

PATIENT RIGHTS IN THE EU



GREECE

EUROPEAN ETHICAL - LEGAL PAPERS N° 6

EuroGenest

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FOREWORD



Within the Center for Biomedical Ethics and Law of the Catholic University of Leuven - one of the leading bioethical and legal research centers in Europe - we are involved as coordinator, partner or participant in different European research projects. Biomedical ethics and law are rapidly evolving disciplines. Although a great number of specialized peer reviewed journals and series of books in both disciplines already exist, we felt a growing need for a medium through which the results of our research can be presented directly to the research community and the interested community at large. To meet this need we decided to start the *European Ethical-Legal Papers*. These papers will also contribute to the transparency we owe to the society that finances our research efforts. We hope that it will contribute to the discussion and the exchange of information and ideas among researchers in Europe and elsewhere.

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I. INTRODUCTION



EuroGentest is a five-year EU funded program that aims to develop the necessary infrastructure, tools, resources, guidelines and procedures that will lead to the establishment of harmonized, qualitative genetic testing services in Europe. Within EuroGentest we are dealing with the ethical and legal issues of genetic testing. Harmonization of the technical aspects of genetic services in Europe requires a legal and ethical framework that respects cultural, religious, philosophical and other domestic characteristics of a given country and its population(s), but at the same time conforms to basic and universally accepted human rights. To continuously supervise the legal and ethical developments regarding the promotion and protection of the rights of patients and users of health services and to make the results of our research publicly available, is a permanent challenge. This publication in the European Ethical-Legal Papers aims to contribute to it.

Opened for signature more than 10 years ago (in Oviedo, Spain, on 4 April 1997), the European Convention on Human Rights and Biomedicine is now becoming increasingly important as a standard to evaluate the efforts and the progress made by the Member States of the European Union to promote and protect the rights of patients and users of health services. In this sixth issue we present the results of this evaluation for Greece, one of the EU Member States that have ratified the Convention.

The content of this publication is as follows.

In an introductory chapter we briefly describe Greece with respect to some of its main features related to its political and legal background and its health care system.

This is followed by an encompassing overview of the rights of patients in Greece. In a first paragraph the legal status of the Biomedicine Convention is situated against the background of Greek constitutional law. Then we turn to a description of the national legislation on patient rights. Many different enumerations of patient rights exist. Since we are particularly interested in the way the

Biomedicine Convention has been received by the Member States of the European Union, we follow the structure of the Convention. The right to informed consent (articles 5, 6, 8 and 9 of the Convention) comes first, followed by different aspects of the right to private life and the right to information (article 10 of the Convention) such as: patient rights regarding the medical file, the right to medical secrecy/confidentiality and the right to privacy and protection of private life. This part of the analysis ends with the right to complain in case of unlawful infringement of a patient right (article 23 of the Convention) and the right to compensation for undue damage (article 24 of the Convention). In the next chapter we look at the rights of patients as users of genetic services: are the rights of patients complemented by more specific rights for users of genetic services? (articles 11 and 12 of the Convention). With some concluding remarks we finish this paper N° 6 of the Ethical-Legal Papers.

Without the help of Takis Vidalis (Scientific officer to the Greek National Bioethics Commission) and Hans Brems (a Belgian lawyer working in Greece), we could not have accomplished this work. They provided us with valuable information on the status of patient rights in Greece and answered our questions accurately and patiently. The possible mistakes and wrong interpretations are our responsibility. We are also aware of the limitations of this endeavor not the least because of differences in languages. Nevertheless we hope that this publication will stimulate the discussion on the promotion and protection of patient rights in Greece. Therefore we welcome all reactions on www.cbmer.be.

Leuven, June 2007

The research for this publication was supported by the Eurogentest Network of Excellence of the EU, FP6 – 512148 and its coordinator Prof. Dr. J.J. CASSIMAN

II. BRIEF DESCRIPTION OF GREECE



§ 1. Political and legal system

In Greece politics takes place in a framework of a parliamentary representative democratic republic, in which the President of Greece is head of the republic and the Prime Minister of Greece is the head of government, and of a pluriform multi-party system. The President is elected by the Parliament for a five-year term, and a maximum of two terms in office. The Prime Minister is appointed by the President and he is usually the leader of the party controlling the absolute majority of Parliament members. The Cabinet of Greece includes the heads of all executive ministries, appointed by the President on the recommendation of the Prime Minister. The Prime Minister and the Cabinet play the central role in the political process, while the President performs some executive and legislative functions in addition to ceremonial duties.

Legislative power is vested in both the Government and the Hellenic Parliament. The Greek Parliament has 300 members, elected for a four-year term by a system of reinforced proportional representation in 48 multi-seat constituencies, 8 single-seat constituencies and a single nationwide list. Greece uses a complex reinforced proportional representation electoral system which discourages splinter parties and makes a parliamentary majority possible even if a leading party falls short of a majority of the popular vote.

Administratively, Greece is divided in 13 peripheries, further divided into 51 prefectures. The prefectures are each headed by a prefect (nomarch), who is elected by direct popular vote. The thirteen regional administrative districts (peripheries), each including a number of prefectures are headed by a regional governor (periferiarch), appointed by the Minister of the Interior. In northern Greece and in greater Athens, three areas have an additional administrative position between the nomarch and periferiarch. This official, known as the president of the prefectural local authorities or "super nomarch," is elected by direct popular vote. Although municipalities and villages have elected

officials, they do not have an adequate independent tax base and depend on the central government for a large part of their financial needs. Consequently they are subject to numerous central government controls. Greece includes one autonomous region (Mount Athos).

In Greece the judicial branch is divided in the civil courts, which judge civil and penal cases and the administrative courts, which judge administrative cases, namely disputes between the citizens and the State. The judicial system of Greece comprises three Supreme Courts: the Court of Cassation (Άρειος Πάγος), the Council of State (Συμβούλιο της Επικρατείας) and the Chamber of Accounts (Ελεγκτικό Συνέδριο). These high courts are composed of professional judges, which are graduates of the National School of Judges. The way the judges are gradually promoted, until they become members of the Supreme Courts, is defined by the Constitution and the existing laws. The Judiciary is independent of the Executive and the Legislature.

§ 2. Health care system

In 1983, a national health-service was introduced. Even though medical training is of a high standard, the health service is suffering from under-funding.¹

Health care costs per head in Greece are the lowest in the European Union and Greece spends a relatively small percentage of its GDP on health related services. Public and private medicine operate alongside each other and complement one another, but public health facilities are limited in some areas, particularly on the islands.

The Government is currently improving the health care system and a substantial investment (much of which comes from EU funding) is being made on upgrading the country's existing hospitals, building new facilities, developing mobile medical units, installing high-tech equipment and improving accident and emergency facilities.

Greece's public health system (IKA) provides free or low cost health care for those who contribute to Greek social security, and their families and retirees (including those from other EU countries).

The Ministry of Health and Welfare is the leading institution in developing and financing health policies. The Ministry is responsible

¹ See "The National Health Service, Health care in Greece", www.justlanded.com.

for the provision and finances of the National Health Service as well as the health and social services for the poor, the elderly and the disabled; a very small part of health and social services is provided by municipal authorities. Local authorities, through the Ministry of Health, play a limited role in the administration of 128 NHS hospitals and 176 rural health centers. The Central Health Council (KESY) and Committees for AIDS, Drugs, Cancer, etc., have an advisory role to the Minister.

The Ministry of Health and Welfare, through its central and regional services, has the responsibility of planning and implementing health-related activities for public health, medical care and social welfare (social security was separated from the Ministry of Health in September 1995). The Ministry also coordinates health-related program activities of private institutions and individuals.

III. GENERAL PATIENT RIGHTS



§ 1. Legal status of the Convention on Human Rights and Biomedicine

Greece signed the Convention on Human Rights and Biomedicine on 4 April 1997 and ratified it by Law 2619/1998 on 6 October 1998. As article 28 (1) of the Constitution lays down the principle of the openness of the Greek legal order to international law, the provisions of the Convention form an integral part of domestic Greek law since 1 December 1999 and prevail over any contrary provision of the law.²

Greece has not made restrictions based on article 26 of the Convention.³

§ 2. National legislation on patient rights

In Greece the relation between patients and physicians is regulated by provisions in various legal acts and not by specific legislation.⁴

Although it has been stated that “the truth is, though, that the ratification of the Convention was a general instrument, a *lex imperfecta*, as it did not contain any sanctions”⁵, one cannot neglect that “from the 1990’s onwards (and particularly after the ratification of the Convention on Human Rights and Biomedicine) the situation

² I. KRIARI-CATRANIS, “Human Assisted Procreation and Human Rights – The Greek response to the felt necessities of the time”, *European Journal of Health Law*, 2003, 272.

³ H. NYS, et al. “Patient Rights in EU Member States after the ratification of the Convention on Human Rights and Biomedicine”, *Health Policy* 2007, (available online at www.sciencedirect.com).

⁴ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, “Hellas”, in H. NYS (ed.) *International Encyclopedia of Medical Law*, Kluwer, 2006, 117.

⁵ M. CANELLOPOULOU-BOTTIS, “The implementation of the European Directive 95/46/EC in Greece and medical-genetic data”, *European Journal of Health Law*, 2002, 210.

has dramatically changed: draft laws are under discussion, new publications are devoted to the interwoven relation among law, ethics and biomedicine; ethics committees have been established...”.⁶ The development of legislation relating to patient rights in Greece has undergone four major phases in the last fifteen years.

In the period up to 1992, patient rights in Greece were indirectly addressed through relevant provisions in Civil, Penal, Administrative and Disciplinary Law. In addition, other legislation focused on the obligations of physicians: the Code on the Practice of Medicine (1939) and the Regulation of Medical Deontology (1955) referred to physicians’ obligations to provide all patients with equal care, to respect patients’ dignity and religious freedom and to protect medical secrecy.

In 1992, based on the European Charter of Hospital Patients’ Rights of 1979, broader health care reform legislation contained provisions directly addressing the rights of hospital patients through the Act on Modernization and Organization of the Health System (No. 2071/92, Article 47). However, no provisions were made for the implementation of this legislation.

In 1997 further provisions extended the rights of patients granted in 1992 to the entire population, and provided for the implementation of the legislative provisions. The key features of this legislation as far as patient rights are concerned, involve (a) the introduction of measures to implement the provisions of article 47 of Law 2071/92 (i.e. on the rights of hospital patients provided by the 1992 act); and (b) the extension of these rights also to all patients seeking primary care. The immediate implementation of the patient rights provisions of the 1997 legislation represents a major step forward with respect to improving the quality of health care services provided.

In 2005 the most important change in medical law in Greece took place: the new Code of Ethics was promulgated. This new Code was ratified by statute and therefore is now Law No. 3418/2005. This new Code of Ethics replaced the old Code on the Regulation of Medical

⁶ I. KRIARI-CATRANIS, “Bioethical Issues and Human Rights in Greece”, *Law and the Human genome Review*, 2002, vol. 16, 38.

Deontology of 1955. The Code of Practice of Medicine of 1939 remains valid.⁷

The new Code is consistent with the International Documents on Medical Ethics, such as the Geneva Declaration, the WMA International Code and the Oviedo Convention.⁸ Chapter 3 of the Code is dealing with the doctor/patient relationship.⁹ Articles 8 to 15 of the Code contain the obligations of physicians to their patients in more detail, and more explicitly than the Code of Practice of Medicine.¹⁰

Greece has no specific regulation of service contracts in its civil code. It is debated whether the contract between the patient and the physician should be qualified as a contract for work, for services or an innominate contract (*sui generis*).¹¹

§ 3. Right to informed consent

Article 5 of the Biomedicine Convention:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

⁷ M. CANELLOPOULOU-BOTTIS, "Recent developments in Health Law in Greece", *European Journal of Health law* 2006, 13, 107.

⁸ National Bioethics Commission, *Report on the collection and use of genetic data*, 27, available on www.bioethics.gr.

⁹ M. CANELLOPOULOU-BOTTIS, *o.c.* 2006, 109. We want in particular thank Hans Brems for translating those articles of the Code.

¹⁰ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 117.

¹¹ M. BARENDRECHT, et al., *Principles of European Law – Service Contracts*, Bruylant, 2007, 797.

A. Right to informed consent as a basic requirement

The doctor who does not inform the patient and does not receive his consent, even in the event that he acts *lege artis* and conducts a medical act successfully, violates the rights to personal freedom, dignity and integrity.¹²

Any medical intervention that infringes the physical integrity of the patient can be seen as a voluntary injury, sanctioned by articles 308, 309 and 310 of the Penal Code. Medical interventions are considered as bodily harm and the illegal character of these acts is only annulled when the valid consent of the patient has been obtained. If no consent is obtained by the physician, he violates the Penal Code and will therefore be liable.

The right to informed consent is also protected by the Greek Constitution and other Greek legislation.

Article 2 (1) (human dignity) in conjunction with article 5 (2) (protection of physical and mental integrity) of the Constitution protect the right to informed consent.

Other legislation that protects the right to informed consent is the following:

- Article 47 (3) of the Hospital Law stipulates that “every patient shall have the right to give or refuse his consent to any diagnostic or therapeutic procedure intended to be carried out on him”. If the patient is suffering from total or partial mental incapacity, the exercise of this right shall devolve upon the person legally acting on his behalf.

- Article 2 of the Code of Ethics of 2005, requires physicians to respect the patient’s person and honour unconditionally. Physicians are forbidden to carry out, unless indicated, any therapy, surgical operation or experiment that might affect the sense of individual liberty and free will of a patient who is of sound mind.

- Article 12 of the same Code also deals with the consent of the informed patient, when stipulating “the physician shall not proceed with the execution of any medical act, unless consent has been secured”. Four conditions for a valid consent are required in this article:

¹² K. MERAKOU and E. TRAGAKES, “Developments of Patients’ Rights Legislation”, *European Journal of Health Law* 1999, 6, 74.

- a. the patient is fully informed, according to the regulations stipulated in article 11;
 - b. the patient is competent to consent;
 - c. consent is not a result of mistake, fraud or duress and is not contrary to good morals;
 - d. consent covers fully the medical act at the time of its performance.
- Because of the ratification of the Biomedicine Convention the provisions of the Convention on consent are also applicable.¹³

Consent of the patient is also needed in relation to the infringement of the physical integrity of the patient caused by a medical intervention, but also as a precondition of a contract for medical services.¹⁴

Information provided to the patient preceding his consent is necessary in order for the consent to be valid. Failure to comply with the duty to inform indicates that the treatment lacks the necessary informed consent. Even, in case the treatment has been performed in a state of the art manner, a claim for damages for failing to inform the patient arises independently and separately. Although the patient may lack cause of action on the basis of a medical error, the breach of the duty to inform forms an independent claim. In effect, the successful medical treatment does not mend the breach of the duty to inform.¹⁵

A physician must consider the consent of the informed patient, who has the right to express his refusal of any intervention, trivial or serious. Consent can be so called *presumed* in case of trivial diagnostic or therapeutic procedure without any risks or so commonly practiced. Whether presumed consent of the patient exists in a case, will depend on the nature of the medical intervention, its possible consequences and the attitude of the patient.¹⁶

¹³ National Bioethics Commission, *Report on the collection and use of genetic data*, 27- 28, available on www.bioethics.gr.

¹⁴ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 126.

¹⁵ M. BARENDRECHT, et al., *o.c.*, 843-844.

¹⁶ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 126-128.

B. Contents of information preceding informed consent

According to article 47 (4) of the Hospital Act, “every patient has the right to request information regarding his situation [...] The information provided to the patient must enable him to obtain a complete picture of the medical, social and financial parameters of his condition, and to take his own decision or participate in any decision – making likely to affect his life subsequently”.

The Code of Ethics of 2005 is completely in line with this. Article 12 of the Code explicitly refers for the content of the information preceding informed consent to article 11. This article stipulates that “a physician bears a duty of candor towards the patient and he shall inform, fully and comprehensibly, his patient on the true status of his health, the content and results of the medical act proposed, the consequences and the possible risks from its performance, the side-effects, the alternatives and the possible time of cure, so that the patient may shape a complete picture of the medical, social, economic factors and consequences of his condition and proceed with his decision.” Article 12 (3) stipulates further that “special attention has to be paid when informing a patient in case of special treatment such as transplantations, change of sex, in vitro fertilization, esthetic and plastic surgery.” According to CANELLOPOULOU-BOTTIS this is a broad kind of information that must be wider to a patient, and certainly wider than what the Convention of Oviedo dictates.¹⁷ The specific addition of social and economic factors, as crucial to patient decisions, is also an important consideration.¹⁸

C. Form of informed consent

Written consent is not obligatory. According to research on patient rights in Greek hospitals, only 5,5% of all patients are required to provide their consent in writing, depending on the hospital.¹⁹

Written forms of contracts are signed more and more by the patient and sometimes by the physician in cases lacking any medical indication, such as sterilizations or cosmetic operations, though they

¹⁷ M. CANELLOPOULOU-BOTTIS, *o.c.* 2006, 110.

¹⁸ *Ibid.*

¹⁹ K. MERAKOU and E. TRAGAKES, *o.c.*, 74.

are not considered as a substitute for informed consent of the patient, especially when the “technical” language of the contract is not fully understood by the patient.²⁰

D. Exceptions to the requirement of informed consent

Article 8 Biomedicine Convention

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

There are certain exceptions which permit medical intervention to take place without the patient’s consent (so-called “non-consensual medical actions”). According to Greek law, these non-consensual medical actions are defined to be “all those interventions on the part of the doctor on the patient (preventive, diagnostic, curative) for which the decision on whether or not the intervention should be undertaken is exclusively the doctor’s responsibility”.²¹

In the case of suicide attempts or hunger strikes, but only in the event that the patient’s life is in danger, the doctor is obligated to intervene against or in spite of the patient’s wishes. This obligation also exists in urgent cases which require surgery and in case of so called extended operations. Even in these cases, for a doctor to act on his own volition the following conditions must be met:

- a) it must be an absolutely indicated intervention considered as essential for the avoidance of death or serious harm to the health of the patient;
- b) postponement of the intervention is absolutely impossible;
- c) it is impossible to obtain the consent of the patient or his legal representative.

In these cases, the obligation to inform the patient does not rest on the physician.

²⁰ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 128.

²¹ K. MERAKOU and E. TRAGAKES, *o.c.*, 74.

Based on article 441 and 473 of the Penal Code, the physician has an obligation to procure assistance in a situation that requires immediate care, for example due to an accident or illness, even if the patient cannot consent. Non-compliance with this obligation can be punished with criminal sanctions. Refusal to assist may only be justified by more urgent professional duties, another exceptional situation or in the case that help may be offered by a physician who is more conveniently nearby.²²

E. Refusal and withdrawal of consent

According to article 47 (3) of the Hospital Act of 1992 “every patient has the right to give or refuse his consent to any diagnostic or therapeutic procedure intended to be carried out on him.”

F. Previously expressed wishes

Article 9 Biomedicine Convention

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

In the past, doctors were not allowed to take previously expressed wishes into consideration due to article 12 of the Code of Medical Deontology. Since Greece ratified the Convention and made no reservation based on article 36 of the Convention, article 12 of the Code on Medical Deontology is overruled by article 9 of the Convention, because of its wider scope.

The Code of Ethics of 2005 which has replaced the Code of Medical Deontology does not contain regulations comparable to article 12 of the Code of Medical Deontology. Therefore, in Greece, article 9 of the Convention is the rule that has to be taken into consideration when dealing with previously expressed wishes.

²² T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 122.

G. Informed consent in case of minor patients

Article 6 Biomedicine Convention

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

In case of a minor patient, the physician is obligated to obtain the consent of a minor's legal representative as determined by the Civil and Penal Codes. Patients under the age of eighteen are regarded as minors.²³ "In the event of minors, consent must be provided jointly by the parents. Any disagreement between the parents is resolved by a court decision; and in the event of a conflict of interest between the parents and the minor a special guardian is assigned".²⁴

Article 12 (2) of Act 3418/2005 on the Code of Medical Ethics provides in this respect: "In case of a minor patient, consent has to be given by the person bearing parental responsibility or the legal custodian. The opinion of the minor is taken into consideration if the physician is of the opinion that bearing in mind the minor's age and mental and emotional maturity he is able to understand his health condition as well as the nature, the consequences, the results and the risks of the treatment".²⁵

²³ Art. 1510 of the Civil Code; K. MERALOU and E. TRAGAKES, *o.c.*, 76.

²⁴ K. MERALOU and E. TRAGAKES, *o.c.*, 75.

²⁵ L. STULTIENS, et al., «Minors and informed consent: a comparative approach», *European Journal of Health Law*, 2007, 28.

According to the Order of Physicians in Greece a distinction has to be made between two categories of minors: those who have attained the age of cognitive competence, and the others. This distinction is not expressed in terms of an age limit. The physician should decide considering the personality of the child, the medical treatment proposed, the family and social background etc. Generally, the age of 15 to 16 years is considered as the turning point between legal incapacity and medical capacity.²⁶

For the medical treatment of an immature minor, the consent of the parents is required, as a rule. The final decision belongs to the parents and not to the doctor, who is liable if he carries out a treatment without the consent of at least one parent, except in cases of emergency.²⁷

A mature minor may give his consent alone, but the consent of his parents may also be required. The physician always has to evaluate the situation and to judge whether the consent of the parents will also be required. Sometimes, the parents' duties of custody and care conflict with the personal rights of the minor.

The implied consent of the minor is considered as given to his physician in order to disclose the minimum information required to justify the fee to his parents. But if the minor specifically requests the physician not to inform his parents, this wish has to be respected. If there is a disagreement between the minor and the parents, a special guardian is assigned.²⁸ Any disagreement between the parents is resolved by a court decision (article 1534 of the Civil Code and article 456/1984 of the Penal Code).²⁹

If the parents of a minor refuse to consent and the life of the minor is in danger, the Greek common medical practice on youth protection allows an *ultimum remedium*. If the parents can not be convinced to cooperate in life or death cases, such as the refusal of blood transfusions by parents who are Jehovah's witnesses, the duty to

²⁶ Art. 128 *et seq.* Civil Code; T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 137-138.

²⁷ Art. 12, par. 3 a of the Code of Medical Ethics of 2005; T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 137-138.

²⁸ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 138.

²⁹ *Ibid.*

rescue obliges the physician to act on his own initiative. This is the *ultimum remedium* which can be found in article 12 of the Code of Medical Ethics. In non-emergency cases the physician should inform the Public Prosecutor.³⁰

Some legislation such as the act on the removal or transplantation of organs contains specific provisions concerning minors.

A prior consent of a minor who has attained 15 years of age is required in the case that the substances removed are regenerable and the removal is intended for transplantation to a brother or sister of the donor. This is the capacity of a “mature minor” to consent to a relatively important procedure. Any minor, regardless of age, may object to removal of his organs after his death, if they are capable of making their wishes known.

Other examples are the legislation on the donation of human blood, which fixes the age limit on eighteen and the law on the prophylaxis of sexually transmitted diseases, which obliges minors of sixteen years of age and over to choose a physician and seek treatment (Act 1193/1981).³¹

H. Informed consent in case of incapacitated adults

Article 6 Biomedicine Convention

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorization procedure.

³⁰ *Ibid.*

³¹ *Ibid.*

In the event that the patient is not capable of providing consent, consent must be given by his legal guardian. Legal guardians are defined by article 13 of the Penal Code to be ‘blood relatives or relatives by marriage, adopted parents and adopted children, spouses or persons specified by law who have the custody of persons with mental disorders according to the Civil Code’.³² Article 11 of the Code of Medical Ethics of 2005 stipulates that “if a patient is not competent, consent for a medical treatment is given by the legal representative if appointed; if this is not the case, consent is given by the relatives of the patient. In any case the physician must try to obtain the voluntary participation and cooperation of the patient, especially of those patients who understand the status of health and their nature, consequences, results and risks of a treatment”.

If persons are unable to consent, article 11 (4) of the Code of Medical Ethics stipulates: “If persons are not able to give consent, the physician has to inform them as much as possible. The physician also informs the persons who are competent to give consent according to this article.”

§ 4. Right to information about his or her health

Article 10 Biomedicine Convention

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

³² K. MERALOU and E. TRAGAKES, *o.c.*, 75.

A. Right to information about his or her health as a basic requirement

According to Greek law, the right to information is protected first and foremost by the Constitution, and more concrete in article 2 (1) and article 5, which protect the right of personal freedom and the right to personal integrity. The right to information is also supported by relevant provisions of the Civil and the Penal Law and even more specified in the Hospital Act and the Code of Medical Ethics.

According to article 47 (4) of the Hospital Act every patient has the right to request information regarding his situation. The patient's interests are determinative and the information provided to him has to be comprehensive and accurate. The information provided to the patient has to enable him to obtain a complete picture of the medical, social, and financial parameters of his situation, and to take his own decision or participate in any decision-making likely to affect his life subsequently.

Article 11 of the Code of Medical Ethics is more detailed and stipulates: "a physician bears a duty of candor towards the patient and he shall inform, fully and comprehensibly, his patient on the true status of his health, the content and results of the medical act proposed, the consequences and the possible risks from its performance, the side-effects, the alternatives and the possible time of cure, so that the patient may shape a complete picture of the medical, social, economic factors and consequences of his condition and proceed with his decision." Section 3 stipulates further that "special attention has to be paid when informing a patient in case of special treatment such as transplantations, change of sex, in vitro fertilization, esthetic and plastic surgery".

The duty to inform is less clear when it is a matter of prediction or when there is no further possible therapy for a patient's condition. However the patient has the right to be informed in these cases as well.³³

³³ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 124.

There is no obligation to inform the patient in writing, thus the right to information in Greece is solely on an oral basis.³⁴

B. Right not to know

Article 11 (2) of the Code of Medical Ethics of 2005 stipulates a right not to know for the patient and an obligation to respect this right for the physician. In these cases, the patient is entitled to ask the doctor to inform exclusively other persons suggested by him. These persons shall receive information instead of the patient. The content of the information does not change because the recipient is not the patient himself.³⁵

In certain cases, the right not to know is not absolute, when not informing would seriously cause harm to the patient or third parties.³⁶

C. Therapeutic exception

This exception should be applied only in specific circumstances and the physician has the burden of proving that the withholding of information from the patient is justified for therapeutic purposes.³⁷

This can be the case when it becomes clear that to inform the patient would either result in a significant deterioration of his health or render the treatment ineffective. This may be particularly so in case of psychological treatment. In cases of physical treatment, one could envision such an exception only in very limited circumstances.³⁸

³⁴ K. MERAKOU and E. TRAGAKES, *o.c.*, 73-74.

³⁵ M. CANELLOPOULOU-BOTTIS, *o.c.*2006, 110.

³⁶ H. POLITI, "Information and consent of the Patient", *Iatriko Vima*, 1990, 42.

³⁷ Art. 12, section 3b Code of Medical Ethics 2005; T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 125.

³⁸ M. BARENDRECHT, et al., *o.c.*, 863.

§ 5. Patient rights regarding the medical file

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*
2. *Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.*

A. Right to a medical file

According to article 14 of the Code of Medical Ethics of 2005 “the physician must keep up a medical file electronically or in printed form that contains data that are (unbreakable) related to the illness or health of his patients”.

Article 14 (3) of the Code of Medical Ethics of 2005 obliges the hospitals to keep in their archives all the results of patient’s tests. Private doctor’s offices shall keep their archives for at least ten years after the last visit of their patients and public health care facilities for twenty years (section 4).

B. Contents of the medical file

According to article 14 (2) of the Code of Medical Ethics of 2005 a medical file must contain the patient’s name, sex, age, profession and address, the dates of consultation, every essential element of the health care to the patient such as his illnesses and the reason for the consultation, the diagnosis and the action taken.

Article 14 (7) stipulates that a medical file may not contain any judgments or comments about a patient except when they concern his illness. No notes on any other matter than a patient’s disease shall be recorded in his file.³⁹

³⁹ M. CANELLOPOULOU-BOTTIS, *o.c.*2006, 111.

C. Right to access and copy the medical file

i. Right to access the medical file

Article 14 (8) of the Code of Medical Ethics stipulates that the patient has the right to access his medical file and to receive a copy of his file. Article 16 of the Act 1599/1986 on Citizen/State relations provides that a subject may not access written documents covered by medical confidentiality that refer to third persons. These documents are accessible only by persons to whom the information therein refers, and only within the presence and under the assistance of a physician. The exact role of this physician remains unclear. It may be that he will make known only a selection of the data so as not to cause distress or damage to health of the patient.⁴⁰

It is also possible to provide such information to legal or physical persons having a right or legal interest by following a procedure established by article 1460 of the Civil Code and article 12 of the Code of Medical Ethics.⁴¹

A third party has no right to access the patient's file. Only judicial or prosecutorial authorities may ask for access during the execution of their duty, or other organs of the Greek State having this right under their constitutions.⁴²

ii. Right to copy the medical file

As already stipulated, article 14 of the Code of Medical Ethics also includes the right to copy the medical file.

There is no right to copy the medical file for third parties.⁴³

iii. Post mortem access by relatives

If the patient has died, the patient's close relatives may exercise the right to access the medical file.⁴⁴

⁴⁰ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI *o.c.*, 133.

⁴¹ *Ibid.*

⁴² M. CANELLOPOULOU-BOTTIS, *o.c.*2006, 111.

⁴³ H. NYS, et al., *Genetic Testing – Patients' rights, insurance and employment. A survey of regulations in the European Union – Greece*, 67.

D. Right to correction, erasure and/ or demolition

No information was found on this topic.

§ 6. Right to medical secrecy/ confidentiality

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*

A. General principle

Physicians are obliged to protect the confidences entrusted by their patients.⁴⁵

According to of article 13 (1) of the Code of Medical Ethics of 2005 the physician has the obligation to keep medical information confidential. This obligation is absolute.

Section 2 stipulates that “in order to strictly and effectively respect medical secrecy, the physician has to observe the necessary discretion regarding his collaborators, assistants or third parties which take part in one or another way or support the medical service”.

According to article 13 (4), the duty to respect medical secrecy may be waived by the consent of the person concerned, except when this consent is not valid as in case of error, deceit, deception, physical or psychological violence or when it violates human dignity.

The physician is obliged to properly supervise his assistants or other persons who support the provision of medical services and to take every necessary measure to safeguard confidentiality even after the termination of his medical practice.⁴⁶

In particular, according to article 8 of the Code of Medical Ethics, the physician is obliged to take every possible measure to ensure that information that could lead to a breach of medical confidentiality is

⁴⁴ *Ibid.*

⁴⁵ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 128.

⁴⁶ M. CANELLOPOULOU-BOTTIS, *o.c.*2006, 110.

excluded from professional or scientific books or articles. Special care shall be taken so that the identity of a patient is not disclosed therein.⁴⁷

The breach of that obligation may give rise to a claim for damages to the party aggrieved by such a breach of duty.⁴⁸

According to article 20 of the Code of Medical Ethics the strict maintenance of medical secrecy is obligatory for all physicians serving in social insurance organizations or foundations under public or private law, of any kind or category. Any declaration contrary to the principle of medical secrecy is to be avoided. The only physicians exempt from this obligation are those executing a task of inspection, certification or evaluation, and then only within the limits of their instructions and the specific task undertaken. Under no circumstances may a doctor undertake an assessment of a patient on behalf of a third party when that patient is or has been under his care.⁴⁹

Article 371 of the Penal Code imposes upon the physician a legal obligation not to disclose confidential information on patients which he has learned in the course of their medical practice, not only from patients themselves but from other sources as well.

The same obligation rests with nurses and paramedical personnel who are also bound to their professional duty of secrecy on medical information circulating within the team. This is the “shared medical secret”.⁵⁰

B. Exceptions

The Greek Code Penal Procedure refers to two exceptions on the duty of medical secrecy of physicians: the disclosure of information before a court and the legal obligations to dissolve such information.⁵¹

i. Testimony in a court

Physicians summoned to testify in court have the duty to speak, according to article 209 of the Code of Penal Procedure. They also have a right to silence not to disclose medical information in court, as

⁴⁷ M. CANELLOPOULOU-BOTTIS, *o.c.*2006, 111.

⁴⁸ M. BARENDRECHT, *o.c.*, 885.

⁴⁹ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 129.

⁵⁰ *Ibid.*

⁵¹ *Ibid.*

the right is expressly recognized by article 212 of the Code of Penal Procedure.

ii. Statutory obligations to disclose confidential information

Certain acts require physicians to disclose information about a patient despite his refusal in certain cases.

Act 1193/1981 on sexually-transmitted diseases compulsorily demands the notification of any confirmed or suspected case of a venereal disease, but only to competent authorities. Act 1193/1981, further states that any physician, midwife, pharmacist, civil servant, municipal employee, or employee of a legal person under private or public law, who, in the course of his duties, or through personal relations with the infected person, discovers any case of sexually-transmitted disease, and communicates this information to any *unauthorized* person, shall be punished in accordance with article 371 of the Penal Code.

Article 371 (4) of the Penal Code includes provisions which pardon breaches of the duty to confidentiality; the act is neither wrong nor punishable if the physician acts according to one of the reasons set out article 371 (4). These are:

- a. the fulfillment of a duty (the obligation to declare births, deaths and transmissible diseases to the competent authorities)
- b. the protection of an essential duty (protection of the disabled, saving of the unjustly accused, avoidance of public danger, cases of accidents at work, cases of persons infected with HIV)
- c. defense or state of emergency (article 22 and 25 of the Penal Code)

In health insurances the physician has no absolute duty to medical secrecy. For instance, the physician is obliged to record the diagnosis in the patient's insurance book, which in turn passes into the hands of third parties. There is a lacuna in the Greek Law as far as this matter is concerned.⁵²

In the course of a criminal investigation, the investigator may obtain and certify documents from a physician. Such documents are passed

⁵² T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 129-130.

to the board of the local medical association. If the board of the local medical association finds that medical confidentiality is not an issue, the investigator may then examine the documents.

C. Notification of criminal acts

There is no legal obligation for physicians to notify a criminal act, whether the patient is the perpetrator or the victim of it. Exceptions may arise on grounds of justification, like the duty in a state of necessity, the right (not the obligation) to notify a case of child abuse to the competent authorities, or duties in other special circumstances. There are cases where higher values and interests prevail over medical secrecy.

D. Consent of the patient or waiver

Physicians cannot be released from the duty of secrecy by the patient's consent to the disclosure of confidential information, (article 212 (2) of the Penal Code). However, the consent or the request of the patient enables a physician to disclose confidential information to a third party. Action for breach of medical secrecy may follow upon a deposition by the person who confided the information to the physician, by the person who suffered harm by the revealing of the confidential information, or by any person who has an interest in it.⁵³

E. Issuing of medical certificates

According to article 5 of the Code of Medical Ethics of 2005 it is forbidden to issue a medical certificate that does not bear the reason for its issue and the name of the recipient. The issue of a false certificate is a criminal offence. By article 221 (1) of the Penal Code, a physician, dentist, veterinarian, pharmacist or midwife who knowingly issues a false certificate destined for a public service or an insurance company may be punished by a term of imprisonment of up to two years, a fine, and dismissal from office or post of employment. A physician who is also a public servant may be punished more severely according to article 242 of the Penal Code. Furthermore, the use of a

⁵³ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 129-130.

false certificate by the patient is punishable under article 221 (2) of the Penal Code.

The validity of medical certificates delivered directly to a third party at the specific request or with the expressed consent of the patient is accepted. The law permits physicians to decide whether or not to deliver a certificate which may or may not be in the interests of the patient.

The attending physician issues the death certificate. His refusal to do so may be considered illegal according to article 48 of the Act 344/1976. Any physician in the clinic may issue the certificate.⁵⁴

§ 7. Right to privacy/ protection of private life

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*

The right of the patient to informational privacy and the obligation of physicians to respect this aspect of the patient's privacy are found in Greek law. The most important pieces of legislation are the Code on Medical Practice 1565/1939, Act 1599/1986 on the state/citizen relationship, Act 1805/1988 on the updating of the criminal record, the modification of penal provisions and the adjustment of other related matters and Act 2400/1996 which ratified Protocol 11 of the Convention on Human Rights and Fundamental Freedoms.

The Hospital Act also contains a disposition to protect the privacy of the patient: "every patient shall have the right, to the extent that it is genuinely possible, to the protection of his private life" (article 47 (6)). This includes the right to expect appropriate and confidential treatment of data, documents and files containing personal information, including observations and medical findings.⁵⁵

⁵⁴ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 129-130.

⁵⁵ H. NYS, *o.c.*, 69.

It is accepted that rules of medical secrecy alone cannot face all the problems raised by the automatic or manual processing of medical personal data, which also involve a number of non-physicians.

In 2001 the revised Greek Constitution introduced a new individual right in article 9A which reads: “All persons have the right to be protected from the collection, processing and use, especially by electronic means, of their personal data as specified by law. The protection of personal data is to be ensured by an independent authority, which is constituted and operating as specified by law.”⁵⁶

A. Processing of data concerning health

In accordance with article 371 of the Penal Code, it is forbidden to process personal data with regard to the state of health, medical examination, medical care and treatment. There are exceptions to this rule.

Without the special written consent of the patient, treating (attending) physicians may process personal medical data under their supervision and responsibility. Persons participating in the processing are to be appointed by name by whoever is responsible for the processing. Personal medical data can be communicated to a third party following the written consent of the patient or to a physician and his medical team to further the medical treatment of the patient.

The Act on Data Protection of 26 March 1997 (No. 2472/97) establishes “the Data Protection Authority” and sets up a set of guidelines for the use, the processing, storage and export of personal data in electronic and paper files. The Act is a framework legislation and needs consequently to be completed with sectoral acts.

The data must be collected for specified, explicit and lawful purposes and subsequently processed fairly and lawfully; data must be adequate, relevant and not excessive; they must be accurate and up to date and not kept for longer than necessary. (article 4 (1))

Medical data are ‘sensitive’ data (article 7 (1)). The Greek legislator preferred the word ‘sensitive’ as an indicator of something more than ‘special’. Medical data, therefore, come as similar in nature with data revealing ethnic or racial origin, data on sex life, on one’s criminal record, political and religious opinions, etc. According to article 7 (2),

⁵⁶ M. CANELLOPOULOU-BOTTIS, *o.c.*2002, 207.

the processing of all sensitive data, including medical data, is only allowed under the following conditions:

- a. if the data subject has given explicit consent to the processing of those data
- b. if processing is necessary to safeguard vital interests of a data subject legally or physically incompetent to give a valid consent
- c. if processing is necessary for the data subject's defense in a court of law
- d. if processing is necessary to protect the data subject's interests in health and it is carried out by a health care provider under the obligation of confidence
- e. if processing is necessary to national security interests and needs of the state's criminal or correctional policies
- f. if processing is related to personal data of public persons connected to the exercise of their public duties and this processing is a part of the exercise of a journalist's duties.

Consent of the person related to the medical data is legal only if it is clear and explicit, and only if it was given after this person has been fully informed on the purpose of processing, the nature of data to be given, the recipients or categories of recipients of the data and the filing system controller (article 7 (2) a). In any case, this controller is obliged to file for a license to process sensitive data to the Greek Authority of Data Protection.⁵⁷

B. Right to access and right to receive a copy

Article 12 (1) of the Act on Data Protection stipulates: "Everyone is entitled to know whether personal data relating to him are being processed or have been processed. Section 6 continues: "Data pertaining to health matters will be communicated to the data subject by means of a medical doctor."

All data subjects should thus be able to inspect the recorded data relating to themselves. This right, however, needs to be exercised through a physician for the protection of the subject and the exact role of the physician remains unclear. It may be that the physician will

⁵⁷ M. CANELLOPOULOU-BOTTIS, *o.c.*2002, 208.

make known only a selection of the data so as not to cause distress or damage to physical health.⁵⁸

The right to receive a copy is not explicitly stipulated in Greek legislation.

C. Right to correction, erasure and/ or demolition

According to article 13 of Act 2472/1997 on Data Protection “the data subject shall be entitled to object at any time to the processing of data relating to him. Such objections shall be addressed in writing to the Controller and must contain a request for a specific action, such as correction, temporary non-use, blocking, non-transfer or deletion”.

§ 8. Right to complain and to compensation

A. Right to complain

Article 23 Biomedicine Convention

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

The right of a patient to complain is protected by the Hospital Act. Article 47 (8) stipulates that “every patient shall have the right to present and submit, in an appropriate manner, any complaints and objections and to be fully informed of the effects and outcome thereof.”

The protection of this right was put into practice by a decision of the Minister of Health and Social Solidarity to establish a “Service and the Committee”. Beside this institution in each hospital a “Communications Office”, or “Secretariat for urgent cases” is established.⁵⁹

Also to be noticed is the Greek Ombudsman.

⁵⁸ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 124.

⁵⁹ T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 133.

The office of Ombudsman is explicitly and statutorily independent, and appears well structured and provided for, with a specific arm dealing with health care and social welfare grievances.

Prima facie the Ombudsman also has wide-ranging powers of investigation, with the statutory provisions for access to records and summoning witnesses.

It is less clear what the ability is of the Ombudsman to enforce these powers. The office of Ombudsman has only been in place for twelve years. Health care represents only a small portion of the Ombudsman's workload as a whole, and there is still much to be done to raise public awareness of the system and its potential.⁶⁰

The small caseload and the newness of the patient rights agenda also mitigates the Ombudsman's power for the general quality improvement of the health care system at this stage. However, because of the zeal for self-improvement, and the strong statutory footing which the Ombudsman has been given, the institution of the Greek Ombudsman has a great deal of potential for the future.⁶¹

B. Right to compensation

Article 24 Biomedicine Convention

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Civil liability of a physician arises when provisions of civil law are violated by act or by omission. The physician is liable for compensation to the person who suffered as a result of the misconduct.⁶²

An obligation to compensate may be incurred in two ways:

⁶⁰ L. FALLBERG and S. MACKENNEY, "Patient ombudsmen in seven European Countries", *European Journal of Health Law* 2003, 351.

⁶¹ *Ibid.*

⁶² T.B. KONIARIS and A.D. KARLOVASSITOU-KONIARI, *o.c.*, 106-107.

1. by a breach of contract for the provision of medical services between a physician together with a hospital and a patient; or
2. by a tort.⁶³

Since 1994 a new civil liability regime applies to the provision of medical services in Greece. The Act 2251/94 on Consumer Protection provides in article 8 rules concerning the liability of the service supplier.

According to article 8, the supplier of services is liable for all damages caused due to the service. The patient needs to prove the damage and the causal link due to the services, whereas the professional supplier of the service needs to prove that he was not at fault in providing the service. Thus, on the one hand the physician will have to prove not only that he was not negligent but also that his services were lawful, i.e. that it was according to the rules, the contract and the duty of care. On the other hand, the patient needs to prove the causal link between the provision of medical services and the damage. It is however well known that proof of causal link in case of medical negligence is particularly difficult. However, in practice a patient is less prone to claim liability of the treatment provider on the basis of contract, whereas more often a case is discussed on the basis of tort law. Finally, some aspects of the provision of medical services and the exercise of the medical profession are regulated in the Code of Medical Practice.⁶⁴

The physician can also be held liable insofar as he breached his duty of care towards the patient. This duty of care is benchmarked by an objective standard set by law. The standard of care is defined with reference to the qualities that a reasonably skilled representative of the profession is expected to possess. Medical treatment must abide by the generally accepted rules of medical science and medical practice. A physician must provide a *lege artis* treatment, though in most cases the obligation is not one of result, but rather one of means.⁶⁵

Also in case the basis of liability is tortious, the patient will have to prove the fault of the physician. However, given a *prima facie* medical error, the fault, as the subjective element of the subjective error, is

⁶³ *Ibid.*

⁶⁴ M. BARENDRECHT, et al., *o.c.*, 800-801.

⁶⁵ M. BARENDRECHT, et al., *o.c.*, 825.

presumed. In case of serious medical error it will be significantly difficult for the physician to rebut the presumption. It is also suggested that in case contractual and tortious liability are concurrent, in both cases the most beneficial contractual rule of reversal of the burden of proof must apply.⁶⁶

The question whether and to what extent treatment institutions such as hospitals and private clinics bear the responsibility for a medical fault is not a straight-forward one. A lot depends on the agreement between the parties, i.e. the patient and doctor and the institution, and the relevant circumstances. If the patient concludes on a personal basis a contract for the provision of medical services with a physician who is an external associate of the institution where the service is carried out, the institution is liable for the provision of the adequate infrastructure and paramedical care. Thus it cannot be held liable for any medical fault. The same view is held with regard to doctors that are not just external associates but employees of the institution in question, in case the patient enters into an agreement with the doctor on a personal basis. However, case law seems inclined to acknowledge liability of the hospital for medical fault in the previous types of cases on the basis of article 922 of the Civil Code. However, if the patient enters into an agreement with a particular physician, the institution undertakes the whole liability, i.e. for medical and other associated services. The institution is liable for the fault of its medical staff on a contractual as well as tortious basis. If the patient can opt for a particular doctor and the doctor accepts the treatment, then there is in addition a contractual bond between patient and doctor.⁶⁷

⁶⁶ M. BARENDRECHT, et al., *o.c.*, 831.

⁶⁷ M. BARENDRECHT, et al., *o.c.*, 898-899.

IV. RIGHTS OF USERS OF GENETIC SERVICES



§ 1. Introductory remark

In Greece, genetic testing is mainly regulated through the legal framework that applies to health services as a whole. The regulations on patient rights are *mutatis mutandis* applicable as rights of users of genetic services. The main principles are completed with specific regulations on genetic testing and recommendations of the National Bioethics Commission.⁶⁸

Because of the ratification of the Biomedicine Convention, this Convention is now part of Greek positive law and binding for any relevant legislative initiative in the future pursuant to article 28 (1) of the Constitution. In this respect, the provisions of the Convention related to genetic services are applicable.⁶⁹

A. Informed consent

The right of a patient to consent to diagnostic procedures (such as genetic tests) is established by article 47 (3) of the Hospital Act. Section 4 and 5 of the same article guarantee the right to prior full information. Pursuant to article 5 of the Convention, the consent is freely revocable. Besides the provisions in the Hospital Act, the Code of Medical Ethics of 2005 establishes the physician's duty to protect personal freedom and the free will of patients in general. Article 34 of the Code of Medical Ethics of 2005 reads: "Interventions in human genes are only allowed for preventive, diagnostic or therapeutic purposes. They may never have consequences for the future generations. Gene technology may not be used for political or military purposes."

⁶⁸ National Bioethics Commission, *Report on the collection and use of genetic data*, 34 p., available on www.bioethics.gr.

⁶⁹ National Bioethics Commission, *Report on the collection and use of genetic data*, 27, available on www.bioethics.gr.

According to a recommendation on Genetic Data of the National Bioethics Commission “respect for the value of human beings requires the free and informed consent of the person whose biological sample is collected for the purpose of genetic testing. In order to ensure genuine conditions of free will, the information should be provided, if possible, in advance of seeking the consent”. It also states that “The consent must be written, specific and revocable at any time before the onset of sample or data processing”.⁷⁰

With regard to the content of the information given to the patient preceding the consent the Bioethics Commission stipulates:

“a) The purpose of the test should be adequately explained in comprehensible language,

b) It should be clarified whether the genetic data will be destroyed or stored after the test; in case they are stored, whether they will be anonymous or confidential as well as whether they are destined to commercial exploitation,

c) It should be clarified whether the biological sample will be destroyed or stored after the test; in case it is stored, whether it will be linked to the resulting genetic data or not.”⁷¹

B. Right to information

Concerning the right to know and the right not to know the Recommendation of the National Bioethics Commission stipulates: “Everyone, in the context of self-determination, has the right to know the results of any medical, diagnostic or preventive genetic tests they were subject to.” However the right not to know is also acknowledged upon explicit request by the person concerned.

In case the results of genetic tests involve the health of third persons:

a) any person exercising his right to know must also assume responsibility for informing any third party involved;

b) in case people exercise their right not to know, the physician may inform third persons, if absolutely necessary, in the context of the general medical obligation to care for human life (Art. 9 Code of Medical Ethics of 2005)).

⁷⁰ National Bioethics Commission, *Report on the collection and use of genetic data*, 24, available on www.bioethics.gr.

⁷¹ National Bioethics Commission, *Recommendation on Genetic Data*, 2002 (available on www.bioethics.gr).

Exceptionally the right to know the results of genetic tests cannot be exercised in the context of research projects when the interpretation of results is uncertain.”⁷²

C. Right to privacy

Apart from article 10 of the Oviedo Convention pertaining specifically to the protection of personal information which applies in Greek law, the recent revision of the Constitution in 2001 has to be noticed. This revision provided the chance for the inclusion of a specific mention of genetic data. Section 5 was added to article 5, being the major provision on the protection of the free development of personality and human freedom. This section 5 reads: ‘everyone has the right to the protection of his health and his genetic identity. A statute shall provide the necessary protection of a person against biomedical intervention’. The phrase ‘protection of genetic identity’ necessarily involves the protection of genetic personal data.

Moreover the Commission noticed that: “Everyone has the right to determine whether genetic information is to be disclosed or not to third parties as well as the content of such information and the time of disclosure. (...)”⁷³

Additionally, a new article 9A was added to the Constitution which embodies the constitutional right to “personal data privacy”.⁷⁴

The combination of section 5 of article 5 and article 9A leads to the conclusion that in Greece, there is a constitutional right to genetic privacy, including the right to the protection of personal genetic data and that this right belongs to the defensive rights; in fact it is a sub-category of the general right to privacy.⁷⁵

All individual and human rights listed in the first 25 articles of the Constitution are deemed applicable not only in the public law relation between a citizen and the State but also in any other private law relation between private parties where they may be applied (article 25, revised in 2001).⁷⁶

⁷² National Bioethics Commission, *Recommendation on Genetic Data*, 2002 (available on www.bioethics.gr).

⁷³ *Ibid.*

⁷⁴ National Bioethics Commission, *Report on the collection and use of genetic data*, 28-29, available on www.bioethics.gr.

⁷⁵ M. CANELLOPOULOU-BOTTIS, *o.c.2002*, 211.

⁷⁶ M. CANELLOPOULOU-BOTTIS, *o.c.2002*, 212.

§ 2. Prohibition of discrimination on grounds of genetic heritage

Article 11 Biomedicine Convention

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited

Discrimination is prohibited by the International Conventions signed by Greece, especially article 11 of the Biomedicine Convention with regard to genetic testing, as well as by the Greek Constitution (article 4 (1), article 5 (1) and article 28 (1)).⁷⁷

Everyone has the right to have access to medical/health care. There are only restrictions for undocumented immigrants who have access to medical/health care in the case of emergency and with regard to minors.

The National Bioethics Commission believes that disclosure of genetic information is unacceptable even with the consent of employees or applicants. This solution is justified by the usually unequal position of employee's vis-à-vis employers.

The Commission recommends the adoption of specific legislation on disclosure of genetic information in the context of labor relations, establishing the principle of prohibition and specifying possible exceptions.

The Commission considers that disclosure of genetic information to public social security funds is unacceptable even with the consent of the insured or the prospective insured. This solution is justified by the nature of social security as public good which should be made available to all without discrimination.

As far as private insurance is concerned, disclosure of genetic information remains unacceptable when the insured or prospective insured is not covered by public social security. This solution is justified by the unequal position of the insured vis-à-vis the insurer.

However, when private insurance is complementary to social security, disclosure of genetic information is allowed provided the insured or

⁷⁷ Personal Communication of D. PARASKEVIS.

prospective insured consents in accordance with the principle of freedom of contract”.⁷⁸

§ 3. Use of predictive genetic tests

Article 12 Biomedicine Convention

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling.

Like other provisions of the Biomedicine Convention, article 12 is directly applicable in Greece.

⁷⁸ National Bioethics Commission, *Recommendation on Genetic Data*, 2002 (available on www.bioethics.gr).

V. CONCLUDING REMARKS



1. Greece signed the *Convention on Human Rights and Biomedicine* on 4 April 1997 and ratified it by Law 2619/1998. As article 28 (1) of the Constitution lays down the principle of the openness of the Greek legal order to international law, the provisions of the Convention form an integral part of domestic Greek law since 1 December 1999 and prevail over any contrary provision of the law.

Greece has not made restrictions based on article 26 of the Convention. Generally speaking, Greek law is in conformity with the Convention.

2. In Greece the relation between patients and physicians is regulated by provisions in various legal acts and not by specific legislation.

The development of legislation relating to *patient rights* in Greece has in the last fifteen years undergone four major phases.

In the period up to 1992, patient rights in Greece were indirectly addressed through relevant provisions in Civil, Penal, Administrative and Disciplinary Law.

In 1992, based on the European Charter of Hospital Patients' Rights of 1979, broader health care reform legislation contained provisions directly addressing the rights of hospital patients.

In 1997 further provisions extended the rights of patients granted in 1992 to the entire population, and in addition provided for the implementation of the legislative provisions.

In 2005 the most important change in medical law in Greece in the last years took place. The new Code of Medical Ethics was promulgated in that year by law.

3. The *right to informed consent* is protected by the Greek Constitution and other Greek legislation under which the Penal Code, the Hospital Act and the Code of Medical Ethics.

If no consent is obtained by the physician, he violates the Penal Code and will therefore be medical liable.

Consent can be *presumed* in case of trivial diagnostic or therapeutic procedure without any risks or commonly practiced. In these cases

there rests no obligation on the physician to inform the patient preceding the consent.

In the event that the patient's life is in danger, the doctor is obligated to intervene against or in spite of the patient's wishes as well as in urgent cases which require surgery and in case of extended operations. The information that needs to be provided preceding the consent of the patient is under Greek law wider than what the Convention of Oviedo dictates. The specific addition of social and economic factors, as crucial to patient decisions is also an achievement.

4. According to the Order of Physicians in Greece a distinction has to be made between two categories of *minors*: those who have attained the age of sound mind, and the others. It is not expressed in terms of an age limit. The physician should decide considering the personality of the child, the medical treatment proposed, the family and social background etc. A mature minor may give his consent alone, but the consent of his parents may also be required. The physician has always to evaluate the situation and to judge whether the consent of the parents will also be required.

If the parents of a minor refuse to consent and the life of the minor is in danger, the Greek common medical practice on youth protection allows an *ultimum remedium*. The duty to rescue the minor obliges the physician to act on his own initiative.

5. Article 11 (2) of the Code of Medical Ethics of 2005 stipulates that the patient has a *right not to know* and for the physician an obligation to respect this right. In these cases, the patient is entitled to ask the doctor to inform *exclusively* other persons, suggested by him.

6. Article 14 (7) stipulates that "the *medical files* may not contain any judgments or comments about patients except when they concern his illness. So no notes on any other matter than a patient's disease shall be recorded in his file."

These documents are accessible only by persons to whom the information therein refers, and then only with the presence and assistance of a physician. The exact role of the physician remains unclear.

7. The physician has a legal obligation not to disclose *confidential information* on patients which he has learned in the course of his medical practice, not only from patients themselves but from other sources too.

Physicians cannot be released from the *duty of secrecy* by the circumstances that the patient has consented to the disclosure of confidential information, though the consent or the request of the patient enables a physician to disclose confidential information to a third party.

8. Medical data are listed as ‘sensitive data’ in the *privacy protection* of Act 2472/97 (article 7 (1)).

The processing of all sensitive data, medical data too, is according to article 7, section 2, only allowed under strict conditions.

All data subjects should, be able to inspect the recorded data relating to themselves. This right, however, needs to be exercised through a physician, for the protection of the subject.

9. In Greece *genetic testing* is mainly regulated through the legal framework that applies to the Greek national health care system as a whole. The regulations on patient rights are *mutatis mutandis* applicable as rights of users of genetic services. The Bioethics Commission completes the legislation on genetic testing with some important recommendations. Because of the direct applicability of the provisions of the Biomedicine Convention related to genetic testing, these provisions are also applicable in Greece.

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