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*Patients' rights,
insurance and employment
A survey of regulations in the
European Union*



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Genetic Testing

Patients' rights, insurance and employment A survey of regulations in the European Union

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FOREWORD

Genetic testing has been facing an exponential growth in the last years. The rapid evolution of research in molecular genetics and genomics has paved the way to a proliferation of novel diagnostic and predictive tests, allowing the detection of single genetic lesions underlying a myriad of genetic diseases. Further recent advances in molecular medicine research, predicting the development of predisposition tests and personalised medicine through pharmacogenomics, are associated with even larger prospects and expected impacts on mankind.

Further to being linked to significant potential benefits for human health, the progress in genetic testing is also associated with major implications of a psychological, ethical and social nature, affecting society at large.

Research towards quality assurance of genetic testing is thus becoming of outmost importance. This research is aimed at the development of quality reference materials and protocols, as well as the training of professionals, in order to ensure the best proficiency and accuracy of tests. “Quality assurance” equally includes respect for ethical aspects - such as patient’s rights, informed consent, genetic counselling, protection of privacy – as well as consideration of legal and social aspects – such as insurance and employment.

Genetic testing represents thus simultaneously i) a complex technical research issue, ii) a topic of public concern and iii) a subject of intense policy debates, involving sectors as diverse as research, education, employment, international trade and, more generally, human rights.

As such, genetic testing has become also the subject of policy debates at different institutional and international levels. Recent work took place at the European Parliament- through the work of the “Temporary Committee on Human Genetics and Other New Technologies in Medicine”-, at the Council of Europe – through the “Working party on Human Genetics”, preparing a preliminary Protocol on Human Genetics – at the European Group on Ethics in Science and New Technologies - who held a debate on ethical issues of genetic testing in the workplace – and at the OECD - through the Working Party on Biotechnology which established a Steering Group (including several EU countries, Japan, Canada and US) to survey the situation of genetic testing world-wide and to issue recommendations for an international and mutually recognised approach for quality assurance in genetic testing.

In this context, the European Commission – DG Research - has supported a series of research projects, networks and studies aimed at improving the quality of genetic services, analysing the ethical, legal and social aspects and providing support for the development of related responsible policies. The present study is an example to illustrate some aspects of the complex research at the core of genetic testing.

Bruno Hansen

Director

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PREFACE

Background

In the beginning of 2000 the EU Commission granted the European Thematic Network on Cystic Fibrosis support during four years. The aim of this Network is to create a unique European interaction platform for scientists involved in fundamental CF research, for the more than 200 genetic diagnostic laboratories, for CF associations of families, patients and clinicians, ethical, legal and IPR experts and representatives of the industry.

The ethical-legal subgroup of the Cystic Fibrosis Thematic Network aims to draft guidelines for the application of new diagnostics and therapeutics in consensus with representatives of the patient organisations and of the medical profession through a translation of the existing clinical, ethical and legal insights. The drafting of these guidelines cannot neglect the actual evolution in Europe whereby the relationship between patient and clinician is being embodied in legal regulations. The 1997 Convention on Human Rights and Biomedicine of the Council of Europe has provoked in many member states of the European Union an intensified activity in this field. This Convention contains two dispositions that are of particular interest for the domain of genetics: articles 11 (prohibition of any form of discrimination on the ground of genetic heritage) and 12 (predictive genetic testing only for health purposes and subject to appropriate genetic counselling). However, a clear understanding of these dispositions requires that they are placed within the general framework of the said Convention and the protection of human rights in health care in general.

Therefore a comparative analysis of the basic principles of patients' rights (informed consent, information about the health status, protection of privacy of medical data) in the different member states of the European Union is required. Without such a broad understanding of patients' rights in general every effort to draft recommendations or guidelines in the domain of genetic testing and screening would be futile.

Scope

The present study that has been performed in 2001-2002 gives an overview of regulations in the 15 member states of the European Union. Although the main focus of this report is to map the regulations for genetic testing in the different countries, we start for every single country with a general overview of the patients' rights in that member state. This necessary step makes clear what the general evolutions are with regard to the principle of informed consent, the access to medical records and the principle of privacy. In a second phase follows an overview of the consequences and implications of the regulatory initiatives regarding patients' rights for the field of genetic testing. In this way it becomes clear how consent, privacy, data protection, etc are integrated in specific regulations or propositions for the domain of human genetics in each of the 15 European member states. In every third and fourth step, we focus on rules, visions and initiatives in these states with regard to the specific context of insurances and employment for genetics and patients' rights.

This overview learns us that the evolution at the regulatory level proceeds as fast as the field of genetics itself. The situation in Europe is also very heterogeneous. Some countries have only

general views on this subject, others already have laws on patients' rights and in some member states one can find concrete regulations for genetic medicine. In order to follow these rapidly changing regulatory evolutions regular updates of this report will be accessible on the website of the CF Thematic Network: <http://www.cfnetwork.be>.

Aim and approach

It has been the aim of the report to provide relevant information with regard to the current evolutions in the domain of the patients' rights and genetic testing. Several approaches were taken to obtain this information for this report. Various national experts in this matter were contacted. A thorough examination of both legislation and authoritative documents was conducted. Relevant and up to date information with regard to our topic was gathered in order to give an actual overview of the opinions, propositions and laws in the different EU member states. Although it was tried to collect the most recent documents and publications it was not the aim to present these materials in an exhaustive and technical-legal way. The reason therefore is that the main target group of this publication are not legal or ethical experts but researchers, clinicians, policy makers and other interested people in the field of medicine, human genetics and biotechnology.

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TABLE OF CONTENTS

<u>PREFACE</u>	1
<u>TABLE OF CONTENTS</u>	5
<u>AUSTRIA</u>	9
1. <u>PATIENTS' RIGHTS</u>	9
1.1. <u>Right to Informed Consent</u>	10
1.2. <u>Right to Information</u>	11
1.3. <u>Access to Medical Records</u>	13
1.4. <u>Confidentiality</u>	13
1.5. <u>Right to Privacy</u>	14
2. <u>GENETICS AND PATIENTS' RIGHTS</u>	15
2.1. <u>Right to Informed Consent</u>	16
2.2. <u>Right to Information</u>	16
2.3. <u>Confidentiality</u>	17
2.4. <u>Right to Privacy</u>	17
3. <u>GENETICS AND INSURANCE</u>	17
4. <u>GENETICS AND EMPLOYMENT</u>	18
<u>BELGIUM</u>	21
1. <u>PATIENTS' RIGHTS</u>	21
1.1. <u>Right to Informed Consent</u>	21
1.2. <u>Right to Information</u>	22
1.3. <u>Access to Medical Records</u>	22
1.4. <u>Confidentiality</u>	23
1.5. <u>Right to Privacy</u>	23
2. <u>PATIENTS' RIGHTS AND GENETICS</u>	24
3. <u>GENETICS AND INSURANCE</u>	24
4. <u>GENETICS AND EMPLOYMENT</u>	25
<u>DENMARK</u>	26
1. <u>PATIENTS' RIGHTS</u>	26
1.1. <u>Right to Informed Consent</u>	26
1.2. <u>Right to Information</u>	27
1.3. <u>Access to Medical Records</u>	28
1.4. <u>Confidentiality</u>	30
1.5. <u>Right to Privacy</u>	31
2. <u>PATIENTS' RIGHTS AND GENETICS</u>	32
2.1. <u>The Scientific Ethical Committee system</u>	32
2.2. <u>The Danish Council of Ethics</u>	32
2.3. <u>Committee on Gene Technology</u>	32
3. <u>GENETICS AND INSURANCE</u>	33
4. <u>GENETICS AND EMPLOYMENT</u>	34
<u>FINLAND</u>	37
1. <u>PATIENTS' RIGHTS</u>	37
1.1. <u>Right to Informed Consent</u>	38
1.2. <u>Right to Information</u>	39
1.3. <u>Access to Medical Records</u>	40
1.4. <u>Confidentiality</u>	41
1.5. <u>Right to Privacy</u>	42

2.	PATIENTS' RIGHTS AND GENETICS	42
3.	GENETICS AND INSURANCE	43
4.	GENETICS AND EMPLOYMENT	43
FRANCE		45
1.	PATIENTS' RIGHTS	45
1.1.	Right to Informed Consent	45
1.2.	Right to information	46
1.3.	Access to Medical Records	47
1.4.	Confidentiality	48
1.5.	Right to Privacy	49
2.	PATIENTS' RIGHTS AND GENETICS	50
3.	GENETICS AND INSURANCE	51
4.	GENETICS AND EMPLOYMENT	53
GERMANY		54
1.	PATIENTS' RIGHTS	54
1.1.	Right to Informed Consent	54
1.2.	Right to Information	55
1.3.	Access to Medical Records	56
1.4.	Confidentiality	56
1.5.	Right to Privacy	57
2.	PATIENTS' RIGHTS AND GENETICS	58
3.	GENETICS AND INSURANCE	61
4.	GENETICS AND EMPLOYMENT	62
GREECE		64
1.	PATIENTS' RIGHTS	64
1.1.	Right to Informed Consent	65
1.2.	Right to Information	66
1.3.	Access to Medical Records	66
1.4.	Confidentiality	66
1.5.	Right to Privacy	67
2.	PATIENTS' RIGHTS AND GENETICS	68
3.	GENETICS AND INSURANCE	68
4.	GENETICS AND EMPLOYMENT	68
IRELAND		70
1.	PATIENTS' RIGHTS	70
1.1.	Right to Informed Consent	70
1.2.	Right to Information	70
1.3.	Access to Medical Records	71
1.4.	Confidentiality	72
1.5.	Right to Privacy	72
2.	PATIENTS' RIGHTS AND GENETICS	73
3.	GENETICS AND INSURANCE	73
4.	GENETICS AND EMPLOYMENT	75
ITALY		76
1.	PATIENTS' RIGHTS	76
1.1.	Right to Informed Consent	76
1.2.	Right to Information	77
1.3.	Confidentiality	77
1.4.	Right to Privacy	78
2.	PATIENTS' RIGHTS AND GENETICS	78
3.	GENETICS AND INSURANCE	79

4. GENETICS AND EMPLOYMENT	80
LUXEMBOURG	81
1. PATIENTS' RIGHTS	81
1.1. Right to Informed Consent	82
1.2. Right to Information	83
1.3. Access to Medical Records	83
1.4. Confidentiality	83
1.5. Right to Privacy	84
2. PATIENTS' RIGHTS AND GENETICS	84
3. GENETICS AND INSURANCE	85
4. GENETICS AND EMPLOYMENT	85
THE NETHERLANDS	86
1. PATIENTS' RIGHTS	86
1.1. Right to Informed Consent	86
1.2. Right to Information	88
1.3. Access to Medical Records	88
1.4. Confidentiality	90
1.5. Right to Privacy	90
2. PATIENTS' RIGHTS AND GENETICS	91
2.1. Right to Informed Consent	92
2.2. Right to Information	92
2.3. Right to Privacy	92
3. GENETICS AND INSURANCE	93
3. GENETICS AND EMPLOYMENT	96
PORTUGAL	99
1. PATIENTS' RIGHTS	99
1.1. Right to Informed Consent	99
1.2. Right to Information	99
1.3. Access to Medical Records	100
1.4. Confidentiality	100
1.5. Right to Privacy	101
2. PATIENTS' RIGHTS AND GENETICS	102
3. GENETICS AND INSURANCE	103
4. GENETICS AND EMPLOYMENT	104
SPAIN	106
1. PATIENTS' RIGHTS	106
1.1. Right to Informed Consent	106
1.2. Right to Information	107
1.3. Access to Medical Records	108
1.4. Confidentiality	108
1.5. Right to Privacy	109
2. PATIENTS' RIGHTS AND GENETICS	110
3. GENETICS AND INSURANCE	110
4. GENETICS AND EMPLOYMENT	111
SWEDEN	113
1. PATIENTS' RIGHTS	113
1.1. Right to Informed Consent	114
1.2. Right to Information	115
1.3. Access to Medical Records	116
1.4. Confidentiality	116
1.5. Right to Privacy	117

2.	<u>PATIENTS' RIGHTS AND GENETICS</u>	117
2.1.	<u>Right to Consent</u>	117
2.2	<u>Access to Medical Records</u>	118
2.3	<u>Confidentiality</u>	118
2.4	<u>Right to Privacy</u>	118
3.	<u>GENETICS AND INSURANCE</u>	119
4.	<u>GENETICS AND EMPLOYMENT</u>	121
	<u>UNITED KINGDOM</u>	122
1.	<u>PATIENTS' RIGHTS</u>	122
1.1.	<u>Right to Informed Consent</u>	122
1.2.	<u>Right to Information</u>	123
1.3.	<u>Access to Medical Records</u>	123
1.4.	<u>Confidentiality</u>	124
1.5.	<u>Right to Privacy</u>	125
2.	<u>PATIENTS' RIGHTS AND GENETICS</u>	126
3.	<u>GENETICS AND INSURANCE</u>	126
4.	<u>GENETICS AND EMPLOYMENT</u>	135
	<u>CONCLUSION</u>	139
1.	<u>PATIENTS' RIGHTS IN THE DIFFERENT MEMBER STATES</u>	139
2.	<u>PATIENTS' RIGHTS AND GENETICS</u>	140
3.	<u>GENETIC TESTS/INFORMATION AND INSURANCE/EMPLOYMENT</u>	141
4.	<u>CONCLUDING REMARKS</u>	142
	<u>SELECTIVE BIBLIOGRAPHY</u>	143
	<u>AUSTRIA</u>	143
	<u>BELGIUM</u>	143
	<u>DENMARK</u>	144
	<u>FINLAND</u>	144
	<u>FRANCE</u>	144
	<u>GERMANY</u>	145
	<u>GREECE</u>	145
	<u>IRELAND</u>	146
	<u>ITALY</u>	146
	<u>THE NETHERLANDS</u>	146
	<u>PORTUGAL</u>	147
	<u>SPAIN</u>	147
	<u>SWEDEN</u>	148
	<u>UNITED KINGDOM</u>	148

AUSTRIA

1. PATIENTS' RIGHTS

Austria has neither signed nor ratified the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine¹.

In Austria patients' rights are laid down in different laws regulating the overall functioning of the health care sector. Patients' rights are protected by virtue of a combination of general federal and regional legislation, common law, charters (agreements between federal government and the provinces) and constitutional provisions.

On the federal level the medical practitioners act, the social security law and the criminal code have to be mentioned.

In 1992 the Austrian Federal Ministry of Health and Consumer Protection drew up a patients' rights charter, but it was not implemented. One year later, an amendment was made to the Federal Hospital Act, adding a list of patients' rights. It starts by providing each person with the right to receive the best health care and treatment currently available, regardless of age, income or social position. The main patients' rights listed are:

- the right to health care under the health insurance system;
- the right to physical security (physicians and other health care personnel have the duty to provide health care services according to the state of the art)
- the right of free choice (people have free choice of a GP but not in public hospitals; patients may refuse treatment)
- the right to information (patients have to be informed about their health status, diagnostic possibilities, the available therapeutic methods, and treatment risks and benefits; patients may refuse to receive this information but they are required to state their refusal clearly; physicians may withhold information in cases where the information could harm the patient);
- the right to private life (strong provisions are made for the respect of patient's privacy, personal data and consent; exceptions are provided in cases of dangerous transmittable diseases, information to public prosecutors and criminal investigations); and
- the right to complain (mediation boards are established on a voluntary basis by the local chambers of physicians; patients have the possibility to complain in civil courts in cases of injuries and damages)

On the provincial level (Länder) there are regulations e.g. in the scope of competence of rest-and nursing homes, of local authorities and care providers.

The character of patients' rights, its fragmentation in numerous regulations, the loss of information caused by this resulted in the decision of the government to elaborate a Bund – Länder agreement, that will compile a complete and well-organised summarizing of all patients' rights, a patients' charter.²

¹ <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>

² H HANIKA, "Patientencharta", MedR 1999, vol. 4, 156

The Patients' charter, BGBl 1999/195, is the first Austrian charter of patients' rights, which came into force on the 1st of September³. The charter represents an agreement pursuant to Article 15a of the Austrian Constitution between the Austrian federation and the province Carinthia (Kärnten). The parties undertake to take care that the rights of patients, listed in the charter, are guaranteed in the fields of their responsibility in legislation and execution. The charter can be seen as a first and important step in the creation of an Austrian patient-rights-movement, that accepts the patient as the weaker part in the patient-doctor-relationship, who therefore needs clearly defined and obvious rights. Since it is, however, a "Gliederstaatsvertrag", a convention between the federation and a province, the rights and duties deduced from it are merely addressed to the participating territorially public bodies and not to patients or physicians. This also implies that no patient can call upon the charter or can deduce any rights from it.

Other Länder following Carinthia which have concluded a Patients' Charter are Burgenland⁴, Upper Austria⁵ and Lower Austria⁶. Styria will promulgate its charter soon and Tyrol has already concluded the charter which is currently under a ratification procedure in Parliament.

1.1. *Right to Informed Consent*⁷

There is a legal obligation for the patient to be informed of his/her diagnosis and treatment options and to give informed consent to treatment⁸. The legal obligation for informed consent extends to genetic information. There are however established protocols for withholding information from patients, when this is at the explicit request by the patient or where the physician considers it necessary to avoid serious harm. Likewise, there are established protocols for refusing treatment, as well as the possibility for legal proxies to be appointed by the patient to give or refuse consent. Patients have a legal right to read their own records.

Concerning the form of the consent there's no explicit general regulation.

In principle, one can state that one can consent informally. This is also the case in practice, except for major interventions.

Austrian courts generally qualify any medical treatment as wrongful infliction of bodily harm unless it has been justified, in particular by the patient's valid consent. Medical treatment without such consent further violates section 110 of the Austrian Penal Code, which penalizes the treatment of another "without that person's consent, even if this is in accordance with the rules of medical science".⁹ Section 8 subsection 3 of the Austrian Federal Hospital Establishment Law of 1957 (Krankenanstaltengesetz, KAG) also contains a provision about informed consent and provides that a patient who is admitted to a hospital must specifically agree to any action taken if there is enough time to ask for such consent without imminent danger to the patient's life or health. If the patient is incapable of consenting, consent can be given by his/her legal

³The Federal Law Gazette (Bundesgesetzblatt) can be found in the Legal Information System (Rechtsinformationssystem; RIS) under <http://www.ris.bka.gv.at/>

⁴BGBl 1 No. 89/2001

⁵BGBl 1 No. 116/2001

⁶BGBl 1 No. 36/2002

⁷<http://www.alzheimer-europe.org/JMA/English/documents/lawnet/austria.pdf>

⁸C., Kopetzki, Landesbericht Österreich, in Regulations of civil law to safeguard the autonomy of patients at the end of their life, Springer-Verlag, Berlin, 2000, 1-63.

⁹Subs. 2 leg. Cit. Rules out prosecution if consent was not waited for because one could expect that life or health of the patient would be in imminent and "serious" danger otherwise. According to subs. 3 leg. Cit., the patient has to request prosecution.

representative. Since the patient's approval serves to justify the otherwise wrongful infliction of bodily harm, it has to be proven by the physician who could else be liable for tort.

According to article 17 of the Patients' Charter, treatment of patients shall take place only with their consent. Treatment of patients without their consent shall only be allowed if the patient concerned is incapable of developing an informed opinion and postponement of the treatment would seriously endanger the life or health of the patient. For patients who are unable to accept the reasons or the importance of a treatment, or cannot decide to accept it, it shall be guaranteed that treatment shall only be carried out with the agreement of a representative appointed in accordance with the law and, if necessary with the authorization of the court. Without agreement of the representative and, if necessary, the authorization of the court, treatment shall only be carried out on grounds of the risk associated with postponement if the time required for acquiring the agreement or authorization would mean danger to life or severe damage to health for the patient. Measures which involve a restriction of personal freedom or other interventions in the personal rights of the patient and which are undertaken without their valid agreement shall – insofar as the time required for acquiring the agreement or authorization would not cause a life threatening danger or a severe damage to the patient's health – only be permissible after appropriate engagement of the legal representative or, if necessary, of the court.

What minors are concerned, article 24 stipulates that treatments necessary on grounds of danger to life or the risk of severe damage to health shall be carried out even against the express wish of the parent or legal guardian if postponement would be dangerous. Otherwise, the authorization of the court must be obtained.

1.2. *Right to Information*

The Hospitals Act states that patients are entitled to an explanation and information on possible forms of treatment, as well as on the risks involved. Furthermore, the patient can request that he/she be given medical information by a doctor who is authorized to exercise his/her profession independently. This information should be given in a clear and considerate manner.

Even though a disclosure has to be documented in writing (if only for evidentiary purposes¹⁰), a mere standard form letter alone can never satisfy the duty to effectively tell the patient what complications might occur.

Article 16 of the Patients' Charter also addresses the issue of informed consent. It is stated that patients shall have the right to be informed from the start about possible diagnoses and kinds of treatment, and about the risks and consequences of them. They shall have the right to be informed about their state of health, about the cooperation required on their part during the therapy and about how to conduct their life in a way which supports the therapy. The way in which this information is provided shall be adapted to the personality and level of education of the patient and in accordance with the circumstances of the case. In the case a treatment is urgently necessary and the special circumstances of the individual case are such that comprehensive information would endanger the well-being of the patient, the scope of the information provided shall be oriented on the well-being of the patient. Patients shall have the right not to be informed; they must not be influenced towards exercising this right. Patients shall be informed from the start

¹⁰ Hospitals are further required by sec. 10 subs. 1 sub par. 2 lit. a Hospitals Act to record the fact that their patients have been informed. The doctors who are in charge of the treatment in general are also required to ensure that such documentation is made (Subs. 3 leg. cit.)

about the costs they can expect to incur. Information will be provided to children in accordance with their respective stage of development. (article 23)

As a result of jurisprudence, several guidelines have been developed.

The Austrian Supreme Court determined in 1982¹¹ that a physician above all has to consider the well-being of the patient when determining whether or not and to what extent he/she should inform the patient. Only as a second determinant should he/she consider the patient's right of self-determination. There are no generally applicable criteria which lead to a list of possible complications that have to be disclosed, as the Supreme Court stresses in all decisions. Instead, one has to look at the circumstances of the case, which should guide a doctor to inform the patient "according to conscientious medical practice and experience. in the light of the characteristics of the clinical picture"

One should primarily consider whether full knowledge of the risk at issue could influence a "reasonable" patient's decision to undergo the planned treatment. This is to be presumed if the complication could threaten the patient's life or basic bodily functions.

The more urgent the treatment is for the patient's health, the less extensive he/she has to be informed, especially if an overly anxious patient could decide against a treatment, which in turn would constitute a much higher risk to his/her health. On the other hand, if the treatment is not imperative, information has to be given as extensively as possible.

Statistical probabilities of the potential risks of a treatment are further criteria to determine the extent to which a patient has to be informed. This does not mean, however, that rare risks never have to be disclosed. Even dangers which are completely insignificant nevertheless have to be communicated to the patient if he/she obviously might be particularly interested in such consequences.

Typical risks of the treatment always have to be disclosed, even if the probabilities of such a development are remote. Whether or not a risk is typical therefore is not determined by statistics, but rather by the fact "that such risk is particularly connected with the operation at issue, that is cannot be avoided completely even if utmost care is employed, and that is would surprise an uninformed patient since he/she would not consider such risk otherwise." Under this test, typical risks only have to be told if knowledge thereof could influence the patient's decision.

If the patient claims that he/she did not receive adequate disclosure of risks, it is the physician who must produce evidence that this is not the case. Here, contrary to the law of medical malpractice, the physician has the burden of proof that he or she did not violate the law. This shift of the burden for proof has been recognized by the Supreme Court (Oberster Gerichtshof, OGH) since 1992¹² and is based on the consideration that only a consent which is free and informed is a ground for justification for the physician's intervention¹³

So far the Austrian Supreme Court has not yet required doctors to give some "basic information" to the patient as a minimum prerequisite to avoid liability. Generally speaking, even overanxious patients in case of emergency have to be informed about the most significant risks of the treatment so that they can base their decisions on at least a rough estimate of the dangers involved. Only in "borderline cases" is it possible to completely abstain from informing the patient if the latter would be excessively alarmed and might overreact in a way completely

¹¹ OGH 23.6.1982, SZ, 55, 114

¹² OGH 12 November 1992, JBl. 1994, 336 – RdM 1994, 28.

¹³ E. Bernat, "Compensation for medical injuries: is there a need for a law reform? An Austrian viewpoint", *European Journal of Health Law* 1998, 118.

disproportionate to a rational evaluation of the benefits and risks involved. Information is further not required if the patient has validly waived such rights.

As far as the information about alternatives of treatment is concerned, a physician does not always have to discuss all theoretically possible techniques of treatment or operation with the patients. Various possible kinds of treatments only have to be mentioned if they bring along less pain or risks, if the success rate varies or even if only another cosmetic result can be reached.

1.3. Access to Medical Records

In the Hospitals Act it is stated that patients must be informed of their rights, including the right to examine their case history. This right to see records kept by the doctor or hospital stems from a decision taken by the Supreme Court on 25 May 1984 (1 Ob 550/84)¹⁴.

The Patients' Charter states in article 19 that patients have the right to inspect documents kept about them containing information on the diagnostic, therapeutic and nursing measures, including any supplementary material such as X-ray pictures. Limitations are only permissible to the extent that these are unavoidable for the well-being of the patient on grounds of special circumstances in the individual case. A representative of the patient also has the unrestricted right to inspect, insofar as the patient has not expressly excluded this.

Of the various provisions in Austrian law which prescribe how long medical documents have to be preserved, two of them shall be specifically mentioned: Section 22a subsection 2 of the Medical Practitioners' Act (Ärztegesetz¹⁵) orders doctors to keep any records of their patients for at least ten years. Section 10 of the Austrian Hospitals Act (Krankenanstaltengesetz, KAG) provides that the provincial legislators have to introduce laws that direct hospitals to store their patients' records for at least thirty years. A shorter period of ten years is required for X-rays and similar enclosures.

Section 1 of the Federal Act concerning the Protection of Personal Data 2000 states that everybody shall have, insofar as personal data concerning him/her are destined for automated processing or manual processing, i.e. in filing systems without automated processing, as provided for by law, the right to obtain information as to who processes what data concerning him/her, where the data originated, for which purpose they are used, as well as to whom the data are transmitted.

1.4. Confidentiality

Confidentiality is dealt with in § 121 of the Penal Code¹⁶ which protects patients against unlawful disclosure by health professionals of information, particularly that relating to the patient's state of health. It is further covered by § 9 of the Hospitals Act and § 54 of the 169th Federal Physician's Law of 1998. The latter states that the doctor and his/her assistants are bound to secrecy in respect of all secrets that are confined to them or become known to them in the exercise of their profession.

¹⁴ Leenen H., Gevers S. and Pinet G. The Rights of Patients in Europe, Kluwer Law and Taxation Publishers, Deverter/Boston, 1993.

¹⁵ Ärztegesetz 1984 (BGBl No 373).

¹⁶ http://www.sbg.ac.at/ssk/docs/stgb/stgb_index.htm

Article 13 of the Patients' Charter confirms that the Data Protection Act applies to health-related data and to other information which can become known as a result of the provision of services within the health service sector and in respect of which patients have an interest in the maintenance of secrecy.

Section 15 of the Federal Act concerning the Protection of Personal Data 2000¹⁷ states that controllers, processors and their operatives - these being the employees and persons comparable to employees shall keep data that have been entrusted or made accessible to them confidential solely for professional reasons, without prejudice to other professional obligations of confidentiality, unless a legitimate reason exists for the transmission of the entrusted or accessed data (confidentiality of data).

Operatives shall transmit data only if expressly ordered to do so by their employer.

Controllers and processors shall oblige their operatives by contract, insofar as they are not already obliged by law, to transmit data only if so ordered and to adhere to the confidentiality of data even after the end of their professional relationship with the controller or processor.

Controllers and processors may only issue orders for the transmission of data if this is permitted pursuant to the provisions of this Federal Act. They shall inform the operatives affected by these orders about the transmission orders in force and about the consequences of a violation of data confidentiality. Without prejudice to the constitutional right to issue instructions, a refusal to follow an order to transmit data on the grounds that it violates the provisions of this Federal Act shall not be to the operatives detriment.

1.5. *Right to Privacy*

Austria signed (28/01/81) and ratified (30/03/88) the Convention 108.

On the national level patient's privacy is guaranteed by the Federal Act concerning the Protection of Personal Data 2000 that implements the Directive 95/46/EC¹⁸.

According to section 1 of this Act everybody shall have the right to secrecy for the personal data concerning him, especially with regard to his private and family life, insofar as he/she has an interest deserving such protection. Such an interest is precluded when data cannot be subject to the right to secrecy due to their general availability or because they cannot be traced back to the data subject.

Section 6 states that data shall only be used fairly and lawfully; be collected for specific, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further use for scientific and statistical purposes is permitted subject to section 46 and 47. Data shall only be used insofar as they are essential for the purpose of the data application and are not excessive in relation to the purpose. They have to be used so that the results are factually correct with regard to the purpose of the application, and the data must be kept up to date when necessary. Data have to be kept in a form which permits identification of data subjects as long as this is necessary for the purpose for which the data were collected; a longer period of storage may be laid down in specific laws, particularly laws concerning archives.

¹⁷ <http://www.bka.gv.at/datenschutz/indexe.htm>

¹⁸ <http://www.bka.gv.at/datenschutz/indexe.htm>

2. GENETICS AND PATIENTS' RIGHTS

In Austria, genetic testing is governed by the Gene Technology Act (Law BGB 510/1994¹⁹) which regulates the contained use of genetically modified organisms (GMO), their deliberate release or placing on the market, the use of genetic testing and gene therapy in human beings. The act also stipulates that an intervention into the human germ line is strictly prohibited.

'*Gene analysis*', as it is defined in this act, comprises molecular biological investigations of human chromosomes, genes or DNA-segments for the identification of disease causing mutations. Such examinations are allowed only for research or medical purposes.

Part IV of the Act addresses the issue of genetic testing; it imposes conditions requiring the fully informed consent of the individual to be tested (Section 65). The consent requirements also apply to the use of prenatal genetic testing techniques. Section 65 stipulates that genetic testing may only be carried out where it is at the request of a doctor specializing in medical genetics and either for verification of a predisposition to a late onset disorder²⁰ or for verification of carrier status²¹ or the diagnosis of an existing disease or late onset disorder. Genetic testing may also be carried out as part of preparation for gene therapy and the monitoring of the effectiveness of any gene therapy treatment.

According to the Act premises, where genetic tests for the diagnosis of a predisposition or for the identification of a carrier status of inherited diseases are performed, have to be approved by the Ministry of Health and Consumer Protection²². Genetic tests for the diagnosis of manifested diseases do not require an authorization but are subject to strict measures for data protection.

For the authorization of premises for the performance of predictive genetic testing on humans certain requirements have to be fulfilled. These requirements pertain to the structural and apparent condition of the premises, an adequate qualification and experience of the performing staff and sufficient measures for quality assurance, in order to ensure that genetic tests are carried out according to the state of the art and that the data gained from these tests are strictly protected. Genetic counselling has to be carried out before and after genetic testing, and has to include psychological or social considerations as well. If all these requirements are met, the premises will be approved by the competent authority on the basis of the opinion given by the relevant scientific committee of the gene technology commission.

Last but not least, the Austrian gene technology act also contains specific regulations for the approval of clinical tests comprising somatic gene therapy and institutions (hospitals) where somatic gene therapy may take place.

In addition to the Gene Technology Act, on 23 January 1998, the Austrian Advisory Board on Gene technology (Osterreichische Gentechnikkommission) adopted a set of additional criteria and requirements Kriterienkatalog for predictive genetic testing²³. This Kriterienkatalog is not legally binding but gives guidelines to which relevant institutions and the competent authority should adhere²⁴.

¹⁹ Gentechnikgesetz, BGB1. Nr. 510/1994

<http://www.gentechnik.gv.at/gentechnik/gesetz/gentechnikgesetz.htm>

²⁰ § 65 Abs. 1 Z. 1 lit. a GTG

²¹ § 65 Abs. 1 Z. 1 lit. b GTG

²² § 68 GTG

²³ <http://www.gentechnik.gv.at> unter Rechtliches – Gentechnikbuch.

There is a standing Advisory Board under the Austrian general Advisory Board on gene technology, the Scientific Committee for Genetic Testing and Gene Therapy (Wissenschaftlicher Ausschuß der Gentechnikkommission für Genanalyse und Gentherapie) which includes eminent figures from different backgrounds and disciplines.; this committee is involved in the approval of institutions to carry out predictive genetic testing and of clinical trials involving somatic gene therapy. This committee was responsible for the Austrian Guidelines on predictive genetic testing.

In general the competence and jurisdiction on clearing diagnostic devices lies with the Austrian Ministry of Labour, Health and Social Affairs, according to the Austrian Medical Devices Act (Medizinproduktegesetz²⁵).

2.1. *Right to Informed Consent*

The patient has to provide written consent prior to the performance of a predictive genetic test (§ 65 Abs. 1 Z. 1 Gene Technology Act) and must have consented to genetic analysis.²⁶

Article 65, al. 1, par. 2 regulates the conditions of admission of genetic tests, except for predisposition or carrier tests. There are three cases mentioned in the law that allow a genetic test on initiative of the treating or diagnosing physician. The written consent of patients according to the intervention is not required according to article 65, al 1, par. 2 Gene Technology Act in the hypothesis mentioned above.

2.2. *Right to Information*

The patient has to confirm in writing that he/she's informed about the character, the scope and the consequences of the genetic test. Before and after carrying out a genetic test in order to detect a predisposition to a hereditary disease, or in order to detect the carrier of a disease, the person undergoing the test shall receive comprehensive counselling from the physician recommending genetic testing (§69 Abs. 2 Gene Technology Act). Counselling shall include relevant and comprehensive discussion of all test results and medical facts including the social and psychological consequences. In the case of prenatal genetic testing counselling should on no account take the form of instructions. Accordingly it is appropriate that additional non-medical counselling be provided by a psychotherapist or social worker. Specific references to such counselling possibilities shall be provided in written form.

The right not to know is in Austria often called a 'right of gene-informational self determination' (Recht auf geninformationelle Selbstbestimmung). To some extent, this right is seen as a constitutionally guaranteed personal right which is supposed to protect the individual's privacy from un authorized investigation and exposure of his genetic disposition. The individual is thus to be protected from having information on his genetic make-up forced upon him/her²⁷.

²⁵ Medizinproduktegesetz - MPG, BGBl Nr. 657/1996 - 29.11.1996.

²⁶ § 65 Abs. 2 GTG

²⁷ Bernat, E., "Legal aspects of developments in human genetics: an Austrian viewpoint"

2.3. Confidentiality

According to § 71-4 of the Gene Technology Act data resulting from genetic testing may only be disclosed to persons who work in the institution in which the patient is treated and perform the immediate conclusion, processing or use of the data; to the patient, to the persons mentioned in § 65 section 3 and 4, namely the guardian of the patient and the specialist who performed the genetic test, to the physician who performed the genetic test and the treating or diagnosing physician, to other persons as far as the patient has given explicit and written consent. Redrawal of consent is possible.

2.4. Right to Privacy

A person who carries out or recommends genetic testing shall assure the confidentiality of data collected, and shall comply with a certain number of provisions. These include that the person undergoing testing shall upon request be allowed to consult all the data concerning him/her. He/she shall have communicated to him/her any unforeseen results that are of direct clinical significance of which he/she has expressly requested. This information shall be presented in such a way that particularly in cases where the person concerned has not requested such communication it does not have a disturbing effect upon him/her. In doubtful cases this information may be completely omitted. Data that are not in anonymous form may not be used for purposes other than those for which they were originally collected, unless the person undergoing the test expressly consents thereto in writing. Data may only be communicated to a specified number of persons including persons on the staff, the person undergoing the test, the physician who recommended genetic testing, and other persons when the person undergoing testing expressly consents thereto in writing²⁸.

Article 71 GTG contains a protection of data.

3. GENETICS AND INSURANCE

Since October 1994, Austria has become the third European country to prohibit genetic testing for insurance purposes. The Gene Technology Act contains a prohibition of requiring and using data of gene analysis for certain aims. Section 67 stipulates that it is forbidden for insurers and employers including their representatives and collaborators to obtain, request, accept or in any other way make use of the results of gene analyses on their employees, candidates, policyholders or insurance applicants.

‘Gene analysis’, as it is defined in this act, comprises molecular biological investigations of human chromosomes, genes or DNA-segments for the identification of disease causing mutations.

This prohibition is similar to the one established under Belgian law. It implies that Austrian insurers may not ask for genetic testing, but also that insurance-applicants may not submit

²⁸ Nielsen, L., “Genetic testing and privacy: a European perspective”, *Law & Hum Gen Rev* 4/1996, 72.

favourable test results to get lower premiums or more interesting insurance contracts. The results of genetic tests may in no way be used for insurance purposes.

Early reviews of the operation of the Austrian legislation suggest that despite these strong prohibitions, there is a divergence between the informal practice of insurance and the strong prohibitions contained in the law. Inquiries made with applicants to the private insurance companies indicate that the insurer cannot force applicants to have genetic tests, and will therefore not pay for tests. However, those at risk and therefore already on a higher premium often organize tests at their own expense and some applicants have had their premium reduced with negative test results. The existence of a law prohibiting insurers from using genetic test information does not necessarily prevent an applicant for insurance from using that information to his own advantage²⁹.

The Austrian statute moreover fails to prohibit the use of family history in the context of insurance. After all, the prohibition refers to information resulting from genetic testing, not to information resulting from questions about family histories³⁰. Thus genetic information based on family histories, which is often already available in medical files, is not covered under this prohibition. As a consequence, insurers remain free to ask questions about diseases that run in families. This basically means that insurers can exclude people on the basis of vague family information indicating the presence of a genetic condition in the family, whereas they could not rely on similar more detailed information resulting from DNA analysis.

4. GENETICS AND EMPLOYMENT³¹

Section 67 of the Gene Technology Act is also applicable on employment since it forbids employers including their representatives and collaborators to obtain, request, take or otherwise use results of gene analyses of their employees, or applicants for employment.

Section 67 of the Gene Technology Act prohibits the employer to ask for a genetic test at the recruitment. This absolute prohibition can be criticized, because it also applies when the applicant undergoes the genetic test aiming at the security in the workplace.

Section 67 completes the Employee Protection Act (*Arbeitnehmerschutzgesetz*) and the additional ordinances. Concerning the health condition of the employee, the employer is prohibited to get information from gene analysis.

Concerning possible threats of the employer towards the employee the regulation is not very clear.

The text of section 67 of the Gene Technology Act stipulates in general that the employer is not allowed to inspect the result of a genetic test. However, since the result of a genetic test can also include that a disease will manifest later and is consequently only latently present at the moment of the diagnosis, section 67 also implicitly applies to the more specific hypothesis of the late

²⁹ G. Hauser and A. Jenisch, "Laws regarding insurance companies", *Journal of Medical Genetics* 1998/35, 526-527.

³⁰ T Lemmens, Socio-Ethical issues in human genetics

³¹ E. Bernat, "Recht und Humangenetik – ein österreichischer diskussionsbeitrag", in E. Deutsch and E. Steffen, *Der Schadensersatz und seine Deckung. Festschrift für Erich Steffen zum 65. Geburtstag*, De Gruyter Berlin, Berlin, 1995, 44-46.

onset genetic diseases. Section 67 even excludes the result of a genetic test if the employee initiated and undergoes the test.

The employer is not allowed to accept nor use the test.

Before the coming into force of section 67 of the Gene Technology Act one could deduce from article 8, al. 8 of the Law of Employees (Angestelltengesetz) that the employer in case of a disease cannot ask for the diagnosis of that disease. Section 67 Gene Technology Act has in this case a more clarifying function than an innovating one³².

³² For more information see E. Bernat, "Recht und Humangenetik - ein österreichischer Diskussionsbeitrag" in E. Deutsch and E. Steffen, *Der Schadensersatz und seine Deckung. Festschrift für Erich Steffen zum 65. Geburtstag*, De Gruyter Berlin, Berlin/NY, 1995, 33-56.

BELGIUM

1. PATIENTS' RIGHTS

Belgium has neither signed nor ratified the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine³³.

Since 2002, Belgium is also one of those EU member states who have legislated patients' rights³⁴.

1.1. *Right to Informed Consent*³⁵

Article 8 of the Act on Patients' Rights 2002 regulates the right to informed consent. The patient has the right to consent informed, in advance and free to every action of the care provider. This consent will be given explicitly except when the care provider, after having sufficiently informed the patient, can reasonably deduce from the attitude of the patient his/her consent.

The patient has the right to refuse or withdraw his/her consent. At the request of the patient or care provider the refusal or withdrawal of the consent will be registered in writing and added to the patient's file.

The refusal or withdrawal of the consent does not have as a consequence that the right to quality service towards the care provider does not exist anymore.

If the patient when he/she was still able to exercise the rights as laid down in this law, expressed his/her wish in writing to refuse his/her consent to a well-defined action of the care provider, than the latter has to respect the refusal as long as the patient does not retract it at a moment that he/she is able to exercise his/her rights himself/herself³⁶.

When there is in an emergency case no clarity about the wishes of the patient or of his/her representative, every action of the care provider does necessarily happen for the sake of the patient's health.

The rights of minors are exercised by the parents having the parental authority or by their guardian. The patient is involved in the exercise of his/her rights, his/her age and maturity taken into account. The rights enumerated by the Act on Patients' Rights 2002 can be exercised by the minor if he/she can be estimated as able to make reasonable judgements of his/her interests (Article 12)

The issue of consent is also covered in the Code of Medical Ethics³⁷. Article 30 states that if a patient is incapable and it is impossible to obtain the consent of his/her legal representative, the doctor must proceed with treatment as dictated by his or her conscience.

³³ <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>

³⁴ Act on Patients' Rights, <http://www.lachambre.be/documents/1642/15.pdf> (in Dutch or French).

³⁵ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/belgium.pdf>

³⁶ D., Clarysse, "De modaliteiten en het bewijs van de geïnformeerde toestemming in de relatie zorgverlener-patiënt", *Jura Falconis*, Jg. 38, 2001-2002, nr. 1, 1-43.

³⁷ <http://www.ordomedic.be/nl/deonton.htm> (dutch language)

1.2. *Right to Information*³⁸

The right to information about the health status is regulated in article 7 of the Act on Patients' Rights 2002. The patient has the right to be informed by the care provider about all information concerning him/her that is required to understand his health status and the probable evolution. The communication with the patient happens in a clear language. The patient can request that the information will be confirmed in writing.

When the patient has expressed the wish not to be informed, no information shall be passed on, except when not informing causes obviously serious disadvantage for the patient or for thirds on condition that the care provider has consulted another care provider in advance and has heard - when that is the case - the designated person of confidence. The request of the patient will be registered or added to the patient's file.

The care provider can exceptionally withhold the information, when informing would cause obviously serious disadvantage for the patient and on the condition that the care provider has consulted with another care provider about this. In that case the care provider adds a written explanation to the patient's file and informs - when that is the case - the designated person of confidence. As soon as the information causes no longer the disadvantage, the care provider still has to inform the patient.

The right to receive information prior to consent is regulated in article 8. The information relates to the purpose, the nature, the degree of urgency, the duration, the frequency, the adverse indications for the patient, effect and risks of the action, the financial consequences and the possible alternatives. In addition, it relates to the possible consequences in case of refusal or withdrawal of the consent, and other by the patient or care provider relevant assumed clarifications.

The information has to be provided in advance and timely.

There are also several provisions in the Code of Medical Ethics regarding the right to information. Article 28, for example, states that it is the doctor's duty to inform the patient of the reasons for diagnostic or therapeutic interventions which he/she proposes. Article 33 - amended in April 2000- now stipulates that the physician informs the patient in time of the prognosis and the diagnosis, this goes for bad and fatal prognosis too. The physician takes the patient's mental capacity into account and the extent the patient want to be informed. The physician assures the patient of an adjusted treatment and counselling. The physician consults relatives about this unless the patient resists. At request of the patient the physician contacts the persons assigned by the patient.

1.3. *Access to Medical Records*

Article 9 of the Patients' Rights Act 2002 contains the following rules regarding the right to access to medical records.

³⁸ Nys, H., "Belgium", in Nys, H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1998, 3-150.

The patient has a right of access to his medical record. The request of the patient to have access to his medical record is immediately carried out and at least within 15 days after receipt. The personal notes of a health professional and the information concerning third parties are excluded from the right to access.

At the patient's request, a designated person of confidence can exercise his/her right to access. If this person is a care provider, he/she also has access to the personal notes of the health professional.

According to the Code of Medical Ethics the doctor should in principle keep a medical file on each patient and is responsible for determining who has access to all or part of the information kept in it (article 38 and 39). According to article 42, the doctor may grant access to objective information in the patient's medical file (such as X-rays and the results of examinations) if he/she feels that it would be useful or if the patient requests it.

1.4. Confidentiality

Doctors are bound to secrecy by the provisions of chapter V of the Code of Medical Ethics. This obligation extends to everything that the doctor sees, learns of, notices or discovers through the exercise of his/her duties. Nevertheless, article 458 of the Penal Code, which also establishes professional secrecy provides exceptions to this obligation.

1.5. Right to Privacy³⁹

Belgium has signed (07/05/82) and ratified (28/05/93) the Convention 108. Since 1992, Belgium has general legislation protecting the individual with regard to automatic or manually processing of personal data⁴⁰. In 1995, the European Community launched a new directive in order to regulate the right to privacy of all citizens in the Member states. The national laws needed, therefore, to be adapted within three years. In the course of 1998, a Government bill was introduced in the Belgian House of Representatives. The Chamber approved the new law on 11 December 1998 in plenary session. On 3 February 1999, it was published in the *Moniteur belge*. The law came into force on September 1, 2001.

Article 7§1 sets as a general rule that the processing of health-related personal data is prohibited. Article 7§2 describes the exceptions on this prohibition of processing data, which are so extensive that the prohibition is largely undermined. The most relevant for health care are those mentioned in Article 7§2 d and j, which describe as an exception: the processing is necessary for the purposes of preventive medicine or medical diagnosis, the provision of care or treatment to the data subject or to one of his relatives, or the management of health-care services operating in the interest of the data subject, and if those data are processed under the supervision of a health professional, respectively the processing is necessary for the promotion and protection of public health, including examination of the population.

³⁹ <http://www.law.kuleuven.ac.be/icri/>

⁴⁰ Law on privacy protection, enacted 08/12/92,
www.law.kuleuven.ac.be/icri/papers/legislation/privacy/engels.

The general conditions of data processing have to be followed by the processing of health-related data.

Besides these general conditions, there are also a number of specific conditions that need to be observed. Article 7§4 stipulates that health-related personal data shall only be processed under the responsibility of a health professional, except for the written consent of the data subject or if the processing is necessary for the prevention of a concrete danger or for the suppression of a specific criminal offence.

If processing is necessary for the purposes of preventive medicine or medical diagnosis, the provision of care or treatment to the data subject or to one of his/her relatives, or the management of health-care services operating in the interest of the data subject, it is also required that the data are processed under the supervision of a health professional. (Article 7§2,j)

Article 10 of the Patients' Rights Act 2002 also contains a disposition to protect the privacy of the patient. The patient has the right to protection of his privacy by every action of the care provider and especially concerning the information relating with his/her health. No intrusion is allowed concerning the exercise of this right other than such as are prescribed by law and are necessary for the protection of public health or for the protection of the rights and freedoms of others.

2. PATIENTS' RIGHTS AND GENETICS

There are no specific legal rules concerning the rights of patients undergoing genetic testing or screening. The general Patients' Rights Act 2002 is applicable.

3. GENETICS AND INSURANCE

Belgium was the first European state to enact legislation addressing the topic of genetics and insurance. A total ban on the use of genetic testing to predict the future health status of applicants for (life) insurance was laid down by article 95 of the Law on Insurance Contract, which came into force in September 1992⁴¹, which lays down that the medical examination necessary to establish and fulfill the private insurance contract “may only depend on the anamnesis of the present health condition of the candidate and not on genetic research techniques which are capable of determining future state of health”⁴².

Article 5⁴³, subsection 1 of the same law which applies to all insurance contracts, obligates the insurance taker to give accurate information of all known circumstances of which he/she can reasonably assume to be of influence on risk-assessment by the insurer, though he/she is not

⁴¹ Law of 25 June 1992 concerning the agreement on land insurance, articles 5 and 95 (Belgian law gazette 20.08.1992)

⁴² N, Jeger en P., Cauwenbergh “Individuele levensverzekeringen “overlijden” en erfelijkheidsonderzoek: een kritische analyse van de artikelen 5 en 95 van de wet van 25 juni 1992 op de landverzekeringsovereenkomst”, *T. Gez.* 1996-97, 239-256.

⁴³ Article 5 states: “The policyholder is obliged to declare exactly, at the time of completing the contract, any particulars known to him or her which he or she could reasonably be expected to consider as constituting risk assessment elements for the insurer. Genetic data cannot be transmitted”.

obliged to give information on circumstances the insurer already knows or within reason should have known. It is not allowed to give genetic information spontaneously (“cannot”, not “may not” be transmitted). The complete ban on giving genetic information concerns information given by physicians, insurance takers and insurers. A notable feature of the Belgian legislation is that it prohibits the use of genetic test information even in circumstances where it is to the benefit of the proposing party. This means that the insurance taker is not allowed to volunteer favourable genetic information to get better conditions and lower premiums.

Nevertheless, the Belgium statute fails to prohibit the use of family history in the context of insurance. This basically means that insurers can exclude people on the basis of vague family information indicating the presence of a genetic condition in the family, whereas they could not rely on similar more detailed information resulting from DNA analysis.

4. GENETICS AND EMPLOYMENT

There is no specific legislation concerning the use of genetic tests within the scope of recruitment.

DENMARK

1. PATIENTS' RIGHTS

Denmark signed the Convention of human rights and biomedicine on April 4, 1997 and ratified it in August 1999⁴⁴. The convention entered into force on the first of December 1999. It has to be mentioned that Denmark made a reservation concerning article 10. According to this provision, all persons are entitled to know any information collected about his or her health. Danish legislation on registers provides that health information may be exempted from the registered person's right to information. Likewise, Section 10, paragraph 5, of the Public Administration Act (Act No. 572-19/12-1985) provides that material provided as a basis for the preparation of public statistics or scientific studies is not subject to access⁴⁵.

In the legal system in Denmark, patients' rights are embodied in a variety of legislation. In 1997, however, the Ministry of Health set up a drafting group, which worked throughout the year. The Ministry of Health submitted the draft law prepared by the group to the Parliament on 26 March 1998⁴⁶.

The Danish Patients' Rights Act includes, in combination with other health legislation, clear-defined patients' rights provisions. The aim of the 1998 legislation is primarily to protect patients' dignity, integrity and autonomy⁴⁷. The patient's right of autonomy is emphasized, as is the fact that no treatment may be started or continued without the patient's informed consent. The law enumerates four situations, where the health care personnel is obliged to respect the patient's wish, even if this may lead to the patient's death. These are: a) hunger-strike, b) refusal to receive blood transfusion, c) refusal of treatment by a dying patient, and d) when the patient's living will states that life-supporting measures may not be undertaken in a situation where the patient is unable to exercise his or her right of autonomy and is terminally ill.

1.1. *Right to Informed Consent*⁴⁸

According to article 6 of the Patients' Rights Act no treatment may be initiated or continued without the patient's informed consent, unless otherwise provided for by the Law in question or in regulations made for its implementation or in pursuance of articles 8 to 10. The informed consent, defined as consent given on the basis of adequate information provided by the health care provider, can be withdrawn in any time and can be written, verbal, or tacit.

With regard to minors, the Patients' Rights Act provides that a patient who has attained the age of 15 years may personally give informed consent to treatment. The person holding parental authority shall also receive information and shall participate in the decision taken by the minor. If the health care provider considers, after carrying out an assessment of the individual concerned,

⁴⁴ <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>

⁴⁵ Denmark has also made two declarations in the instrument of ratification concerning articles 20 and 35.

⁴⁶ Lovtidende, 1998, Part A, 2 July 1998, No. 99, pp. 2883-2888

<http://waml.haifa.ac.il/index/reference/legislation/denmark/denmark1.htm>

⁴⁷ Fallberg, L.H., "Patients rights in the Nordic Countries", *European Journal of Health Law* 2000/7, 131.

⁴⁸ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/denmark.pdf>

that the 15-year-old patient is not capable on his own of understanding the consequences of his decision, the person holding parental authority shall be empowered to give informed consent (Article 8 Section 1-3).

If a patient who is temporarily or permanently incapable of giving informed consent or who is under 15 years of age, finds himself/herself in a situation in which he/she requires immediate treatment in order to survive or in order to improve his/her chances of survival or considerably improve the outcome of the treatment, a health care provider may begin or continue such treatment without the consent of the patient, the person holding parental authority, the next-of-kin, or the guardian (Article 10).

Government order on informed consent were issued in 1982 (covering somatic patients) and 1983 (for psychiatric patients). The Government Order No. 665 of 14 September 1998 on information and consent and the communication of information relating to health, etc.⁴⁹ made in pursuance of the Patients' Rights Act contains more detailed provisions.

Chapter 1 reads as follows:

'Informed consent' means consent given on the basis of adequate information provided by a health care provider. Consent to treatment shall be given by a patient who has attained the age of 15 years. The patient shall be capable of grasping the implications of his actions. Consent may be given by a representative provided that the requirements laid down in subsection 2 of Section 8⁵⁰ and subsection 1 of Section 9⁵¹ of the Patients' Rights Act are satisfied.

Consent to treatment must be freely given. The health care provider responsible for the treatment may request written consent if the intervention concerned is a major one and complicated treatment is involved, or if there is any possibility that doubts might be raised with regard to the granting of consent and its extent. Tacit consent may, according to the circumstances, be considered sufficient if there is no doubt that the patient is in agreement with the treatment. Consent given by a representative shall always be explicit.

A patient shall give consent to a specific treatment in connection with his/her current state of health.

If further explanations have to be provided or if changes are made to the treatment protocol, fresh consent shall be obtained. A patient may at any time withdraw his consent.

1.2. *Right to Information*

According to article 7 of the Patients' Rights Act, the patient has the right to obtain information on his/her state of health and on the possibilities of treatment, especially on the risk of

⁴⁹ Lovtidende, 1998, Part A, 22 September 1998, No. 133, pp. 3877-3880

<http://waml.haifa.ac.il/index/reference/legislation/denmark/denmark2.htm>

⁵⁰ If the health care provider considers, after carrying out an assessment of the individual concerned, that the 15-year-old patient is not capable on his own of understanding the consequences of his decision, the person holding parental authority shall be empowered to give informed consent.

⁵¹ If a patient is permanently incapable of giving informed consent, the person most closely related to him may give informed consent to treatment. In cases where the patient is placed under guardianship that encompasses his personal circumstances, including his health, as referred to in Section 5 of the Guardianship Law, the guardian shall be empowered to give informed consent.

complications and side effects. This right to information is part of the free choice of the patient, which is one of the most important purposes of the law. As a consequence, everyone can refuse the information.

The information has to be provided in an accurate and anticipating way. It has to be appropriate to the situation of the patient, especially his/her age, maturity and experience. It has to be communicated orally and completed with written elements when the action is hard or the treatment is complex. In this case, the information needs to be more complete. The information needs to be communicated early enough so that the patient can ask questions and think it over.

A doctor can decide not to inform a patient about his/her medical condition if he/she feels that such information could result in considerable mental harm to the patient but if the patient insists the information must be given in a way as gentle as possible.

Order No. 665 of 14 September 1998 on information and consent and the communication of information relating to health, etc.⁵² contains more detailed provisions.

A patient who has attained the age of 15 years shall have the right to be informed concerning his state of health and the possibilities of treatment available to him, including the risk of complications and side effects. The information shall include explanations of the relevant prevention, treatment, and care possibilities, as well as explanations with regard to other possibilities of treatment and also explanations concerning the consequences of not providing any treatment. The information shall be more comprehensive if treatment involves an immediate risk of serious complications or side effects.

If he/she considers that the patient is unaware of circumstances that are of importance in order to take a decision concerning him/her, the health care provider shall provide him/her with the necessary information, unless the patient has expressed the wish not to be informed, in accordance with Section 6.

The information shall be communicated verbally and supplemented by written information in the case of major interventions and complicated treatments.

The information shall be communicated with sufficient time for the patient to ask questions and weigh up the situation. The information shall be communicated in such a way that the patient has the necessary understanding of its content and significance.

The patient shall have the right not to be informed concerning his/her current state of health and the treatment dispensed to him/her and concerning any diseases that he/she is likely to suffer from at a later stage in his/her life.

1.3. Access to Medical Records⁵³

The Patients' Rights Act also affirms the right the right to access to his medical record.

⁵² Lovtidende, 1998, Part A, 22 September 1998, No. 133, pp. 3877-3880

⁵³ Les documents de travail de sénat. «L'information des malades et l'accès au dossier médical », Octobre 2000.

Chapter 4 of the Patients' Rights Act stipulates the right to access of the patient to medical files prepared by medical and paramedical personnel or under their authority, in health establishments, irrespective of their nature. The act is not applicable when specific texts constitute particular rules for certain professions. Thus, these rules are not applicable to the registers covered by the Law on the Registers of Public Authorities or to registration carried out for scientific or statistical purposes.

A patient who has attained the age of 15 years shall have the right of access to the files concerning him/her, in accordance with the provisions of chapter 4 of the act, and may give his consent to the disclosure of information relating to his health, etc., in accordance with the provisions of chapter 5 of the act.

This right applies to all files, either containing indications on diagnostics, ways of prevention or care. The right is however not applicable to the registers carried out purely for scientific or statistical purposes.

More precisely, the right to access implies the right to take note of the following information:

- the nature of the data used;
- the purposes of such use;
- the categories of recipients of the data; and
- any information available on the origin of such data

The regulating note issued on September 14, 1998 by the Ministry of Health on the access to medical files specifies that the right to access applies to the entity of information in the file, included for instance the personal notes of the physician and the comment of the X- Raying⁵⁴. The right also applies to the elements whose presence in the file is not obliged, such as for instance correspondence between physicians.

This right belongs to the patient himself/herself. When the patient however has given authority to the insurer to have access to his/her medical file, the latter is allowed to inspect the parts in the file that enable him/her to evaluate the risk he/she considers.

Every request is appreciated separately, because the right to access needs to be weighed up against other interests, of the patient or of a third party. Decisions concerning the right of access to files shall be taken by the authority, establishment, or health care provider holding the patient's files.

The competent authority, establishment, or health care provider shall decide as rapidly as possible whether a request to consult a file can be complied with, and whether such consultation should take the form of on-the-spot examination of the patient's file, etc., or whether a transcript or copy of the file should be communicated to the person concerned⁵⁵.

If a request to consult a file has not been complied with or refused within 10 days of its reception by the competent authority, establishment, or health care provider, the authority, establishment, or health care provider shall inform the patient of the reasons for this delay and shall indicate when a decision can be expected to be taken.

⁵⁴ Ministerialtidende, 1998, 24 September 1998, No. 20, pp. 1715-1725

⁵⁵ Article 21

The persons whose request is not fulfilled can lodge an appeal to the Commission who examines complaints of patients, who has to hear all the complaints of patients concerning the exercise of health professions.

If a patient so requests, he/she shall be informed of the extent to which use is made of the health data concerning him/her and contained in his/her file, etc. If use is made of such data, the patient shall be informed, at his/her request and in easily comprehensible terms, of:

1. the nature of the data used;
2. the purpose of such use;
3. the categories of recipients of the data; and
4. any information available on the origin of such data.

This right may, however, be restricted to the extent that the patient's interest in being informed of the data must be sacrificed in favor of considerations that are of crucial importance to the person concerned or to other private interests⁵⁶.

The rights of minors younger than fifteen years old are exercised by those who have parental authority. The access to the medical file of their children can be refused, if for instance the children got medical care or have undergone an intervention without the knowledge of the parents. In this way, the information concerning a voluntary interruption of pregnancy of a minor without the consent of the parents may not be communicated to the parents.

Those who have parental authority share with their children the right to access to the medical file when the minor is older than fifteen years old.

Their rights are exercised by their legal representatives, who only have access to the information necessary to permit the appreciation of the interest or the needs of a patient in a certain situation.

1.4. Confidentiality

Article 23 of the Patients' Rights Act states that a patient shall have the right to demand that health care providers respect the confidentiality of the data that have come to their knowledge during the practice of their profession or the assumptions that they may make concerning his/her state of health, as well as the confidentiality of other strictly private or confidential information, subject to the rules laid down in this respect by the law. Medical confidentiality is also covered in the Practice of Medicine Act. Moreover, if a person, such as health professional, wrongfully disseminates confidential information about a person's health or other related information, he/she would be liable for punishment according to §§ 152-152f of the Penal Code.

Nevertheless, according to article 24 of the Patients' Rights Act, information relating to the patient's state of health, strictly private conditions and other confidential information linked to treatment can be disseminated to other health care providers, provided that the patient has consented to this. The same information can be disseminated without the patient's consent if it is necessary for the progression of a treatment or for the justified care of the patient and if this corresponds with his/her interests and needs. Such information can also be passed on to a substitute doctor.

Health care providers can give the above-mentioned information to authorities, organizations, private persons and others if the patient has consented to this, but can also provide such information without having consent if this is considered necessary in the public interest or as a

⁵⁶ Article 20

result of significant concern to the patient, the professional or others. (Article 26 Patients' Rights Act)

1.5. *Right to Privacy*

Denmark has signed (28/01/81) and ratified (23/10/89) the Convention 108.

Denmark has passed two acts relative to the protection of privacy and access to information: the Private Registers Act and the Public Registers Act⁵⁷. These acts were adopted by the Danish Folketing (Parliament) in 1978 and became law January 1, 1979. Amendments were made in 1987.

The Private Registers Act relates to registration of Electronic Data Processing (EDP) registers as well as manual registers. Private persons are not allowed to establish the registers covered by this Act. It refers to business, political organizations, trade organizations and to limited liability companies including banks, medical practices, and law firms; all of whom must establish a register of their customers. Certain sensitive personal data - including race, religion, political, sexual and criminal matters and health concerns - cannot be registered absent the individual's consent

The Public Registers Act stipulates that only data that are clearly relevant for the purposes of the authority concerned can be registered. The following **cannot** be registered:

1. data on political matters not accessible to the general public;
2. data on purely personal matters such as race, religion, skin color, membership in organizations, sexual or criminal matters, health, social problems and excessive use of intoxicants;
3. data which may harm the national interest

The guidelines No. 155 of 14 September 1998⁵⁸ on the right to inspect documents in connection with health information implement Directive 95/46/EC. The topics covered include: the purpose and scope of the right of inspection; the purpose of the guidelines; the procedure for submitting a request to inspect documents; the procedures for granting the right of inspection; the conditions governing the refusal to grant requests to inspect documents; appeals to the Board authorized to receive patients' complaints; and the keeping of files.

The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 was further implemented in Denmark by sec. 7 of the Law No. 429 of 31 May 2000 on the processing of personal data⁵⁹ which prescribes, inter alia, that the processing of personal health-related data is permissible only with a view to preventive care, medical diagnosis, the treatment of patients, or the administration of medical and health services, provided that such data processing is carried out by a person within the health sector who is subject to a legal obligation of professional secrecy.

⁵⁷ <http://www.privacyexchange.org/legal/nat/omni/danishlaw.html>

⁵⁸ Ministerialtidende, 1998, 24 September 1998, No. 20, pp. 1715-1725

⁵⁹ Lovtidende, 2000, Part A, 2 June 2000, No.86, pp. 2663-2679, www.datati/synet.dk/include/show.article.asp?art_id=443&sub_url=/lovgivning/indhold.asp&nodate=1.

2. PATIENTS' RIGHTS AND GENETICS

2.1. *The Scientific Ethical Committee system*⁶⁰

At the end of the 1970's a Scientific Ethical Committee system was set up in Denmark. In 1992, a legally binding framework for the work of the committee system was established with a system made up of seven regional committees and one Central Scientific Ethical Committee. The task of the last –mentioned is to coordinate the work of the regional committees and to assess appeals against the regional committees' decisions. The task of the committee system is to judge and approve biomedical research projects on the subject of experiments on humans, deceased human beings, human fertilized eggs etc. according to scientific ethical criteria. The main aim of the committee system is to ensure protection of the subjects who take part in biomedical research projects while at the same time creating the possibility of developing new, worthwhile knowledge⁶¹.

2.2. *The Danish Council of Ethics*⁶²

The Council of Ethics was established by the Danish Council of Ethics Act of 1988 and comprises 17 members who are appointed by the Minister for Health.

Part of the Council's function is to inform and encourage debate in the public sector. The council also has an advisory function for the health authorities on general ethical issues (for instance new methods of treatment, medical technology and setting priorities) and on ethical questions regarding recording, forwarding and using information on hereditary diseases. It may address issues within its field on its own initiative.

According to the legislation, the Council must give recommendations to the Ministry of Health on the establishment of rules and provisions in statutes on fertilized eggs, embryos, genetic experiments on sex cells, new techniques for pre-diagnosis and other issues.

The Danish Ethics Council stated that "no unsolicited approach may be made by the health authorities in the case of an examination that may show any hereditary disease in the family. This should also be the case in situations where it can have serious consequences".

2.3. *Committee on Gene Technology*

The Danish Ministry of Information Technology and Research in collaboration with the Ministry of Health has started appointing a Committee on Genetic Technology.

The Committee attends to present to a number of complex cases in healthcare and health research, uncovering possibilities as well as risks associated with the new biotechnology and genetic engineering.

Furthermore the Committee will make a survey of the latest breakthroughs in genetic research and treatment and evaluate the health related and societal consequences. The Committee will also evaluate the ethical implications of the new technologies, including the welfare of animals used for experiments and donor animals. The regulatory aspects, including international rules and regulations, will also form part of the Committees deliberations.

⁶⁰ <http://www.forsk.dk/eng/cvk/index.htm>

⁶¹ Health Care in Denmark, Summary, Ministry of Health

⁶² http://www.etiskraad.dk/english/index_main_en.mhtml

The primary subjects for investigation by the Committee are the following:

- Stem Cell Cloning: Cloning by cell nuclear transfer in order to obtain pluripotent stem cells for therapeutic purposes.
- Xenotransplantation: Transfer of living cells, tissue and organs from animals to humans.
- Gene therapy: Transfer of genetic material to a human being for therapeutic purposes.
- Predictive genetic tests: 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.

The Committee is composed of representatives of the Ministry of Health and the Ministry of Information Technology and Research plus one representative from the following committees, councils and boards: The Central Scientific Ethical Committee, The Danish Council of Ethics, The Danish Medical Research Council, The National Board of Health, The Danish Medicines Agency, The Board of Technology, The Danish Agricultural and Veterinary Research Council, The Danish Ethical Council for Animals and The Danish Forest and Nature Agency.

In 2001, the Committee presented its report which is directly applicable to decision-makers, politicians, scientists and research institutions and those immediately concerned⁶³. The report lays the groundwork for an informed debate among the politicians and the Danish population and form the basis of possible future legislative initiatives.

3. GENETICS AND INSURANCE

On April 25, 1991 the Danish Parliament resolved to ban the use of genetic testing for the purposes of employment, pensions and insurance. The Minister of Employment was to draft a bill before the end of 1991. In November 1991 the first version of the 'Bill to prohibit the use of genetic tests in appointments and in underwriting pensions and insurance' was introduced. The bill (No. L44) denied employers or insurance companies the right to ask for or to use any type of genetic tests. Section 5 of the bill reads as follow: "In the Insurance Contracts Act, section 3a is inserted: "When concluding agreements in accordance with this Act; companies may not demand or make use of genetic tests". The first version of the bill was rejected by parliament in the middle of 1992. The bill was further amended by a Law Reform Commission in 1994 and extended to regulate the use of all health information. The bill was endorsed by the Danish Parliament on April 1996.

The Act to Amend the Insurance Agreement Act and Act on the Supervision of Company Pension Funds, 1997 forbids insurers from using genetic information of applicants or their relatives, but allows diagnostic genetic testing for risk evaluation.

The Danish Parliament agreed that there was need for protection of the applicant/policyholder in insurance contracts from the invasion of privacy that could follow the development of genetic testing. As a result of this need the Danish Insurance Contract Law has been provided with a new provision - §3a - prohibiting the insurance companies from using information from predictive tests when assessing the risk. "When concluding the contract or hereafter the company is not to

⁶³ http://www.etiskraad.dk/publikationer/annual_2001/indhold.htm

request, obtain or receive and use information, that can cast light on the gene and the risk of a person of developing or incurring diseases. Neither may the company demand tests that are necessary in order to provide such information”. Exceptions are made regarding information about the person’s present or previous health condition. The Act thus prohibits the use of genetic testing but not, on the other hand, the collection and use of information on the person’s or family members’ present or previous health condition.

The law also established the duty of policyholders, as previously, to submit health statements containing information on their present and previous state of health.

When it comes to the policyholder’s current state of health, there is thus nothing in the law to prevent companies from obtaining information if the person in question suffers from cancer, for example, even if the diagnosis is made on the basis of a genetic test.

4. GENETICS AND EMPLOYMENT

Danish legislation aims to ensure that health checks focus on actual/present health conditions and that those conditions are relevant to the employee’s work.

Before taking the job the prospective employee has a duty to inform the employer about matters of importance for the appointment including relevant information about diseases. Under the ethical rules of the Danish Medical Association, members may not issue declarations of health to be used by an employer in assessing applicants, unless so ordered through legislation, or unless indicated by reasons in the patient’s favor.

The Act No. 286 of 24 April 1996 on the Use of Health Information on the Labor Market⁶⁴ decreases in a wide range employers’ possibilities to ask potential employees for health information including information based on genetic testing⁶⁵.

This act provides guidelines for collection, taking and use of health information in the workplace. The aim is protecting privacy and integrity of the individual person without hindering beneficial effects of modern technology. A main purpose has been to secure the quality of health information.

According to the Act the employer may obtain information about the employee’s health in the following cases:

- when the health information is relevant for the ability of the employee to perform the specific work
- with the approval of the Minister of Labour with the aim of making allowance for essential considerations regarding the security and health of consumers and others as to outer environment or to other societal interests
- according to agreement with the trade union or after permission from the Minister of Labour with the aim of making allowance for essential considerations regarding the running of the firm

⁶⁴ Law No. 286 of 24 April 1996 on the Use of Health Information on the Labor Market, *International Health Digest Legislation*. 1996;47:371-72

⁶⁵ Nielsen, L., “The legal aspects of occupational health”, EGE, 2000.

- as a novel offer to the employee, if conditions in the working environment makes it reasonable and desirable in relation to the employee himself or other employed

The employee must on his own initiative inform the employer about health information, relevant for the employee's ability to perform the specific work, if he or she is familiar with this information.

The employer is not allowed to collect information about the employee's health:

- when the information is not relevant for the ability of the employee to perform the work
- when the information to a larger or smaller degree concerns the probability of the employee coming to suffer from diseases in the future.

Health information includes diseases the employee suffers from, has suffered from or has symptoms of. When requesting health information the employer is obliged to point out the diseases or symptoms the employer wishes to obtain information about.

The quality assessment is secured by regulations securing professional contribution in connection with the examination, confidentiality for the persons involved on the examination, and regulations about informed consent. The person performing the examination must secure that the employee has given informed consent, based on information given orally and in writing. This information should include the purpose of the examination, its kind and method, possible risks attached to it, possible consequences for the employee, storing of the results and conditions of passing the information on. Information should include the possibility that the result of the examination may influence the investigated persons life expectancy and self-perception. Finally it is stressed that the person performing the examination must treat this confidentially. The employee is the person who is to receive the result of the examination, and the employer has no possibility of collecting the information from other persons than the employee. This does not, however, free the employee from the obligation to pass on information to the employer in certain situations. When health investigation is performed, the employer is obliged to pay the expenses attached to the investigation.

FINLAND

1. PATIENTS' RIGHTS

Finland has signed the European Convention on Human Rights and Biomedicine (04/04/1997), but has not yet ratified it⁶⁶.

The National Board of Health made in 1979 a proposal to the Ministry of Social Affairs and Health to draft a compact text on the patient's rights. A Committee on the Protection of Legal Rights in the Field of Health Care, set up by the Ministry for Social Affairs and Health, proposed a law in 1982.

Finland was the first country in Europe to enact a law on patients' rights: the Act on the Status and Rights of Patients, later the "Law on Patients' Rights", was passed in 1992 and enforced on 1 March 1993⁶⁷ following a long, almost 20 year debate. Although labeled a "law of rights", the law is built on obligations of the staff and the healthcare principal in relation to the patient. The need for such a law was first discussed in the early 1980s.

The Law laid down provisions covering patients' rights to:

- good health care and treatment when needed;
- access to treatment;
- information and self-determination;
- emergency treatment.

The Law also addresses the status of minor patients, through a provision requiring that the opinion of a minor patient (under the age of 18) on the treatment he or she receives be assessed, taking into account his or her age and level of development. Another provision addresses the powers of patients' representatives in certain situations.

In 1996, the Ministry for Social Affairs and Health assessed the experience gained in implementing the Act. Its report concluded that the Act was influencing positively the overall functioning of the health care system, making people more aware of their rights in using the health care services and affecting the attitudes of health care professionals. The younger generations of health professionals already appeared to be more willing to adopt new behavior towards their patients. However, the authors of the report criticized the Act's handling of the question of informed consent as vague. Two issues, patients' access to information and right to self-determination, were identified as needing further consideration.

Law No. 653 of 30 June 2000 amended the Law on the status and rights of patients⁶⁸. Amendments to the principal Law of 17 August 1992 concern the following Sections: 2. Definitions; 3. Right to good health and medical care and to considerate treatment; 4. Access to

⁶⁶ <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>

⁶⁷ Act on the Status and Rights of Patients, No. 785 issued in Helsinki, 17th August 1992. [Lag om patientens ställning och rättigheter](http://www.mhbibl.aland.fi/patient/patientlag.html) (785/1992); IDHL, 1992, 43, 760, Fin. 92.29. <http://www.mhbibl.aland.fi/patient/patientlag.html> (Svensk)

⁶⁸ *Finlands Författningssamling*, 7 July 2000, Nos. 648-657, pp. 1736-1738

care; 5. The patient's right to information; 12. Patient records and other material relating to care and treatment; 13. Confidentiality of information contained in patient records; and 14. Violation of the confidentiality requirement.

1.1. *Right to Informed Consent*⁶⁹

Consent to treatment is covered by section 7 of the Constitution, as well as by the Law on Patients' Rights⁷⁰. Section 7 of the Constitution states that everyone has the right to life and personal liberty, physical integrity and security of person and that no-one should be tortured or otherwise treated in a degrading manner. The concept of individual freedom is seen to contain that of the physical integrity of the individual. Thus the right of patients to make decisions on their treatment is based on this paragraph in the Constitution. Chapter 2, section 6 of the Law on Patients' Rights also protects the patient's right to self-determination. Care and treatment shall be administered with the patient's agreement. If the patient refuses to accept a certain form of care or treatment, he/she shall be cared for in some other way acceptable to him/her, and which is acceptable from the medical standpoint.

If a major patient because of mental disturbance or mental retardation or for any other reason, cannot decide on the treatment given to him/her, the legal representative or a close family member, or another close person of the patient has to be heard before making an important decision concerning treatment to assess what kind of treatment would be in accordance with the patient's wishes. If this matter cannot be assessed, the patient has to be given a treatment that can be considered in accordance with his/her personal interests.

In these cases, the patient's legal representative, a close relative, or other person closely connected with the patient must respect the patient's previously expressed wishes or, if no wishes had been expressed, the patient's well-being. If the patient's legal representative, next of kin or other person closely connected with the patient forbid the care or treatment of the patient, care or treatment must, as far as possible in agreement with the person who refused consent, be given in some other medically acceptable manner. If the patient's legal representative, close relative, or other person closely connected with the patient disagree on the care or treatment to be given, the patient shall be cared for or treated in accordance with his or her best interests. Care irrespective of the patient's wishes is regulated by the Mental Health Law (116/90), Law No 41 of 17 January 1986 on Social Work with Intoxicant Abusers, the Law on Communicable Diseases, and Law no. 519 of 23 June 1977 on Special Care for the Mentally Handicapped.

Chapter 3, section 7 of the Law on Patients' Rights concerns the status of minor patients. Minors are according to Finnish legislation those under 18 years of age. The opinion of minor a patient concerning care or treatment measures shall be assessed, if this is at all possible in view of his/her age or level of development. If a minor patient owing to his/her age and level of development can decide on the treatment given to him/her, he/she has to be cared in mutual understanding with him/her.

If a minor patient is unable to take a decision regarding care, he/she shall be treated in consultation with his/her guardian or legal representative. The guardian or legal representative of a minor patient shall not have the right to forbid such care as is necessary in order to ward off a threat to the life or health of the patient. (Section 9)

⁶⁹ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/finland.pdf>

⁷⁰ http://www.uni-wuerzburg.de/law/fi00000_.html

Chapter 3, section 8 of the Law on Patients' Rights deals with emergency treatment. A patient has to be given treatment necessary to ward off a hazard imperiling his/her life or health even in case it is not possible to assess the patient's will because of unconsciousness or other reason. However, if the patient has earlier steadfastly and competently expressed his/her will concerning treatment given to him/her, he/she must not be given a treatment that is against his/her will. In the sense that this section refers to the necessity to respect the previously expressed wishes of a person who is no longer able to state his/her preference regarding treatment, this could be considered as legitimizing a kind of advance directive.

The latter part of this section is aimed at guaranteeing the patient's right to self-determination. For instance the patient's right to draft a valid living will is based on this provision, as is the right of a Jehovah's witness to refuse a blood transfusion even after losing his/her consciousness – both are topics constantly debated in health care.

1.2. *Right to Information*

The Law on Patients' Rights specifies that various alternative methods of treatment and their effects have to be explained to the patient. The Law also gives the patient the right not to know and recognizes the "therapeutic exception", the withholding of information from a patient in certain cases. The information given should be tailored to the individual patient and interpreters should be used if needed.

According to chapter 2, section 5 a patient shall be given information about his/her state of health, the significance of the treatment, various alternative forms of treatment and their effects, and about other factors associated with his/her treatment that are significant when decisions are made on the treatment given to him/her. However, this information shall not be provided against the patient's will, or when it is obvious that giving the information would cause serious hazard to the life or health of the patient. Health care professionals should try to give the information in such a way that the patient can understand it. If the health care professional does not know the language used by the patient or if the patient because of a sensory handicap or speech defect cannot be understood, translation should be provided if possible.

According to Chapter 3, section 9 the patient's legal representative, close relative, or other person closely connected with the patient shall be entitled to receive any information regarding the patient's state of health that may be required to enable them to express an opinion and give their consent.

If a minor patient because of his/her age or level of development can decide on the treatment given to him/her, he/she has a right to forbid providing his/her guardian or other legal representative with information on his/her state of health and care.

If a minor patient cannot decide on the treatment given to him/her, the information shall be given to the guardian or other legal representative of the minor patient. The guardian or other legal representative of the minor patient does not have the right to forbid treatment necessary to ward off a threat to the life or health of the patient. The guardian or other legal representative shall not have the right to forbid any care which may be required to avert a threat to the patient's life or health.

1.3. Access to Medical Records

Concerning the right of the patient to check the data concerning himself/herself in the patient documents, the provisions of sections 26 to 28 of the Personal Data File Act (523/99)⁷¹ apply. Concerning the patient's right of access to information, the relevant provisions of sections 11 and 12 of the Act on the Openness of Government Activities (621/99) apply in addition⁷².

The Personal Data File Act, 523/1999 regulates that personal data may be processed for purposes of scientific research. Regardless of secrecy provisions, everyone shall have the right of access, after having supplied sufficient search criteria, to the data on him/her in a personal data file, or to a notice that the file contains no such data. There is no right of access if providing access to the data would cause serious danger to the health or treatment of the data subject or to the rights of someone else or if the data in the file are used solely for scientific research or statistical purposes. If only part of the data on a data subject is such that it falls within the restriction on the right of access, the data subject shall have the right of access to the remainder of the data.

Concerning the storage of the patients' documents section 12 of the Law on Patients' Rights states that health care professionals shall record in patient documents the information necessary for the arranging, planning, providing and monitoring of care and treatment for a patient. Health care units and health care professionals practicing their profession independently shall keep the patient documents as well as the samples containing biological material that arise in the context of examinations and care and models of organs for a period necessary for arranging and providing care and treatment for a patient, for investigating possible claims for compensation related to care, and for scientific research. Patient documents, samples and models shall be disposed of immediately after there are no grounds as referred to above for keeping them.

Further provisions on the drawing up of patient documents and on keeping them and the samples and models referred to in paragraph 1, and on the periods of keeping them determined on the basis of their use shall be issued by a Decree of the Ministry of Social Affairs and Health. Patient documents, samples and models may be kept after the period prescribed by a Decree of the Ministry of Social Affairs and Health has expired, if that is necessary for arranging or providing care for a patient. The need for keeping them after the period prescribed by a Decree of the Ministry of Social Affairs and Health has expired shall be assessed at least at five years' intervals, unless otherwise provided elsewhere in the law, or in the permission granted by the Data Protection Board as referred to in paragraph 2 of section 43 of the Personal Data File Act. Provisions on retention of documents on a permanent basis are laid down in the Archives Act (831/94).

⁷¹ www.tietosuoja.fi/uploads/hopxtvf.htm

⁷² <http://www.om.fi/1184.htm>

1.4. Confidentiality

According to section 13 of the Law on Patients' Rights, the information contained by patient documents is confidential. Health care professionals or other persons working in a health care unit or carrying out its tasks shall not give information contained in patient documents to outsiders without a written consent by the patient. If a patient is not capable of assessing the significance of the consent, information may be given by his/her legal representative's written consent. In this Law outsiders refer to persons other than those who participate in the care of the patient or in carrying out jobs related to it in the health care unit in question or by its order. The secrecy obligation remains in force after termination of the employment relationship or the job.

The previous paragraph notwithstanding :

- information included in patient documents may be given if there are express provisions on giving it or on the right of access to it in the law;
- information necessary for the arranging of examination and treatment of the patient may be given to another health care unit or health care professional, and a summary of the treatment provided may be given to the health care unit or the health care professional that referred the patient for treatment and to a physician possibly appointed to be responsible for the care of the patient in accordance with the patient's or his/her legal representative's orally given consent or consent that is otherwise obvious from the context; and
- information necessary for arranging and providing the examination and care of a patient may be given to another Finnish or foreign health care unit or health care professional, if the patient, owing to mental health disturbance, mental handicap or for comparable reason is not capable of assessing the significance of the consent and he/she has no legal representative, or if the patient cannot give the consent because of unconsciousness or for comparable reason;
- information about the identity and state of health of a patient may be given to a family member of the patient or to other person close to the patient, if the patient is receiving treatment because of unconsciousness or for other comparable reason, unless there is reason to believe that the patient would forbid this; and
- information on the health and medical care of a deceased person provided when the person was still living may be given upon a justified written application to anyone who needs the information in order to find out his/her vital interests or rights, to the extent the information is necessary for that purpose; the acquiring party may not use or forward the information for some other purpose.

Access to secret documents (such as patient documents in public health care) may be granted also for research purposes if it is apparent that it will not infringe the interests for which the secrecy was regulated for. (Act on the Openness of Government Activities, 621/1999)

Section 14 of the above-mentioned Law on Patients' Rights deals with penalties for breaking the secrecy obligation. This can lead to punishment under section 1 or 2 of Chapter 38 of the Penal Code or section 5 of the Penal Code, unless there is a more severe punishment for the offence elsewhere in law. The Penal Code regulates the obligation to secrecy of public officials, as well as that of doctors, doctors' assistants and other health care professionals. The regulations on confidentiality, except for those on the obligations of public servants, apply to both the private and the public sectors.

1.5. *Right to Privacy*

Finland has signed and ratified (02/12/91) the Convention 108.

Section 8 of the Constitution states that the private life, honour and home of every person shall be secured and that detailed provisions on the protection of personal data shall be prescribed by Act of Parliament.

The Personal Data Files Act (30/04/87) contains the right to know whether a file including data about him/herself, the right to demand and in most cases get such information from a file-keeper, the right to require the correction of incorrect information on a file concerning him/herself, the right to be informed of the source of information, how that information is used and to whom that information is given.

On 24 July 1998 the Government submitted a Bill to Parliament for a law on personal data and a number of associated laws (Government Bill 96/98). Besides the EU Directive on data protection, the Bill was based on the 1995 revision of the legislation on fundamental rights (according to Section 8 of the Constitution, the protection of personal data must be laid down by law), experience with the previous Personal Data Files Act and developments in information technology. Parliament discussed the Bill during the whole of autumn 1998, but adoption and entry into force was postponed until 1999⁷³.

According to section 11 of this Personal Data Act (523/1999) the processing of sensitive data is prohibited. Personal data are deemed to be sensitive, if they relate to or are intended to relate to among other things the state of health, illness or handicap of a person or the treatment or other comparable measures directed at the person. Sections 12 provides several derogations from the latter prohibition. For example, the prohibition does not prevent a health care unit or a health care professional from processing data collected in the course of their operation and relating to the state of health, illness or handicap of the data subject or the treatment or other measures directed at the data subject, or other data which are indispensable in the treatment of the data subject.

2. **PATIENTS' RIGHTS AND GENETICS**

As mentioned above, Finland has not yet ratified the Convention on Human Rights and Biomedicine. Regarding article 12 on predictive genetic tests, Finland does not intend to make any reservation.

Genetic testing has been performed in Finland since the beginning of the 1990's. There are no specific regulations of genetic testing in laboratories. State authorities supervise genetic testing as part of supervision and quality control of both the public sector and the private laboratories. External quality control exists for DNA-testing for determination of fatherhood. There is also a quality control scheme being set up for Huntington's diseases as a result of international cooperation. The quality assessment of genetic tests in Finland is still in need of improvement. A

⁷³ <http://www.tietosuoja.fi/uploads/hopxtvf.HTM>. An Act on the amendment of the Personal Data Act (986/2000) was adopted in 2000 (<http://www.tietosuoja.fi/uploads/p9qzq7zr3xxmm9j.rtf>).

Working Party set up by the Ministry of Social Affairs and Health has recently given recommendations concerning quality assessment, supervision, counselling, information use and other aspects of genetic testing.

The Gene Technology Act (1995) aims to promote the safe use and development of gene technology in a way that is ethically acceptable; and to prevent and avert any harm to human health, animals, property or the environment that may be caused by the use of genetically modified organisms. The Act does however not apply to modification of human genetic material by genetic techniques.

The Medical Research Act (1999) regulates the general conditions governing medical research carried out on persons, human embryos and human fetuses: respect of the inviolability of human dignity, favourable opinion of the ethics committee, informed consent of a research subject, etc...

3. GENETICS AND INSURANCE

There is no legislation concerning insurance and genetic testing in Finland. Thus, by law, policyholders are obliged to give correct and complete answers to questions posed by insurance companies before policies are approved. In principle, such questions include those about genetic tests⁷⁴. However, the Finnish Insurance companies have adopted a policy of not asking questions about genetic tests in connection with their risk assessment. Nor do they make use of such information if they obtain the results of genetic tests undergone by their customers. Nor, in their risk assessment, do they pose questions or use information on the state of health of applicants' relatives (Federation of Finnish Insurance Companies, 1999).

In 1997, the Ministry of Social Affairs and Health appointed a group of experts charged with investigating whether genetic screening should be permitted in, for example, job recruitment and approval of insurance policies. The group's report was issued in summer 1998. According to the group, insurers should not be permitted to require genetic tests when people apply for insurance, and the results of such test should be disclosed only with the permission of the applicants concerned. On the other hand, the group considered that the company should have the right to ask whether the customer had already undergone a genetic test, and what the test had shown. The working group did not propose any legislation on the matter.

4. GENETICS AND EMPLOYMENT

A working group reporting to the Finnish Ministry of Social Affairs and Health has recommended that employers should not be allowed to subject job seekers to genetic testing during recruitment, or to test employees already hired.

⁷⁴ Insurance Contract Act, No. 543, June 28, 1994

The Act on the Protection of Privacy in Working Life, subsequently, the Act on Data Protection in Working Life entered into force on the first of October 2001⁷⁵. The act supplements the Personal Data Act which incorporates a number of mutually complementary provisions associated with data protection in working life, such as fundamental rights, labour law, the law on civil servants, law on safety at work and criminal law. The purpose of the Act on Data Protection is to respond to questions concerning protection of private life specifically in the area of working life. The Act applies to employment relationships, civil service relationships and to comparable service relationships and also to job applicants and people applying for service relationships.

An employer is prohibited to require a job applicant or an employee to take part in genetic testing. An employer is also not entitled to know whether an employee has taken part in genetic testing at some point in his or her life. This means that an employer is not allowed to process data obtained by means of genetic testing, even though the testing might have been conducted with the employee's specific consent and for health reasons.

Even in the event that an employer receives a statement on an employee's suitability for a job, the employer is not entitled to obtain information on the fact that the result has been obtained by means of genetic testing.

Genetic testing in the Data Protection Act refers to all genetic investigations including prognostic gene tests involving examinations of the relatives of individuals with hereditary diseases.

If, contrary to the provision, an employer or his or her representative requires an employee to take part in genetic testing or obtains information about genetic testing performed on an employee, he/she can be ordered to pay a fine for violating the Act on Data Protection in Working Life.

⁷⁵ The Act on the Protection of Privacy in Working Life, N° 477, 1 October 2001.

FRANCE

1. PATIENTS' RIGHTS

France has already signed the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine, though still has not ratified it⁷⁶.

An evaluation in 1999 of the existing regulations revealed that they were imperfect and that they had to be redefined and elaborated. This resulted in the "Law concerning the rights of patients and the quality of the health system"⁷⁷. The French legislator opted for the integration of the regulations in the existing law.

The law principally guarantees and completes the patients' rights and the rights of users of the health system.

The following fundamental rights have been enumerated in the law:

- The right to respect of dignity in situations such as for instance the end of life.
- The right to non-discrimination: This general principle is transposed to health situations and applied to the access to prevention and care. It is also applied to discrimination based on sexual orientation and discrimination based on genetic characteristics.
- The right to respect of the medical secrecy is one of the fundamentals of the relation between the physician and the patient. The patient has the right to decide about information on his/her health situation and authorizes the share of the medical secrecy only in few cases.
- The right to have access to the most appropriate care in relation to his/her health situation, to the sanitary security and to the continuity of care.
- The respect of the patients' rights is one of the elements taken into account when evaluating the provided care and is part of the politics of public health.

In addition to these fundamental individual rights, the right to access to the medical file and the redefinition of the relation between the health professional and the patient are one of the main objectives of the law. The enumeration of the fundamental patients' rights in itself has to be connected with procedures to guarantee their effectiveness. Therefore, by analogy with the patients' right to access, the position of the users of the health care system and the position of the associations representing them have been recognized and reinforced in Title II of the law.

1.1. *Right to Informed Consent*⁷⁸

Law N°94-653 of July 1994 concerning the Respect of the Human Body contains provisions intended to safeguard the dignity of the body. Article 16-1 and article 16-3 are both relevant to

⁷⁶ <http://conventions.coe.int/treaty/EN/cadreprincipal.htm>

⁷⁷ http://www.legifrance.gouv.fr/html/codes_lois_reglt/dossiers_legislatifs/loisrecpub/2002-303/malade.htm

⁷⁸ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/france.pdf>

the issue of consent. Article 16-1 stipulates that everyone has the right to respect for his/her body. The human body is inviolable⁷⁹.

Article 16-3, §2, of the Civil Code confirms what was already established in doctrine and case-law: 'The prior consent of patients must be received except in those cases where his or her conditions necessitates a therapeutic action to which he or she is not in a fit state to consent'.

The Law concerning the rights of patients and the quality of the health system, article L. 1111-3, states that every person accompanied by the professional has the right to decide about his/her health condition, the information and the recommendations taken into account. The physician has to respect the wish of the person concerned after he or she has informed him/her on the consequences of the choice.

No medical act may be executed without the free en informed consent of the person. This consent may be withdrawn any moment. The patient is allowed to exit the health institution at any time, unless exceptions provided by the law, after being informed on the risks.

Written consent is not obligatory, but due to the ruling of the Court of Cassation of 25 February 1997 the doctor must be able to prove that he/she has provided the patient with the relevant information in order to give informed consent and as a consequence written consent is increasingly requested.

General provisions surrounding the issue of consent can also be found in article 36 of the Code of Medical Ethics⁸⁰. A physician who treated a patient without his/her consent, would be guilty of an offence according to the Code of Medical Ethics which would entail disciplinary measures. In France, the medical code is a legally binding instrument adopted by the Minister for Health on the basis of more general laws regulating the profession of doctors.

1.2. *Right to information*

The physician has a duty to explain as fully as possible the risks and advantages of the proposed treatment, insofar as they are predictable, so that patients may weigh the chances for themselves. However, there are no stringent formalities to be observed: except in special circumstances, valid information (Court of Cassation, 4 April 1995) may be delivered in approximate and honest terms, adapted to the practical understanding of the patient, which is not an easy matter in an increasingly multicultural society. However, the courts are perfectly aware of the fact that to rigorous requirements in matters of information would be likely to paralyze the physician's initiative and activity and that one cannot force the physician to reveal the patient the possibility of rare occurrences that might cause them unnecessary anxiety. The Court of Cassation even accepts that overcoming the immediate and most serious dangers takes priority over the provision of complete information. If there is no choice of treatment or if the matter is urgent, failure to provide complete information does not constitute an offence.

Article L. 1111-2 of the law concerning the rights of patients and the quality of the health system states that every person has the right to be informed on his/her health condition. This information concerns the different examinations, the treatments or the actions of prevention, their use, their eventual urgency, their consequences, the frequent risk or serious normally predictable risks and the other possible solutions and the predictable consequences in case of refusal. If, after the execution of the examinations, the treatments or the actions of prevention new risks have been

⁷⁹ A., Garay "Consentement aux actes médicaux et droits des patients", *Gazette du Palais* 1999, 26-36.

⁸⁰ Decree N°95-1000 of 6 September 1995 on the Code of Medical Ethics.

identified, the person concerned has to be informed, except in case of impossibility to find that person.

This duty to inform is imposed to every health professional in the scope of his competence and with respect to the applicable professional code. Only urgency or the impossibility to inform can discharge him/her.

The obligation to inform the patient is also covered by article 35 of the Code of Medical Ethics, which states that "The doctor must provide the person whom he/she examines, to whom he provides care or whom he advises, with honest, clear and suitable information concerning his condition and the investigations and care which he proposes. Throughout the duration of the disease, he must take into account the personality of the patient in his explanations and make sure that they understand them.

However, in the interests of the patient and for legitimate reasons which the practitioner is to judge carefully, a patient may be kept in ignorance of a serious diagnosis or a prognosis, except in cases where the case or the illness from which he is suffering exposes third parties to a risk of contamination.

A fatal prognosis should only be revealed circumspectly, but persons close to the patient must be warned, unless the patient has previously forbidden such revelation or has designated those third parties to whom it must be revealed."

1.3. Access to Medical Records

Computer storage of nominative data concerning individuals must be undertaken in conformity with rules of medical confidentiality and privileged information as set out in law n° 78-17 of 6th January 1978 concerning the use of computers, computer data bases, and individual liberties, as complemented by law n° 94-548 of 1st July 1994 concerning the processing of nominative data with a view to health research.

Recommendations for the establishment and use of electronic medical records were defined by The National Consultative Bioethics Committee (Comité Consultatif National d'Ethique) in its Opinion n°4 of 6th May 1985 and also in Opinion n° 25 of 24th June 1991. The above rules and recommendations can be summed up as follows:

- the right for the individual concerned to oppose electronic processing of his/her personal data or to ask for its deletion from the records, if he/she has good reason to do so;
- right of access, through a physician of his/her choice, to recorded information;
- right of rectification;
- right to oppose the transmission of data concerning him/her;
- obligation to obtain informed and express consent from the person concerned, before any computerization of data for research purposes, since the nature of this research calls for biological samples to be identifiable;
- forbidding access of any third party, in particular employer or insurance company, to any information contained in a record and furthermore, forbidding third parties from asking the individual concerned to produce any such information;
- the keeping of these records should be confidential.

Article L. 1111-7 of the Law concerning the rights of patients and the quality of the health system states that every patient has the right to access to the standardized information concerning his/her health condition, held by professionals or standardized health institutes, that has contributed to the diagnosis and its consequence and to the treatment or to an act of prevention, or to

information concerning the exchange of notes between health professionals, namely results of examinations, consultations, interventions, examinations, hospitalization, protocols and therapeutic prescriptions, documents of supervision, correspondence between health professionals taken into account, except for information mentioning that it has been obtained by a third non intervening in the therapeutic field or information concerning such a third.

Provisions are also contained in the decree N°92-329 of 30 March 1992⁸¹ relating to the Medical File and Information regarding People who are being cared for in Public and Private Health Establishments. According to article 710-2-1, a medical file must be made for every person being cared for in a private or public establishment. The file must contain personal information about the patient, an indication of the reason for hospitalization, results of medical and complementary paramedical examinations, reports made by the anesthetist, therapeutic aims and nursing files. Patients who would like to consult their medical file can do so on simple request. A patient's legal representative can also be granted access. However, before granting access, the identity of the patient is verified. The physician chosen by the person requesting to see the file can decide on the manner by which the information will be given. He/she must give the information to the patient or legal representative according to the rules laid down in the Code of Medical Ethics and also respecting the rules of medical secrecy.

1.4. Confidentiality⁸²

In French law, the physician is under a contractual duty to maintain medical confidentiality⁸³.

In addition, the code of professional ethics also imposes on the physician an obligation to medical confidentiality. Article 4 of the Code of Medical Ethics 1995⁸⁴ states that 'Professional secrecy, instituted in the interests of the patient, is required from all doctors under the conditions imposed by law. Secrecy covers everything which comes to the knowledge of the doctor in the exercise of his/her profession; that is to say not only information which is given to him or her but also what he or she has seen, heard or understood'. However, the discussion of the duty to maintain medical confidentiality mainly focuses on the relevant provisions of the criminal code, as in French law, a breach of the duty to medical confidentiality is a criminal offence. Article 378 old criminal code was replaced by Article 226-13 when the new criminal code came into force in 1994, which states that: 'The disclosure of any secret information by a person who is the depository of such information because of his/her social position or profession or on the grounds of a temporary office or mission, will be punished with imprisonment of one year and a fine of 15.000 €'⁸⁵.

It has been decided that the duty to maintain confidentiality, established and sanctioned by Article 378 old criminal code to guarantee the confidence necessary for the exercise of certain professions, is imposed on physicians as a duty in relation with their function, that it is general and absolute and that no one can relieve the physician from it. French courts have made it clear that the notion of 'no one' includes the patient him/herself, so that, according to this theory, the

⁸¹ http://www.anks.org/TEXTES/d_92-329.htm

⁸² Meméteau, G., "France", in Nys, H., *International Encyclopaedia of Laws - Medical law*, The Hague, Kuwer Law International, 1998, 1-159.

⁸³ S., Michalowski, "Medical confidentiality and medical privilege – a comparison of French and German law", *European Journal of Health Law* 1998/5, 89-116.

⁸⁴ Décret n° 95-1000 du 6 septembre 1995 portant code de deontology médicale
[http://www.conseil-national.medecin.fr/CNOM/Deontologie.nsf/V_DE/\\$first](http://www.conseil-national.medecin.fr/CNOM/Deontologie.nsf/V_DE/$first) (French)

⁸⁵ http://www.legifrance.gouv.fr/html/frame_codes1.htm (French)

physician's obligation to medical confidentiality is not at the disposition of the patient. The patient therefore does not have the right to relieve the physician from his/her duty to medical confidentiality.

Article L. 1110-4 of the Law concerning the rights of patients and the quality of the health system states that the medical secret has to be guaranteed. Unless exceptions in the law, the secret contains the information concerning the patient, obtained by the health professional or by every member of the personnel of the health institution. The medical secret is obliged for every health professional intervening in the health system.

1.5. *Right to Privacy*

France has signed (28/01/81) and ratified (24/03/83) the Convention 108. The data protection in national legislation is embodied in the Act on data Processing, Data files and Individual Liberties (06/01/78)⁸⁶.

There are three major provisions to the Act. Most significantly, it created the National Commission for data processing and Licensing (Commission National de l'Informatique et des Libertés) (CNIL). The CNIL is an independent agency which advises and reports on all matters relating to data processing. It advises on the legitimacy of planned data processing systems and ensures the public access to information. It also serves as an important research and monitoring functionary to the government and the judiciary. The CNIL is charged with ensuring observance of the tenets of the Act "by informing all persons concerned with their rights and duties, cooperating with them and monitoring data processing to personal data." The CNIL must prepare and publish a list of all data processing activity and must report annually to the President and Parliament on its duties. The CNIL reports to the Ministry of Justice.

Secondly, the Act establishes "preventive guarantees" to ensure that certain guidelines are followed prior to the setting up of a data processing system. Lastly, the Act establishes the rights of access and rectification to data subjects.

The Act is based on the important principle that data processing "shall infringe neither human identity, nor privacy, nor individual or public liberties."

The provisions of the Act are generally the same for both public and private sectors.

If the CNIL gives an unfavourable opinion regarding disclosure or access, it may be disregarded only by a decree issued on the favourable opinion of the Council of State (Conseil d'Etat). If the CNIL fails to issue its opinion within two weeks of receipt of the declaration, the opinion will be deemed favourable.

"Acquisition of data by any fraudulent, dishonest or illegal means is prohibited."

In July 2001 a draft law implementing Directive 95/46 has been proposed⁸⁷.

The Law concerning the rights of patients and the quality of the health system guarantees the individual autonomy, the right to dignity (article L. 1110-2) and the right to privacy of the patient (article L. 1110-4). The patient must be treated with respect. His religious, philosophical beliefs and his political convictions must be respected. The patient's intimacy as well as the confidentiality of personal information have to be guaranteed.

⁸⁶ <http://www.cnil.fr/frame.htm?http://www.cnil.fr/textes/text02.htm> (French only)
www.bild.net/dataprFr.htm#art01 (English version)

⁸⁷ www.justice.gouv.fr/actua/loicnild.htm (French only)

2. PATIENTS' RIGHTS AND GENETICS

In France, regulations about genetic testing were voted in July 1994. In addition, the National Consultative Ethics Committee for the Life and Health Sciences (CCNE) has released opinions and guidelines related to genetics since the early 1980s, on predictive genetic testing in 1996 and on related ethical issues in 1998. These latter dispositions were adopted by the Parliament in the frame of so called "Bioethical Laws". Because of the frequent coming out of medical innovations, and because it is useful to evaluate their efficiency, these laws (those who are included in Public Health Code) were re-examined in 1999 and will be reconsidered on a regular basis⁸⁸.

The Law No 94-653 of 29 July 1994 on respect for the human body⁸⁹ modifies the Civil Code by introducing the notions of two fundamental rights: respect for the human body, and therapeutic necessity as the only acceptable reason for violating the integrity of the body and this only if the concerned individual has consented. In addition, it states that "genetic studies of an individual's characteristics can only be carried out for medical purposes or scientific research", and only after consent has been obtained from the individual concerned. Severe penalties can apply in case of abuse. A specific paragraph has been introduced in the Penal Code, article 226-26, according to which the use of results from the analysis of the genetic characteristics of an individual is subject to penalties of up to 15.000 Euro and up to one year in prison.

Article 16-10 of the Civil Code imposes the preceding consent of the examinee.

In the first place written consent is needed for genetic examination of a person or his/her identification by genetic fingerprinting for medical purposes⁹⁰. Furthermore, in case of examination or identification by genetic fingerprinting for medical purposes, the consent can only be obtained in the interest of that person and with respect to his or her confidentiality (C. santé publ., article L. 145-15, al. 3).

The Public Health Code is amended by the insertion, in Book I (Second Part: Decrees made after consulting the Conseil d'Etat), of a Title VI entitled "Predictive medicine, genetic identification, and genetic research", comprising a Chapter I entitled "Examination of a person's genetic characteristics and identification by means of genetic fingerprinting for medical purposes" (Articles R. 154-15-1 to R. 154-15-20)⁹¹. Under Article R. 145-15-1, the examination of a person's genetic characteristics for medical purposes, within the meaning of this Title, may be carried out in order: to confirm or invalidate the diagnosis of a genetic disease in a person who presents the symptoms of such a disease; or to detect, in an asymptomatic person, the characteristics of one or more genes likely to give rise in the future to a disease in that person or in his/her descendants.

⁸⁸ Comité consultative national d'éthique pour les sciences de la vie et de la santé (CCNE). Avis n° 25 Avis sur l'application des test génétiques aux études individuelles, études familiales et études de population, Paris, juin 1991

⁸⁹ Law No 94-653 of 29 July on respect for the human body. IDHL (45)1994: 498-500

⁹⁰ (C. santé publ., article L. 145-15, al. 1^{er}).

⁹¹ Decree No. 2000-570 of 23 June 2000 determining the conditions governing the prescription and conduct of examinations of a person's genetic characteristics and the identification of that person by genetic fingerprinting for medical purposes, and amending the Public Health Code (Second Part: Decrees made after consulting the Conseil d'Etat). (*Journal officiel de la République française, Lois et Décrets*, 27 June 2000, No. 147, pp. 9652-9654)

The donation and use of parts and products of the human body, medically assisted procreation and prenatal diagnosis are dealt with in Law No 94-654 of July 29, 1994⁹². Prenatal diagnosis is defined as medical techniques aimed at detecting *in utero* a particularly severe disorder. It must be preceded by genetic counselling and must be carried out in authorized establishments. Preimplantation diagnosis is only allowed in certain circumstances: A physician working in a multidisciplinary prenatal diagnosis centre must attest that a couple runs a high risk of having a child who suffers from a particularly severe genetic disease that is incurable at the time of diagnosis; the genetic anomaly must have been identified in one of the parents; both members of the couple must give written consent in the test. The purpose of the test is limited to finding the affection, and looking for ways to prevent and treat it.

The report Genetics and Medicine from Prediction to Prevention of the National Consultative Ethics Committee for the Life and Health Sciences outlines the ethical principles that must be respected in testing for genetic disorders⁹³. Its recommendations cover the following topics and ethical principles: respect for the autonomy of the subject; respect for medical confidentiality; respect for the privacy and confidentiality of personal data; the use of biological samples; the prohibition of using results of genetic tests for other than medical or scientific purposes; procedures of accreditation of materials involved in genetic testing; evaluation of the impact of the tests; education and training of all medical personnel who might be involved in counselling and genetic testing; the need to guarantee correct public information; prohibition of all uses of the information that could produce any form of stigmatization or unfair discrimination.

The Law n°. 2002-303 of the 4th of March 2002 deals with the rights of patients and the quality of the health system. Article 1 of the law recognizes the right to non-discrimination: This general principle is transposed to health situations and applied to the access to prevention and care. It is also applied to discrimination based on genetic characteristics.

Article 4 of the law states that chapter III of the Civil Code is completed by an article 16-13 that applies the principle of non-discrimination to genetic characteristics.

Likewise the Penal code has been modified. The first and the second paragraph of art 225-1 are completed by the words "of their genetic characteristics".

The first paragraph of article 225-3 has been reviewed as following: "however, these discriminations are punished by penalties mentioned in the previous article if they are based on the fact that the predictive genetic test whose object is a non diagnostic disease or a genetic predisposition to a disease has been taken into account."

In the first paragraph of article 122-45 of the Labour Code the words "of their genetic characteristics" have been added.

3. GENETICS AND INSURANCE

In 1994, the Law n. 94-653 on respect for the human body introduced new provisions on genetic testing and DNA identification into the French Civil Code. According to article 16-10, the genetic study of the characteristics of a person may be undertaken only for medical purposes or for scientific research.

⁹² Law No 94-654 on the donation and use of elements and products of the human body, medically assisted procreation and prenatal diagnosis. IDHL (45)1994: 473-482

⁹³ http://www.ccne-ethique.org/english/avis/a_046p03.htm

The Code of Public Health affirms this principle but adds that genetic tests can only be realized "in the patient's interest" (Art L. 145-15-1). This necessarily excludes every genetic test contrary to the patient's interest. Consequently genetic testing for the purpose of the conclusion of an insurance contract is prohibited.

Article 25 of Chapter III on the identification of persons and their genetic characteristics by genetic examination reads as follows: it is not allowed to carry out genetic examinations on the characteristics of persons other than for reasons of medical or scientific research or in cases provided by law. The consent of the person involved is needed before examinations are carried out, except in case of medical necessity.

The use of information about an individual which has been obtained by studying his genetic characteristics other than for medical purposes for scientific research is punishable with one year's imprisonment and a fine of 15.000 Euro (article 226-26 Penal Code). French bioethics legislation specifically prohibits access by any third party, notably employers and insurance companies, to information held in databanks and makes it illegal for them to ask individuals to provide such information.

While this seems to prohibit insurers from using genetic tests for underwriting purposes, it does not prevent insurers from obtaining genetic-test information from medical files. Under public pressure, however, in 1994 the French Federation of Insurers imposed a moratorium on its members⁹⁴. This moratorium implies that insurers may not take the results of genetic characteristics (unfavourable or favourable test results) of a candidate insured into account even if the candidate insured offered the information by himself. Initially the moratorium was adopted for five years, which coincides with the 5-year period upon expiry of which the law n. 94-653 of July 29, 1994 was to be revised. In 1999 the insurers have extended the moratorium for another five years, i.e. until the year 2004. The underlying idea of the moratorium is that the experimental character of the genetic information prohibits to use it for purposes such as insurance contracts. This implies that insurers may not ask questions related to genetic tests and their results in risk questionnaires. Moreover, insurers may not ask the candidate insured to undergo genetic tests or to give them the results of previous tests.

The Universal Sickness Cover Act (CMU)⁹⁵, in particular Section 5 entitled "Social and health modernization" states that any use of genetic testing by complementary insurance and health insurance bodies is prohibited. According to article 62 of the Act, such bodies "may not take account of the results of a genetic study of the characteristics of a person requesting the benefit of supplementary health cover, even if those results are provided by himself or herself. Moreover they may not ask any question relating to genetic tests and the results thereof, nor ask for anyone to undergo genetic testing prior to arranging a contract providing supplementary health cover and for the entire duration thereof."

Decree n. 2000-570 dated June 23, 2000 fixing the conditions of prescription and implementation of genetic characteristics and genetic identification investigations of persons for medical reasons and modifying the Public Health Code, fixes 5 conditions for prescribing and implementing genetic testing for medical purposes:

1) condition of prescription;

⁹⁴ T. LEMMENS, "Selective justice, genetic discrimination, and insurance: should we single out genes in our laws?", *McGill L.J.* 2000/45, 347.

⁹⁵ Loi n°99-641 du 27 Juillet 1999 portant création d'une couverture maladie universelle. Lois et Décrets 99, 28 Juillet 1999.

- 2) condition of approval from appropriate authorities both for clinicians and laboratories;
- 3) conditions of reporting results;
- 4) conditions of medical record protection; and
- 5) approval from the National Consultative Commission created for this purposes.

4. GENETICS AND EMPLOYMENT

The legal provisions recently developed with a view to genetic testing may have important consequences for (all) medical examinations, since they require that such testing may only take place if it has a medical aim or serves a research purpose e.g. French Civil Code.

According the Law n. 94-653 on respect for the human body addresses the issue of genetic screening of children or adults, genetic testing can be used as a means to detect genetic disorders. The law provides that this type of genetic testing can be designed solely for medical or scientific ends. Of course, the law requires the prior consent of the person who is to be tested, or in the case of a child, the consent of his or her parents.

While these provisions are very general, they would probably bolster a claim against an employer who refused to hire someone who has been identified as having a genetic predisposition to certain serious diseases. It might also support a suit against an insurance company that refused to accept a new client on the basis of the results of genetic screening. The law does not prohibit these activities; it requires that genetic diagnosis must have a medical aim⁹⁶.

In France, labour law contains article L. 122-45, which determines that nobody can be excluded from a selection procedure because of his or her health condition or handicap. In accordance with article 4 of the Law concerning the rights of patients and the quality of the health system article 122-45 has been applied to genetic characteristics. Article 120 – 2 of the same law specifies that no one is allowed to restrict Human Rights or collective freedom, unless this is justified by the nature of the job or would be proportionate to the aimed purpose.

⁹⁶ Lenoir, N., « French, European and international legislation on bioethics », 81.

GERMANY

1. PATIENTS' RIGHTS

Germany has neither signed, nor 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.

In Germany, provisions in constitutional law deal with patients' rights and refer to the right to life and to physical integrity. Patients' rights are also enshrined in the 1983 health insurance law and in the Social Code. Nevertheless, the Concerted Action in Health Care (Konzertierte Aktion im Gesundheitswesen) recommended in 1992 that existing provisions be brought together in a patients' rights charter⁹⁷.

1.1. *Right to Informed Consent*⁹⁸

In the Professional Rules for German Doctors⁹⁹, two paragraphs deal with the issue of consent. §7.1 states that in all medical treatment, human dignity must be ensured and the personality, will and rights of the patients, in particular the right of self-determination must be respected. §8 obligates doctors to require the consent of the patient in order to provide treatment. In principle consent must be preceded by the necessary explanation in personal discussion.

The issue of consent is also dealt with by various high level Court decisions which have consequently set precedents. A basic principle is that any treatment carried out on a person against his/her will constitutes bodily injury. For this reason consent is necessary in all cases. The doctor has to prove that consent was given. "This is based on Article 2 (2) of the German Constitution"¹⁰⁰. If the person undergoing treatment is unable to consent, in certain cases the decision can be taken by a legal representative. According to §1904 of Guardianship Law (Betreuungsgesetz¹⁰¹), the guardian can consent to health examinations, medical treatment or surgery, but must obtain authorization from the Guardianship Court if there is a reasonable risk that the ward could die as a result of the measure or might suffer from serious and more prolonged damage to health. Nevertheless, if not carrying out the measure immediately would endanger the health of the patient, it can be carried out without prior authorization.

⁹⁷ For further information see <http://patientenstellen.de/patientencharta.html>

⁹⁸ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/germany.pdf>

⁹⁹ The Professional Rules for German Doctors quoted in this report are part of the model version which was decided upon at the 100th German Medical Parliament in Eisenach in 1997. They take on legal validity when adopted at the council meetings of the State Chamber of the Medical Council and Approved by the supervisory authorities. They are legally binding for doctors who are members of the chamber in their respective "Land". Membership of such a chamber is obligatory and there are only marginal differences between the model rules and the actual rules adopted by the chamber in each Land.

<http://www.bundesaerztekammer.de/30/Berufsordnung/Mbopdf.pdf>

¹⁰⁰ <http://www.verfassungsgericht.de/gg.htm#2>

¹⁰¹ <http://home.t-online.de/home/birkf.skfm/btg.htm>

Whether a person is capable of consent is not based on legal criteria but rather on whether a person can understand the consequences of an intervention or treatment for his/her body, profession and private life. It is not always possible to determine whether a person has this capacity. In an emergency situation, a doctor must decide on the basis of the presumed will of the patient. In order to determine what this might be, he/she should ask relatives and then respect this will. Even if the presumed will of the patient seems unreasonable, it must still be respected. If it is not an emergency but the patient is unable to consent, the doctor should contact the Guardianship Court in order to appoint a guardian rather than rely on relatives to make decisions.

1.2. *Right to Information*

The fact of performing a medical treatment without having provided the patient of the appropriate information is considered by jurisprudence as an arbitrary act, violating the right to self-determination and dignity.

According to the highest judicial authorities, information must be "by and large" provided. This means that the kind of information to be given depends on each individual and his/her particular medical case¹⁰².

Jurisprudence has set the elements on which the right to information is based:

- the present health condition and the diagnostic on which the treatment is based;
- the name of the physician who has to operate or who has the responsibility;
- the nature of the treatment;
- the possible secondary effects and the other risks related to the treatment and the possible alternatives;
- the chance of success;
- the degree of urgency of the treatment;
- the costs.

Moreover, the information has to be communicated by the physician and in a clear and comprehensive way. The patient has to be informed in time so he/she can think about the decision. The patient has the right to ask questions in any moment. Every patient has a right to information, independent on age and level of comprehension. It applies to every type of treatment, from the most difficult surgery to the order of medicines. The physician can not invoke the therapeutic exception to refuse the informing of a patient who's in a desperate situation. On the other hand, the physician can invoke it in case of psychiatric treatments, if he or she can prove that care risks to fail if information is provided. The right to information can also be refused if there's a risk to harm thirds.

The refusal of providing important information can be considered as a fault that leads to responsibility of the physician.

On the other hand every patient has the right to refuse explicitly his/her right to information.

¹⁰² H. Leenen, S. Gevers and G. Pinet, *The rights of patient in Europe*, Kluwer Law and Taxation Publishers, Deventer/Boston, 1993.

1.3. Access to Medical Records

Article 810 of the Civil Code¹⁰³ states that "Every person who has a legitimate interest to consult a document kept by an other person can demand the permission to consult the document from the owner, if the document has been set in his/her interest (...)".

Based on this regulation, jurisprudence has confirmed and defined the right to access of the patient to the medical file¹⁰⁴.

§ 10 of the Professional Rules for German Doctors states that the doctor must grant access to the patient's medical files. However, those parts that contain the doctor's subjective impressions or perceptions are excluded from this. It is not mentioned whether such access can be granted to third parties.

Since there is no specific legislation concerning longer periods, the medical data have to be stored during the ten years following the end of the treatment. The X-rays have to be stored during 30 years. The period of prescription of 30 years applicable to the damages claims taken into account, it is recommended to keep the files for 30 years.

The patient has the right to consult all the objective elements of his file (the results of an examination, the X - rays, correspondence between physicians...). On the other hand, the access to subjective elements (commentaries of analysis for instance) can be refused. In order to avoid problems, the Supreme Federal Court (Bundesgerichtshof) advises to the physicians to keep two files: one of their own and an other which can be consulted by patients. The restrictions to the right to access to the medical file are identical to the restriction of the right to information.

The right to access belongs to the patient, who can delegate the right to a person of confidence, to a solicitor or a physician for instance. On the other hand, the heirs have a right to access to the medical file of the deceased person if they can justify the interest and if the permission of the deceased person can be presumed (for instance cause of death is uncertain or if a demand of damages is started by the heirs).

The patients don't have to justify their wish to consult their file. They only have to contact, in a direct or an indirect way, the provider of care who has to admit within a reasonable term. The patients do not have to justify their wish to consult their file. They only have to, directly or indirectly by an authorized person, contact the care provider who has the obligation to give satisfaction in a reasonable term.

Usually, they get a copy of the file and they have to pay the costs. The X-rays can be loaned but have to be returned.

In practice, paradoxically, the patients who are refused to have access to their medical file can only lodge an appeal if there's also a fault of the physician and if a procedure has consequently been started.

1.4. Confidentiality

In German law, the physician is under a contractual duty to maintain medical confidentiality and the code of professional ethics imposes a similar duty. § 9 of the Professional Rules for German Doctors obliges doctors to maintain confidentiality in respect of any information that is entrusted

¹⁰³ <http://jurcom5.juris.de/bundesrecht/bgb/index.html> (Bürgerliches Gesetzbuch - German only)

¹⁰⁴ Les documents de travail de sénat. «L'information des malades et l'accès au dossier médical», Octobre 2000.

to him/her in his/her capacity as a doctor. This obligation exists even after the death of the patient.

In addition, the issue of confidentiality is addressed in the Penal Code. Paragraph 203 states that it is a punishable offence (with imprisonment of up to one year or with a fine) for anyone to reveal without authorization a fact that another person told in confidence due to the former's professional capacity¹⁰⁵. This applies to doctors, dentists, veterinary surgeons, pharmacists, members of a state controlled and recognized medical profession and professional state recognized psychologists. It also applies to assistants of the latter acting on a professional basis and those working for them in preparation for the profession.

The principle of medical confidentiality even receives constitutional protection¹⁰⁶. Articles 2(1) (freedom of self-determination), and 1(1) (respect for human dignity) Basic Law have been interpreted by the German Federal Constitutional Court as protecting the individual's right to private and intimate sphere free from state intrusion and as protecting the right of the individual to decide autonomously whether or not to reveal intimate facts. As all state authority is bound by the Constitution, the state has to respect the principle of medical confidentiality as part of the patient's privacy rights.

1.5. Right to Privacy

The disclosure of personal information to third parties is prohibited by article 823 of the Civil Code which governs the protection of personal rights.

Data protection in Germany is provided by the *Federal Data Protection Act* 1990¹⁰⁷, which is intended to protect individuals' right to privacy from being impaired through the handling of their personal data. The Act applies to the collection, processing and use of personal data by public bodies, and also private bodies insofar as they process or use data in or from data files for business, professional, or commercial purposes.

Under section 4 of the Act, processing and using personal data is only permissible to the extent that it is authorized by the Act or another legal provision, or if the data subject has consented. Consent should be given in writing.

Part II of the Act regulates the collection of data by public bodies. Firstly, it provides that public bodies may only collect personal data if it is required to enable them to perform their duties. Secondly, it specifies that personal data should normally be collected from the data subject. In such circumstances, the data subject must be informed of the purpose of the collection. However, the Act provides other circumstances in which personal data may be collected without the subject's participation.

In general, storage, modification or use of personal data by public bodies is only permissible if it is necessary for the performance of the duties of the data controller, or if it serves the purpose for which it was collected. However, the Act provides other specified circumstances in which personal data may be stored, modified or used for purposes other than those for which it was collected.

¹⁰⁵ <http://www.bib.uni-mannheim.de/bib/jura/gesetze/stgb-inh.shtml> (German only)

¹⁰⁶ <http://www.jura.uni-sb.de/law/GG/gg0.htm> (English, however for the latest version German/French)

¹⁰⁷ http://www.bfd.bund.de/information/bdsg01_eng.html

Part III of the Act applies to processing and use of personal data (in or from data files) in the normal course of business, or for professional or commercial purposes by:

- private bodies, defined as “natural or legal persons, companies and other private law associations”;
- public bodies of the Federation or the Länder insofar as they participate in competition as public law enterprises.

Under the terms of section 28, it seems that the storage, communication, modification, or use of personal data by private bodies for own purposes is only permissible if the data can be obtained from generally accessible sources. Secondly, subsection 28(2)1(b) states that it can generally be assumed that the data subject has a legitimate interest in excluding communication of personal information which was stored for the purposes of a contract or a quasi-contractual fiduciary relationship and which concerns, among other, health matters.

There is an exception, however, where the personal information is necessary for scientific research, if scientific interest in the research outweighs the interest of the individual in excluding the change of purpose, and if the research purpose cannot be attained by other means or can be attained thus only with disproportionate effort.

Section 29, which provides for the storage or modification of personal data in the normal course of business for the purpose of communication, is also unlikely to extend to genetic information, as it is only permissible if there is no reason to assume the data subject has a legitimate interest in excluding his/her data from storage or modification in the normal course of business, or the data can be taken from generally accessible sources.

2. PATIENTS' RIGHTS AND GENETICS

In Germany there are no specific legal regulations on the application of genetic testing in a narrow sense. There are however, regulations on the introduction of DNA tests as evidence in criminal courts of justice and within the course of prosecution and crime control. In view of the importance of the issues, however, the federal government has decided to address genetic testing. As a first step, the federal government is considering ratification of the Medical Devices Act, Directive 98/79/EC of 27 October 1998, which, on the basis of a EU regulation, can be applied as of 7 June 2000. Thereafter it will examine whether and to what extent there is need for legal regulations.

As regards the application of genetic testing, professional organizations and vocational associations have issued a large number of comments and guidelines. For example, in 1998 the Federal Medical Council published a guideline on the diagnosis of the genetic disposition to carcinosis. A comment on the so-called genome analysis of employees has already been presented. The German Society for Human Genetics also commented on the issue of genetic testing in its position paper of 1996 and made various statements on detailed questions¹⁰⁸. These statements are based on the principles of counselling and education, autonomy and confidentiality. However, these comments and guidelines do not have a legally binding character, but are only recommendations to their members.

¹⁰⁸ http://gfhev.de/kommission/eng/e_pospaper.htm

An important step toward legislation in the Federal Republic of Germany was made in 1987 when a parliamentary commission of inquiry established by the lower house of Parliament, the Bundestag, presented its report on 'Chances and Risks of Gene Technology'¹⁰⁹. Several areas of human genetics were then covered in the Act on the Protection of the Human Embryo of 1990, although most relevant questions are still not covered by statutory law¹¹⁰. This law regulates research and diagnosis with embryonic material. Genetic tests with embryonic cells are not allowed. There is an intensive discussion about the question under which circumstances genetic test are allowed a later stages of development.

The Position Paper of the German Society of Human Genetics (Deutsche Gesellschaft für Humangenetik¹¹¹) published in 1996, emphasizes the importance of the principle of confidentiality. The nature of genetic information is such that it is generally significant to the health, life and reproductive plans not only of the person affected, but also their family and relatives. Accordingly, the GfH states that genetic data should not be generally accessible, and must be particularly protected from third party inquiry and interest. Genetic data should only be passed on when the individual has been fully informed of the usefulness and purpose of communicating the data, and has given written permission for the data to be released. Thus, the GfH advises that a medical geneticist must only release data if the patient expressly addresses a request for release of data to him/her, if the purpose of releasing the data is defined, and if the physician is satisfied that the patient is aware of all the possible consequences of releasing the data.

The GfH recognizes that these obligations go beyond the general concept of confidentiality in medical practice, and that they may sometimes conflict with the medical tenet to prevent harm and suffering to a third party. This conflict will arise particularly if the genetic data is relevant to other family members' health and could lead to preventative medical treatment. The GfH advises that in such circumstances, no matter what the physician does, important ethical principles will be compromised. Thus, there can be no general rules about what should be done in these circumstances; rather, each case should be considered individually, involving as many of the parties concerned as possible. However, if the condition is neither treatable nor preventable, the right to self-determination concerning genetic information must take precedence over the interests of third parties in obtaining that information.

The Office of Technology Assessment at the German Parliament (TAB) published in 2000 a report on genetic testing in Germany¹¹². This summarizes the prospects of human genome research and the current types of DNA analysis and genetic tests used in medical practice. It also gives an overview of tests used for genetic counselling, prenatal diagnostics and pre-implantation genetic diagnostics. The report expands on the current practice and potential use of genetic tests in employment and insurance. On the basis of this analysis, the report outlines problems attached to genetic testing and makes recommendations on aspects to be addressed by appropriate statutory regulations.

For instance, there should be regulations to safeguard adequate counselling and to guarantee high quality standards of DNA diagnostics. The use of genetic test should be restricted to medical

¹⁰⁹ Bericht der Enquete-Kommission 'Chancen und Risiken der Gentechnologie', in *Bundestags-Drucksache* 10/6775 of 6 January 1987.

¹¹⁰ Bernat, E., "Legal aspects of developments in human genetics: an Austrian viewpoint", *Law & Hum Gen Rev* 3/1995, 36

¹¹¹ <http://gfhev.de/>

¹¹² Some English-language information on the structure and priorities of the TAB can be found on the Internet at <http://www.tab.fzk.de> The report on the status and perspectives of genetic testing in Germany - "Stand und Perspektiven der genetischen Diagnostik" (in German only)

purposes, matters of public safety, or to applications that are in the best interest of an individual. The report also proposes that the protection of personal genetic data be safeguarded, unfair discrimination be prevented and professional advice be made obligatory. An individual's right not to know ought to be respected. The authors of the report also recommend statutory regulations to ensure that tests in the workplace are used for the benefit of employees and do not lead to the discrimination of employees and applicants.

The Genetic Engineering Act (Gentechnikgesetz) emphasizes the following aims: (1) to protect life and health of human beings, animals and plants against possible threats of gene technology and (2) to give a legal framework for research, development and support of scientific, technical and economic possibilities of gene technology.

An increasing number of self-support groups formulated often in conjunction with expert groups recommendations for genetic testing. An important example are *Guidelines for the molecular genetics predictive test in Huntington's disease*, which are now regarded as obligatory in practical application of DNA tests¹¹³.

The Enquete Commission Enquiry into Law and Ethics of Modern Medicine recently presented its final report to the President of the German Bundestag¹¹⁴. It gives a view of the ethical, legal and scientific framework of modern medicine and makes recommendations on necessary legislation and further research. The report covers assisted reproduction, including pre-implantation genetic diagnosis (PGD), and the handling of genetic data. It also expands on research on individuals unable to give informed consent, the treatment of the terminally ill, and transplantation medicine.

What the handling of genetic data concerns, the Enquete Commission has made several recommendations. At present there is no law in Germany which regulates the handling of genetic data, except the regulations on forensic DNA analysis of 1997. The commission has identified a number of areas where legislation is needed. This includes access to genetic counselling – both prior to genetic testing and after the tests have been carried out. Additionally, quality assurance and control mechanisms for genetic tests should be developed and implemented in order to prevent the premature marketing of genetic test kits, to safeguard high-quality tests and to ensure state-of-the-art evaluation of test results. The commission recommends that suitable legislation should be introduced to regulate the protection of genetic data. It also proposes that the German Bundestag should consider the introduction of legislation on the use of genetic tests and the handling of test results in the workplace, for insurance purposes, and as part of genetic screening for pharmacogenetic purposes.

The German Federal Government's data protection registrar, Dr Joachim Jakob, presented his 2000 data protection report¹¹⁵. This gives an overview of current data protection issues, including the implementation of the European data protection directive in Germany. The report contains chapters on data protection issues within the remit of individual government departments. It also highlights a number of problems arising from the acquisition, storage and processing of personal - including genetic - data. Up to now, the handling of genetic data has only been covered by the

¹¹³ <http://www.hdfoundation.org/testread/testwfn.htm>

¹¹⁴ <http://www.bundestag.de/gremien/medi/schlussbericht.pdf> (German only)

¹¹⁵ The 2000 report by the Federal Government's data protection registrar was published by the German Parliament (Bundestag) as "Drucksache 14/5555". The report may be downloaded from the Internet at <http://dip.bundestag.de/btd/14/055/1405555.pdf>.

general data protection legislation¹¹⁶, which the federal data registrar considers inadequate for that purpose. At a conference in October 2000, the data registrars of the Federal and Länder Governments reinforced a number of data protection principles with regard to genome analysis and individual's rights to self-determination that were set out as early as in 1989. The main guidelines proposed in these recommendations are:

- Genome analysis should only be permitted on the basis of informed consent with the exception of criminal court cases or in order to determine an individual's line of descent.
- The right of individuals to revoke their consent at any time must also cover the further use of personal genetic data.
- Genetic tests must be carried out on a purpose-specific basis, i.e. the type of genetic analysis used in any one case should be relevant to the purpose of the test and produce a minimum of additional genetic data.
- There should be an investigation whether genetic tests need to be licensed by a government authority. There is already a case to be made for licensing the use of DNA probes.
- The use of genome analysis in court cases must be restricted to the determination of an individual's identity. Further genetic tests must not be carried out.
- The use of genetic testing in employment should be explicitly banned. Any exceptions from that rule should be set out in adequate regulations. Genetic testing in employment must not be allowed on a voluntary basis.
- Genetic testing for insurance purposes is considered unnecessary and incompatible with the principles of insurers to cover – and not exclude – risks.
- For prenatal genetic diagnosis, genetic testing should be restricted to conditions that can be treated or that are serious enough to justify a legal abortion. Genetic screening of newly-borns should only be allowed for the early diagnosis of conditions that can be treated. Parents must be given the right to make their own informed decision on whether or not genetic testing should be conducted.

3. GENETICS AND INSURANCE

In Germany, there are no specific legal regulations on the use of genetic testing and genetic information by insurers. However, the Federal government recently announced that the legal and ethical impacts of biotechnology are key issues to be addressed in the following years, and encouraged national debate. As a starting point, the German Bundestag has set up a Commission of Inquiry into "Law and Ethics in Modern Medicine" which has considered, among other things, genetic information¹¹⁷. The Commission recommended that insurance companies should not be allowed to ask for the results of predictive genetic tests.

Contractual liberty allows insurers asking applicants to undergo tests that are relevant for the determination of risks. According to the medical committee within the German insurance federation, paragraph 16 of the German insurance contract law states that an insured is already bound to give information regarding all particulars known to him/her which could be important for the acceptance of a risk. This includes the results of a genetic test. However, the 1988

¹¹⁶ http://www.bfd.bund.de/information/bdsg01_eng.html

¹¹⁷ English-language information on the Enquete commission enquiry on the Internet is available at http://www.bundestag/gremien/medi/medi_law.pdf. The final report can be downloaded from <http://www.bundestag.de/gremien/medi/schlussbericht.pdf> (German only).

moratorium stating that insurers neither make genetic tests a prerequisite for insurance contracts nor do they ask for the results of genetic tests performed in the past, has been renewed in 1999. Furthermore, the members of the German Insurance Association¹¹⁸ signed in December 2001 a voluntary agreement on the use of genetic testing for insurance. This commits German insurance companies not to use predictive genetic tests for insurance purpose, except for high policies. For private health and life insurance policies up to 250,000 Euro insurers will not ask for the disclosure of the results of genetic tests carried out previously for some other purpose. In the moratorium, the German insurance industry underlines that they will not grant discounts to individuals that voluntarily disclose test results, for instance, to show that they do not have a genetic disposition towards a specific critical illness. This moratorium will expire at the end of 2006¹¹⁹.

The five-year moratorium states that for insurance policies that exceed 250,000 Euro German insurance companies may ask applicants to disclose the results of predictive DNA tests previously carried out. In this case, the German insurance industry is committed to keeping only that part of the genetic information that is relevant for the specific insurance purpose. Additionally, genetic information and application forms will be handled separately to safeguard a maximum level of data protection. The voluntary agreement also commits insurance companies to limiting the access to genetic information to a very small, strictly controlled group of experts responsible for risk assessment. Additionally, the use of any DNA test results disclosed to insurance companies will be limited to the risk assessment of the applicant only. The moratorium explicitly excludes the possibility of using any individual's genetic test results to assess the potential insurance risk of any relations.

German ministers are planning legislation to prohibit the use of genetic test by insurance companies. Currently Germany does not have a law regulating the use of genetic tests by third parties. It is expected that the new German law will prevent insurers and employers requesting, using, or communicating genetic test results.

4. GENETICS AND EMPLOYMENT

As in the case of genetic testing in insurance, there is no German regulation at present that addresses the issue of genetic testing in employment. However, this issue was also addressed by the German Bundestag Commission of Inquiry into "Law and Ethics in Modern Medicine." They recommended that employers should not be allowed to ask for the results of genetic tests as a prerequisite for employment. Equally, job seekers should be banned from revealing genetic test results to prospective employers.

Regarding genetic testing in the workplace, there is a requirement to obtain genetic knowledge for certain occupations at pre-employment stage. This consists of traditional questions, such as those about family history. Genetic testing designed to analyze genes in relation to employment is not undertaken. Because of the dynamic character of molecular genetics and the fact that future

¹¹⁸ The membership of the German Insurance Association includes 456 companies, including 408 German Firms. In terms of gross income the association accounts for an estimated 97 % of the German insurance market.

¹¹⁹ The German-language text of the voluntary moratorium can be found on the Internet at <http://www.gdv.de>.

developments can hardly be predicted there is general agreement that legal regulations are not suitable for the regulation of genetic testing (Karlic & Horak 1998)

GREECE

1. PATIENTS' RIGHTS

Greece signed the European Convention on Human rights and Biomedicine on April the 4th, 1997 and ratified it in October 1998 by Law 2619-15.6.1998. The Convention entered into force on the first of December 1999¹²⁰.

The development of legislation relating to patients' rights in Greece has undergone three phases.

In the period up to 1992, patients' 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, Section 47). However, no provisions were made for the implementation of the legislation.

In 1997, again as part of broader health care reform legislation of 17 July 1997 (Law 2519/21-8-97), 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. The key features of this legislation as far as patients' 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 legislative act); and (b) the extension of these rights also to all patients seeking primary care. The immediate implementation of the patients' rights provisions of the 1997 legislation represents a major step forward with respect to improving the quality of health care services provided¹²¹.

In particular, the 1997 Hospital Law provides the following in connection with patients' rights:

Article 1 (Instruments for the Protection of Rights)

- (i) The provisions of article 47 of Law 2071/92 are extended and are applied uniformly to all citizens seeking primary care services.
- (ii) For the protection of the rights of hospital patients granted by the 1992 legislation, as well as the basic rights to health care of the total of the population as foreseen in the provisions of article 1 of Law 1397/83 (legislation of 1983

¹²⁰ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹²¹ K. Merakou and E. Tragakes, "Development of patients' rights legislation", *European Journal of Health Law* 1999/6, 71-81.

establishing Greece's National Health Service), the following services are to be introduced within the Ministry of Health and Welfare:

- An Independent Service for the Protection of Patients' Rights, at the level of a Ministry Department, and under the jurisdiction of the General Secretary of the Ministry of Health and Welfare.
- A fourteen-member Committee for Regulation of Protection of Patients' Rights, also within the Ministry of Health and Welfare, to keep informed with respect to hospital compliance with patients' rights regulations and to follow up on patient complaints.
- An Office of Communication with the citizen, in each hospital, operating under the direct supervision of the chairman of the board of directors;

With the provision of Law 2716/1999, article 2, this state protection was extended to include persons with psychiatric disorders.

1.1. *Right to Informed Consent*¹²²

The right to informed consent is protected by the Greek Constitution and Greek legislation. However, there are certain exceptional situations in which the patient's consent is not required for medical interventions. These so-called 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"¹²³.

Section 47 (3) of the Hospital law¹²⁴ stipulates that every patient shall have the right to give or refuse his/her consent to any diagnostic or therapeutic procedure intended to be carried out on him/her. 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/her behalf.

According to section 47 (5) of the same law every patient, or his/her representative in the case referred to in sub-section 3 shall have the right to be thoroughly informed in advance of any risks likely to arise as the result of unusual or experimental diagnostic or therapeutic procedures performed on him/her. Such procedures may only be performed with the patient's express consent. Consent may be withdrawn by the patient at any time. The patient must feel that he or she is entirely free in deciding whether or not to agree to collaborate for the purposes of research or training. The patient's consent to such participation is his/her right, and may be withdrawn at any time.

By article 8 of the Royal Decree of May 25/ July 6, 1955, on the Code of Medical Deontology physicians are required to respect the patient's person and honour absolutely. 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.

According to article 9 of the same Royal Decree, the physician owes unlimited care for the maintenance and preservation of human life. He/she is obliged to refrain from any action that

¹²² <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/greece.pdf>

¹²³ K. Merakou and E. Tragakes, "Development of patients' rights legislation", *European Journal of Health Law* 1999/6, 71-81.

¹²⁴ Hospital Law of 1992 (N° 2071).

might result in hindrance to the reproduction of, or in hazard to, life; exception is made only for indicated and unavoidable therapeutic need. Besides, article 25 of the Penal Code states that no act is illegal which is executed in order to overturn a present or certain danger that threatens a person.

In the case of minors, the doctor is obligated to obtain the consent of a minor's legal representative as determined by the Civil and Penal Codes. A minor is regarded as being under the age of 18. According to article 1510 of the Civil Code, consent must be provided jointly by the parents. Any disagreement between the parents is resolved by a court decision and in the case of a conflict of interest between the parents and minor a special guardian is assigned. Law No. 1329 of 1983 introduced a new article giving doctors the right to act against the patient's parents. Namely, in the event of a case requiring urgent attention where the parents refuse to provide consent, consent may be immediately provided by the prosecutor of the district court following a request by the responsible doctor or service (Article 1534 of the Civil Code and article 456/1984 of the Penal Code).

1.2. *Right to Information*

Every patient shall have the right to request information regarding his/her situation. The patient's interests shall be determinative and it shall be guaranteed that the information provided to him/her is comprehensive and accurate. The information provided to the patient shall be such that he or she is able to obtain a complete picture of the medical, social, and financial parameters of his/her situation, and to take his own decision or participate in any decision-making likely to affect his/her life subsequently. (Section 47 (4) of the Hospital Law)

1.3. *Access to Medical Records*

By Article 16 of Act 1599/1986 on Citizen/State relations, a subject may not have access to written documents covered by medical confidentiality and which refer to third persons. These documents are accessible only by persons to whom the information therein refers, and then only with the presence and assistance of a physician. Nevertheless, 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 law.

1.4. *Confidentiality*¹²⁵

Greek law protects medical confidentiality as part of the principle of personal freedom and integrity, which are protected by the Constitution, the European Convention of Human Rights which exists as national legislation since the Legislative Decree 53/ 1974, the Penal Code (article 371), the Civil code (articles 57, 914, 932), the Medical Deontology (articles 22 and 23 of Emergency Law 1565/1939 and article 15 and 18 of the Royal Decree 25-5/6-7-1955), as well as the disciplinary regulations of medical associations and hospitals.

The issue of medical confidentiality is covered by article 23 of the Obligatory Act 1565/1939 on the Code of Practice on the Medical Profession which institutes that the physician is obliged to

¹²⁵Koniaris, T.B. and Karlovassitou-Koniari, A.D., "Greece", in Nys, H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1-186.

keep secret whatever he or she sees, hears, learns or understands in the course of his or her profession and which constitutes confidential information for the patient or his or her family, with the exception of those cases in which particular provisions of the law oblige the disclosure of confidential information.

Further references to confidentiality are found in articles 15 and 18 of the Royal Decree of 25/5-6/7/1955.

In particular, Article 15 states that the physician is obliged to take any possible measure to insure that indications that might lead to a breach of medical confidentiality are not included in the professional or scientific books or articles. The issue of certificates or any kind of medical opinion is forbidden if they do not include a clear reference to their purpose as well as the name of the recipient. It is forbidden to issue certificates or prescriptions for therapeutic procedures or appliances without including the name of the recipient as well as the written declaration that he/she recognizes the obligation not to make public the certificate, declaration or prescription in non-scientific periodicals, newspapers, or leaflets, or another profit-making publicity medium.

Further, article 18 rules that the strict maintenance of medical secrecy is obligatory for all physicians serving in organizations or foundations under public or private law, of any kind or category. Physicians must be inflexible in maintenance of confidentiality. Any declaration contrary to the principle of medical confidentiality is to be avoided. The only ones 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/her care.

If a physician knowingly and willingly exposes confidential data, he/she will be punished under criminal law (article 371 Penal Code). According to paragraph 4 of article 371 of the Penal Code, violation of the principle of medical secrecy may be justified under certain conditions. These include situations where the doctor in question is carrying out particular duties such as declaring certain events or if in the position of an inspector, expert or auditor; where he/she is protecting legal or otherwise justifiable third party interests or where he/she is acting to protect a public or private interest.

1.5. *Right to Privacy*

Protection of the privacy of the patient can be found in the following pieces of legislation: Obligatory Act 1565/1939 on the code of practice of medical profession, Law 1599/1986 on the state/citizen relationship, the establishing of a new national identity card, Law 1805/1988 on the updating of the criminal record, the modification of penal provisions and the adjustment of other related matters, and Law 2400/1996 which recognized Protocol 11 of the Convention on Human Rights and Basic Freedoms (FEK A' 96, 04/06/1996).

In accordance with article 371 Penal Code, it is forbidden to process personal data with regard to the state of health, the medical examination, the medical care and the treatment. Exception is made when the data subject consents in writing to the processing of personal medical data by anyone, not physicians only. Without this written consent of the patient, treating physicians may process personal medical data under their supervision and responsibility. Personal medical 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 subjects of data have the right to inspect the recorded data relating to themselves, though this right needs to be exercised through a physician.

The Hospital Law 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/her private life (Section 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.

The Greek law on data protection (law 2472/97 on the protection of individuals with regard to data processing of a personal nature) was ratified by the Greek Parliament on March 26, 1997 and was published on April 10, 1997¹²⁶.

The Act establishes the Data Protection Authority and sets up a set of guidelines for the use, processing, storage and export of personal data in electronic and manual files. The Act is true framework legislation, it needs to be complemented with sectoral laws.

The new Greek law applies not only to personnel records but to marketing databases (such as those of travel agents) and other databases maintained by banks, insurance companies and credit checking agencies.

The principles of both the EU Directive and the Convention are present. Namely, 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; it must be accurate and up to date and not kept for longer than necessary.

In accordance with the provisions of the law, the Chairman of the authority (who has to be a Judge at the Supreme Court) was nominated by the government and six members appointed by the Parliament. These appointments were made in 1997, and the authority is now operational.¹²⁷

2. PATIENTS' RIGHTS AND GENETICS

In 1977, legislation was enacted concerning termination of pregnancy for medical reasons up to the 24th week, but there is at yet no legislation concerning practice in genetics. Since 1981, the Hellenic Association of Medical Genetics has been trying to obtain government approval for a national genetics program which would cover all existing units and establish new units with a specific structure and organization throughout the country. So far, however, formal guidelines and standards have not been established. National quality control systems do not exist, and the Hellenic Association of Medical Genetics has not so far been involved in the organization of such a system.

3. GENETICS AND INSURANCE

To date, there is no legislation concerning practice in genetics. Insurance companies have agreed to a voluntary code of conduct and do not ask for genetic testing prior to insuring patients.

4. GENETICS AND EMPLOYMENT

¹²⁶ www.europa.eu.int/comm/internal_market/en/dataprot/law/el10-2001.pdf

¹²⁷ Data protection working party, Third annual report, E.U.

There is no specific legislation concerning the use of genetic tests within the scope of recruitment.

IRELAND

1. PATIENTS' RIGHTS

Ireland has neither signed, nor ratified the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine¹²⁸.

In Ireland a Charter of Rights for Hospital Patients was published in 1995. The objectives of this charter were to ensure that the health service becomes more responsive to the needs of individual patients and that there is a code of practice available which sets out what patients have to expect when they make use of hospital services. The government was firmly committed to raising standards in hospitals and to guaranteeing that everybody, irrespective of income, will have access to high quality medical care.

1.1. *Right to Informed Consent*¹²⁹

Although the term 'informed consent' is used widely in Irish medical and legal circles, there is no Irish judicial or statutory definition of this term. It is not a term of legal art in Ireland¹³⁰.

Under common law, it is illegal to give treatment to a person who has not consented to it, unless the treatment is of an urgent nature. Such consent must be based on an understanding of the nature of the treatment, likely effects and risks of the treatment, the likelihood of success and details of any alternative treatment possible. Furthermore, consent must be freely given without any coercion or pressure. The more a patient is capable of understanding, the more detailed the explanation should be and vice versa.

The doctor must give the patient, or the patient's guardian or parent, information about the patient's condition, the effects (including side effects) of treatment, including, where appropriate, alternative forms of treatment. It is usually said that this is to enable the patient to give consent to treatment.

1.2. *Right to Information*

The right to be informed is mostly derived from the right to bodily and mental integrity, which is guaranteed by the Irish Constitution¹³¹. In Ireland the standard of care to be exercised by a medical practitioner in his duty to inform and the giving of the warning of the consequences of proposed surgical procedures is not in principle any different from the standard of care to be exercised by medical practitioners in the giving of treatment or advice. A doctor is likely to be in breach of his/her duty of care, if he/she fails to make a full disclosure of all the factors that a

¹²⁸ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹²⁹ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/ireland.pdf>

¹³⁰ D. Tomkin and P. Hanafin, Irish Medical Law, Round Hall Sweet and Maxwell, 1995.

¹³¹ <http://www.uni-wuerzburg.de/law/ei00000.html>

reasonable person would wish to consider before deciding whether to consent. There are a number of factors which qualify this general statement on the information a doctor must disclose.

The greater the patient's capacity to comprehend the issues involved and come to a decision about them, the greater will be the extent of the duty to disclose relevant information. Conversely, the more restricted his/her capacity, the less may be the extent of any duty to inform.

In *A Guide to Ethical Conduct and Behaviour and to Fitness to Practice* the Medical Council stresses that a request for information by a patient always requires a positive response. In general, the more a patient asks, the more the doctor should tell him/her¹³².

Where the proposed procedure is thought to be essential for the patient's health, the obligation to disclose information will generally be much less than it is where the procedure in question is not essential. It was held in the case of *Walsh v. Irish Family Planning Services Ltd.* that there may be instances where as a matter of medical knowledge, notwithstanding substantial risks of harmful consequence, the carrying out of a particular surgical procedure is so necessary to maintain the life or health of the patient and the consequences of failing to carry it out are so clearly disadvantageous that limited discussion or warning concerning possible harmful side-effects may be appropriate and proper. The obligation to give warning of the possible harmful consequences of a surgical procedure which is elective is more stringent and more onerous.

In the absence of other considerations the greater the risks to the patient which the doctor knows or ought to know, but which the patient cannot be expected to know, the greater will be the duty to disclose information about them.

In those rare cases where information is likely to have a directly detrimental effect on the patient's health, a doctor will not normally be in breach of his/her duty of care if he/she does not disclose this information.

1.3. Access to Medical Records

It would appear from *Toal v. Duignan (No. 1) (1991)* which dealt with the problem of patient records, and access by the patient to these records, that there is a duty to keep proper medical records. However, this case does not state for how long medical records should be kept, nor whether a hospital which moves premises and thereby fails to keep all records of a patient who attended there, is ipso facto negligent or otherwise in breach of some duty.

The Freedom of Information (Fol) Act 1997 covers the issue of access to information¹³³. According to this act, all patients (treated under the public health system) have the right to access their health records. Previously, the only legislation relating to access to information concerned that which was held on computer and hence came under data protection laws. Under the Fol access to records covers information in any form which relates to medical, psychiatric and psychological treatment or care and may include opinions made about patients on this basis. Requests for access to records should be made in writing to the head of the relevant public body (the Chief Executive Officer). This is radically different from the previous system, whereby it was the responsibility of the doctor to decide on access to records. Not later than four weeks after

¹³² The Medical Council, *A Guide to Ethical Conduct and Behaviour and to Fitness to Practise*, 4th ed., The Medical Council, Dublin, 1994.

¹³³ <http://193.120.124.98/ZZA13Y1997.html>

receipt of a request, the CEO must decide whether or not to grant access to the information and determine how access will be arranged. In the case of a favourable response the requester should be notified of this, provided with details of when the request was granted and the name of the person dealing with the request and details of any fee to be charged. In the case of a negative response, the requester should be informed of the reasons.

If access to a record is granted, the request can be provided in a number of ways, e.g. a copy of the record, a transcript of the information concerned, a computer disk or other electronic device, the opportunity to inspect the record, written notes of shorthand or coded information or a combination of these forms.

Access to information can be denied for various reasons. Access can be refused if in the opinion of the CEO the information might be prejudicial to the mental health, well-being or emotional condition of the person making the request. However, in such cases the patient would still be able to access the required records, but through the intermediary of a health professional which he/she had specified.

1.4. Confidentiality

There is no specific legislative provision governing the duty of confidence in the physician-patient relationship. The duty of confidence in the medical context is more in the line of a moral duty. It is therefore governed by codes of professional conduct as well as by the general common law duty of confidence.

The 4th edition of the Medical Council's Guide to *Ethical Conduct and Behaviour and to Fitness to Practice* deals with confidentiality. The Guide provides that confidentiality is a time honoured principle of medical ethics. There are four circumstances where exception may be made:

- when required by a judge in a court of law;
- when necessary to protect the interests of the patient,
- when necessary to protect the welfare of society;
- when necessary to safeguard the welfare of another individual or patient.

The Guide specifically endorses the safeguarding of medical records, whether held in hospitals or by doctors. In particular, the Council endorses the statement on confidentiality in the use of computers and electronic processing in the field of health service administration, passed by the 27th World Medical Assembly.

The Guide specifies that doctors belonging to certain *disciplines* may experience problems in relation to the conduct of medical examinations, and when reporting to a third party. The doctors in this category are medical officers of health, occupational physicians, doctors employed by and/or acting for the Police, Defense forces, prison medical officers and civil service doctors.

1.5. Right to Privacy

One of the rights not expressly guaranteed by the Constitution, but which has been recognized by the courts as one of the unenumerated personal rights guaranteed by Article 40 of the Constitution of Ireland is the right to privacy.

In 1988, the Data Protection Act was passed in order to implement the 1981 Council of Europe Convention for the Protection of Individuals with Regard to Automatic Processing of Personal

Data¹³⁴. It is designed to afford protection to individuals in relation to personal data kept on computer about them. As to whether medical records constitute data, this depends on how the information is stored. It is worth noting that the existence of the Data Protection Act 1988 does not preclude an action at common law.

Section 4 of the Data Protection Act 1988 guarantees a right of access to personal data. Subject to some quite substantial limitations set out in the Act, an individual who so requests a data controller in writing, shall be informed whether the data kept by the data controller includes personal data relating to that individual and further, the applicant shall be supplied with a copy of the information constituting the data. Section 4 provides that if the information given by the data controller is provided in a form which is not intelligible to the average person without explanation, the information should be accompanied by an explanation of those terms. This is particularly useful for those seeking medical records. A data controller is not obliged to disclose to a data subject personal data relating to another individual unless that other individual consents to the disclosure.

An individual has certain rights in respect of erroneous data. These include rectification or where appropriate erasure. The data controller is deemed to have satisfied the rights of the individual concerned if he completes the statement with a statement (to the terms of which the individual has assented) and provides that the data is no longer inaccurate.

The Minister of Justice is responsible for legislation on data protection. The legislation necessary to implement the Directive 95/46/EC of the European Parliament and of the Council has not yet been adopted. In January 2000, the European Commission initiated a case before the European Court of Justice against Ireland and four other countries for failure to implement the Data Directive at time. The Data Protection (Amendment) Bill, 2002, contains proposals for updating data protection law, to give effect to EU standards¹³⁵. Nowadays a draft bill to implement the Directive 95/45 on the protection of individuals with regard to the protection of personal data is to be approved by the government¹³⁶.

2. PATIENTS' RIGHTS AND GENETICS

There is no specific legislation.

3. GENETICS AND INSURANCE

There are no specific regulations in place regarding genetic testing. The only restrictions on seeking genetic data are those contained in the insurance contract law.

However, the Irish Insurance Federation (IIF) announced on April 30, 2001 that its life assurance members have agreed a voluntary Code of Practice restricting the circumstances in which insurers

¹³⁴ <http://www.dataprivacy.ie/6ai.htm>

¹³⁵ http://www.dataprivacy.ie/images/annual_report_2001.pdf

¹³⁶ <http://www.irlgov.ie/oireachtas/frame.htm>

will seek access to genetic test results¹³⁷. The IIF is the representative association for insurance companies in Ireland. The Code took effect 1st May 2001 and is intended to stay in effect until the end of 2005 at which stage the position will be reviewed in the light of developments.

The general provisions of the Code of Practice on Genetic Testing state that:

1. Applicants must not be required to undergo a genetic test in order to obtain insurance.
2. Except as provided in 3 below, the applicant is obliged to disclose at application stage all material facts, including any genetic test results. A material fact is one, which an insurer would regard as likely to influence the assessment and acceptance of the proposal.
3. Disclosure of the result of a genetic test will not be required in new applications for life cover unless the sum assured on the new application exceeds £300,000 (approx. 469,562 Euro) or the total of the sum assured on the new application and other policies, if any, taken out with any insurer between 1st April 2001 and 31st December 2005 exceeds £300,000.
This exemption from the normal duty of full disclosure of material facts applies until 31st December 2005.
Where the sum assured exceeds £300,000, the normal underwriting regime will apply only to the excess over £300,000.
In the case of life cover exceeding this limit, and for critical illness and disability insurance, only approved tests (see below) will be used in the underwriting process by insurers.
In the case of a proposal where genetic test results are not required to be disclosed, a proposer who has had a negative result under an approved test may ask the insurer to take the result into account in the underwriting decision.
4. Life Assurance members of the Irish Insurance Federation shall only take a genetic test result into account only when its reliability and relevance to the insurance product has been established. (Such tests are referred to in this Code as "approved tests".)
5. An "approved test" is one which has been approved by the Genetics and Insurance Committee (GAIC) in the UK¹³⁸. In the event of this Committee ceasing to operate, or of a material change to its role or responsibilities, IIF members will agree an alternative mechanism for determining the relevance and reliability of tests.
6. Whereas the applicant must disclose genetic test results at application stage, there is no need to disclose
 - (i) a genetic test result of a blood relative.
 - (ii) the results of future genetic tests after the policy has been taken out (if, at application stage, the applicant has fulfilled his/her obligation to disclose all relevant information and the insurer has issued the policy in good faith).
7. A genetic test result disclosed by an applicant will not be taken into account when assessing another individual's insurance application.
8. As with all medical information the applicant's consent must be obtained by the life assurance company before:
 - (i) personal data, which includes a genetic test result, can be processed.
 - (ii) information can be requested from the applicant's General Practitioner (GP).
 - (iii) information can be requested from or shared with another life assurance company.
9. The chief underwriter in the life assurance company is the central reference point where all applications containing a genetic test result must be referred. The chief underwriter must consult the company's Chief Medical Officer (CMO) before reaching a decision on the application.

¹³⁷ <http://www.iif.ie/media.htm>

¹³⁸ For the moment, the only approved genetic test is Huntington's Disease (October 2000)

10. A genetic test result must have no effect on the premium or on the terms offered by the insurer unless the result indicates an increased risk. An increased risk may not necessarily result in an increased premium. However a result indicating the absence of a condition present in the family history would avoid a raise of the premium.
11. Life assurance companies must not offer applicants lower than standard premiums on the basis of a genetic test result.
12. Applications for insurance shall be impartially assessed based only on relevant evidence. The decision must be based on fact, expert medical and genetic opinion. CMOs must provide a written explanation if the application is rejected or the premium increased to an applicant's GP on request. The underwriters' decision-making process must therefore be recorded in detail.
13. In a case where the underwriter concludes that the risk is too great to insure, alternative terms should be offered where possible. This may be more practical with some types of cover than with others e.g. it may be possible with critical illness cover to exclude the known risk and provide cover for other risks.
14. If the underwriter or CMO believes that an applicant is or may be unaware of a genetic test result he/she will contact the applicant's GP before informing the applicant of a decision to increase the premium or decline the application.

4. GENETICS AND EMPLOYMENT

The Guide to Ethical Conduct and Behaviour and to Fitness to Practice of the Medical Council states that when a doctor reports to a patient's employer, the doctor must 'interpret the medical findings'. An employer has not got the right to be informed of the clinical details of illness or injury without the consent of the patient, though the guide does permit (with the consent of the patient) an employer to have access to a patient's medical record where an occupational physician is presenting to an employer the significant aspects of a medical condition.

Exceptions arise where there is a statutory duty to report notifiable, communicable diseases, and/or there is a real or potential risk to public health¹³⁹.

¹³⁹Tomkin, D. and Hanafin, P., "Ireland", in Nys, H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1998, 1-194.

ITALY

1. PATIENTS' RIGHTS

Though signed, Italy still has not ratified the European Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine¹⁴⁰.

The medical deontology code adopted by the National Federation of Physicians Order (Federazione Nazionale degli Ordini dei Medici) on the 15th of July 1989, has not got the binding force of a law in the Italian system. Consequently the code can not be invoked and does not represent an ineligible regulation that regulates the operational scope of the professional organization¹⁴¹. One of the most significant issues of the Code are the regulations concerning the relation between the physician and the patient: the obligation to restrain from what is called therapeutic or diagnostic persistence (Article 20) and the obligation to restrain from every diagnostic or curative act «when the competent patient explicitly did not consent » (Article 40). Concerning the treatment one has to inform «the clearest possible on the diagnosis, the prognosis, the therapeutic prospects and their consequences, the limits of the medical knowledge taken into account and respecting the right of the individual «this is information that the physician has to provide to the patient, his/her cultural level and power of discernment taken into account.» (Article 39)

On the 24th and the 25th of June 1995 the National Federation of Physicians Order has adopted the new Code on medical deontology which- knowing that its regulation value is limited to this professional organization- has introduced important innovations relating to the preceding Code, dating from 1989. It is important to mention in particular: in the scope of norms concerning «the information and consent of the patient» (article 29/34) the prohibition of the physician to «perform any diagnostic or therapeutic act without the informed consent of the patient» (article 31); the possibility of informing spouses «only if the patient permits it» (article 30); the obligation of the physician «to inform the Judicial Authorities as soon as possible» in case the legal guardian «refuses the application of the necessary treatments of minors or incapable adults» that can not be postponed (article 32) and the regulations concerning « the interventions on the genome and on the conception» (article 42), which are only permitted if they aim to prevent and correct the pathologies situated in the fetus». Genetic manipulation is always prohibited.

1.1. *Right to Informed Consent*¹⁴²

Consent to medical treatment is covered by article 32 (2) of the Italian Constitution, which states that no one may be forced to undergo any particular medical treatment, save under the provisions of the law¹⁴³. In no case shall the law violate the limits imposed by proper respect for the human

¹⁴⁰ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹⁴¹ www.fnomceo.it

¹⁴² <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/italy.pdf>

¹⁴³ <http://www.uni-wuerzburg.de/law/it00000.html>

person. It is interesting to note that Italy is the only country which directly deals with the issue of consent in the Constitution.

Article 13 (1) of the Constitution states that personal liberty is inviolable. As a person's moral liberty, the right to self-determination and physical liberty (the right to respect for bodily integrity) are all elements of personal liberty, this article can also be understood to cover the issue of consent.

Consent is also covered by the New Italian Code of Medical Ethics, more specifically by article 31 and 32. Article 31 states that the doctor cannot undertake any diagnostic or therapeutic procedure without the informed consent of the patient. The doctor's actions must be guided by the will of the patient which should be freely and explicitly expressed. This should be supplemented by written consent. Diagnostic or therapeutic procedures which could be seriously hazardous to the safety of the patient, can only be undertaken in the case of extreme necessity. The doctor must explain the possible consequences of the proposed procedures and obtain documented and informed consent. If a patient who is capable of comprehension and intention explicitly refuses treatment, the doctor cannot go ahead with any diagnostic or curative action.

Article 32 provides for the situation where a person may be unable to consent due to infirmity of the mind. In this case, the person's legal representative can consent on his/her behalf. If the legal representative opposes treatment which the doctor considers to be essential and urgent, the doctor must inform the judicial authorities. Such opposition is ineffective in cases where the law provides for compulsory medical treatment. If treatment is necessary and urgent and the patient is unable at that particular moment to object to it, the doctor can provide any essential treatment and care.

1.2. Right to Information

The right to be informed of one's diagnosis and state of health is covered by the New Italian Code of Medical Ethics. According to article 29, the doctor must provide the patient with clear and appropriate information on the diagnosis, prognosis, prospective treatment and the likely consequences of treatment or non-treatment. If the patient has additional questions, these must also be answered. If the information to be given includes a serious or fatal prognosis or something which is likely to cause anxiety or suffering to the patient, it must be provided with circumspection, using terminology which is unlikely to traumatize the patient, making sure to include any element of optimism.

The doctor must take into account the particularities of each patient to whom he/she gives information. This includes the patient's level of education, emotionality and reasoning capacity. He/she must further ensure that information about diagnostic and therapeutic procedures is limited to what the patient is capable of receiving and accepting in view of his/her education and psychological condition.

1.3. Confidentiality

According to article 30 of the New Italian Code of Medical Ethics information can be provided to a spouse provided that the patient consents to this. In the event of grave danger to the health or life of any third party information can be given without consent.

1.4. *Right to Privacy*

What the right to privacy concerns, the law on the protection of personal data was adopted on 31 December 1996 and came into force on 8 May 1997¹⁴⁴. The Parliament authorized the government to make regulations to amend and supplement the law for transposition of the directive 95/46/EC.¹⁴⁵ It covers both electronic and manual files, for both government agencies and the private sector. There have also been decrees approved relating to -among other things- processing of personal information for scientific or research purposes and health. Italy is a member of the Council of Europe and has signed and ratified the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data.

2. **PATIENTS' RIGHTS AND GENETICS**

In the deontological guidelines for doctors there are no dispositions specifically concerning the genetic tests¹⁴⁶.

One of the National Bioethics Committee (set up in 1988) tasks is to express opinions and suggest solutions, also for the purpose of preparing legislative acts, to address the ethical and legal problems that may emerge as a result of the progress of research and the emergence of possible new applications of clinical interest, taking into account the safeguarding of fundamental human rights and human dignity and the other values as expressed in the Constitutional Charter and in the International instruments supported by Italy¹⁴⁷.

Work groups on best practice guidelines for specific genetic tests are operative within the Italian Society of Human Genetics (S.I.G.U.).

In 1997 the Italian government (Presidenza del Consiglio dei Ministri-Comitato Nazionale per la Biosicurezza e le Biotecnologie and Istituto Superiore di Sanità) has organized a Task Force in order to prepare national Guidelines for genetic testing. A first draft of the text received the general approval of Committee on 18 December 1998, but was updated in the light of the European Convention on Human rights and Biomedicine and the further developments in the bioethical debate. The statement on genetic testing was definitively approved by the National Bioethics Committee on 19 November 1999¹⁴⁸.

The general objectives are:

- ensuring the safety and effectiveness of both existing and newly introduced genetic tests;
- defining the criteria for quality assurance of laboratories performing genetic tests;
- ensuring both adequate counselling and the free decision of individuals and families; this will include social and psychological support by qualified professionals and a particular attention to problems concerning ethics and privacy.

¹⁴⁴ www.dataprotection.org/garante/preview/1,1724,448,00.html?sezione=120&LANG=2

¹⁴⁵ Data protection working group, third annual report, EU.

¹⁴⁶ Nielsen, L., "Genetic testing and privacy: a European perspective", *Law & Hum Gen Rev* 4/1996, 69.

¹⁴⁷ <http://www.governo.it/bioetica/>

¹⁴⁸ <http://www.palazzochigi.it/bioetica/english/geneticstest.html>

Some topics deserving a specific concern have been identified, namely: genetic testing for prenatal diagnosis; genetic testing for susceptibility to cancer; genetic testing for rare diseases. The implementation of the criteria laid down in the guidelines will contribute to integrate genetic testing in the Italian national public health system.

Article 16 of the law no. 291 of 30 July 1999 which contains "provisions concerning the treatment of personal data for the purposes of case history, statistics and scientific research" that specifically regard genetic data states that: "The treatment of genetic data, regardless of who processes them, is permitted only when specifically authorized by the Guarantor (authority set up under law no. 675 of 31 December 1996¹⁴⁹: Protection of persons and other subjects in the case of the treatment of personal data, which, within the broad notion of personal data treatment provided by article 1, par. 2, sub-section b, is without doubt applicable also to genetic tests), after hearing the opinion of the Ministry of Health, who requested the opinion of the Higher Health Council for this purpose. Treatment authorized by the Guarantor may be continued until the issue by the authorization provided for in the present article is issued within twelve months after the data it comes into effect". Consequently, the delicacy of the genetic data issue resulted in further legislative steps to surround the issue of the authorization by the Guarantee Authority with further precautions, as follows:

- 1) it must be specific and not just issued for the treatment of health data;
- 2) it is necessary for the treatment of genetic data performed by any subject (and not just that carried out by public bodies);
- 3) it is subject to the approval of the Ministry of Health (although it is not clear whether this approval is binding or not);
- 4) it seems to imply a competence concerning the identification of the cases (and thus of the purposes) for which the treatment is allowed.

3. GENETICS AND INSURANCE

There is no specific legislation on the use of genetic information by insurers and employers in Italy.

The guidelines of the Italian Committee on Bioethics on genetic tests¹⁵⁰ (19 November 1999) state that genetic information must be treated as the general medical information and therefore it is forbidden to give this information to insurers or employers without consent.

It is recommended that insurance companies for the time being do not take genetic information into consideration, particularly that referring to polygenic and multifactorial diseases - which in any case account for by far the highest relative percentage of pathologies among those requesting insurance -both because of the still incomplete knowledge of the molecular mechanisms underlying their onset, and because of the difficulty of devising actuarial calculation systems for life expectancy and death rate in which this information is taken into account. The estimated risk ascribable to predisposition towards polygenic diseases should in fact be formulated individually, on a case by case basis (Section 14 Bioethical guidelines for genetic testing).

¹⁴⁹ www.garanteprivacy.it/garante/frontdoor/1.1003,.00.html?LANG=2

¹⁵⁰ Orientamenti bioetici per I test genetici

In Italy, the need for the insurance companies to have access to certain sensitive data, and above all, those related to health, has been announced on a number occasions, right up to the most recent parliamentary work preceding the introduction of the much cited law 675/1996, but has always encountered a strong resistance. The general authorization of the Guarantee Authority (replaced by law no. 5/1998) referring to the treatment of sensitive data by banks, insurance companies, brokerage companies, etc. in particular does not allow genetic data to be processed by subjects exercising insurance activities. Section 5 of authorization no. 2/1998 bans any communication of genetic data, among other things by banks and insurance companies¹⁵¹.

4. GENETICS AND EMPLOYMENT

In both the private and the public sectors, the existing laws permit an examination of the conditions of health of the subject to be employed as well as – in certain cases – of the workers already in activity. Using private doctors is not permitted: only doctors of the competent public agencies or of the national health service can be used. These dispositions comprehend medical inspection of any type: selective health inspection before the engagement, routine inspections during the employment, as well as inspections aiming to verify the conditions of a worker absent because of illness. The law does not exclude the possibility to test the existence of a genetic disease in the applicants, in order to select the fit ones for a specific public employment. In general, it seems that the trend is towards increasing the use of medical examinations as a tool to select the applicants for specific employment¹⁵².

The bioethical guidelines for genetic testing of the National Bioethics Committee also address this issue. The bioethical problems to be considered here partly overlap those considered previously in relation to the genetic diagnosis of disease or pathological predisposition, and partly refer to the possibility of genetic discrimination, in terms of hiring or of career, against employees displaying a greater proneness to certain pathogens. Such discrimination would be even more serious and unjustifiable in the eventuality - fortunately still remote, in view of the technical difficulties and high costs involved - of genetic screening aimed at evaluating whether employees or job applicants are liable to late onset diseases not related to their working activities. (Section 13)

¹⁵¹ <http://www.palazzochigi.it/bioetica/english/genetictest.html#14>

¹⁵² Nielsen, L., “Genetic testing and privacy: a European perspective”, *Law & Hum Gen Rev* 1996/4, 69.

LUXEMBOURG

1. PATIENTS' RIGHTS

Luxembourg signed the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine on April 4th, 1997, though still has not ratified it¹⁵³.

Patients' rights for Hospitalized patients are provided in the Law of 28 August 1998 on hospital establishments¹⁵⁴.

Chapter 10 reads as follows:

“Every patient shall have the right to the preventive, curative, or palliative care necessitated by his state of health, in accordance with the current state of scientific knowledge and deontology. Care shall be organized in such a way as to assure its continuity under all circumstances.

Every patient shall have the right to the protection of privacy, confidentiality, dignity, and respect for his/her religious and philosophical convictions.

Except in an emergency, the patient shall have a free choice of hospital and of physician from among those authorized to practice in the hospital.

At the time of his/her admission to hospital or to a specialized hospital establishment, and during his/her stay there, the patient shall, with a view to his informed consent, have the right to appropriate information concerning his/her state of health and the proposed treatments.

It shall be the duty of the attending physician to inform the patient accordingly. This information may be supplemented by other health care providers with due regard for the relevant rules of deontology.

The patient shall have the right to refuse or accept any diagnostic or therapeutic intervention, without prejudice to the provisions of subsections 2 and 3 of Section 7 of the law of 10 August 1992 on the protection of young persons.

He/she shall, in any event, have the right to the administration of care aimed at alleviating his/her pain and suffering.

All patients in the same hospital or specialized hospital establishment shall have the right to the same quality of care. They shall, to the extent necessitated by their state of health, have an equal right of access to all therapeutic or diagnostic means and equipment available to the hospital or specialized establishment, without prejudice to priorities dictated by the degree of urgency of the care provided.

¹⁵³ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹⁵⁴ Mémorial : *Journal Officiel du Grand-Duché de Luxembourg, Part A*, 18 September 1998, No. 78, pp. 1564-1672.

The internal regulations of each hospital or specialized hospital establishment shall contain the necessary provisions to assure the safety of patients and visitors. In particular, such regulations shall determine visiting times and procedures.

In the case of incurable and terminal conditions, the attending hospital physician shall alleviate the patient's physical and mental suffering by providing him/her with the appropriate treatments, while avoiding any hopeless therapeutic overzealousness and maintaining as far as possible the quality of what remains of his/her life.

The physician shall attend the dying person up to the end and act in such a way as to permit the patient to retain his/her dignity.

Similarly, he/she shall offer appropriate support to the patient's associates in order to alleviate their suffering in connection with the situation.

At the approach of death the patient shall have the right to be permanently accompanied by at least one person of his/her choice under conditions that respect his/her dignity.

The hospital or specialized hospital establishment shall inform the patient in an appropriate manner of the provisions of this Chapter, the practical modalities, and the financial conditions of his stay, including the amounts chargeable to the patient.

The identity and qualifications of persons providing care and hospital services shall be easily recognizable at any time by the patients with whom such persons are in contact.

The director of each hospital establishment shall set up a mechanism whereby the suggestions, grievances, and complaints addressed to him may be/she aired and discussed.

Without prejudice to the preceding provision, the Director of Health shall examine any complaint from a patient reporting non-compliance with this Law or, more generally, the defective operation of a hospital service.

In carrying out the task of examination, the Director of Health or the official of his administration delegated by him/her for his/her purpose shall, in particular, have access to the complainant's file referred to in Section 36 of this Law.

The Director of Health shall inform the complainant and the director of the establishment of the outcome of his/her examination.

In the case of a minor, legal or mental incompetence, or the decease of the patient, the complaint in question may be brought, respectively by the patient's legal representative or his/her next-of-kin, providing an account of a concern of a moral or material nature."

1.1. Right to Informed Consent¹⁵⁵

According to article 8 of the Code of Medical Ethics¹⁵⁶, doctors are obliged as far as possible to respect the patient's wishes. If a patient is unable to express his or her wishes, his/her relatives

¹⁵⁵ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/luxembourg.pdf>

must be contacted and informed, except in cases of emergency or if this is impossible. The doctor must make every attempt to explain clearly the effects and consequences of each proposed examination or treatment, except in case of emergency. He/she must obtain the patient's consent, particularly for acts which entail a serious risk

It is the doctor's duty when treating a minor or an incapable adult to try to notify the parents or legal representative and to obtain their consent. In case of emergency, if the parents or legal representative cannot be contacted, the doctor can give the necessary treatment. However, if the incapable person is able to express an opinion on the matter, the doctor must take it into account as far as possible.

1.2. *Right to Information*

Article 36 of the Code of Medical Ethics grants the doctor the right to withhold a serious diagnosis or prognosis from the patient if he/she sincerely believes that there are legitimate reasons for doing so. It is also stated that a fatal prognosis should only be revealed to the patient with the utmost caution. In such cases, the family should generally be informed, unless the patient previously forbade this or designated another person.

1.3. *Access to Medical Records*

Hospitalized patients are entitled to consult their medical file in accordance with the Law of 28 August 1998 on Hospital Establishments. The patient may exercise this right either personally or through the intermediary of a doctor designated by him/her who does not necessarily have to be attached to the hospital. The patient also has the right to request copies of information contained in the file. In case of death, access to the patient's medical file may be granted to his/her spouse, his/her children or any other person who was living with the patient at the time of death.

In accordance with the Law of 31 March 1979 on the Use of Nominative Data in Computer Processing, patients may also have access to computerized information kept on them, although this must be communicated by a doctor designated by the patient for this purpose. Article 22 of this law states that the patient can request the correction completion, clarification, updating or destruction of personal data if it is inaccurate, incomplete, ambiguous or out of date. The patient cannot, however, forbid the recording of such data in this way.

1.4. *Confidentiality*

Chapter II of the Code of Medical Ethics deals with professional secrecy. It states that professional secrecy, established in the interests of the patient, is imposed on every doctor subject to the conditions laid down by law. Professional secrecy is total and includes not only what the patient has confided in the doctor, but any information which the doctor might have obtained based on what he/she saw, heard or understood. This obligation extends beyond the patient's death (article 35)

Article 39 states that it is the doctor's duty to make sure that a patient's medical file as well as clinical files and documents containing information on the patient are protected from any form of

¹⁵⁶ The Code of Medical Ethics is legally binding due to the fact that it is inscribed in article 4 and article 18 of the Law of 29 April 1983 concerning the exercise of the profession of doctor, dentist and veterinary surgeon. It was also promulgated by the Minister of Health through the Ministerial Decree of 21 May 1991.

indiscretion. A medical certificate which contains a medical secret can only be given to the patient in person, who is then free to dispose of it as he/she sees fit. In case of necessity, the doctor can give the certificate to another person, provided that the patient has consented to this. If the patient is incapable or unconscious, the certificate can be given to the patient's legal representative.

The issue of confidentiality is also addressed in article 458 of the Penal Code, which punishes any doctor, surgeon, health official, pharmacist, midwife, or any other person, who by nature or by profession, is in possession of confidential information entrusted to him/her, and who discloses such information other than in circumstances where he/she is called as a court witness or where the law obliges him/her to disclose such information.

1.5. Right to Privacy

Luxembourg is a member of the Council of Europe and has signed and ratified the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data.

Collecting and registering nominal and medical information on computer must be carried out in accordance with the Law of 31 March 1979 on the Use of Nominative Data in Computer Processing¹⁵⁷. The law pertains to individually identifiable data in both public and private computer files. It also requires licensing of systems used for the processing of personal data. The law considers all personal data to be sensitive, although special provisions may be applied to medical and criminal information. For personal data processing by the private sector, an application must first be made to the Minister for Justice who thereafter issues an authorization for such processing to take place.

As a member of the European Union, Luxembourg should have amended this law by October 1, 1998, in order to implement the European Data Protection Directive 95/46/EC. An amending bill was introduced in the Parliament in 1997, but withdrawn in 1998 and not reintroduced due to Parliamentary elections. In January 2000, the European Commission initiated a case before the European Court of Justice against Luxembourg and four other countries for failure to implement the Directive on time. In October 2000 however a new Data Protection Bill has been submitted to the Parliament but hasn't been adopted yet.

2. PATIENTS' RIGHTS AND GENETICS

There exists no specific legislation

¹⁵⁷ [http://www.vocats.com/vocats/leGoueff.nsf/LABNewsEng/3156D7B31F758BE5C12569EE005686DE/\\$file/THE_LINK_Issue_6.doc](http://www.vocats.com/vocats/leGoueff.nsf/LABNewsEng/3156D7B31F758BE5C12569EE005686DE/$file/THE_LINK_Issue_6.doc).

3. GENETICS AND INSURANCE

The use of genetic tests and the use of genetic information is prohibited by the Insurance contract act of 27 July 1997¹⁵⁸. Given that the concept of consent when applying for insurance is deceptive, legislators from Benelux consider the prohibition on using genetic tests to be a public matter that cannot be bypassed, even with the consent of the insurance applicant.

4. GENETICS AND EMPLOYMENT.

There is no specific legislation with regard to the use of genetics in the context of employment.

¹⁵⁸ Article 11, Loi du 27 juillet 1997 sur le contrat d'assurances,
http://www.commassu.lu/Lois/Contrat/L_Contrat.htm (in French).

THE NETHERLANDS

1. PATIENTS' RIGHTS

The Netherlands signed the European Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine on April 4, 1997, though still has not ratified it¹⁵⁹.

The general patients' rights are laid down in the Act on the Medical Contract which has been incorporated in the Civil Code. The law came into force on April 1, 1995.

Intended as a law stipulating the principal rights of patients, the Act on the Medical Contract contains provisions on:

1. informed consent;
2. information;
3. access to medical records/data;
4. retention periods for medical data;
5. confidentiality;
6. the legal position of minors and incompetent adults and their representatives;
7. the use of medical data, of rest material and of anonymous human material for research purposes;
8. medical liability.

Of importance is also that the Act contains a general provision which requires the health care provider to provide the care due from a 'good health care provider'. In this provision reference is made to the professional responsibility of the health care provider, to be derived from the professional standard. It should be stressed that the health care provider will never be able to override the attributed rights of patients as such, with an appeal to his professional autonomy. This is only allowed when this is explicitly laid down in law.

The scope of the legal provisions on patients' rights is also extended to medical actions which are not performed by virtue of a contract, such as medical examinations preceding a private insurance or employment contract. According to Article 7:464 Civil Code, this extension applies only insofar as the nature of the legal relationship permits. This only in as far as the nature of the situation allows for the application of the provisions.

1.1. *Right to Informed Consent*¹⁶⁰

One has to make a difference between the requirement of consent to engage the medical contract on the one hand and the requirement of consent to medical treatment on the other hand. The act of contracting between the provider of care and the patient does not imply the patient's consent to medical treatments.

¹⁵⁹ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹⁶⁰ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/netherlands.pdf>

The requirement of consent to medical treatment can be directly derived from the Constitutional provision on the protection of physical integrity. As such it is a fundamental right.

According to article 7:450 Civil Code, an examination or a treatment requires the consent of the patient. However, consent may be presumed if the procedure in question is not of a radical nature. In case of radical procedures, consent has to be given in writing, but only at the request of the patient.

Generally speaking the legal age of majority and therefore the age at which it is allowed to independently enter into contracts is set at 18 years. the Act on the Medical Contract grants minors the right to independently enter into a medical contract with a health care provider from the age of 16(article 7:447 Civil Code.) For minors under the age of 16, the act works with fixed age groups. Minors under the age of twelve are represented by their parents or guardian. When the minor is over twelve but has not yet attained the age of sixteen, both the consent of the parents (or the guardian) and the minor's own consent are required. There are some exceptions to this rule of double consent.

The consent of only the parents (or guardian) is needed, if the minor is incapable of weighing his/her interests in a reasonable way. However, if the minor objects to a medical procedure of a radical nature for which the parents have given their consent, the procedure may be carried out only if it is manifestly required to prevent serious harm to the minor's health.

The consent of only the minor is sufficient in two cases: firstly, if the examination or treatment is manifestly necessary in order to avoid serious harm to the minor, and secondly, if the minor still deliberately wishes to undergo treatment after the parents have refused their consent.

For all minors (including the ones under the age of twelve) the law rules that the examination or treatment may be carried out without the permission of the parents if there is no time to request consent because the medical procedure has to be performed immediately in order to prevent serious harm to the minor. Minors of sixteen years or older (majority is reached at the age of eighteen years) do not need the consent of their parents.

If an adult patient cannot be deemed capable of making a reasonable assessment of his/her interests in a certain situation, the care provider shall fulfil his/her obligation, in hierarchical order, to a legal representative, to a person authorized by the patient or to the spouse or other partner of the patient, a parent, child, brother or sister of the patient. Their permission may be presumed if the examination or treatment is not of a radical nature. If the incompetent patient objects to a radical medical procedure, the procedure may be carried out only if this is clearly required to prevent serious harm to the patient. No proxy consent is required if there is no time to request consent and the treatment cannot be postponed without causing serious harm to the patient.

A care provider has to fulfil his/her obligations to the representatives of minors or incompetent adults only if this is compatible with good care. This provision leaves the care provider some room to ignore a decision of their representatives when he/she believes that the decision is not in the best interest of the patient. A representative is obliged to exercise the duty of care of a good representative and he/she has to involve the patient as much as possible in the carrying out of his/her duties.

1.2. *Right to Information*¹⁶¹

The right to information is laid down in article 7:448 Civil Code. The patient has to be clearly informed about the proposed examination and treatment and about his/her state of health. Some guidelines are given concerning the aspects the patient reasonably should know: the nature and purpose of the examination or treatment the care provider deems necessary and the procedures to be carried out, the foreseeable risks to and consequences for the health of the patient, alternatives for examination or treatment and, finally, his/her state of health and its future prognosis in relation to the examination or treatment. At the request of the patient the information has to be given in writing.

It goes without saying that, in spite of the elaborate legal provisions on the right to information, it will not always be clear what information the doctor exactly has to divulge to the patient in a particular situation. The criterion of fairness is applied here. As general standard one can use the providing of information about facts and possibilities that a reasonable person in certain circumstances is expected to consider before taking a decision or information that he/she needs to determine his/her behaviour. From case law it can be derived, as a rule of thumb, that the less the treatment is necessary, the more information should be given. Whether or not a patient has to be informed about certain risks depends furthermore on the seriousness of the risk and the chance that the risk will manifest itself. The law explicitly states that minors under the age of twelve shall be provided with information in a way they are able to understand.

Information may be withheld when this would unmistakably cause serious harm to the patient (article 7:448, 3 Civil Code). The doctor is not allowed to invoke this so-called therapeutic exception unless he has consulted a colleague in order to further objectivity when using the therapeutic exception. In any case, if required by the interest of the patient, the doctor should give the information to someone else than the patient. When there is no longer any danger of causing harm, the patient has to be informed as soon as possible.

In a separate provision the right of the patient to refuse information (also called the right not to know) is recognized (article 7:449 Civil Code). When the patient has expressed the wish not to be informed, no information shall be passed on, except when the interest of the patient is outweighed by the harm to him/herself ensuing from withholding information or by possible harm to others.

1.3. *Access to Medical Records*

The right of access to medical records has been recognized in jurisprudence and in law. In 1988 the Supreme Court ruled that the right of access to medical records is closely linked to the constitutionally protected right of privacy, but also has a separate identity. At present the legal basis for the right of access to medical records can be found in both the Civil Code and the Data Protection Act. Meanwhile jurisprudence has a tendency of enforcing this requirement by placing the burden of proof in for instance malpractice suits on the health care provider when such a file does not exist.

The care provider is under a statutory duty to record data on the treatment of the patient (article 7:454 Civil Code). The documents shall be kept for a period of ten years (counted from the date

¹⁶¹ Akveld, H., Hermans, H., "The Netherlands", in Nys, H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1998, 1-112.

on which they were produced) or for as much longer as is reasonable in order to provide the proper standard of care¹⁶². The patient is allowed to add his/her comments to the medical record, but they are not entitled to amend the data as is the case under the Personal Data Protection Act¹⁶³. According to the latter, a patient is entitled to amend his/her record when the data are factually incorrect, incomplete, irrelevant or in contravention of a statutory provision. Patients can demand a copy of their medical records, but are expected to pay the costs.

The records have to be destroyed within three months after receiving the patient's request to that effect. This request may be ignored if it concerns documents which retention is of considerable importance to other persons (including the doctor) or which destruction conflicts with legal provisions. Without such a patient's request, records will be kept for a set period of at least ten years, or so much longer as reasonably follows from the care due from a good health care provider.

The right to access is incorporated in article 7: 456 of the Civil Code and the Personal Data Protection Act (article 35). The right to announcement of registered data is mentioned. This right is also incorporated in section 3 of article 10 of the constitution that contains the right to respect of private life.

According to article 7:456 Civil Code the doctor shall, on request of the patient, provide him with access to and copies of his medical records. Access can be denied only insofar as this is necessary to protect the privacy of others. Access to the physicians' persona notes can be denied. It should be stressed that the care provider cannot invoke the therapeutic exception in order to prevent access to medical data. As a consequence, the patient by using his right of access possibly gets information that the doctor wished to withhold for therapeutic reasons. This is a deliberate choice of the legislator and justified by taking into consideration the different nature of the right to information and the right of access. The aim of the right of access is not to provide the patient with new information, but to allow him to control the information recorded. For providing copies the care provider may charge a reasonable fee.

Besides the right to announce of the demander concerning registered personal data, the Personal Data Protection Act contains a right to correct, to complete and to remove data if they are inaccurate, or if they are incomplete or irrelevant for registration or if they are processed illegally (article 36 Personal Data Protection Act). The Medical treatment Act does not contain a right to

¹⁶² <http://www.gr.nl/nederlands/welkom/frameset.htm>

Health Council of the Netherlands. The term for keeping medical records. The Hague: Health Council of the Netherlands, 2000; publication no. 2000/15.

The present legal requirements for the keeping of medical records raise several questions. Scientists are concerned about the (permanent) availability of medical data, since the law requires such data to be saved in principle for ten years, or so much longer as follows reasonably from the duties of a health care professional.

On 19 April 2000 the Health Council of the Netherlands organized a workshop dedicated to this topic. The discussions during this workshop did point out that there is indeed a problem. Scientific developments show a steady increase in volume as well as in importance, whereas after 2005 a significant fraction of medical records older than ten years may no longer be available.

Three recommendations emerge from the workshop. Firstly: play for time by using the breathing pause until 1 April 2005 offered by the legislator. Secondly it is a matter of importance to thoroughly investigate the possibilities that the law already provides and to fully utilize these. In the third place there is reason to engage in a more fundamental debate about saving medical records. Such debate should take into account the developments in medical care and clinical science, the background of the present legal framework and international aspects.

¹⁶³ http://home.planet.nl/~privacy1/wbp_en_rev.htm

correct but the patient can add a statement concerning the documents incorporated in the file (article 7:454 section 2).

1.4. Confidentiality

The Medical Contract Act stipulates that information about the patient can only be provided to others with the explicit consent of the patient. An exception to this rule can only be made by a legal provision¹⁶⁴. Although this is not explicitly laid down in law, it is generally assumed that disclosure is also permitted in case of conflicting interests. It should be noted that confidentiality is also safeguarded in other legislation; The Criminal Law and numerous provisions in health legislation, for instance the Individual Health Care Professions Act and the Abortion Act.

No (explicit) consent of the patient is required when information is disclosed to persons (not necessarily doctors) who are directly involved in the carrying out of the medical contract, in so far as they need the information to perform their duties in the context of the medical contract.

According to article 8 of the Personal Data Protection Act, Personal data may only be processed where:

- the data subject has unambiguously given his consent for the processing;
- the processing is necessary for the performance of a contract to which the data subject is party, or for actions to be carried out at the request of the data subject and which are necessary for the conclusion of a contract;
- the processing is necessary in order to comply with a legal obligation to which the responsible party is subject;
- the processing is necessary in order to protect a vital interest of the data subject;
- the processing is necessary for the proper performance of a public law duty by the administrative body concerned or by the administrative body to which the data are provided, or the processing is necessary for upholding the legitimate interests of the responsible party or of a third party to whom the data are supplied, except where the interests or fundamental rights and freedoms of the data subject, in particular the right to protection of individual privacy, prevail.

1.5. Right to Privacy

In the Dutch constitution one can find the right to privacy in article 10, that besides the restrictions under the law, gives the right to privacy to everyone.

Data protection in the Netherlands is provided by the *Personal Data Protection Act 2000*¹⁶⁵. This act is a revised and expanded version of the 1988 Data Registration Act that will bring Dutch law in line with the European Data Protection Directive and will regulate the disclosure of personal data to countries outside of the European Union. The Act replaces the Data Registration Act of 1988¹⁶⁶. The new law went into effect in January 2001.

The general scope of the Personal Data Protection Act offers the possibility to more specific regulations concerning the processing of personal data in health care.

¹⁶⁴ Article 7:457 Civil Code.

¹⁶⁵ <http://www.cbip-info.nl/>.

¹⁶⁶ C., Ploem, "Informatieprivacy in de gezondheidszorg: algemene privacywetgeving overbodig?", *Privacy & informatie* 1999, 52-59.

For the purposes of the Act, “personal data” refers to any information relating to an identified or identifiable natural person, and “processing of personal data” means any operation concerning personal data, including the collection, recording, storage, updating and modification, retrieval, use, distribution, linking, blocking, erasure or destruction of data.

Part 2 of the Act contains provisions which apply to the processing of ‘special personal data’. Under section 16, it is prohibited to process personal data concerning a person’s health. However, section 21 contains several exceptions to this general prohibition.

Prior to obtaining personal data about an individual, the responsible party must provide the data subject with certain specified information, including the identity of the responsible party and the purposes of the processing for which the data is intended. More detailed information must be provided if the nature of the data, or the use to be made thereof, is such that this is necessary to guarantee, with respect to the data subject, that the processing is carried out in a proper and careful manner.

The Act provides data subjects with certain rights relating to the processing of personal data that concerns them. Firstly, a data subject has the right to request the responsible party to inform him/her as to whether personal data relating to him/her is being processed.

Secondly, a person who has been informed about personal data relating to him/her has the right to request that the data is corrected, supplemented, deleted or blocked if it is inaccurate, incomplete or irrelevant to the purpose(s) of the processing. Where the data subject is a minor under the age of 16, or a person placed under legal restraint, the requests referred to in sections 35 and 36 must be made by their legal representative.

Article 41 of the Act further provides that a data subject has the right to object to data being processed in connection with the creation or maintenance of a direct relationship between the responsible party or a third party and the data subject with a view to recruitment for commercial or charitable purposes. In the event of such an objection, the responsible party must stop this form of processing with immediate effect.

2. PATIENTS' RIGHTS AND GENETICS

The regulations on clinical genetic testing and counselling of the Standing Committee on Genetics apply to “postnatal and prenatal chromosome, biochemical and DNA testing, the clinical removal of fetal material, advanced ultrasound scanning for fetal abnormalities and complex genetic counselling”. The regulations are designed to assure the quality and continuity of the procedures in question, which are regarded as a form of medical care¹⁶⁷.

The regulations on clinical genetic testing and counselling have been successful in promoting high quality standards. In addition, the relevant professional associations have set up committees to monitor quality and raise quality levels. In the advisory report referred to above, the Health Council expressed its approval of the quality standards in clinical genetic testing. A report into

¹⁶⁷ Clinical genetic testing and counselling. The Hague: Health Council of the Netherlands, Standing Committee on Genetics 1999: publication no. 1999/07 <http://www.gr.nl/engels/welcome/frameset.htm>

clinical genetic testing commissioned by the Health Insurance Funds Council also drew a positive conclusion regarding the quality of test activities.

The committee does not believe that it is necessary to revise the definition of the forms of care covered by the regulations on clinical genetic testing. It is also concluded that concentration of clinical genetic testing in university centers has contributed to continuity and quality improvement. This concentration should be maintained in view of the nature of genetic counselling.

In the light of recent developments in the field of clinical genetics, the committee makes the following recommendations:

- Genetic counselling and the associated test activities should continue to be concentrated in the nominated centers.
- The professional groups involved in clinical genetics should have responsibility for drafting and updating quality requirements; in this context, the government's role should be supervisory.
- Forecasts regarding the level of provision required in this field should take account of the rapid increase in demand for counselling regarding hereditary forms of cancer.

2.1. *Right to Informed Consent*

The consent of the patient has to be explicit because predictive genetic testing has to be considered as radical. Therefore article 7: 466 section 2 of the Civil Code (presumed consent for non – radical treatments) can not be applied. The right to refuse information has a special meaning at the genetic examination.

The fact that a person doesn't want to know if he has a predisposition to a particular disease can be very important to that person within the scope of his/her conception of life. The fact of not knowing can also be important in connection with the duty to announce at examinations preceding the contracting of insurance (infra).

2.2. *Right to Information*

Accurate information is needed to offer the demander of help the opportunity to make a good decision about a possible examination. Information about the eventual consequences of relatives respective about eventual social implications is in this case part of "what the patient reasonably needs to know"(article 7:448 sec.2).

2.3. *Right to Privacy*

Genetic data are important for a long time because of their character and therefore they're preferably longer stored than other medical data. Their importance can be stored several generations. The period of storage according to the Act on the Medical Contract (article 7: 454 section 3 Civil Code) is ten years or can be prolonged as long as reasonably results from the care of a help provider. Based on this phrase genetic data can and shall be stored for a longer period. There has to be responded to the demand of destruction of genetic data. The destruction results in the fact that unwanted information is no longer available. The destruction can be refused if the storage has a considerable importance for another patient (Article 7:455 section 2 Civil Code).

As mentioned above the prohibition to process medical data doesn't apply to the in article 21 of the Personal Data Protection Act mentioned persons and institutions. The 4th section of article 21 regulates a particular aspect of the use of genetic data, namely that this kind of data can only be processed for the benefit of (the treatment of) the person concerned whom the data come from. Because of this, insurers, employers and others are not allowed to use the genetic data which they already possess – by family members for instance-to determine the risk.

In two cases however, the processing of genetic data is allowed: if an important medical interest has priority; and for scientific research and statistics (in the latter case the principle of article 23 Personal Data Protection Act, that in many cases-as general law- will be set aside by the specific and more severe regulation in the Medical Contract Act can be applied).

If the prohibition to process can't be cancelled by article 21 of the Personal Data Protection Act, one has to appeal to article 23 of the Personal Data Protection Act.

As to the processing of sore data (medical data among which also genetic data) for the benefit of scientific or statistical aims- under the circumstances that the requirement of (explicit) consent is impossible or requires a disproportionate effort- a separate legal basis is created (article 23, second section of the Personal Data Protection Act)

It should be noticed that the Act on the Medical Contract (article 7: 458 Civil Code) contains a more severe regulation concerning scientific research. Taken into account that genetic data are rarely collected outside the scope of a medical contract, the restrictive regulation of the Medical Contract Act will have to be applied in most cases.

3. GENETICS AND INSURANCE

Based on the fifth section of article 21 of the Personal Data Protection Act more specific regulations can be set by an order in council for the processing of medical data by insurers, as far as necessary to judge the risk that has to be insured and the person concerned doesn't object or for the execution of the insurance contract by the minister of justice as far as necessary to the imprisonment or measures of detention. For the processing of medical data by the insurers, who insure the financial risk of employers concerning the disease and the disability of their employees, the government has announced that they will use this possibility.

In 1990 the Dutch insurance companies agreed with the Dutch government to comply with the recommendation of the Health Council that genetic testing in connection with access to insurance should not take place¹⁶⁸. The insurance companies promised not to require testing during a period of 5 years, after which they would reassess the situation.

The insurers have prolonged the expiring moratorium on (genetic and HIV-) tests permanently in 1995. In the moratorium, genetic testing is described as: "a medical examination by or via a doctor at chromosome or DNA level with regard to hereditary characteristics".

Insurers are only allowed to ask for a HIV- test if the insured amount exceeds f300.000-(aprox. 136134 Euro),-. A similar regulation is applied to genetic examinations at applicants.: ' By setting the moratorium concerning the genetic examination, the insurers indicated that cooperation to genetic examination is no condition to contract an insurance. Below the limit of f300.000, -(aprox. 136134 Euro), -(insured amount at life insurance) respectively f60.000, -(aprox. 27227 Euro)) /f40.000,- (aprox. 18151Euro) (first/ next risk based o a year at disability insurance) the

¹⁶⁸ Association of Insurers, Moratorium on Genetic Investigation - Policy of Disablement and Life Insurers on Genetic Investigations, December 1990, (1995)

insurers don't require that the applicants announce the result of earlier executed genetic examinations.

Insurers must abstain from using existing genetic test results for life applications up to f300,000 and for disability applications up to f60,000. Insurers must abstain from requesting genetic tests for all application¹⁶⁹.

This moratorium may be cancelled unilaterally with a "waiting period" of a minimum of two years¹⁷⁰.

Partly due to the (theoretical) possibility of canceling the moratorium, the policy concerning the non-performance of genetic testing on persons to be insured, and questions about previous genetic testing on persons to be insured or their families outlined above was incorporated by the legislators into the Medical Examinations Act of 1998¹⁷¹. The Netherlands is the first European country where a comprehensive law on medical examinations was approved by the Parliament. The Medical Examinations Act seeks to regulate the use of medical examinations and to restrict the scope of health inquiries in the context of access to employment and private insurances. This act, that followed the publication of a draft text in August 1992, was introduced in the Second Chamber of Parliament in August 1993. This proposal of law follows extensive discussions in Parliament and society at large on the rights of testees and the permissibility of pre-employment and pre-insurance medical examinations. Regular health check-ups on employees fall beyond the scope of this proposal of law. The bill primarily seeks to regulate the use of pre-contractual medical examinations in the private sector. The act entered into force on the 1st of January 1998.

The Act applies to medical examinations in connection with, among other, a civil pension or life insurance contract, or a civil occupational disability insurance contract. The basic principle of the Act is that individuals must have unimpeded access to socially important facilities such as work and certain insurance; the statute may pose a barrier to the use of genetic testing for insurance purposes, without fully excluding it.

Concerning insurances concluded by the employer, such as retirement or disablement- gap-insurances, no medical examination can be required. It is allowed if an insurance is contracted by an individual or if a self employed person wants to conclude a civil occupational disability insurance contract or if an employee wants to change a former insurance policy.

Sec. 1 of this Law defines "medical check" as follows: "enquiries regarding the health of a subject and medical tests, made or performed in connection with the establishment or amendment of any of the following: (1) a civil contract of employment recognized under or pursuant to the Sickness Benefits Law or the Disability Insurance Law; (2) a contract of public service; (3) a civil pension or life insurance contract; (4) a commitment as referred to in Section 2 of the Pension and Savings Funds Law; (5) a civil occupational disability insurance contract; or (6) a contract of insurance, as referred to in subsection 5 of Section 4, against a risk which exists in the Netherlands".

With regard to their nature, content and scope, medical examinations must be restricted to the purpose for which they are performed. The provision involves a so-called "open standard" which, on the basis of article 9 of the Medical Examinations Act, must be determined by self-regulation.

¹⁶⁹H.C.Q., Van der Giessen, "Is voorspellend medisch onderzoek door verzekeraars toelaatbaar?", *Tijdschrift voor gezondheidsrecht* 1996, 73-76.

¹⁷⁰C.A., Varkevisser "Speelveld of spanningsveld. Is kennis van erfelijke ziekten van nut voor patiënten of verzekeraars?", *Tijdschrift voor Gezondheidsrecht* 1996, 71-73.

¹⁷¹<http://home.planet.nl/~privacy1/wmk.htm>

Furthermore, where medical examinations are permitted, the medical examination may not entail a disproportionate infringement on the prospective insured's personal life. However, two types of medical examinations which, according to the legislature, will in any event entail a disproportionate infringement on the prospective insured's personal life and are thus prohibited in the second paragraph, namely:

- medical examinations regarding the risk of serious, untreatable diseases and
- research into the presence of a serious, untreatable disease that will only manifest itself in later life.

The Medical Examinations Act makes one exception to this prohibition: insurers are allowed to ask about HIV or Aids in two situations. One situation relates to the situation where the insured amount exceeds a certain amount. The other situation concerns the case where an HIV test is permitted if the answers to a number of justified questions regarding the risk of HIV infection give rise to such.

Under section 3 of the Act, the enquiries made, or the test performed, as part of the medical check must not unreasonably infringe the subject's privacy; a medical examination cannot involve inordinate intrusion into the privacy of the individual being tested. Specifically, a medical check must not include a test that entails a disproportionate risk for the subject as against the usefulness of the test to the commissioning party. The example is given of a test intended to provide information regarding the likelihood of the subject developing a serious condition which is untreatable or which cannot be prevented or stabilized by medical intervention, or regarding the presence of a serious, untreatable condition which might not become manifest until some time after the medical check. Accordingly, this provision effectively prohibits the use of presymptomatic or susceptibility genetic testing for serious, untreatable disorders. Regarding genetic testing, when carrying out a medical examination for taking out or changing insurance, insurers may not ask an insured whether the prospective insured has any hereditary, serious, untreatable disease, unless the illness has already manifested itself in the prospective insured. This offers the opportunity to perform genetic tests on less serious, curable diseases when carrying out a medical examination. The law thus embraces a proportionality test for the determination of the acceptability of genetic tests.

Furthermore, section 5 deals specifically with medical checks connected to the closure or amendment of insurance contracts. It provides that no such medical test shall involve questioning the applicant's blood relatives - not even if the illness has already manifested itself or the blood relative has died from it -or, unless the condition is manifest, the applicant him/herself, about hereditary conditions, or about genetic tests which the applicant or his relatives have undergone, or the results of such tests, unless the sum insured exceeds the enquiry limit. The enquiry limit is currently set, in the case of disability insurance contracts, at 60,000 Dutch guilders (approx. 27227 Euro) for the first year of occupational disability, and 40,000 Dutch guilders (approx. 18151 Euro) per year thereafter. Where life insurance contracts are concerned, the enquiry limit is set at 300,000 Dutch guilders (approx. 136134 Euro). Subsection 5(2) states that these enquiry limits are to be adjusted every three years, in line with the cost of living index. (Goedvolk 1999). From the first of January on, the so-called enquiry limit of the Medical examination Act is adjusted. The limit of life insurance was f300.000,- and is raised to f321.300,- (approx. 145800 Euro). The limit of disability insurances was f60.000,- for the first year risk and f40.000,- for the following years. These amounts are raised to respectively f64.260,- (approx. 29160 Euro) and f42.840,- (approx. 19440 Euro).

If the assured amount exceeds that stated then the insurer may ask for the results of any genetic test which has already been taken. However, the insurer cannot require an individual to actually take a genetic test. Below the sum mentioned above the insurer is allowed to perform a HIV test

if the answers to specific questions give cause to. The questions are mentioned in the HIV code of conduct. If the sum assured exceeds the amounts an HIV test can be performed.

It has to be noted that the moratorium and the Medical examinations Act are complementary. The Medical Examinations Act can be completed by agreements of insurers or patients' organizations. In the meantime the moratorium is the first source of interpretation till parties have agreed.

In an evaluation on the Act on Medical Examinations article 5 of the Act has been criticized¹⁷².

Article 5 is too complex and consequently difficult to explain. The complexity of the regulation is not only caused by the dual character but particularly by the second part since a rather innocent hereditary disease does not have to be announced if the knowledge results from former examinations. However it has to be announced if the carrier knows about the disease from other sources.

A second issue is that the diseases mentioned in article 5 refer to the serious and untreatable diseases of article 3. One can question which specific diseases can be considered as serious and untreatable. As there is no such thing as an exhaustive list of serious and untreatable diseases the concept is rather vague. Moreover, the article states that one does not have to announce when the disease is not yet manifest. The problem is that often it is not clear when a disease is manifest. One can interpret for instance a headache as a result of stress but it also can be the start of a disease. The most fundamental problem is the right to keep silent about certain things versus the duty to announce any information that can be relevant to the insurance. What does the person whose father died of Huntington have to do with the question concerning the cause of his father's death?

The next question is what an insurer has to do with information that does not belong to him but that reaches him anyway?

The Personal Data Protection Act advances more severe requirements to the processing of genetic data than to the processing of regular medical data. Genetic data may only be processed in favour of the patient. This implies that the insurer who receives genetic data concerning the contracting of a life insurance or a civil disability insurance can only use these data for that purpose and only related to the person concerned, and not related to possibly insurable or already insured family members. This also implies that the insurer is not allowed to ask questions to the person who wants to conclude an insurance contract about genetic data of family members by means of the application form of the insurance.

3. GENETICS AND EMPLOYMENT.

The concerned organisations bound themselves to the regulations formulated in the Protocol recruitment examinations KNMG. First of all the aim of the recruitment examination is accurately described: " the evaluation of the aptitude of the testee for the post (article 2.1.1.). The examining physician has to be independent and competent and the testee has to be accurately informed.

The articles 2.3.7 en 2.3.8 of the Protocol deserve special mention:

2.3.7 The questions and the examinations have to be relevant to the recruitment examination and have to be necessary to get information about the aptitude of the testee for the job.

¹⁷² M. Westerveld, M. Aersts, "Nieuwe regels voor het verzekeringskeuren: Evaluatie van drie jaar wetstoepassing", *NJB*, januari 2002, 118-126.

2.3.8 Examination and questions that are performed respectively asked in the scope of the recruitment examination may not infringe unnecessarily the physical or mental integrity and the personal life of the testee. If in spite of this such examination are executed or such questions are asked the testee has the right to refuse all cooperation, without any consequences concerning the result of the examination

2.3.9 About the reporting the protocol states that:

Reporting to the principal only contains the consequences of the recruitment examination and can only take place after consent of the testee.

As mentioned above the Medical Examination Act seeks to regulate the use of medical examinations and to restrict the scope of health inquiries in the context of access to employment and private insurance.

Concerning the access to employment the Medical Examinations Act seeks to restrict medical examinations for appointment to a job.

The Act defines a medical examination as following:

- Written questions on health situation
- Oral questions on health situation
- A physical examination

Medical examinations must be performed by a physician. This implies that an applicant does not have to tell anything about his or her health condition to an employer or to a personnel official, besides if it's important for the post someone applies for.

During the selection procedure (the selection interview or the use of selection forms) there is a prohibition for the employer to ask for the health condition and of the applicant.

Medical examinations for appointment to a job have to be aimed at the medical requirements of the post which is tested for. According to the Medical Examinations Act the examinations for appointment to a job can only be performed if there are special medical requirements for that post. The duty to inform of the applicant concerning the condition of health is also restricted to that which is medically required in the scope of the post.

If there's such a post with medical requirements there are a few conditions:

- The medical requirements and the way of examination need to be described before the selection procedure starts.
- At the start of the selection procedure, the applicants have to be informed about the medical requirements related to the job and about the fact that a medical examination will be performed and how the examination will be performed
- A medical examination for appointment to a job (written, oral or physical) is always performed at the end of a selection procedure, when a candidate is chosen for the job if he or she is medically eligible.
- No one is allowed to get information from third parties such as the family doctor or the former employer about the health condition of an applicant without the consent of the applicant

The procedure of a medical examination for an employment has to comply with the following regulations:

1. A medical examination can only be performed if the employer intends to employ the applicant.
2. Preceding the medical examination the employee receives written information on the aim of the examination, on the questions that will be asked and the examinations that will be performed. Furthermore the applicant will be informed on his rights.
3. The medical examination can be performed if the job requires special medical aptitude. It is however not clear what jobs require those medical requirements. The aim is that employers and employer organizations in different branches point out by agreement which jobs need special requirements. If they don't agree within three years this subject will be treated under an order in council.
4. Tests specifically aimed at the detection of (future) incurable diseases are forbidden. This also applies to questions or tests that represent a large infringement on the personal life of the applicant.
5. If the employer doesn't agree with the result he may require a new examination.

The Medical Examinations Act does not contain any sanctions. At the moment it's not clear how the observation of the Act can be forced. The employee could require damages but a procedure to compensation costs a lot of money and time. One can note that the applicant will probably prefer to apply for another job somewhere else.

PORTUGAL

1. PATIENTS' RIGHTS

Portugal signed the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine on April 4th, 1997, and ratified it in August 2001. The ratification is considered to be of great importance for Portuguese health law. The Convention entered into force the first of December 2001¹⁷³.

In Portugal a patients' rights charter was drafted by the Directorate General for Health and issued in 1997 by the Ministry of Health as National Charter¹⁷⁴. Its adoption is presently in force. The majority of the rights listed in this charter are also promoted by civil, penal and traditional health care legislation, which makes patients' rights defensible in court.

1.1. *Right to Informed Consent*¹⁷⁵

On the legal duty of obtaining informed consent before treatment see article 14, n°11, paragraph b), of Law n° 48/90, of the 24th of August¹⁷⁶, and article 80, n°3 of Decree-Law n° 48 357, of the 27th of April 1968. Clause 5 of the Mental Health Act No. 36/98 of 1998 on the rights and duties of the user also covers the issue of consent.

The Penal Code permits a person between ages of fourteen and eighteen to give valid consent to medical treatment if he or she has the ability to fully understand what is involved in the medical treatment in question. Otherwise, consent must be given by the legal guardians of the child, and may only be given to promote the interests of the child¹⁷⁷.

1.2. *Right to Information*

The Code of Medical Ethics of 1985 addresses the issue of informing the patient of his/her state of health. According to article 40, prognoses and diagnoses shall be revealed to the patient, unless the physician, for reasons which his/her conscience tells him/her are important, feels that they should not be revealed. A prognosis of fatal illness may, however only be revealed to the patient

¹⁷³ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹⁷⁴ <http://www.dgsaude.pt/carta.html>

¹⁷⁵ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/portugal.pdf>

¹⁷⁶ *Lei de Bases da Saúde* published in Diário da República, I Série, N° 195, of the 24th of August 1990, pp. 3452-3459.

¹⁷⁷ See article 38°, n°3 of the Penal Code and article n°1878 of the Portuguese Civil code, approved by Decree-Law n° 47 344, of the 25th of November 1966. About the genetic testing of the mentally ill, see article 5, N°1 of Law N°36/98, of the 24th of July (Law on Mental Health). This article prescribes that a mental patient has the right to decide to receive or not to receive medical treatment, except in situations of compulsory placement, or when the absence of treatment would represent a serious danger to the person suffering from a mental disorder or to other persons.

subject to the precautions dictated by a thorough knowledge of his/her temperament, specific health conditions and character; but as a rule it should be revealed to the nearest of kin considered by the physician as suitable, unless the patient has previously forbidden this or has indicated other persons to whom the information should be divulged.

The right to information is also covered by the Law on Mental Health which grants the patient the right to be informed, in an adequate fashion, of his/her rights, as well as the plan for therapy being proposed and the predicted effects.

1.3. *Access to Medical Records*

According to article 35 of the Portuguese Constitution, all citizens have the right of access to any computerized data relating to them and the right to be informed of the use for which the data is intended, under the law; they are entitled to require that the contents of the files and records be corrected and brought up to date. Access to personal data of third parties is prohibited, except in exceptional cases as prescribed by law. Everyone shall be guaranteed free access to public information networks and the law shall define the regulations applicable to the transnational *data* flows and the adequate norms of protection for personal data and for data that should be safeguarded in the national interest.

1.4. *Confidentiality*

Article 26 of the Constitution of the Portuguese Republic prescribes that “everyone is recognized as having the right to protection of the privacy of his or her personal and family life”. Protection of genetic privacy requires that physicians have the duty of respecting the confidentiality of this kind of intimate, personal, information.

In Portugal, the confidentiality of medical information is protected by law (article 14, n°1, paragraph d), of Law n° 48/90, of the 24th of August), and the accepted standards of the confidentiality of medical practice are to be followed as far as possible in what concerns the results of genetic testing¹⁷⁸. Thus, one of the most important ethical and legal obligations of the medical profession is to hold in confidence all patient information acquired during the course of treatment.

The confidentiality of medical information is also protected by professional rules and codes of conduct such as the Code of Ethics of the National Physician’s Association, which states in article 68 that patients are entitled to expect that the information about themselves or others which the physician learns during the course of medical consultation will remain confidential, respectively the Nurses’ Code of Ethics, which prohibits the disclosure to unwanted people of confidential information.

On the other hand the right to confidentiality of personal medical information, is not wholly unqualified. Article 70 of the Code of Ethics of the National Physician’s Association allows the disclosure of medical information if the patient consents so, but article 71 states that, in spite of the doctor’s duty of confidentiality, he/she can take preventive measures when there is danger for life or health of third parties, namely for the other family members. These cases must be dealt on a casuistic basis, by the physician.

¹⁷⁸ See n°8 of Decree n°9 108/97, of the 18th September 1997

1.5. *Right to Privacy*

Portugal is a member of the Council of Europe and has signed and ratified the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data.

The Civil Code has a specific rule to protect privacy (Article 80) and, in a broadly formulated rule, defends individuals against any kind of offence to the basic aspects of their personality (Article 70).

The Portuguese Constitution was revised by constitutional law N° 1/97 of 20 September 1997 in order to be able to transpose the European directive 95/46/EC¹⁷⁹. Indeed, the Portuguese Constitution includes provisions on data protection which, in certain cases, are more restrictive than those of the directive. The Portuguese authority for data protection played an important role in the working group created by the Minister for Justice in order to write the preliminary bill transposing the directive. This preliminary bill was distributed for consultation and was published on the Ministry of Justice's Internet site. The draft law was submitted to Parliament on 2 April 1998 and finally adopted on 26 October 1998¹⁸⁰.

According to article 35 of the Constitution of the Portuguese Republic, computerized storage shall not be used for information concerning a person's ideological or political convictions, party or trade union affiliations, religious beliefs, private life or ethnic origin, except where there is an express consent of the data subject, authorization provided for under the law with guarantees of non-discrimination or, in case of data for statistical purposes, as long as they do not identify individuals. Identical protection is provided to personal data kept on manual files.

The Constitution also states that the access to personal data of third parties is prohibited, except in exceptional situations as prescribed by law. The law shall determine what is personal data as well as the conditions applicable to automatic processing, connection, transmission and use thereof, and shall guarantee its protection by means of an independent administrative body.

The Act on the Protection of Personal Data, Law n° 67/98, of the 26th of October, transposes into the internal legal system Directive 95/46/EC of the 24th of October, on the protection of individuals with regard to the processing of personal data and on free movement of such data¹⁸¹. It limits the collection, use and dissemination of personal information in manual or electronic form. It also applies to video surveillance or "other forms of capture processing and dissemination of sound and images". It replaces the 1991 Act on the Protection of Personal Data with Regard to Automatic Processing.

The Act prohibits automatic processing of personal details relating to "health" (article 11) unless the requirements of article 17 are fulfilled, particularly the stipulation that the processing body must be a public service which has been approved by special law and certified by the National Data Protection Agency, or a private service subject to even stricter requirements¹⁸².

¹⁷⁹ http://www.parlamento.pt/leis/constituicao_ingles/IND_CRP_ING.htm

¹⁸⁰ Third annual report, data protection working group, EU.

www.cnpd.pt/leis/lei_6798en.htm

¹⁸¹ http://www.cnpd.pt/leis/lei_6798en.htm

¹⁸² Guilherme Freire Falcão De Oliveira, LL.D. , Juridical implication on genome knowledge

For instance, the processing of these data is permitted under this law, if it is necessary to protect the vital interests of the data subject. Or if it is necessary for the purposes of preventive medicine, medical diagnosis, the provisions of care of treatment or the management of health-care services, provided those data are processed by a health professional bound by professional secrecy or by another person also subject to an equivalent obligation of secrecy and are notified to the National Commission of Data Protection (called Comissão Nacional de Protecção de Dados). The right to access to genetic data can only be exercised by means of the physician chosen by the data subject.

The processing of personal data (being understood as that information of any type relating to an identified or identifiable natural person, thus the data subject) also has to be carried out transparently and in strict respect for privacy and for other personal rights, freedoms and guarantees. Personal data must, as well, be processed lawfully and with respect of the principle of good faith.

2. PATIENTS' RIGHTS AND GENETICS¹⁸³

The principles that underline the use of genetic tests are contained in the Decree of the Minister of Health n°9108/97, of the 18th of September¹⁸⁴. According to this Decree, physicians can use genetic tests for several reasons: for clinical diagnostic testing, for carrier diagnostic testing, for presymptomatic diagnostic testing, or for prenatal diagnostic testing.

This Decree states that the offering of tests for genetic diseases is always considered to be “a medical act that is done in the interest of the patient”. Tests may only be performed under the responsibility of a physician. This because article 8 of the Statutes of the Physician's National Association¹⁸⁵ (called Ordem dos Médicos) determines that the exercise of the medical profession in Portugal can only be done by a person who is a member of this association. And, according to the following article of these statutes, article 9, the only people who can be admitted into this association are physicians.

Being qualified as a clinical intervention, the tests should be administered, according to article 26 of the statutes mentioned¹⁸⁶, in the clinical benefit of the person who undertakes them.

According to the principles of self-determination and personal autonomy, each individual has the right to decide to do or not to do a genetic test.

Article 25 of the Constitution of the Portuguese Republic defends individuals against any offence to their physical or moral integrity. Consequently, it demands the obtaining of an informed consent prior to any practice of medical intervention regarding genome analysis and it reserves for the individual all power to decide about the knowledge and disclosure of results of genetic testing¹⁸⁷.

¹⁸³ Rui Nunes and Helena Pereira de Melo, “Genetic testing in the workplace. Medical, ethical and legal issues”.

¹⁸⁴ Published in *Diário da República*, II Série, n° 237, of the 13th of October 1997, pp. 12 539- 12 540.

¹⁸⁵ Approved by the Portuguese Government through Decree-Law n°. 282/77 of the 5th of July.

¹⁸⁶ Published in *Revista da Ordem dos Médicos*, n°3/85, Lisbon, March 1985, p. 1.

¹⁸⁷ Guilherme Falcao de Oliveira, Portuguese General Report, 1994.

Article 157 of the Penal Code requires that genetic testing, as any other health procedure, may only be carried out after the subject has given free and informed consent to it. And informed consent to genetic testing means that the person shall, beforehand, be given appropriate information about the nature, benefits, consequences and risks of the procedure.

Decree n° 9108/97, of the 18th of September states that the information that people need to help them decide whether or not to be screened for a genetic disease shall be given in a neutral non-directive way by genetic counselling.

A person is not only allowed to decide if she or he agrees to do the genetic test, but may also refuse or withdraw consent at any time¹⁸⁸.

Portuguese law recognizes the right of the person who was tested to know his or her genetic characteristics since it imposes upon physicians a duty of disclosure of medical results¹⁸⁹. Thus the patient has the right to receive adequate information concerning the nature and extent of his/her genetic disorder, the planned course of treatment, when treatment is possible, and about the prognosis. Although he/she is entitled to know all the information collected about his/her health, the patient may not be fully informed, if he/she wishes not to be informed or if the doctor thinks that the potential benefits of disclosure came to be overshadowed by its potential for harm¹⁹⁰.

Decree n° 9108/97, of the 18th of September, also states that genetic testing of children which is not of immediate benefit to them should normally be deferred until they can give valid consent. An exception may be where testing of the minors is essential for offering advice about the reproductive options open to them (n°7 of this Decree). This, because according to article 1601 of the Portuguese Civil Code, marital capacity is acquired at the age of sixteen, and Law n°3/84, of the 24th of March (on sexual education and family planning) determines that the State shall provide genetic counselling in order to prevent the transmission of genetic diseases (articles 4 and 9 of this law).

3. GENETICS AND INSURANCE¹⁹¹

There is no legislation concerning genetic testing in Portugal but its principles and constitutional norms¹⁹² (especially Article 13, Principle of equality and non-discrimination) are in harmony with Articles 11 and 12 of the European Convention on Human Rights and Biomedicine.

¹⁸⁸ See article 38°, n°2 of the Penal Code.

¹⁸⁹ See article 14, n° 1, paragraph e), of Law n° 48/90 of the 24th of August.

¹⁹⁰ See article 40 of the Code of Ethics of the Physician's National Association, and article 82, n°2 of Decree-Law n° 48 357, of the 27th of April 1968.

¹⁹¹ Eurogapp project 1999-2000.

¹⁹² According to DIAS/VIEIRA/CORTE-REAL, "... no serious objections will be raised about Article 11 of the Convention, according to which: 'Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited'. This solution is just a specific application of the principle of equality, which is enshrined in the Constitutions of all so-called civilised States and, in our country, in Article 13 of the Constitution of the Portuguese Republic. Consequently, any kind of discrimination in the labour or insurance world is illegitimate and any legislation intended to legitimize it is *unconstitutional*'".

Moreover some important guidelines prepared by a task force were published by the Ministry of Health. These guidelines are concerned with the most important ethical and professional rules on genetic testing, namely confidentiality, privacy, and genetic counselling.

In dealing with the issue of the legitimacy of genetic testing by insurers, one should not forget that insurance seekers have a duty to disclose what they know about their own health. In spite of the danger of discrimination in terms of genetic heritage, the insurance contract stands on the declaration of good faith made by the candidate. This duty is crucial in an insurance contract and non-compliance may result in the contractual arrangement becoming null and void under current law (article 429, Portuguese Commercial Code). In this context, the candidate should answer all questions truthfully¹⁹³.

4. GENETICS AND EMPLOYMENT

Portugal does not have any specific law to rule the possible use of genetic information in the context of the employment relationship.

The National Council on Ethics of the Life Sciences published a working paper on the Human Genome in 2000¹⁹⁴. According to this document, the carrying out of genetic tests with the aim of detecting the geno-toxic effects of substances or other factors found in the workplace is justified. However, if the employee has not given his/her consent, after having been fully informed, his/her decision must be respected and he/she may not be dismissed for this reason.

The same solution should hold for genetic screening for predisposition, with the aim of preventing workers who may have a predisposition from having jobs that entail high risk of exposure. In both cases, the intention is to protect the employee, but they should in no case whatsoever degenerate into tests for detecting hereditary diseases in general, which might lead to the genetic discrimination of employees, or become a form of saving costs relative to the improvement of safety conditions in the workplace.

Another solution would be the pre-symptomatic diagnosis of diseases that manifest themselves later on and which are neither caused nor affected by the working environment, but could lead to the employee becoming disabled in the future. According to the National Council on Ethics of the Life Sciences, the employer can only influence employment on the basis of the present, not future, state of health of the applicant. “Excluding persons from the possibility of working, on the basis of genetic tests, is only ethically acceptable when proved to be absolutely necessary for the health of the employee or the safety of third parties.”¹⁹⁵

¹⁹³ Guilherme de OLIVEIRA, Juridical Implications on genome Knowledge, *Law & Human Genome Review*, 7/1997

¹⁹⁴ The Conselho Nacional de Etica para as Ciências da Vida: Working paper on the Human Genome (31/CNECV/2000)

¹⁹⁵ Preliminary Working Paper on the Human Genome (31CNECV/2000), www.cnecv.gov.pt

The confidentiality of data is guaranteed and the right of access is granted only to official inspection authorities. The potentially more informative character of tests based on DNA techniques suggests there is a need to reinforce caution, to guarantee confidentiality.

SPAIN

1. PATIENTS' RIGHTS

Spain has signed and ratified the Convention for the protection of the Human rights and dignity of the human being with regard to the applications of Biology and Medicine, which entered into force the 1st of January of the year 2000¹⁹⁶.

In Spain, patients' rights are dealt with in the 1986 General Law on Public Health and in the 1994 Charter of Rights and Duties of Patients. In addition, the General Council of the Medical Order of Spain has recognized patients' rights in Chapter III of the Code of Deontology.

The General Health Law (Ley General de Sanidad) of 1986 is based on the principle of individual autonomy and the principles of respect for one's personality, dignity and privacy and the prohibition of discrimination (article 10.1). It sets out in Articles 10 and 11 a series of rights and duties of patients and users of public (and in some cases private) health services. These are truly subjective and claimable rights. The General Health Law does however not exhaust the entire range of rights in its regulations, and it is quite possible to find legal grounds for other rights which experts have tended to include in their lists or which have already been set out in so-called Bills of patients' rights and duties¹⁹⁷.

In order for patients' rights to be classified correctly and systematically a specific methodology is required, which would consist of inferring them from the constitution, the General Health Law or any other applicable legal provision.

1.1. *Right to Informed Consent*¹⁹⁸

There is no disputing a patient's right to decide with respect to his/her own treatment. This implies the need for consent on his part – or that of his/her legal representative – once the patient has received the necessary information and also the right to refuse consent if he/she considers it appropriate for his/her personal interests.

The General Health Law assumes this twin right and stipulates that patients and their next-of-kin or relations shall be given full and constant verbal and written comprehensible information on the process, including diagnosis, prognosis and alternative forms of treatment (article 10.5), and also that the patient shall be entitled to choose freely between options given by the physician in charge, in which case the written consent of the patient shall be necessary before any intervention may be carried out (Article 10.6), save where the patient does not have the capacity to take decisions (the consent would then be given by his next-of-kin or those close to the patient). However, there may be nobody available to consent on behalf of an incapacitated person. This situation is covered by article 10.5 of the Spanish Code of Medical Ethics which states that if a

¹⁹⁶ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

¹⁹⁷ Romeo Casabona, C.M., Hernandez-Plasencia, J.U. and Sola-Reche, E., "Spain", in Nys, H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1998, 1-250.

¹⁹⁸ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/spain.pdf>

patient is unable to grant his/her consent and it is impossible or inadvisable to obtain consent from his/her family or legal representative, the doctor may and must provide the care that his/her professional conscience dictates¹⁹⁹.

Article 10.9 of the General Health Law deals with refusal to consent and states that a patient may refuse treatment, in which case he/she shall request to be discharged of his/her own wish. It denies this right to people who are not capable of taking decisions but grants the right to relatives or close friends. The Spanish Code of Ethics also deals with refusal and stipulates that if a patient after having been duly informed about a particular examination or treatment refuses to consent to it, the doctor may refuse to give his/her care on the grounds that the relationship of confidence no longer exists.

1.2. *Right to Information*

The principle of the right to know is not enshrined anywhere in Spanish law although it is applied in various specific regulations, mainly the General Health Law , Sections 10.5 and 61.

Only after a patient has been given the relevant material information he/she will be in a position to give conscious and valid consent. However, the right to information goes beyond this and needs not even be linked to a voluntary act on the part of the patient, as is acknowledged by Article 10.5 of the General Health Law, where it is stated that the information in question needs not always be conceived as being a prior condition for a patient to choose freely and give his/her consent. It implies also that the patient has the right to know about his condition and the treatment process, as well as the right to be given therapeutic information.

It should be noted that not all the information has to be given in both verbal and written form: the choice will depend on the nature of the information and the link between it and a subsequent intervention requiring patient consent. In addition, it should be noted that although Spanish jurists are generally in favor of the criteria governing so-called 'therapeutic privilege', case law support is not yet at hand because the courts have yet to give rulings on the issue.

From the legal standpoint, and in the light of the explicit wording of the General Health Law, the duty to inform admits no exceptions: information must be full and constant and cover the entire process, including diagnosis, prognosis and alternative treatments. In Spain, however, some debate exists as to whether in spite of this some restrictions of or exceptions to this duty to inform may be admitted, especially where a serious or fatal diagnosis and/or prognosis is involved. Although the physician is obliged to give clear and adequate information to the patient, it is possible for him or her to give partial or gradual information only, provided that in doing so his/her intended purpose is not to fraudulently evade his/her duty and that in his/her sound judgement, and in view of the specific circumstances of the case, he/she considers that full information might seriously impair the patient's recovery and hinder beyond repair the success of the treatment. Brief or limited information given to a patient should in all cases accompanied and compensated for by fuller information given to the next-of-kin, since at the end of the day they will have to serve as substitutes for or complement the self-determination of the former.

Article 10.4 of the Spanish Code of Ethics states that the doctor should reveal the diagnosis to the patient, but may be justified in withholding a serious or fatal prognosis. In all cases, the doctor should act with the utmost care, circumspection and sense of responsibility. Nevertheless, it

¹⁹⁹ <http://www.uv.es/~fevepa/2%20CPTA%20SEGUNDA%20omc.html>

should be remembered that the Code serves as a guideline only and has no legal force, and thus does not take precedence over the General Health Law.

1.3. *Access to Medical Records*

Spanish law has resolved the issue of patients' access to their hospital records by granting unrestricted access under the General Health Law, which stipulates that hospital or health records "shall be made available to patients" and that "the authorities shall adopt measures to guarantee these rights and duties" (article 61)

Section 61 of the General Health Law provides the right of access to be exercised directly.

In referring to hospital records in a general sense, regardless of whether they are stored on computer or in written form, the provision covers all forms in which records may be kept; hence, the right of access to the record as recognized in the General Health Law extends also to any information stored on computer.

1.4. *Confidentiality*

The legal situation in Spain has changed in relation to the duty of confidentiality that rests with doctors and other health care professionals, in the light of the right of privacy set out in the Constitution (article 18.1) and recognized explicitly in the General Health Law. This law sets out in very clear terms patients' right to confidentiality, an obligation which extends to all matters relating to the illness, including the very fact that the patient is hospitalized; if so requested by the patient, confidentiality covers the giving of information to family members. The Law also stipulates that full guarantees must exist for patients' right to personal and family privacy and the duty of secrecy incumbent on any person who, in the course of his or her work, is given access to clinical histories (article 61).

Although criminal law protection of professional secrecy in medicine is insufficient, further guarantees are provided in civil law through the Organic Law on the civil protection of the right to honor, personal and family privacy and to one's reputation: Article 7.4 classifies as unlawful intrusion of privacy the disclosure of private information concerning a person or family, knowledge of which is obtained in the course of professional or official activities; this applies equally to ambulatory, hospital and private consultation of patients. In conclusion, the duty of confidentiality is overridden only where expressly stipulated by law or when ordered by a judge on the grounds of a higher legal interest. In all other circumstances it can not be overridden by the doctor without the prior consent of the patient. The passing on to others of information obtained via genome analysis is prohibited unless consent is given by the person concerned or by his or her legal representatives, even where a conflict of interests arises when the third party is a member of the affected person's family and requests the information in order to know whether a pathological gene similar to that discovered in the patient and inherited from the parents might be present in him or her also²⁰⁰.

According to article 14 of the Spanish Code of Ethics, "a doctor's oath of secrecy should be inherent to the exercise of the profession and is established to ensure person safety."

²⁰⁰ Carlos Maria Romeo Casabona, LL.D., M.D., "Legal aspects of genetic counselling", 167-168.

1.5. *Right to Privacy*

Until legislation was passed in 1992 to conform with the requirement laid down in the Constitution to restrict the use of electronic information so as to safeguard the honor and personal and family privacy of citizens and assure full enjoyment of their rights (article 18.4 of the Constitution), a lead was taken from the provisions of the European Convention for the protection of persons with respect to the processing of personal data, done in Strasbourg on 28 January 1981. The Convention became part of internal law in Spain following ratification in 1984, although application often proved complicated because certain crucial parts had not been developed fully by the appropriate legislation.

An Organic Law regulating the computer processing of personal data was passed by the Parliament on 29 October 1992, which stipulates that health-related data may only be collated, processed and passed on when, in the general interest, the Law so provides or when the person to whom they refer gives his express consent (Article 7.3). Public and private health institutions and health-care professionals are authorized to process personal data of persons who seek their help or who are treated by them in accordance with the provisions of the General Health Law, the Drugs and Medicines Law of 1990, Organic Law 3/1986 of 14 April governing Special Public Health Measures and other health laws (Article 8).

This law was repealed by the Organic Law 15/1999 of 13 December on the Protection of Personal Data, which entered into force on 14 January 2001²⁰¹. This Law transposes into Spanish law Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

This Organic Law is intended to guarantee and protect the public liberties and fundamental rights of natural persons, and in particular their personal and family privacy, with regard to the processing of personal data. It applies to personal data recorded on a physical support which makes them capable of processing, and to any type of subsequent use of such data by the public and private sectors²⁰².

This Organic Law governs any processing of personal data: when the processing is carried out on Spanish territory as part of the activities of an establishment belonging to the person responsible for the processing; when the person responsible for the processing is not established on Spanish territory but is subject to Spanish law pursuant to the norms of public international law, when the

²⁰¹ https://www.agenciaprotecciondatos.org/ley_15_ingles_v2_pdf.pdf

Boletín Oficial del Estado of 14 December 1999

²⁰² On 30 November 2000 the Spanish Constitutional Court handed down a judgment in which it declared articles 21.1, 24.1 and 24.2 of Spanish Law 15/1999 on Personal Data Protection (the "LOPD") null and void on the ground of contravention of the Spanish Constitution. Article 21.1 of the LOPD was declared anti-constitutional as it permitted subsidiary legislation to authorise the disclosure of data between public administration, for purposes other than those for which such data was gathered, without the prior consent of the data subject, thus contravening article 53.1 of the Spanish Constitution which lays down that the exercise of fundamental rights can only be re

24, which set

out a series of exceptions to the exercise of the right to access, rectify and cancel personal data, were declared contrary to the Spanish Constitution on the grounds that they were contrary to article 18.4 of the Spanish Constitution. The most striking point about this judgment is that it recognised a fundamental right to data protection, which differs from the right to privacy set out under article 18.1 of the Spanish Constitution. This fundamental right comprises the power to have access and control over personal data which empowers a person to decide which data to provide to a third party, either the State or an individual, or which data such third party may request. It also permits the individual to know who holds such data and for what reason, allowing the individual to object to such possession or use. This judgment has been criticised on the basis that the Constitutional Court cannot admit fundamental rights other than those provided for under the 1978 Spanish Constitution.

person responsible for the processing is not established on the territory of the European Union and is using for the processing means situated on Spanish territory, unless such means are used solely for transit purposes.

Article 8 of the Organic Law 15/1999 on the Protection of Personal Data, states that public and private health care institutions and centers and the corresponding professionals may process personal data relating to the health of persons consulting them or admitted to them for treatment, in accordance with the provisions of the central or regional government legislation or health care.

According to article 6 data subjects from who personal data are requested must previously be informed explicitly, precisely and unequivocally of the following:

- a) The existence of a file or personal data processing operation, the purpose of collecting the data, and the recipients of the information.
- b) The obligatory or voluntary nature of the reply to the questions put to them.
- c) The consequences of obtaining the data or of refusing to provide them.
- d) The possibility of exercising rights of access, rectification, erasure and objection.
- e) The identity and address of the controller or of his representative, if any.

2. PATIENTS' RIGHTS AND GENETICS

The Spanish Kingdom has been Part of the European Convention on Human Rights and Biomedicine, signed by European States in Oviedo, on the 4th April 1997. It has also been part at the UNESCO's Universal Declaration on the Human Genome and Human Rights of 1997. Both international legal texts are very important for an adequate protection of human rights concerned with genetic testing. But it is a common opinion that there is a need for specific regulation, taking into account that the former explained national current rules are not enough for these purposes. It is why Spain is expecting the achievement of a European common legal framework in this field and is looking forward to taking part in the joint works addressed to this main purpose of harmonization of standards and regulations.

In Spain, best practice guidelines for genetic testing have not been developed. Neither does a specific committee on genetic testing exist²⁰³.

3. GENETICS AND INSURANCE²⁰⁴

Article 89 of the Law of Insurance Contracts extends to the specific sphere of life insurance the requirements governing the declaration of risk contained in article 10 of the general provisions of the said law. The law imposes on the applicant the duty, prior to the conclusion of the contract, to inform the insurer of all circumstances known to him or her that might have a bearing on the assessment of the risk. It is for this reason also that in insurance practice all relevant information for the correct evaluation of the risk is gathered by insurers through the twin avenues of a health questionnaire and medical examination.

²⁰³ http://www.oecd.org/dsti/sti/s_t/biotech/prod/gt_spain.htm

²⁰⁴ *ibidem*

The health questionnaire is crucial in terms of the understanding of the rule imposed in article 10, in which the (pre-contractual) duty to provide information is provided; this imposes on the applicant a duty to answer the questions deemed appropriate by the insurer for the purpose referred to above. The applicant or person in whose name insurance is taken out shall be exonerated from any such duty if the insurer does not furnish him/her with a questionnaire or when, where one is provided, circumstances are involved which might influence the evaluation of the risk but have not been included in the questionnaire (Article 10-II). As a rule one can say that the applicant is released from this duty as soon as he/she completes the questionnaire, and cannot be required to furnish a supplementary statement over and above the questionnaire.

Unlike the health questionnaire, the medical examination is not explicitly mentioned in article 10. The Regulations on Private Insurance stipulate that the technical conditions of life insurance must include among the risk selection criteria the requirement of a prior medical examination (Article 57-2 a). The check-up must be accepted by the insured, and is part of his pre-contractual duty, which means that a refusal to undergo an examination or complementary test brings to an end the selection process and releases the insurer from any undertaking to enter into the contract and, consequently, to issue the policy.'

Thus, genetic information of relevance in personal insurance is obtainable from two separate and yet complementary avenues:

- from health questionnaires in which, as occurs in practice, questions are first asked about family background (age and cause of death of relatives) in order to provide an initial impression of hereditary factors which might have a bearing on the risk in respect of which insurance is sought
- via medical reports based on specific testing of the genome of the person concerned.

In order to equate the risk declared pre-contractually with the true or real risk, the Law adds to the aforementioned duty to declare at the time of the contract the obligation to notify any subsequent aggravation of the risk. What about the genetic information to which the insurance company gains access following the signing of the contract?

Under current law insurers do not have an *ex lege* right entitling them to gather genetic information concerning a potential applicant. Neither do they have a right which is born out of the contract itself, since the contract does not actually exist at the moment in time taken into consideration by article 10 in establishing the various cases it covers.

Note that even the health questionnaire itself, notwithstanding the fact that it is mentioned explicitly in article 10, has been the target for criticism by a number of the leading authors because of the disproportionate intrusion into the private life of the applicant.

The Spanish constitution of 1978 forbids any kind of discrimination on grounds of any personal or social circumstance or condition. This prohibition should be applicable too for employers as well as for insurers, if they try to refuse to contract with some applicants being carriers of genetic susceptibility for certain diseases (Karlic & Horak 1998)

4. GENETICS AND EMPLOYMENT

In Spain, legislation makes provisions to distinguish between predictive testing for general health and testing for the protection of workers who are especially sensitive to specific work environments.

In the Spanish Law we can distinguish two types in the context of genetic testing in the workplace:

- a) Genetic testing, that refers to the identification of workers with characteristics or particular inherited illnesses, even of those that present a major susceptibility of being affected in their health by the environment. This kind of test addressed to the protection of the specially sensitive workers to determined risks is ruled in the Labour Risk Preventive Act of 8 November 1995, but there is no provision for applicants to a job.

It is doubtful that it also refers to the situation of susceptibility to known genetic predispositions or to future monogenetic illnesses also known without any type of symptomatology in the moment of entering the work post. The answer to this doubt is negative.

- b) Genetic monitoring, that refers to the periodical examinations to workers with the purpose of identifying mutations in the genetic material of a person induced by the environment, allowing to establish and prevent the damage that because of this matter could happen to the worker, at the time of identifying the risks in a given labour environment, with the purpose of eliminating or reducing them (Labour Risk Preventive Act, article 23)

SWEDEN

1. PATIENTS' RIGHTS²⁰⁵

Sweden has signed, though not ratified the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine²⁰⁶.

In Sweden, patients' rights are promoted in two different ways. Patients' rights pertaining to information, consent, care and treatment are embodied in the Health and Medical Personnel Duties Act. Specific provisions for consent given by a legal representative are laid down in the Code on Parents, guardians and children. The rights to confidentiality and privacy are spelled out in the Secrecy Act and the Health and Medical Personnel Duties Act. Along with the existing legislation, the Federation of County Councils has issued a Charter that contains several principles based on existing legislation and agreements between the Federation of County Councils and the State for promoting patients' rights. This document has been distributed to all county councils with the purpose that the councils should - although on a voluntary basis - build their patients' rights policies according to the principles set out in this document. However, the charter was not designed for providing any legal rights defendable in court, and could not therefore be considered as a national charter.

The Swedish Parliamentary Priorities Commission delivered its final report in March 1995. In the report, the Commission analyzed the pro's and con's of legislation on patients' rights in Sweden. The individual would, no doubt, be in a better position to predict his or her rights and to control that they had been respected if there was a patients' rights legislation. It would also strengthen the position of health services when competing for county council and municipal resources. However, the Commission also found arguments against legislation:

1. It is difficult to define rights of the patient to health care as clearly and meaningfully as, for example, the right to a certain type of housing, financial support or child car from a particular age for handicapped persons.
2. The courts will have difficulty in assessing caring needs, deciding whether measures have been properly taken, and resolving disputes in health care.
3. It is difficult to define legal sanctions which will benefit the individual patient.
4. Administrative overhead costs would increase, both in the administration of justice and in health services.
5. The health services already occupy a strong position in popular opinion, and an adequate monitoring influence is exerted by the preamble to the Health and Medical Services Act.

In 1997, the official report, "The Patient is Right" concluded that patients' rights in Sweden are well protected but the aim should be to propose patients' rights law within the next few years to come. However, in the mean time, a number of complementary provisions have been proposed. These came into force in 1999²⁰⁷.

²⁰⁵ L., Westerhäll, "Sweden", in Nys H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1998, 128 p.

²⁰⁶ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

²⁰⁷ Fallberg, L.H., "Patients rights in the Nordic Countries", *European Journal of Health Law* 2000/7, 123-143.

1.1. *Right to Informed Consent*²⁰⁸

The basis for the requirement of consent is found in the Constitution which states that all citizens are protected against physical measures being taken against their will. This general principle may only be restricted when explicitly provided by law²⁰⁹.

The issue of consent is further addressed in the Health and Medical Services Act (1982:763) in section 2a, which states that health and medical services shall be conducted so as to meet the requirements of good care, one such requirement being the obligation to respect the patient's self determination. This article further stipulates that care and treatment shall as far as possible be designed and conducted in consultation with the patient.

Healthcare personnel have an obligation to obtain consent from the patient prior to every form of physical or mental intervention. There are no special formal requirements for the consent except for pervasive interventions such as sterilization. However, even if the rules of consent are found both in the Medical Services Act and in the Constitution, the provisions are not linked to other rules of sanction than those existing in the Criminal Code. This means that health care personnel who violate patients' right of autonomy can, besides purely public law sanctions, in practice only be prosecuted on grounds of varying degrees of crimes against life and health. Further, patients have no other means of remedy in the case of infringement of the rules of consent than according to the criteria stated in the Tort Liability Act as well as obviously groundless deprivation of freedom at the hands of public authorities.

Relatives are generally consulted but they do not have a specific right to consent to treatment on behalf of an incapacitated person. Consent can be obtained from a custodian who is responsible for ensuring that his/her ward receives the care that he/she needs. If this is not possible and the patient is unable to consent, the doctor must decide on the appropriate treatment in the light of medical science and proven experience²¹⁰.

Regarding to the parents' right to consent for medical care for their children, it should be noted that children are under their parents' custody until they reach the age of 18, or are married. As a rule, both parents are joint guardians. When only one of the parents is the guardian the other parent usually retains some parental rights, but not guardianship. However, when rendering medical care the doctor should always be taken into consideration if the young person is mature enough to understand her/his own situation and the consequences of a particular medical treatment. No precise age limits are provided for in the legislation, but the development in recent years has been that greater consideration must be accorded to a young person's own desires and opinions, increasing with her/his age and maturity²¹¹.

²⁰⁸ <http://www.alzheimer-europe.org/JMA/English/documents/lawnet/sweden.pdf>

²⁰⁹ <http://www.uni-wuerzburg.de/law/sw00000.html>

²¹⁰ H. Leenen, S. Gevers and G. Pinet, *The rights of patients in Europe*, Kluwer Taxation and Law Publishers, Deventer/Boston, 1993.

²¹¹ See: the Parents and Children Code 6:11.

1.2. Right to Information²¹²

In accordance with the Health and Medical Services Act patients must be informed of their state of health and of the treatment methods available (including diagnostic methods) available within the county council area. If this information cannot be supplied to the patient, it must be supplied to a close relative. This obligation is echoed in the Health and Medical Personnel (Duties) Act (1994: 953).

The latter Act requires that medical care personnel shall, to the extent possible, cooperate with the patient when planning the treatment and when treating her/him (§2). As a part of this, the person with the responsibility for the care must make sure that the patient receives information about her/his state of illness and the methods of treatment available. If for some reason the information cannot be given to the patient, the information shall be given to someone close to her/him. This is especially the case when the patient is very young, or unconscious. The information, however, may not be given out if there are grounds to believe that providing such information would be in conflict with the restrictions contained in any statute. (§3)

No regulations exist which require notations to be made in the patient's journal of what information has been given to the patient. The Patient Journal Act has, however, some general instructions concerning for example the fact that the journal must contain the information which is needed for good and safe care (§3) and that information in the journal be written in a way which respects the personal integrity of the patient (§4).

If a patient makes it quite clear that he or she does not want to know the whole truth, supplying information is regarded as inappropriate. In a situation of this kind a doctor may refer to the provision in the Health and Medical Services Act requiring that respect and consideration be shown to the patient.

Among the rules introduced in 1999, the health care personnel's obligation of providing information is specifically emphasized. The provision states that the obligation of disclosure should be adapted to the patient's ability to understand and assimilate it. When there is a choice of equally good treatment alternatives, the patient has the final decision. However, the effect of an alternative has to be related to the costs for the health services system, which is evaluated by the doctor. All information given and the patient's decision are to be documented in the patient's medical record. The provisions are aimed at improving and individualizing the information as well as at increasing patients' influence in the doctor-patient relation²¹³.

Another provision, which did not previously exist within Swedish healthcare, is the right to a second opinion. This possibility has existed earlier in practice in that a patient can turn to another doctor than the one who first gave his opinion. However, the new provision is restricted to patients with a life-threatening or particularly serious disease and where the medical decision is of great importance to the patient or may involve special risks.

²¹² Westerhäll, L., "Sweden", in Nys H., *International Encyclopaedia of Laws - Medical Law*, The Hague, Kluwer Law International, 1998, 1-128.

²¹³ Fallberg, L.H., "Patients rights in the Nordic Countries", *European Journal of Health Law* 2000/7, 136.

1.3. *Access to Medical Records*

The patient has a right not only to receive information orally about the state of her/his health (or disease), but also to read her/his own patient journal. The medical records at public hospitals are public documents, according to the decision of the Supreme Administrative Court in 1951. The right to read public document is regulated in the Freedom of the Press Law, according to which a public documents must, upon request, immediately or as soon as possible and free of charge, be provided. Thus, a patient journal, which is a public document, must as a rule be made available without delay to a person who wishes to see it. The Privacy Act contains some limitations on this general rule (see 1.4).

Concerning patient journals in private health care, the Patient Journal Act contains some special regulations (§12). The statutory text gives the patient a right to read his/her patient journal or to obtain a copy of it. However, no one other than the patient herself/himself is entitled to access under this rule, which means that medical records in private health care are not public documents in the meaning of the Freedom of the Press Law. The person in charge of the medical records decides whether to grant the request or not. If she/he is of the opinion that the patient journal ought not to be supplied, she/he is obligated to report the reasons for her/his decision to the National Social Welfare Board.

1.4. *Confidentiality*

Secrecy provisions covering public health and medical care precluding the supply of information – oral or written – on health status or other personal circumstances in certain situations are contained in the Privacy Act. Substantially identical provisions on private care are contained in the Health and Medical Services Supervision Act.

In the Health and Medical Services (Supervision) Act (1996: 786) it is stated that health professionals may not improperly divulge matters which come to their attention concerning the state of health or other personal matters of individuals. Provisions covering public health and medical care are also contained in the Privacy Act and the Health and Medical Personnel (Duties) Act. According to section 8 of the latter, confidentiality of information also applies to the patient in that information about a patient's state of health may be withheld if it is felt that, bearing in mind the purpose of the care or treatment, it is highly important that it is not supplied to the patient.

The Privacy Act (1980:100) contains the rules on privacy (or secrecy) which provide that certain 'public documents' may not be released to the public, and confidentiality which means that certain information may not be given out orally either. The Privacy Act contains regulations on the limitations of the right of public access to documents, rules on prohibition of releasing certain information, and the duty to observe confidentiality.

The basic rule in the Privacy Act is that information about 'an individual's state of health or other personal conditions' is confidential (7:1). It is not the intention that the information should be kept from the patient (14:4). Exceptions to the rule that the individual has the right to information about herself/himself exist when there are sufficient reasons for concealing the information from the patient in a particular instance (7:3). Another exception concerns reports or statements made by other people (7:6). In addition, as a consequence of the right of the patient to obtain information about herself/himself which for others is confidential information, she/he can consent

to the release of personal information requested by an individual or company, or by a government agency.

Persons not involved in the provision of health and medical care may also be obligated to maintain the secrecy of a person's state of health. A supervisor at one's place of employment may become informed of the health status of her/his employee, and may not pass on this information to another person who does not have a legitimate need for the information. If she/he does, she/he may be liable under the Penal Code for a violation of the obligation of professional secrecy, and in addition if the person is government employed, under the Public Employment Act.

1.5. *Right to Privacy*

The Personal Data Act (1998:204) was adopted by Parliament on 16 April 1998 and came into force on the 24th of October 1998. It replaces the out-dated Swedish Data Act from 1973 which only remains of relevance for processing operations underway on 24 October 1998. The Personal Data Act is based on Directive 95/46/EC which aims to prevent the violation of personal integrity in the processing of personal data²¹⁴.

In addition, the Personal Data Ordinance (1998:1191) was issued on 3rd September 1998. It designates the *Datainspektionen* as the supervisory authority in the sense of Article 28 of Directive 95/46/EC. The Ordinance furthermore delegates the power to decide some exemptions from the provisions of the Personal Data Act such as transfers of data to third countries, notification, prior checking. On 8th September 1998 the *Datainspektionen* issued two regulations on the basis of the Ordinance: one on exemptions to the prohibition for persons other than authorities to process personal data concerning violations of laws etc.; and one concerning the notification of personal data processing to the supervisory authority²¹⁵.

2. PATIENTS' RIGHTS AND GENETICS

In 1982, the Swedish Government appointed a commission to make an inquiry into the ethical, humanitarian and social issues, arising from the use of genetic engineering. The members of the Gene-Ethic Commission represented the various political parties in the Riksdag, and included experts from various fields of science and society.

2.1. *Right to Consent*

There are some statutes that contain specific provisions concerning consent. The Act on using some genetics at general health investigation is also of interest in this connection. According to this act, the study of human genetic codes by analyzing genetic DNA requires special permission if it constitutes or forms part of a screening program. Among other things, the granting of permits takes into account whether the study has a clear medically justified aim and whether the genetic information collected will be effectively safeguarded. Participation in any study is voluntary, and

²¹⁴ http://www.datainspektionen.se/in_english/

²¹⁵ Third annual report, data protection working group, EU.

written consent must be obtained from the participant. Questions relating to permits are decided by the National Board of Health and Welfare.

2.2 *Access to Medical Records*

When genetic testing using DNA or RNA analysis is performed at the request of the individual or in connection with medical screening, any data derived from the genetic analysis will come under the provisions of the Individual Medical Records Act. This means that the data will be entered in the individual's medical record. In principle, the individual has a right of access to his or her medical record. Moreover, like other medical information, genetic data held in an individual's medical record may not in principle be divulged to third parties such as employers or insurance companies without the person's consent.

2.3 *Confidentiality*

Data entered in records kept by public health and medical services come within the Secrecy Act 1980, specifically the provisions contained in Chapter 7 of the Act. Data in an individual medical record kept outside the public health and medical sector comes under the Act concerning the supervision of health and medical personnel and others (the Supervision Act) 1980. The result is that the data are subject to the secrecy applying to health and medical care. If genetic data are to be used for purposes other than the needs of the individual himself (e.g. it is to be used in the planning of medical services), then the individual's consent must be obtained. The physician must explain to the individual as clearly as possible the implications and possible consequences of disclosing the data before they are divulged. Furthermore, information used for the purpose of medical planning and so forth is usually de-identified.

2.4 *Right to Privacy*

The Swedish Ministry of Health and Social Affairs has stated that there is no reason why genetic information should require special privacy protections. The rationale for adopting this position is that any data obtained in the course of a genetic examination already comes under existing privacy protections, and "ought in principle to be treated in the same way as other information with a sensitive bearing on personal integrity and privacy".

The Swedish Ministry of Health and Social Affairs considers that these protections adequately protect genetic information from potential misuse. However, the National Board of Health and Welfare is tasked with monitoring developments in the treatment of genetic information. This board has the right to raise the question of supplementing existing safeguards through legislation or other means if it considers such measures would be appropriate, though, as yet, it has not done so.

The use of information about an individual which has been obtained by studying his/her genetic characteristics other than for medical purposes is prohibited by the Act 114 of March 1991 on the Use of Certain Gene Technologies within the Context of General Medical Examinations (1993). Genetic discrimination can be subject to penalties in the form of fines or prison sentences up to a maximum of 6 months.

3. GENETICS AND INSURANCE²¹⁶

A memorandum on genetic information of individuals in certain particular cases was produced by the Ministry of Social Affairs in 1996. Paragraph 1 of this memorandum prohibits requesting or using “genetic information about an individual’s susceptibility to a certain disease, which cannot be detected in any other way by any party other than the one for which the information was obtained. Such information is only to be used for medical purposes.” The definition of genetic information extends to information obtained through family histories. Paragraph 7 of the memorandum refers to the penal code, and indicates that genetic discrimination may be subject to severe fines or penalties.

On 1 January 1998, the Federation of Swedish Insurers released a statement whereby “the insurer will not inquire about results from genetic testing or take into consideration such results when assessing risks below SEK 250 000 (27158 Euro)”.

The voluntary code is an agreement amongst members of the Insurance Federation selling life or disease-benefit insurance to limit the use of genetic information in risk assessment. For the purpose of the agreement, “genetic testing” means “a genetic diagnosis of inherited predispositions in the genes and chromosomes in those instances where the predisposition has not yet given rise to a disease”, i.e. pre-symptomatic genetic testing.

Under this agreement, insurance companies may not require insurance applicants to undergo genetic testing in order to obtain an insurance policy, or extend an existing insurance policy. The agreement also sets a limit on the sum insured, below which insurers are not permitted to take into account the results of any genetic tests an applicant has already undergone. Accordingly, insurers may not consider existing genetic test results in connection with an insurance application (or an application to extend an existing policy) when the total risk exposure is less than:

- SEK 250,000 if the sum insured is to be paid as a lump sum upon the death of the insured, or SEK 15,000 (1629 Euro) per year if the sum insured is to be paid as annuity to the survivors upon the death of the insured;
- SEK 250,000 if the sum insured is to be paid as a lump sum when the insured becomes ill, or SEK 15,000 per year if periodic compensation is to be paid during the insured’s illness.

Under this agreement, the Federation’s member companies have undertaken not to require or request genetic investigations when insurance contracts are signed or existing contracts extended, up to an inflation-indexed once-only lump sum of, at present, just over SEK 500.000.

The Federation also undertook in the agreement to set up a complaints body for insurance companies’ conduct with respect to genetic information. A committee for dealing with genetic information has existed in the Federation since 1 July 1999.

During 1998 and early 1999, a working group of the Ministry of Health and Social Affairs, in which the Swedish Insurance Federation was represented, looked at the issue of genetic testing

²¹⁶Eurogap; Human Genetics Commission, Protection of genetic information: an international comparison, 34-37

and insurance. In particular, the working group considered the likely consequences of a statutory ban on using results from genetic testing in insurance operations. The work culminated in the signing of an agreement between the Swedish State and the Swedish Insurance Federation on 31 May 1999, governing the use of genetic testing and genetic information by insurance companies²¹⁷. The agreement aims to attain a reasonable balance between the interests of insurers in obtaining information and the public interest in maintaining genetic integrity.

The agreement applies to insurance companies that belong to the Swedish Insurance Federation and market either life or health insurance in Sweden. However, it does not apply to “child insurance”, occupational group life insurance or collectively agreed group health insurance.

The agreement entered into force on 1 July 1999 and applies up to and including 31 December 2002. Under section 8, the agreement is to be extended by two years at a time. However, the agreement may be cancelled by either party, if effected in writing at least 6 months before its period of validity expires. The State is entitled to cancel the agreement with immediate effect in the event of an insurance company disregarding what the Insurance Federation has undertaken to ensure under the terms of the agreement.

For the purposes of the agreement, ‘genetic testing’ means:

- genetic tests carried out prior to the appearance of symptoms;
- genetic tests carried out for predictive purposes; and
- genetic tests carried out in order to demonstrate or exclude the possibility of people being genetically predisposed to a hereditary disorder or disease that manifests itself only in subsequent generations.

In accordance with section 3 of the agreement, the Swedish Insurance Federation undertakes to ensure that its members do not require insurance applicants to undergo genetic testing as a condition for taking out insurance, or for extending existing insurance contracts.

Section 4 of the agreement provides that the Insurance Federation undertakes to ensure that its members do not inquire as to whether the applicant or policy holder has undergone genetic testing, or request the results of any such tests, nor demand family particulars. It also provides that members of the Insurance Federation are not permitted to take into account in their risk assessment any data from genetic testing or family particulars. “Family particulars” means information relating to the incidence of hereditary disorders or diseases among an applicant’s relatives.

However, the section also provides that in certain specified circumstances, the general prohibition will not apply, including:

- if the sum insured that is due as a lump sum on the death of the insured exceeds 15 times the ‘price base amount’ (the price base amount is a figure in Euro linked to price trends and is adjusted annually) under the *National Insurance Act* 1962; or
- if the sum insured that is due as a periodic survivor’s pension or survivor’s annuity on the death of the insured exceeds one ‘price base amount’ a year; or
- if the sum insured that is due, if the insured falls ill, to be disbursed in the form of a lump sum exceeds 15 times the ‘price base amount’ under the *National Insurance Act*; or
- if the sum insured that is due, if the insured falls ill, to be disbursed in the form of a periodic allowance exceeds one ‘price base amount’ a year.

²¹⁷ Agreement Between the Swedish State and the Swedish Insurance Federation Concerning Genetic Testing (May 1999).

In terms of life insurance, the ‘sum insured’ refers to the total sum insured for death risks for the insurance policies applied for and for policies already taken out. In health insurance, the ‘sum insured’ refers to the total sum insured for health risks for the insurance policies applied for and policies already taken out. Thus, the exceptions also apply when policyholders apply to increase the scope of their insurance beyond the specified thresholds.

The agreement also specifies that members of the Insurance Federation are prohibited, in the terms and conditions of their health and life insurance, from exempting any illness with respect to disbursement of insurance indemnity, except on the basis of symptom-based assessment.

Under the terms of the agreement, the Insurance Federation is required to set up a review board charged with issuing recommendations concerning reassessment in cases where insurance applicants are dissatisfied with the way an insurance company has dealt with genetic information. A review board has existed since 1 July 1999 and, to date, no case has been referred for review. The State assumes responsibility for ensuring that developments in medical and clinical genetics are continuously monitored and comprehensively analyzed by a public body specially appointed for the purpose.

The agreement reached between the Swedish State and the Swedish Insurance Federation in 1999 has, in principle, the same effect as the Insurance Federation’s voluntary code, which has been in effect since 1998²¹⁸.

4. GENETICS AND EMPLOYMENT

There is currently no legislation in Sweden that deals specifically with the use of genetic information by employers, or prohibits employers from requiring applicants or employees from undergoing genetic testing. However, under existing legislation, genetic information, like other medical information, may not in principle be disclosed to third parties such as employers without the individual’s consent.

Moreover, the Ministry of Health and Social Affairs has stated that it would be unethical to require genetic analysis as a condition of employment, as this would violate the liberty of the individual and be incompatible with humanist principles.

Furthermore, in 1999, the Swedish Parliament resolved on a communication from the Government stating its intention to appoint a parliamentary committee to consider how genetic integrity is to be maintained in every sector of society. It is likely, therefore, that the committee will consider the issue of genetic testing in employment.

²¹⁸ Swedish Insurance Federation, “Agreement on limiting the use of information derived from genetic testing during risk evaluation of life and sickness-benefit insurance” (24 September 1997).

UNITED KINGDOM

1. PATIENTS' RIGHTS

The United Kingdom has neither signed nor ratified the European Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine²¹⁹.

The commitment to patients' rights in the United Kingdom is enshrined in the Patients' Charter (England, Wales, Scotland and Northern Ireland have separate charters), which is part of the Citizens' Charter initiative. The government first issued the Patients' Charter in 1991 to create a better National Health Service (NHS). The Charter lays down ten rights and ten national standards that are not legal rights but reflect the aim of the NHS to provide additional services to its users, "as circumstances and resources allow". In 1995 a revised version of the Charter was issued, extending its coverage to dental, ophthalmological and community pharmaceutical services²²⁰. When the Labour government took office in 1997, it instigated a review of the Charter, and the report produced later that year "The new NHS Charter – a different approach"²²¹ identifies many shortcomings. As of 1 April 2001, "Your Guide to the NHS"²²² has replaced the Patients' Charter in England. The Patients' Charter still applies in Wales, Scotland and Northern Ireland.

1.1. *Right to Informed Consent*²²³

In medical negligence cases, courts in Britain use the tests set out in *Bolam* and in *Hunter v Hanley*. What has become known as the *Bolam* test is a common law elaboration of the tests set out in these two cases and 'may be formulated as a rule that a doctor is not negligent if he or she acts in accordance with a practice adopted at the time as proper by a responsible body of respectable medical opinion'. These tests inhibit importation of the informed consent doctrine because they test negligence relative to the medical profession rather than relative to the patient's point of view.

However, several cases indicate a greater judicial sensitivity to patients and show *Bolam* to be useful to plaintiffs. Assessing 'materiality' relative to current medical practice means that as the medical profession acknowledges a greater need for patient autonomy, courts will have to take the patient's point of view increasingly into account under the *Bolam* test. Given the Patients' Charter and documents like the European Convention on Human Rights and Biomedicine, the medical profession and the law will move in the same direction, this is that informed consent will come to the United Kingdom, though not as a wholesale doctrine²²⁴.

²¹⁹ <http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=7&DF=>

²²⁰ <http://www.health.fgov.be/WHI3/periodical/months/wwhv2n1tekst/WWH19019807.htm>

²²¹ <http://www.doh.gov.uk/charter.htm>

²²² www.nhs.uk/nhsguide

²²³ http://www.alzheimer-europe.org/JMA/English/documents/lawnet/england_wales.pdf

²²⁴ Earle, M., "The future of informed consent in British Common Law", *European Journal of Health Law* 1999/9, 235-248.

1.2. *Right to Information*

According to jurisprudence, the duty to inform patients is one of the elements of the ‘duty of attentiveness’ of the care providers. On the other side, the Patients’ Charter, a document published by the Ministry of Health which contains the rights of patients towards the providers of care of the National Care Service, specifies that preceding a decision, the patient has the right to get clear information about the offered treatments and their secondary effects and the considerable alternative solutions.

1.3. *Access to Medical Records*²²⁵

It might be supposed that patients have a proprietary right in their own medical records and thus have a right of access to them as consequence. However, in the public sector such records are the property of the appropriate health authority or NHS Trust, and in the private sector such matters are determined by reference to the precise contractual arrangements made between the parties. The only English case to directly address the question as to whether patients have a right to access to their health records under common law is *R v. Mid Glamorgan Family Health Services Authority, ex parte Martin* in which the Court of Appeal displayed implicit support for a limited right of access.

The Access to Medical Reports Act 1988 governs reports made for employment and insurance purposes by the subject’s own medical practitioner and requires the permission of the subject for the report to be made. In addition, this Act entitles the subject to the opportunity to see the medical report before it is forwarded to an employer.

Like all the other electronic files, the medical electronic files can be consulted by the interested persons, who have a right to access according to the law of 1984 on the protection of personal data. Those regulations related to the right to access that are incorporated in the law of 1998 on the protection of personal data, which repeals the law of 1984, came into force in October 2001. The patients have the same right according to the non-electronic medical files, based on the law of 1990 on the medical files.

The medical files introduced from the 1st of November 1991, the date the law of 1990 on the Health Files came in to force, can be consulted by the patients. The law applies to all files administrated by or for professionals and related to physical or mental health.

The Data Protection (Subject access Modification) (Health) Order 2000 stipulates that the right to access does not apply to a health record where disclosure would be like to cause serious harm to the physical or mental health or condition of the data subject or any other person.

Access may only be denied where either, in the opinion of the holder, access to the information would be likely to cause serious harm to the physical or mental health of the patient or any other individual, or would disclose information, unless the individual concerned has consented to the application, or is a health professional who has been involved in the care of the patient (Section, 5). Where access is excluded there is no duty upon the record holder to inform the applicant that information exists and has been excluded, only to inform him/her that he/she does not hold any information that he is required by law to disclose.

²²⁵ Les documents de travail du sénat belge. « L’information des malades et l’accès au dossier médical », Octobre 2000.

The persons who didn't obtain the right to consult their file can bring the case before the court, which can impose that satisfaction has to be given.

The law of 1990 qualifies as children the minors younger than 16 years old. To the extent their capacity of comprehension is established, they have the same rights of adults. If the children can't exercise their rights themselves, their parents can do it, unless the children explicitly objected. The rights of the incompetent adults are exercised by the person the court has pointed out.

1.4. Confidentiality

There is no definite statement in English law to what constitutes "confidential information", but it would certainly extend to all information which the doctor receives from the patient in the course of the professional relationship, including information that was not strictly medical information. It would also encompass information about the patient which the doctor receives by virtue of his/her professional position, such as test results, X-rays, etc. It might even include information about the patient communicated by a third party who was aware of the doctor's professional relationship with the patient. Information already in the public domain will typically not be confidential. No obligation attaches to information from which the patient cannot be identified.

Apart from the duties at the common law, there are also certain specific statutory duties of confidence attaching to health professionals. These include:

- The duty imposed upon every health authority under the National Health Service Regulations 1974 to take all necessary steps to secure that any information capable of identifying any individual being examined or treated for any sexually transmitted disease should not be disclosed except for the purpose of communicating that information to a medical practitioner (or to a person employed under his direction), in connection with the treatment of persons suffering from such a disease or the prevention of the spread thereof and for the purpose of such treatment or prevention. These regulations have not however as yet been amended to apply to NHS trusts.
- The duties imposed under the Human Fertilization and Embryology Act 1990 upon members of the Human, Fertilization and Embryology Authority and upon license holders.
- The duty remaining from the Police and Criminal Evidence Act 1984 under which certain material is 'excluded material' from the normal provisions enabling courts to make special orders for the production of documents required for criminal investigations (Section 9(1)). This covers personal records (which includes health records) created or acquired for professional purposes, and human tissue or tissue fluid taken for the purpose of diagnosis or medical treatment, and held in confidence.
- The duty under the Data Protection Act 1998 relating to the 'processing' of personal data, which includes also the disclosure of such information to employers or insurance companies. According to this act, a person cannot apply to a medical practitioner for a medical report about someone else for insurance or employment purposes unless he/she has notified that person and received the consent of that person.

There is no statute which specifically and solely deals with the issue of confidentiality. However, in a statement of 1995 by the general Medical Council, it is stipulated that doctors may disclose relevant information to an appropriate person being or authority if the patient is mentally incapacitated, he/she would not consent to the appropriate person being involved in the consultation and the doctor considers that disclosure would be in the patient's best interests.

In addition there are powers contained in the Health and Social Care Act 2001 permitting the Secretary of State, by regulations, to make provision for and in connection with requiring or regulation the processing of patient information for medical purposes as he/she considers necessary or expedient in the interest of improving patient care or in the public interest.

The General Medical Council's Guidance, Confidentiality (2000) states that protecting and providing information suggests disclosure which is permissible with the patient's voluntary consent, for instance to employers or insurance companies, and even despite the lack of consent in various instances e.g. for research, teaching and audit, as well as certain managerial purposes. As a general proposition this is also the case under the common law. Indeed, the Courts have paid much heed to the General Medical Council's Guidance in the past in this context. In order to consent to disclosure the patient must be able to understand what will be disclosed, the reason for disclosure and the potential consequences of disclosure. Such consent may be express or implied. The General Medical Council's Guidance states that express consent is usually not needed before relevant personal information is shared to enable medical treatment to be given, provided patients are aware that personal information about them will be shared within the health care team, unless they object. Such wishes should be respected unless this would put others at risk of death or serious harm.

1.5. *Right to Privacy*

In the United Kingdom, the Home Office is responsible for legislation on data protection. The UK government decided to replace the 1984 Data protection Act by a completely new Data Protection Act. A bill to this effect was submitted to Parliament on 14 January 1998, and passed in July 1998²²⁶ (Royal Assent was given on 16 July 1998). The bill establishes the core elements of the new UK data protection regime. The content of further necessary subordinate legislation has been subject to consultation, and the necessary instruments have been drafted and laid before Parliament. The main provisions of the Act came in to force on 1 March 2000. The Data Protection Act 1998 gives effect to the EU Data Protection Directive.

Under the Data Protection Act, there are conditions which must be met before personal data can be processed (a term which encompasses everything from collection to destruction). Data protection considerations impact on the collection, storage and use of genetic test information by employers and the Data Protection Act extends data protection law in the UK for the first time to certain types of manual records. The handling of genetic test results, which are sensitive personal data, should meet the standards set by the Data Protection principles of fairness and lawfulness.

The Data Protection Act 1998 sets the following principles:

- Personal data shall be processed fairly and lawfully and can only be processed in specific circumstances.
- Personal data shall be obtained only for one or more specified and lawful purposes and shall not be further processed in any manner incompatible with that purpose or those purposes.

²²⁶ <http://www.legislation.hmsso.gov.uk/acts/acts1998/19980029.htm>

- Personal data shall be adequate, relevant and not excessive in relation to the purpose(s) for which they were processed.
- Personal data shall be accurate and where necessary kept up to date.
- Personal data processed for any purpose(s) shall not be kept longer than necessary for those purposes.
- Personal data shall be processed in accordance with the rights of data subjects under the Act.
- Appropriate technical and organizational measures shall be taken against unauthorized or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
- Personal data shall not be transferred to a territory outside the European Economic Area unless that territory ensured an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

2. PATIENTS' RIGHTS AND GENETICS

There is no specific legislation.

3. GENETICS AND INSURANCE²²⁷

In UK insurance contract law, the applicant must give all material information to the insurer when the contract is made. Information is 'material' if it would influence the judgement of a prudent underwriter and affect the underwriter's decision when fixing the premium or deciding to insure the risk at all. Factors which are relevant to insurers are similar to those used by doctors to help establish health risks for individuals and patterns of risk across the population. They vary according to the type and length of insurance contract being offered, but generally include: age, sex, height, weight, occupation, lifestyle, personal medical history, including genetic test results, and family history.

Genetic testing in relation to insurance received little public attention until it was raised after the 1991 International Workshop on Human Gene Mapping, held in London, since when it has had widespread media coverage and professional discussion.

In the United Kingdom, the use of genetic tests in insurance is not regulated by statute but is subject to a system of reflexive procedural regulation where the use of genetic tests in insurance is subject to oversight by government advisory bodies. The United Kingdom insurance industry plays a significant role. In 1997 there were 840 insurance firms employing almost 250,000 people. The economic power of this industry may explain the relatively light regime of regulation which has been developed. The regulatory structure which has been set in place in the United

²²⁷E.D., Cook "Genetics and the British insurance industry", *Journal of Medical Ethics* 1999/25, 157-162.

Kingdom depends on co-operation between the insurance industry, as represented by the Association of British Insurers(ABI)²²⁸, and government-appointed advisory bodies.

The Nuffield Council on Bioethics is an independent body established by the Trustees of the Nuffield Foundation in **1991** to consider the ethical issues arising from developments in medicine and biology²²⁹. Immediately the Council set up a working party on Genetic Screening. Parts of the reference of the Working Party was to look at the ethical issues affecting both individuals and society which arise or may arise in the future in relation to genetic screening and insurance. The working party published in **December 1993** (reprinted in 1995, 1996) the report *Genetic Screening: Ethical Issues*²³⁰. Recommendations were made that British insurance companies should adhere to their current policy of not requiring any genetic tests as a prerequisite of obtaining insurance and should accept a temporary moratorium on requiring the disclosure of genetic data, except :

- in the case of those individuals where there is a known family history of genetic disease that can be established by the conventional questions about families, then individuals may be asked to disclose the results of any relevant genetic tests; and
- the moratorium should apply only to policies of moderate size.

Subsequent to the publication of the Nuffield Council, Parliament asked the House of Commons Select Committee on Science and Technology to hold a major and wide-ranging review of the science of human genetics and it's impact, both now and in the future, on individuals, institutions and society.

In **July 1995**, the Select Committee on Science and Technology published its Report, *Human Genetics: the Science and its Consequences*²³¹.

On the issue of insurance, the Committee suggested that it would be possible to find a way for insurers to protect themselves and for as many people as possible to obtain insurance. It was surprised that the ABI felt that "the use of genetic information in insurance is limited and raises no new problems" and drew attention both to the risks of adverse selection and to the potential creation of a group unable to obtain insurance. In conclusion, the Committee recommended that "the insurance industry be allowed one year in which to propose a solution acceptable to Parliament, and that if it fails to do so a solution should be sought, by legislation if necessary".

In its Response to the Committee, the Government confirmed that it would keep in touch with developments in the area, but could not see any widespread problems at that time²³². It stated that "the Government does not believe that legislation would be appropriate now or in the foreseeable future". Nor did it believe that a deadline should be imposed on the insurers for their response, but rather that the insurance industry could be expected to develop its own code of practice. It also thought that a Human Genetics Commission was unnecessary.

²²⁸The ABI represents over 400 insurance companies, which between them account for over 96% of the business of UK insurance companies. The association represents insurance companies to the Government and to regulatory and other agencies, and it provides a wide range of services to its members.

²²⁹<http://www.insurance.org.uk/>

²²⁹<http://www.nuffieldbioethics.org/home/index.asp/>

²³⁰http://www.nuffieldbioethics.org/publications/pp_0000000005.asp

²³¹ Human Genetics: The Science and its Consequences; Third report. House of Commons Science and Technology Committee. July 1995. HC231. HMSO.

²³² Government's Response to the Third Report of the House of Commons Select Committee on Science and Technology, 1994-95 Session, DTI, Cm 3061, January 1996.

In a follow-up *Report on the Government's Response* in **1996**, the Committee expressed its regret that the Government had ignored its chief concern, that the use of test results might lead to significant differentials in insurance pricing, and that the Response might actually have reduced the urgency with which insurers were developing their own code of practice. Subsequently, the Government did agree to another of the Committee's recommendations, however, that a body be appointed which could offer "a timely and independent view" on genetic testing. The Advisory Committee on Genetic Testing²³³ (ACGT) was established in **June 1996** as part of the 1995 Select committee on Science and Technology report on Human Genetics to advise on the ethical, social and scientific aspects of genetic testing. In their 1995 report on human genetics, the House of Commons Select Committee on Science and Technology highlighted concerns over genetic testing services offered direct to the public as mentioned above. ACGT gave this issue early attention and consulted in late 1996 on a draft voluntary Code of Practice. The final version was published in September 1997. In **July 1996**, a major debate on the review of the Select Committee's Report was held in Parliament and prior to this debate the ABI was urged by the Minister of Technology and Science to make a public statement on progress. On the 17th July 1996 the ABI announced its intention to appoint an independent Genetic Advisor whose role would be to advise the ABI and the Consultant Medical Officers of Insurance Companies on genetic development and the proper interpretation of these developments. In the Parliamentary debate on the 19th July 1996 there was strong criticism of and frustration at the ABI's lack of progress in developing a code of practice with interested parties. There was somewhat grudging acceptance that the ABI had done something in announcing the appointment of a Genetics Advisor. Subsequently, the Minister wrote to the ABI seeking assurance that much more would be done more quickly. As a result of this in October 1996 the ABI appointed Prof. Sandy Raeburn as its Advisor on Genetics and it also set up a Genetics Committee in December 1996 to formulate a code of practice and which would report direct to the Management Committee of the ABI.

The *Human Genetics Advisory Commission* (HGAC), though not the statutory body recommended by the Select Committee on Science and Technology, was established in 1996²³⁴. The commission was set up in **December 1996** as a non-statutory advisory body to report on issues arising from developments in human genetics that have wide social, ethical, and economic consequences to both Industry and Health Ministers. It had a membership of both expert and lay members, with a secretariat drawn from the Office of Science Technology. Its terms of reference were: to review scientific progress in human genetics; to report on issues arising from developments that could have wider social, ethical and/or economic consequences; and to advise on methods to build public confidence in, and understanding of, genetics. At its first meeting on 27 February 1997, the HGAC identified the issue of genetic testing for insurance as meriting early consideration and established a sub-group which was tasked with examining the interaction between predictive genetics and insurance.

During 1996 and 1997, the ABI consulted its members on the use of genetic test results and produced a statement in February 1997, which the Committee reported on²³⁵.

The ABI's Genetic Committee was set up in **January 1997** and its first action was to formulate a policy statement on Life Insurance and Genetics. The Policy Statement about life insurance

²³³ <http://www.doh.gov.uk/genetics/acgt.htm>

²³⁴ <http://www.doh.gov.uk/hgac/>

²³⁵ Association of British Insurers' Policy Statement on Life Insurance and Genetics, Second Report of the Science and Technology Committee, Session 1996-97.

issued by the ABI in **February 1997** sets out a series of decisions made by the ABI's life insurance members, namely that for a period of two years:

- its members will continue not to ask people to take genetic tests when applying for life insurance;
- for new applications for life insurance of up to a total of £ 100,000, which are directly linked to a new mortgage, the results of any genetic tests will not be taken into account by the insurance company. Account will continue to be taken of family history and of other medical information;
- for new applications for other life insurance policies, individual companies will decide whether or not they wish to take account of the results of genetic tests previously taken.

For this statement genetic tests are taken to mean "an examination of the DNA pattern to find out if it differs from normal. In the insurance context a genetic test is one which is regarded as predictive in an asymptomatic individual". The Association argued that if individuals had access to genetic information that the insurer lacked, then individuals could use this information to secure a better deal than would be the case if information were fully shared.

The publication of this policy was to let government, genetic interests groups and the public know that the ABI was taking the matter seriously and also to gain time to formulate a good code of practice rather than be rushed into it. The committee continued its work on the code but before finalizing it subjected the concepts contained in the draft code to a Citizen's Jury which took place over a four day period in November 1997. This involved providing basic education on genetics and the basis of insurance and sought, in particular, guidance from the Jury, a totally uninformed randomly selected group of people, as to whether insurers should have access to the results of tests for monogenetic diseases. The outcome was interesting and quite satisfactory to the ABI in that the Jury concluded, that it was only right to access to results of test already carried out for monogenetic diseases.

The Genetic Testing – ABI Code of Practice²³⁶, launched in **December 1997** and revised in August 1999, is followed by all ABI members in respect of all relevant types of insurance. The ABI Code of Practice on Genetic Testing lays down proper practice in relation to the use of genetic test results by insurers. The Code clearly states that there will be no request for a genetic test by any applicant as a precondition of obtaining life insurance, but applicants will be asked to reveal the results of previous tests. This will not be required of applicants for life insurance required to be taken out to obtain a private house purchase mortgage of up to £100,000. The Code also sets out arrangements for appeals against insurers' decisions.

The Code tackles several other important issues: it requires each company to appoint a Nominated Genetics Underwriter, with sufficient experience and seniority, who will be responsible for all underwriting decisions involving genetic tests; it lays down security and confidentiality guidelines for the handling of genetic data; requires insurers to "keep themselves informed of wider developments in genetics"; and requires each company's Chief Executive Officer to certify their compliance with its conditions annually. It also established an independent tribunal system for customers to appeal against underwriting decisions.

The Government received the HGAC's Report and the ABI's Code for Practice and did not respond to either until November 1998.

The HGAC's report "*The Implications of Genetic Testing for Insurance*" which was published on the same day as the recommendations of the ABI did not consider that a permanent ban on the

²³⁶ <http://www.abi.org.uk/members/industrybrief/abikey/genetics/gentest99/gentest99.asp>

use of genetic tests in insurance would be appropriate²³⁷. However, it was concluded that “a requirement to disclose results of specific genetic test... would only be acceptable when a quantifiable association between a given pattern of test results and events actuarially relevant for a specific insurance product had been established”. Like the Select Committee, it recommended that the insurance industry should respect a moratorium on requiring disclosure of genetic test results pending review of the actuarial evidence. It also urged the Government to “establish a mechanism to evaluate the scientific and actuarial evidence presented in support of the specific genetic tests or insurance products”.

Founded in 1996, the British Society for Human Genetics²³⁸ (BSHG) is a forum for professionals working in all aspects of Human Genetics, from cutting edge research to the delivery of genetics services to the population of the UK. In their Statement on Genetics and Life insurance²³⁹, **May 1998**, they recognized that insurers need to protect themselves against an unacceptable degree of anti-selection. It endorses the recognition of the ABI stating that applicants must not be asked to undergo a genetic test in order to obtain any type of insurance. Genotypes present in more than 5% of the population should not be disclosed or considered for any life insurance. Cover up to an agreed sum should be available for all life insurance purposes without any genotype disclosure. If an insurer requires disclosure of any genetic test results, that requirement should be restricted to results where published and actuarially validated data allow evidence-based underwriting. Finally, insurers should recognize and counter the fear of undue discrimination. This BSHG statement will be reviewed not later than summer 2003.

The *government response* in **October 1998** to the HGAC report concurred with the Commission that a permanent ban on the use by insurers of genetic information would not be appropriate. It welcomed the ABI Code of Practice, which states that applicants must not be asked to take a genetic test in order to obtain insurance. Paragraph 4 of the code states that: ‘Insurers may take account of existing genetic test results only when their reliability and relevance to the insurance product has been established’. It also announced the formation of a Genetics and Insurance Committee²⁴⁰ (GAIC), acting under the auspices of the ACGT.

In November 1998, separately from the Code of Practice, the ABI issued a list of ten tests for seven conditions, which they recommended as sufficiently reliable to be used by the insurance industry. These seven diseases were: Huntington’s chorea, early onset familial Alzheimer’s Disease, hereditary breast and ovarian cancer, myotonic dystrophy, familial adenomatous polyposis, multiple endocrine neoplasia and hereditary motor and sensory neuropathy. The Code of Practice requires all ABI members to agree that if the GAIC decides a test is not relevant the customers affected should be re-assessed back to November 1, 1998. All ABI member companies abide by the Code, but some regard it as a “minimum standard” and have chosen to take different positions.

In response to the HGAC’s recommendation that there should be “an effective mechanism ... to evaluate the reliability and actuarial evidence relating to specific genetic test results ... [which] should involve people with sufficient expertise and independence to meet concerns about interpretations of ... results”, the Government set up the *Genetics and Insurance Committee*

²³⁷ <http://www.doh.gov.uk/hgac/>

²³⁸ <http://www.bshg.org.uk/>

²³⁹ <http://www.bshg.org.uk/Official%20Docs/Insurance/insuranc.htm>

²⁴⁰ <http://www.doh.gov.uk/genetics/gaic.htm>

(GAIC) in **April 1999**, which includes representatives of the insurance industry as well as independent geneticist, actuaries and consumer representatives.

This is a non-statutory advisory body whose task is to assess the scientific and actuarial reliability and predictive value of genetic tests that insurance companies would like to be able to take into account in setting insurance premiums. But its role is not only to evaluate genetic tests; it is also responsible for reporting to Government on the subsequent level of compliance by the industry with its recommendations..

As part of streamlining the framework, three advisory human genetics committees have been wound up and their responsibilities have passed to the *Human Genetics Commission*²⁴¹ (HGC). These are: the Advisory Committee on Genetic Testing, the Advisory Group on Scientific Advances in Genetics and the Human Genetics Advisory Commission. The HGC is one of three “strategic” scientific advisory bodies, which have a policy evaluation, as well as an advisory, role and were set up by the government to look at the “big picture” on certain key areas, taking ethical and social issues into account, in addition to the science. The membership of these three bodies includes people from a wide range of backgrounds, such as journalists and representatives of consumer interest groups, as well as scientists.

The Genetic Therapy Advisory Committee will continue to provide advice on the ethical acceptability of proposals for gene therapy research on humans and to offer its opinions on developments in gene therapy research to ministers within the UK. The Genetics and Insurance Committee will similarly continue as a non-statutory body to guide insurance providers. Both of these bodies will, however, be expected to “have regard to” the Human Genetics Commission.

The UK Forum for Genetics and Insurance²⁴² (UKFGI), of which the ABI was a founder member, was set up on the initiative of the Institute of Actuaries in **November 1999**, after the publication of the HGAC’s report, entitled *Implications of Genetic Testing for Insurance*. This report called for increased collaboration between geneticists, doctors, medical researchers, actuaries and other working in this exceptionally complex area with all its medical, social, financial and ethical implications. The UKFGI seeks to “analyze the implications of advances in genetic knowledge for insurance in all its forms and to serve the public interest by reporting on its findings”. Founder members include the Association of British Insurers, the British Society for Human Genetics (BSHG), the Genetics Interest Group (GIG), the Royal Society and the Wellcome Trust.

The draft application form and accompanying notes of the GAIC were subject to a wide public consultation in **February 2000**. A total of 19 responses were received including responses from the insurance industry and from support groups and charities representing those with genetic conditions. Several patient support organizations responded to the consultation on applications to GAIC. The Committee is keen that they should be included in the process of reviewing applications to GAIC. GAIC sees it as an important safeguard for the views of those who may be affected by any decisions to have an input into the deciding process. Representatives will also be able to attend the GAIC meeting to decide on relevant applications as observers, by arrangement with the Secretariat.

The GAIC has adopted the definition used by the Advisory Committee on Genetic Testing, that a genetic test is ‘a test to detect the presence or absence of, or change in, a particular gene or chromosome.’ However, the GAIC felt the need to add two qualifications to this definition. The first was that the genetic test in question should be predictive of, or associated with, significant health effects relevant to either health or life insurance. The second caveat was that information generated by clinical examinations or by other non-genetic investigations should not be

²⁴¹ <http://www.hgc.gov.uk/>

²⁴² <http://www.ukfgi.org.uk/>

considered a genetic test. This is typical of the strategies adopted to ensure a degree of protection against potential genetic discrimination while still facilitating the practice of underwriting.

The GAIC published in **June 2000**, after extensive consideration and consultation, its criteria for tests to be approved, with an application form of 11 questions that all those seeking verification of tests would have to complete. The GAIC deems a test to be suitable for use in assessing insurance proposals if it meets three conditions:

- (i) Technical relevance – Is the test technically reliable? Does it accurately detect the specific changes sought for the named condition?
- (ii) Clinical relevance – Does a positive result in the test have any implications for the health of the individual?
- (iii) Actuarial relevance – Do the health implications make any difference to the likelihood of a claim under the proposed insurance product?

It is the responsibility of the insurers who wish to use a particular test (usually through the ABI) to make the formal application to the GAIC, by means of the application form, supported by relevant scientific and actuarial data.

The ABI has identified seven disorders for which they consider that any genetic test results should be disclosed. These are: Huntington's disease; myotonic dystrophy; familial adenomatous polyposis; multiple endotrophy; familial Alzheimer's disease; hereditary breast cancer, and hereditary motor and sensory neuropathy. The argument presented by the ABI for the disclosure of test results for these diseases is that such information will, in certain circumstances, be actuarially relevant. The GAIC will only authorize the use of a genetic test for underwriting purposes following an adjudication process to determine the technical merits of the test and the overall actuarial relevance of the results. The common denominator between the test listed by the GAIC would appear to be high penetrance for severe disease. This does, of course, raise serious questions about adequately defining thresholds for the concepts of penetrance and severity.

In **September 2000** a Report to the Human Genetics Commission on Public Attitudes to the Uses of Human Genetic Information was sent, which aim was to discover, by means of a literature review, what work has been done in the UK investigating public attitudes towards genetic information, and how these attitudes have changed over the past decade. By informing the HGC which research has already been done, it will be possible to design studies using, amongst others, the people's panel, which will not duplicate work already performed. (infra Whose hands on your genes)

In **October 2000** GAIC announced that the reliability and relevance of the genetic test for Huntington's Chorea was sufficient for insurance companies to use the results. Applications are currently being considered by GAIC for: Huntington's disease tests in relation to critical illness cover, income protection cover and long term care cover; APP and presenilin 1 (PS1) gene tests for early-onset familial Alzheimer's disease in relation to life insurance, critical illness cover, income protection and long term care cover; and BRCA1 and BRCA2 tests for hereditary breast/ovarian cancer in relation to life insurance, critical illness cover and protection cover. The intention is to complete a review of these applications by June 2001. GAIC is also working with HGC in the wider review of genetic testing and insurance.

The ABI has agreed to abide by GAIC's decisions. As mentioned above, in its Code of Practice it undertakes not to require applicants to take any genetic test. In addition, genetic test results are disregarded when setting premiums for life insurance policies up to a value of £100,000 that are linked to new mortgage applications. Insurers may not ask for the results of tests taken by other family members, nor offer individuals lower-than-standard premiums on the basis of genetic test

results, nor disclose test results to any other party without the individual's consent. Genetic test results are only used in applications for certain types of insurance cover. In the interim before GAIC's decisions on the current applications are announced, ABI member companies may continue to require disclosure of test results for hereditary breast/ovarian cancer (BRCA1/2 mutations) and early-onset familial Alzheimer's disease (PS1 mutations) for some types of insurance. If any of these tests are subsequently rejected by GAIC, the insurance companies will refund any extra premiums paid by applicants on the basis of their results, or contact them to offer them insurance if it had been refused. The ABI has decided not to pursue applications to GAIC to use tests for four other conditions (myotonic dystrophy, multiple endocrine neoplasia, hereditary motor and sensory neuropathy and familial adenomatous polyposis), or for presenilin 2 tests for early-onset familial Alzheimer's. These tests had previously been approved by the ABI's genetics adviser. The ABI has also announced that it will not require disclosure of the results of genetic tests carried out for research purposes.

On 27 **November 2000** the Human Genetics Commission launched a major public consultation entitled '*Whose hands on your genes?*'²⁴³. It outlines the recent advances in analyzing people's genetic information, and discusses the areas likely to be affected, such as insurance policies, medical and forensic databases, and even employment. At the specific request of ministers, the HGC has included the wider social and ethical issues involved in the use of genetic data by insurers in its consultations. The HGC held an *information-gathering meeting on genetics and insurance* on the 9 **February 2001** in London on this issue, where different perspectives of those on all sides of the debate were highlighted and an informal discussion took place, involving members of the public.

As part of this work MORI was commissioned to carry out a detailed survey of people's attitudes, using the People's Panel, which was established by the Modernizing Public Services Group at the Cabinet Office in Summer 1998. It is a randomly recruited panel of the general public, aged 16 and over, which is representative of the UK population.

The HGC held an *information-gathering meeting on genetics and insurance* on the 9 **February 2001**, where different perspectives of those on all sides of the debate were highlighted.

On 2 **March 2001**, the Human Genetics Commission published '*Public attitudes to human genetic information*', the results of a major MORI survey on attitudes to genetic information²⁴⁴. A total of 6,105 people were recruited of which 1038 interviews were conducted between 6 October and 17 December 2000. The results have been weighted to the profile of all adults in the UK. The MORI report shows that four in every five respondents reject the suggestion that insurance companies should be able to ask to see the results from genetic tests to assess premium levels. When asked to consider the appropriateness of providing test results, a majority thinks it is inappropriate, irrespective of the type of policy that is being applied for. However, those policies that have a more direct relationship to an applicant's health are more likely to thought instances where it would be appropriate to provide this information to insurance companies.

There is considerable controversy about the current position in the UK. Critics fear that, especially if an increasing number of tests is approved by GAIC, an insurable "genetic underclass" could be created. They are also concerned that people could be deterred from taking genetic tests that are important for their health and medical treatment. Reflecting these concerns, the Science and Technology Select Committee of the House of Commons set up a short enquiry in December 2000 and came up with a lengthy list of recommendations in just three months. It

²⁴³ http://www.hgc.gov.uk/business_consultations2maintext.pdf

²⁴⁴ http://www.hgc.gov.uk/business_publications_morigeneticattitudes.pdf

published its *Fifth Report of Session 2000-2001, on genetics and insurance* on **3rd April 2001** recommending a research on the actuarial relevance of test results²⁴⁵. (Note that some insurance companies, for example Standard Life and Virgin direct, already only use negative test results). The committee's principal recommendation is that the insurance industry agrees to a two-year moratorium on the use of any positive genetic test results when deciding upon insurance premiums. The report stated that insurance companies rarely use the information from genetic tests, meaning that they could easily stop their use for the short-term future, allowing time for the necessity of such tests to be considered. It also noted that when insurers do use the information, they are governed by the code of practice of the ABI. For the definition of genetic test reference is made to the 'Notes to accompany applications to GAIC for approval to use genetic test results for insurance risk assessment'. (supra)

The *Government* has welcomed the report and has secured agreement from the ABI that certain test results will not be used. It has asked the HGC to look at the wider social and ethical issues involved in the use of genetic data in insurance, and the GAIC is to look at the clinical and actuarial evidence for specific genetic tests. A draft report from the HGC has been published in 2001²⁴⁶.

The *Association of British Insurers* has confirmed that insurers will extend their existing moratorium on the use of genetic test results. The existing Code includes a moratorium on the use of test results in respect of life insurance linked to a mortgage of up to £100,000. The ABI proposes to extend this moratorium to cover all classes of insurance up to £300,000.

At the request of Ministers, the Human Genetics Commission (HGC) has been reviewing the wider social and ethical implications of the use of genetic information in insurance. The HGC interim recommendations published on **1 May 2001** were the result of a series of information-gathering exercises and discussions since November 2000 and in which they considered consultation responses, additional information from the insurance industry and the report of the House of Commons Science and Technology Committee. The HGC recommended to the Government that there should be an immediate moratorium on the use of genetic test results by insurance companies for all classes of insurance, and that this moratorium should be backed by legislation.

The moratorium should last *for no less than three years*, to allow time to collect data that is not currently available and to consider adequately the complex issues involved. It is essential to have a system that enjoys the confidence of the public.

It has reached its conclusions because the existing system of self-regulation has failed, because there is much disagreement and uncertainty about the interpretation of many genetic tests, because the HGC believes that there needs to be effective regulation of this area and because public trust in genetic testing is essential. Exceptions on the moratorium are made when policies exceed £500,000 and in the case where an applicant for insurance has a favorable genetic test result and the applicant chooses to reveal this to a potential insurer.

The ABI published **23 October 2001** an *agreement with the Government* on a five-year moratorium on the use of DNA genetic test results by insurers. The agreement covers all but the largest quantities of insurance, enabling consumers to obtain up to £500,000 of life insurance, and £300,000 of critical illness, income protection and long term care insurance, without having to disclose any genetic test results. The agreement follows comprehensive discussions between the Association and the Department of Health. The ABI moratorium lasts for a longer period than

²⁴⁵ <http://www.parliament.the-stationery-office.co.uk/pa/cm200001/cmselect/cmsctech/174/17402.htm>

²⁴⁶ <http://www.hgc.gov.uk/papers/hgc01-p16.pdf>

the two years recommended by the House of Commons Science and Technology Committee and the three years suggested by the Human Genetics Commission.

The agreement includes:

- a five year moratorium on the general use of DNA genetic test results by insurers from 1 November 2001, except in circumstances detailed below;
- continued use of genetic test results by insurers only when authorized by the government's Genetics and Insurance Committee (GAIC) for life policies of over £500,000 and other insurance policies of more than £300,000;
- a review of these financial limits after three years;
- an impartial and independent complaints mechanism;
- monitoring by the ABI of companies' compliance with its Code and moratorium, with annual publication of the ABI's compliance report.

In May 2002 the HGC published the report *Inside information – Balancing interests in the use of personal genetic information*²⁴⁷ which results from HGC's review of the use of personal genetic information. The recommendations, a result of a year's consultation involving the public, organisations and the HGC's recently formed consultative panel, are based on the overarching premise that everyone should have their rights and dignity respected, regardless of their genetic characteristics: everyone is entitled to genetic privacy and should not have to disclose information about their personal genetic characteristics; private genetic information should not be obtained or held without a person's consent; private personal genetic information should be treated as confidential and not communicated to others without a person's consent; and no one should be unfairly discriminated against on the basis of his or her genetic characteristics. The report contains significant recommendations to the Government, which if implemented will improve public trust at the same time as enabling exciting advances in medical science. The main recommendations include new protections for individuals: It should be a criminal offence to test someone's DNA or access their genetic information without their knowledge or consent for non-medical purposes, except as allowed by law - forensic uses; employers must not demand that an individual take a genetic test as a condition of employment or employment benefits and we will continue to monitor any proposals for voluntary use. Measures should be introduced to protect individuals from unfair genetic discrimination.

4. GENETICS AND EMPLOYMENT

Thus far in the United Kingdom terms of employment seem not to have been a constraint on health care, nor has health care constrained people to refrain from moving jobs. Only one employer's genetic screening program could be identified in 1993 and it seemed to meet the very stringent conditions that had been suggested by the Nuffield Council on Bioethics²⁴⁸.

A draft Code of Practice "The use of personal data in employer/employee relationships" is issued by the Data Protection Commissioner in accordance with her powers under Section 51(3)(b) of the Data Protection Act 1998.

²⁴⁷ <http://www.hgc.gov.uk/insideinformation/index.htm#report>

²⁴⁸ Nuffield Council on Bioethics. Genetic screening: ethical issues. London: The Council, 1993.

It is aimed at employers and addresses the use of personal information that is likely to arise in any employer/employee relationship from recruitment through to termination and beyond. The code is intended to be of general application and is drafted in two parts: Part I sets out the standards which must be met if the code is to be complied with. Part II sets out the interpretation of the Data Protection Act 1998 on which the standards are based. In relation to genetic testing, they broadly take the view that genetic testing might, in exceptional circumstances, be valid on health and safety grounds but considerable advances will be needed before it can safely be used to take decisions based on predictions of possible future ill health.

The standards are the following:

- unless justified on the grounds that an employee with a particular, detectable genetic condition is likely to pose a serious safety risk to others only introduce genetic testing of current or potential employees if it is part of a voluntary program where it is known that a specific working environment or practice might pose specific risks to employees with particular genetic variations
- ensure any genetic test used for employment purposes is subject to assured levels of accuracy and reliability, reflecting best practice. Any use of genetic testing should be evidence based and consensual. Ensure the results of any test undertaken are always communicated to the person tested and professional advice is available. Ensure test results are carefully interpreted, taking account of how they might be affected by working conditions.
- Do not require an individual to disclose the results of a previous genetic test unless there is clear evidence that the information it provides is needed to assess either current ability to perform a job safely or susceptibility to harm from doing a certain job.

There is at present no UK legislation which directly regulates genetic testing in relation to employment. An employer may lawfully require a prospective employee to undergo genetic testing as a condition of obtaining appointment and may request an employee to submit to such a test. It is not unlawful to discriminate on the basis of the result of such tests.

Some fortuitous protection against discrimination by employers on the basis of genetic test results for current conditions may be found in the case of certain conditions which occur primarily in one sex or in particular races. Discriminating in these cases on the grounds of genetic characteristics may amount to a breach of the Sex Discrimination Act 1975 or the Race Relations Act 1976 and any employer or prospective employer would be required to justify the action they were taking.

Similarly, an employee who has the necessary period of continuous service with an employer and who refuses to undergo a genetic test at the request of his employer would be protected by the Employment Rights Act 1996 from being dismissed unfairly as a result of that refusal unless an issue of public safety is involved.

The Disability Discrimination Act 1995 provides a further range of protection²⁴⁹. It requires employers with 15 or more employees to make a reasonable adjustment if their premises or working arrangements place a disabled person at a substantial disadvantage compared with people who are not disabled.

The Disability Discrimination Act can offer employees with an adverse genetic test result some protection from discrimination by employers if they are currently disabled and the test was done for a reason relating to that disability. However, the definition of “disability” in the Act does not cover people who have a susceptibility to a future disability. So, employers could avoid the

²⁴⁹ <http://www.hms0.gov.uk/acts/acts1995/1995050.htm>

provisions of the Act by refusing to employ pre-symptomatic individuals who might become entitled to the protection of the Act at a later date. The weakness of the UK Act compared with its US counterpart is that it lacks the ‘perception of disability’ provision which could protect individuals identified with genetic predispositions against employment discrimination.

The Health and Safety at Work Act 1974 and related regulations (for example, the Management of Health and Safety at Work Regulations 1992 and the Control of Substances Hazardous to Health Regulations 1999) put the onus on employers to ensure, as far as reasonably practicable, the health of all their employees at work. The approach under the Health and Safety at Work Act 1974 is that employers should either prevent exposure to risks or reduce the risks to the health of the worker so far as is reasonably practicable.

In July 1999 the HGAC reported on the implications of genetic testing for employment²⁵⁰. The definition of genetic testing is similar to that of the ACGT. HGAC concludes that if and when genetic testing in employment becomes a real possibility, a common set of policy principles should be observed:

- (i) an individual should not be required to take a genetic test for employment purposes – an individual’s “right not to know” their genetic constitution should be upheld;
- (ii) an individual should not be required to disclose the results of a previous genetic test unless there is clear evidence that the information it provides is needed to assess either current ability to perform a job safely or susceptibility to harm from doing a certain job;
- (iii) employers should offer a genetic test (where available) if it is known that a specific working environment or practice, while meeting health and safety requirements, might pose specific risks to individuals with particular genetic variations. For certain jobs where issues of public safety arise, an employer should be able to refuse to employ a person who refuses to take a relevant genetic test;
- (iv) any genetic test used for employment purposes must be subject to assured levels of accuracy and reliability, reflecting best practice. We recommend that any use of genetic testing should be evidence-based and consensual. Results of any test undertaken should always be communicated to the person tested and professional advice should be available. Information about and resulting from the taking of any test should be treated in accordance with Data Protection principles. Furthermore, test results should be carefully interpreted, taking account of how they might be affected by working condition; and
- (v) if multiple genetic test were to be performed simultaneously, then each test should meet the standards set out in (ii), (iii) and (iv)

The Government response took the form of a letter from Ministers to HGC in July 2000. It invited the HGC to work with other bodies and Government Departments to address two of the main recommendations of the report. These were:

- HGAC’s proposed policy principles which should be observed if and when genetic testing in employment becomes a real possibility; and
- A further review of genetic testing in employment in 5 years time.

The interim findings of the survey, commissioned by the HGC using the People’s Panel, shows that there was support for the use of genetic information to see if new or existing employees were sensitive to something (e.g. chemicals) at work. There were mixed views about using genetic information to see if an employee might suffer from something that poses a danger to work

²⁵⁰ <http://www.doh.gov.uk/hgac/>

colleagues or the public. There was clear opposition to using genetic information to see if employees would be prone to ill health or likely to take early retirement (71-72%).

A recent study by Jo Lenaghan of The Institute for Public Policy Research has suggested that far too little attention has been given to the issue of employers' access to genetic information. There is little evidence to date that employers have carried out genetic screening of current or potential employees. However, where genetic conditions are associated with racial origin a number of equal opportunity cases are gradually emerging. Recently, a UK building society was taken to an employment tribunal because they refused a job to someone who admitted to suffering from the onset of sickle cell trait. A House of Commons Select Committee has looked into the issue of genetic screening at work and concluded that employment decisions should normally be based on "current ability to do the job". However, they make two exceptions. These are situations where:

- 1) there is a danger that others may be put at risk, and
- 2) an individual may be found to be more sensitive than others to the environment effects of particular substances.

The first exception might be used as the justification for wide-scale testing in sectors such as the transport industry, the health service and even manufacturing industry as a whole. Individuals would find themselves either effectively unemployable, or denied the training/development to advance in their careers? Lenaghan points out that the significance of the second exception would be to shift both the responsibility and the cost of health and safety risks from the employer to the individual.

Until the Disability Discrimination Act is revised to cover people with a predisposition to a disease or a condition, The Data Protection Act will provide the only real protection for employees in the face of rapid advances in microbiology and consequent genetic tests available to employers. It is therefore critical that such data be subject to the provisions of Schedule 3 of the Data Protection Act 98 and that Data Protection Principle 1 should allow for unlawful processing on grounds of 'unfairness' even though an individual has given their formal consent.

CONCLUSION

1. PATIENTS' RIGHTS IN THE DIFFERENT MEMBER STATES

To a growing extent the position of the patient has become subject matter of international standard setting. This is exemplified by the growing number of resolutions, recommendations, guidelines and conventions issued at **international level**, both by private international groups and by international public organizations, e.g. Declaration on Helsinki on medical experimentation of the World Medical Association which was revised in 2000. As to international organizations in the European region mention can be made of the European Convention on Human Rights and Biomedicine (1997) and the Charter of the fundamental rights of the European Union (2000). However, not only on an international or European level patients' rights are developing, in all European countries the interest in patients' rights is increasing.

It appears that many **countries** are party to one or more international treaties or conventions, such as the 1997 *Convention on Human rights and Biomedicine*. This Convention is also ratified by more and more EU Member States in which countries the principles set out in the Convention have become the rules of law. During the last three years the Convention entered into force in Denmark (1999), Greece (1999), Spain (2000) and Portugal (2001). In Luxembourg, the bill approving the Convention on Biomedicine is at the final government drafting stage and also Finland is on its way to ratify the Convention.

Although patients' rights can often be derived from general legal norms, legislators have become more involved in drafting legislation on patients' rights. To *legislate* patients' rights two options are possible. One way of proceeding is to include patients' rights in laws on specific subjects. For instance in 1998 new legislation was passed on organ and tissue transplant in Italy. Another way of proceeding is to adopt a general law on patients' rights. Finland was the first country in Europe to enact such a law on the rights of patients which came in force on 1 March 1993. It was followed by the Netherlands (Medical Contract Law, 1995), Greece (1997), Denmark (Patients' Rights Act 1998), France (2002) and Belgium (2002). Thus, almost eight years after the WHO Declaration on the Promotion of Patients' Rights in Europe six EU Member States already have a patients' rights act.

Other countries have used *Patients' Charters* as a tool to promote patients' rights, for instance Ireland, and the United Kingdom.

The overall picture of patients' rights in Europe is that they are on the move and that they more and more get a legal base in legislation or regulation, so their promotion is not any more limited to the Scandinavian countries as it was the case some years ago. Further advances in medical technology are now resulting in the further development and elaboration of patient's rights. One of the most debated new technologies which have considerable impact on patients' rights is genetic testing.

2. PATIENTS' RIGHTS AND GENETICS

On a **European level**, one can already notice the interest the Council of Europe has for these recent developments in the field of human genetics. The Convention on Human Rights and Biomedicine contains some principles relating to genetics (Articles 11 to 14), namely prohibition of discrimination, of testing for other reasons than health purposes, of modifications in the genome of any descendants, of sex selection. Besides the convention however, a working party of the Steering committee on Bioethics is preparing a *draft Protocol on Human Genetics*, which will extend the protection of individuals in this area and which will consist of two main parts: one relating to medical applications of genetics and the other to non-medical applications.

Not many **countries** have already enacted laws with regard to this issue. The most comprehensive texts can be found in the Austrian and French legislation, which more or less foresee the four major themes handled by the Convention as just mentioned. Most countries opt for a non legal framework and a strategy based on professional voluntary regulation, guiding principles, recommendations or explicit statements. Therefore, to a number of states, the Convention is the first provision and the initial standard, which they accept to comply with. Nevertheless, all countries are confronted in one way or the other with the impact of genetic testing on the traditional patients' rights.

Since genetic testing also is a medical intervention, all the afore-mentioned patients' rights apply to persons undergoing a genetic test. The patient therefore has a right to consent, to information, to privacy, to confidentiality, etc. The developments in genetic technology raise however many questions about patients' rights, particularly the information on health status, the right to informed consent, to confidentiality and to privacy protection.

Informed consent: communicating information to the individual has become a major issue in genetic medicine since it often constitutes the starting point for decisions pertaining to reproduction, life and death. Thereby, most genetic information is only predictive and probabilistic – a certain gene may increase the likelihood of developing a disease. To be sure the tested person is completely aware of all social, psychological and other consequences, article 12 of the said Convention adds a supplementary condition to the free and informed consent which is that a predictive test must be accompanied by appropriate genetic counselling. The same supplementary provision can be found in national legislation, e.g. Austria's Gene Technology Act stipulates that comprehensive counselling from the physician recommending genetic testing is required before and after carrying out a genetic test. Another protective measure that is used is the requirement that the consent needs to be in written.

Information on health status: The ability to identify individuals at risk for genetic diseases often exceeds our ability to prevent or treat the diseases. It is not impossible that a patient prefers not to be informed about the possibility that he is a carrier of a deadly genetic disease for which no treatment is available for the moment.

The right to confidentiality: in addition to the impact that genetic information may have on the individual, it is important to remember that it also pertains to other family members. The question then is to determine to what extent and in what way genetic information should be transmitted to the relatives concerned. From the perspective of the individual tested, the transmission of personal information to relatives can only be done with his informed consent, but what if he/she refuses? What about the duty to secrecy of the physician? Countries with a Common law tradition generally tend to be more willing to recognize this exception to the obligation to ensure

confidentiality, while countries with a Civilist or Germanic tradition tend to have a more strict and more absolute conception of medical privilege.

The right to privacy: in addition to the claimed rights of other individuals to access to genetic information, there are arguments for the rights of institutions such as insurance companies. Specific problems however arise here...

3. GENETIC TESTS/INFORMATION AND INSURANCE/EMPLOYMENT

Since the problems resulting from using genetic tests before recruitment are similar to those in the context of insurance and since a lot of countries have not yet addressed the problem, only the problems of genetic examinations in the context of private insurance will be mentioned.

As already mentioned, an individual must give informed *consent* before a genetic test can be performed. However, it is difficult to ensure that the individual is giving voluntary consent or is able to exercise the right not to know. In addition to the breach of physical integrity that these tests involve, or the breach of privacy resulting from the use of genetic information, there is also the possibility of discrimination that could result from the use of this information. Thereby, it might be doubtful whether insurers can keep genetic information they obtain confidential.

These arguments however need to be counterbalanced by the problem of adverse selection, which can occur when more high-risk people find it worthwhile to take out insurance. This drives up the prices of premiums, so that low-risk people may be deterred from taking out policies and may withdraw, while this leads to a vicious circle of worsening of the risk pool and increasing costs.

At a **European level**, the *European Union* adopted in 1989 a resolution in which a complete ban on the use of genetic testing in insurance matters was favoured by the European Parliament. In the Charter of Fundamental Rights the discrimination based on genetic features is prohibited. The same policy was adopted by the *Council of Europe* in the Convention. Article 11 explicitly prohibits any form of discrimination on the grounds of genetic heritage, while article 12 prohibits the carrying out of predictive tests for reasons other than health-related research, even with the assent of the person concerned. The requirement of article 12 prohibits insurers from conducting genetic test on insurance applicants, while article 11 renders it impossible to make distinctions based on people's genomes. Nevertheless, article 26 lists certain circumstances which permit the rights and protection granted by the Convention to be restricted, although only where so provided for by law and provided they are necessary in a democratic society. However, no restrictions may be placed on the provision concerning prohibition of discrimination.

If one looks at the policies proposed and the measures adopted in individual European **countries**, there is more diversity.

Some countries have *legislated to prohibit* insurance companies from using genetic tests. This has been the case in Belgium, Denmark and France. Such a strategy faces definitional problems, namely what actually constitutes genetic information and what in fact is a genetic test. In addition, such a ban would expose the insurance industry to the dangers of adverse selection and selective withdrawal which, if experienced on a large scale, could threaten the viability of the industry.

The adoption of voluntary *moratoria* on the use of genetic testing has been a widespread response of the insurance industry throughout Europe. The reason is that there are very few relevant and accurate genetic tests available. Moratoria are either indefinite (e.g. Finland, Germany), or for a limited number of years (e.g. France), or still limited to insurance policies which do not surpass a certain value (e.g. the United Kingdom).

Other countries have taken the middle road, only authorizing the use of genetic susceptibility tests beyond a certain level of insurability and with the consent of the individual concerned. This is the case in the Netherlands and Sweden. The attraction of a *ceiling system* of insurance is that it reduces the effects of adverse selection by permitting the insured to seek bargains or to transfer risks but only within well-defined financial limits.

The United Kingdom is an example of mandated *self-regulation* of the use of genetic information by the insurance industry. However, there are obvious problems with relying on self-regulatory systems which exist when there is no external sanction imposed on a financially powerful institution. Since October 2001 the self-regulation concerning genetic information has been turned into a moratorium.

4. CONCLUDING REMARKS

Patients' rights have become an important item on the political agenda for most of the European countries. Leenen already stated in 1994 that the overall picture of patients' rights in Europe is that they are on the move and that they more and more get a legal base in legislation or regulation and by the courts²⁵¹. This report points out that the law on patients' rights is still in motion in different European countries.

In numerous countries, discussions have also started on the acceptability of using genetic testing in the frame of insurance contracts and recruitment. There is an ongoing discussion on the extent of the measures to be taken as well as on the instruments to be applied in order to bring the opposing interests into balance. To find the right balance however will be the challenge for the years to come.

²⁵¹ H.J.J. Leenen, "The rights of patients in Europe", *European Journal of Health Law* 1994/1, 13.

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