the need for the adoption of a *presumed consent*), but which do not have a specific legal regulation. However, for the political class in our country, bioethics issues are not among the major themes requiring urgent legislation. Bioethics is considered to be an exciting, wonderful subject, but a subject that... does not find its place among the legislative priorities, being considered only a *beautiful and useless accessory*.

In the legislative post-December landscape, the problems of Bioethics have been addressed in a cursory manner: either the legislation of more advanced European states has been borrowed either certain solutions have been applied, solutions that were guided by certain political circles or simply debates were left in *stand by*. We speak about the *bioethics of loan*, consisting of the *importation of certain western laws*, some imposed by the European Commission, others, following the example of other European countries, by taking legal regimes from the European Union, but without adjusting them to our society and to the cultural and Christian values of the Romanian people. (\* <http://egophobia.ro/?p=8984>).

This is the explanation for the legal provisions, relatively reduced in number at this moment, being scattered across several acts, with no unitary, coherent and articulated system of legal norms, likely to provide viable solutions to the specific problems of Bioethics.

Therefore, in a joint action, all policymakers, physicians, ethicists, economists, lawyers and politicians should acknowledge the need to adopt a Law on Bioethics now, at a new beginning of a millennium, that are likely to ensure legal protection to all citizens, facing the perils of modern biotechnology advances.

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