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European Society of Human Genetics
Public and Professional Policy Committee

**GENETIC INFORMATION AND TESTING IN INSURANCE AND
EMPLOYMENT: TECHNICAL, SOCIAL AND ETHICAL ISSUES**

BACKGROUND DOCUMENT

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Introduction

The predictive value of certain genetic tests may have consequences in many non-clinical situations, particularly those involving insurance or employment. Insurers might wish a genetic test result for underwriting, to be used just as are other medical or family history data. Employers might wish to ensure that an individual does not have risk of genetic characteristics, which might affect the ability to work or which might lead to problems of safety to the individual or to others. The technical aspects of genetic testing are developing rapidly. The social and ethical issues which could arise need to be very carefully assessed. Even now, accurate genetic prediction remains difficult and varies with the disease and the type of tests available. As well as the problems associated with the application of new genetic knowledge on individuals, there is also an impact on families and ethnic groups. The volume of potentially available data, the way it could be stored and used in the future, and the impact of its use for non medical purposes justify special attention. Being denied insurance or employment on the basis of genetic traits could have serious consequences and would affect families and groups who are already disadvantaged. How do the selection and differentiation methods of insurers and employers affect a person, who has additional health care needs, and his or her family?

A number of national and international committees and advisory groups have developed and published recommendations for policy makers to protect individuals against genetic discrimination. Three solutions are usually proposed: 1) Prohibition of any use of genetic information; 2) Legislation prohibiting this below a certain amount of coverage; and 3) Moratoria. The approaches used in different countries vary greatly¹. In Five European countries - Austria, Belgium, Denmark, France and Norway - any use of genetic information for business purposes is prohibited. In Four countries - France, Germany, Sweden, and the United Kingdom - a moratorium or partial moratorium on the use of genetic information by insurers has been established. In the Netherlands, the Medical Examination Act (1998) prevents the acquisition of genetic information by insurers and employers below a certain amount of coverage. At the European level, the Council of Europe signed a Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine in 1997. The same year, the UNESCO Universal Declaration on the Human Genome and Human Rights was signed. In the United Kingdom, there is a Human Genetics Commission which is addressing these policy issues, with specific committees in which consumers, business interests, geneticists and other stakeholders, work together to advise Government of developments and options.

Despite the desire to restrict the use of genetic information for non medical purposes, a balance appears necessary between the economic interests of insurers and employers, the interests of applicants, and the interests of other policy holders and other employees. This is especially relevant and sensitive under health care systems and welfare sectors with increasing budgetary restrictions.

¹ The present document addresses the issues raised by the use of genetic information by insurers and employers in Europe. The literature on genetics and insurance is dominated by USA discussions of healthcare financing. In Europe, the situation is different because the population does not depend on private insurance contracts for their healthcare provision. The issue in Europe is not healthcare but life insurance and reading across from the US experience is not very appropriate.

I- Advances in genetics

Genetic disorders show different degrees of severity and diverge with respect to the age of onset. Moreover, more than one change in DNA can be responsible for the same disease. Predictions are therefore complicated by these phenomena.

Genetic tests are likely to become available for two forms of genetic diseases: monogenic and multifactorial diseases. Monogenic disorders are rare but highly penetrant; the genetic test will indicate whether a person has or will get the disease. Without the genetic test, we may already know that the person has a significant risk of developing the disease from the knowledge of the parents' health. Multifactorial diseases are frequent and most likely triggered by specific combinations of functional DNA polymorphisms interacting with the environment in ways that are subject to behavioral changes. The most that the genetic test can do is to show a propensity to a disease (Holtzman 1996).

Genetic information can be used to prevent the onset of diseases, to assure early detection and treatment and to make reproductive decisions. This information can be used by probands and their relatives, but also by third parties such as insurers and employers. There are concerns that this information could lead to discrimination and social exclusion (Harper 1997, Lemmens & Bahamin 1998).

II- State of technical, social, economical, and ethical aspects

2.1- Calling ethical principles into question

Ethical principles in medicine apply to medical genetics, even if this has been questioned by arguments which suggest that there is something special about genetics. These principles are: respect for the autonomy of persons, beneficence, non-maleficence, and justice. At present, these principles are not applied with equal force around Europe. The principle of non-maleficence which aims at avoiding and preventing harm to persons, is called into question if genetic information is used for discrimination or favoritism in insurance and employment. The principle of justice, which may consist in distributing benefits and burdens fairly and with equity, varies depending on whether healthcare is founded on the principle of social solidarity or on the basis of mutuality. Although the market for private health insurance in Europe is small and in some countries non-existent, the possible use of genetic information in insurance and employment has gradually generated debate and increasingly causes concern (McGleenan et al 1999, Morrison 1998, Morrison et al 1999, Nys 1993, Rosén 1999).

2.2- Uncertainty

Some genetic disorders affect people with near-certainty but others indicate only an increased risk of developing diseases. At present, genetic tests are available mainly for mendelian diseases and they – very often – really tell that the person is going to get the disease.

Presymptomatic testing identifies healthy individuals who may have inherited a gene for a late-onset disease and if so will develop the disease if they live long enough. However,

presymptomatic testing presents some limits, including the possibility of uninformative results and the inability to predict the exact age of onset or the severity of symptoms.

Susceptibility testing identifies healthy individuals who may have inherited a gene that puts them at increased risk of developing a multifactorial disease, although these individuals may never develop the disease in question. Genetic tests cannot account adequately for the external factors which can be as important as inborn characteristics (Lemmens & Bahamin 1998).

Tests using genetic markers linked to a disease gene (as opposed to testing directly for disease-causing mutations) are not totally reliable since they provide only statistical probabilities based on the presumption that people have inherited genes with the identified markers. In other respects, a clear distinction must be drawn between genetic tests carried out in a research setting (aimed at establishing new genetic tests or developing quality control of tests) and those carried out in clinical practice. Research projects can be experimental and the results of the tests can be uncertain.

Genetic testing classifies people into those who have the mutant gene and those who do not have it. Now, a mutant gene is not a disease. The use of computerized medical data banks within large companies could exacerbate this problem, genetic information becoming not only a medical fact but also a disease (Lemmens & Bahamin 1998, MacDonald 1997).

Just like conventional tests, uncertainty applies to genetic tests. Insurance medicine mostly deals with uncertainties and an exact prediction can never be made for one individual life, only for setting up group prognoses.

2.3- Special aspects of genetic information

Medical geneticists' concerns extend beyond the traditional sources of ethical guidelines in medicine. Genetic information may affect an entire family rather than only one individual, and the choices of the present may affect future generations. The results can be either beneficial or harmful.

Family cooperation is often necessary to detect genetic problems. Even if people have the right to refuse genetic tests, could they be forced to take them for the benefit of others? Genetic testing for insurance and employment purposes could disturb family relations. Privacy, personal autonomy, confidentiality could become a real problem in connection with genetic information for family members.

Genetic information links the members not only of families but also of whole communities. Genetic disorders are often over-represented in ethnic groups and intensive genetic research on some populations could exaggerate the presence of problems (Lemmens & Bahamin 1998, Sandberg 1995).

In other respects, our ability to identify individuals at risk for genetic diseases often exceeds our ability to prevent or treat the diseases (Kevles & Hood 1992, Reilly 1998). This has been described as the "therapeutic gap" and as a reason for tension between policy makers and health professionals (Kumar et al 1999). Some authors consider that the increasing understanding of genetics will make the insurers and the employers able to distinguish

treatable and preventable conditions and fatal diseases (Lowden 1996). Nevertheless, some people will prefer not to know whether they carry a mutation.

III- Concerns of the insurers

Genetic information through family history was already used by some insurance companies before anyone considered genetic testing, and individuals were covered or denied coverage or charged higher premiums. The progress made in predicting diseases alters the information available with regard to the risk of disease. This may have important consequences for insurance industry.

3.1- Goal of insurers

Mutual insurance refers to the notion of forming a risk pool in which each of the members participate according to the risk they represent to the pool. The cost of the insured risk is distributed between the members of the pool, each paying its own part (Ewald & Lorenzi 1997). Underwriting is the method used to classify people according to their risk. Usually, underwriting leads to classification in three groups: standard, substandard, and uninsurable. Individuals in the first group have few problems getting insurance. Individuals in the second group must pay higher than average premiums, based on the risk they represent. Some pre-existing conditions are often excluded from coverage. Individuals in the third group are excluded because the cost of their coverage is unquantifiable or would exceed any reasonable premium. Detailed underwriting is often undertaken for individual life insurance, depending on the value of the contract (Le Grys 1997).

The insurers' goal is to maximize their profits. This is usually reached with an increased number of people under coverage. Developments in medical science have resulted in an increase of life insurance sales. Genetic information contains more certainty than information traditionally gathered by insurers to investigate the existence of diseases running in the family (Lemmens & Bahamin 1998). In other respects, experience shows that the assessment of substandard risks due to genetic information is proved fair since the observed mortality is very close to what had been expected (Chuffart 1997).

3.2- Sources of information

In the underwriting process, the expectations of individuals in relation to longevity and health are quantified and expressed as statistical probabilities. Insurers can predict that the overall mortality rate of a specific group of people, classified in the same substandard risk category, will be higher than the mortality rate in the general population (Lemmens & Bahamin 1998). Insurers classify the risk by asking questions and through medical investigation. The questions sometimes cover the medical histories of family members. Depending on the case and the amount of coverage involved, medical questions might be followed by medical tests or complete medical examinations (Roscam-Abbing 1994).

The duty of disclosure which is established by legislation states that the insurance applicants must declare everything relevant to their risk's appreciation and their classification (Lemmens & Bahamin 1998, McGleenan et al 1999). The registered information in medical

files is usually more accurate and complete than what is known by the insurance applicants (Rosén 1999). Since genetics is more and more integrated in medical practice, insurers will have access more and more to genetic information. This will allow insurers to know whether applicants have neglected to mention that they are carriers of genetic disorders or that these run in the family. This information could be invoked to prove that the applicant has made a false declaration and that the contract is invalid (Lapham et al. 1996).

Requesting genetic tests from insurance applicants could constitute another source of information for insurers. This would permit to classify individuals more accurately in various categories of risk, or to assess risk premiums more accurately. The concept of equity in insurance means that people who have similar health or similar life expectancies should pay equal premiums and those who have worse health or lower life expectancies should pay more. Genetic testing would then enhance equity by allowing a precise calculation of which people are really in the same situation and which are not (Lemmens & Bahamin 1998).

3.3- Constraints imposed on insurers

To date, insurers do not require applicants to submit to genetic testing. In some countries, this is due to legal barriers which prohibit insurers from asking for genetic tests. This is also due to the lack of information on the predictive value of tests and on the costs of diseases (Lemmens & Bahamin 1998, Ross 1997). But that does not mean that insurers are not using genetic information such as genetic information available in medical files. Insurers can currently make genetic inferences from routine and well-accepted questions on family history.

Insurers will probably not wish to deny coverage to a significant segment of the population. Everyone carries some potentially abnormal genes and if the Human Genome Project identifies all these genes in the near future, mathematical models will have to be developed to determine under which conditions carriers of mutations will be insurable (Morrison 1998). In addition, educational programs on the basic principles of genetics and insurance will have to be developed to improve the insurance coverage. This is important especially since the funding problems of most welfare programs lead many governments to shift a portion of the State's financial burden onto private insurers, particularly in relation to medical costs and the costs of long term care.

IV- Concerns of the employers

Concerns of employers and of insurers are very similar. The main difference between life insurers and employers is that for employers, sickness represents a greater financial risk than death, while for health insurers, the opposite is (usually) the case. Health insurers are those offering cover for medical care and long term care costs, for income protection and policies which pay out a lump sum on diagnosis of a serious disease (critical illness cover).

4.1- Goal of employers

It is in employers' interests to have a healthy workforce. More and more employers provide facilities to encourage the staff to achieve a good health, like regular medical check-ups and sport. It has been argued that if it could be demonstrated that genetic screening would

encourage more healthy lifestyles, it would be possible to envisage that employers would fund such screening for their staff (Ross 1997).

Many employers provide a range of health insurance coverage for their employees: sick pay, permanent health insurance, spouse's pension, retirement pensions, healthcare benefits. Most employees are covered without having to provide any information about their health. But in recent years there has been some trend towards flexible remuneration packages, under which employees get some measure of choice as to which employees benefits they take. Where employees have a choice, some measure of individual underwriting is required (Roscam-Abbing 1994, Ross 1997).

Employers are particularly interested in the health of the employees for jobs where there is a substantial investment in training or for very senior positions. For most jobs, employers do not insist on intensive health testing of prospective employees, because the extent of the employers' investment in new employees is not great enough to warrant such expense (Ross 1997). The prospective employees are simply asked to make a declaration about their state of health.

4.2- Sources of information

Different sources of information can be used to assess whether an individual has a risk of either sickness or death: medical history, family history, age, lifestyle, socio-cultural criteria, medical examination. The family history may suggest that an employee has a high risk of developing a monogenic disease. Genetic testing might confirm the risk, which for some jobs could make the person unacceptable (Ross 1997). What would also change is that some employees would move from 50% to 0% chance and they would have opportunities which are currently denied them.

Although the use of genetic information might conceivably be of some benefit for employers, it runs counter to the fundamental rights of workers to non-discrimination for health reasons and those relating to protection of privacy. For instance in France, such rights which have been reinforced by the laws on bioethics in 1994, are proclaimed in several articles in the labor and penal codes.

4.3- Constraints imposed on employers

The costs of any health investigation by employers are significant: if employers investigate every prospective, employees they will have to pay the investigation costs for all of them, but in only a few will the investigation show anything at all. The decision for employers, where there is a known health risk, is whether the value that employees will give to the firm justifies the risk (Roscam-Abbing 1994, Ross 1997). Recently, in the United States, a presidential order prohibited every federal department and agency from using genetic information in hiring and firing decisions. The American President also endorsed the Genetic Non-discrimination in Health Insurance and Employment Bill 1999. This seeks to extend these protections to the private sector and in respect of health insurance as well as employment (The Nuffield Trust 2000). A number of US states have been exploring legislative prohibitions on employment or health insurance discrimination.

V- Concerns of the public

People are becoming aware that they are exposed to global risks, such as rising unemployment, collapse of pension funds, funding problems of welfare programs, and are therefore vulnerable. In this context (of cost-shifting), public funding for insurance may be threatened, while community rating in commercial insurance may happen, as for instance with private medical insurance cover in Ireland. As to private insurance it is based on mutuality and consequently discriminates in setting premiums. Individuals assessed as representing a higher perceived risk may pay more, and some may be denied cover, although the great majority are treated as standard risks (Bonn 2000, Hall & Rich 2000, Human Genetics Advisory Commission 1997, Morrison et al 1999).

5.1- Right to underwrite

For monogenic disorders, the effect of any anti-selection by an individual exploiting knowledge of his undisclosed genotype depends largely on the size of the sum for which his life is insured (Macdonald 1997). The British Society for Human Genetics (1998) suggests that all life insurance should be offered without genotype disclosure up to an agreed maximum sum. This sum should be no less than the limit for each age bracket that the company sets for a Medical Examination. It is also suggested that where there is no disclosure of genotype, the insurance companies should not request family history information either.

For multifactorial diseases, it is difficult to establish genotype-specific predictive empirical risk figures. Therefore, there should be no role for genetic data concerning multifactorial diseases in underwriting decisions (British Society for Human Genetics 1998).

5.2- Duty of disclosure

Disclosure and confidentiality issues are some of the most frequent ethical problems appearing in genetics. For instance, in the United Kingdom, The British Society for Human Genetics (1998) states that in so far as any genetic test data are sought, the applicant should not be asked to disclose any existing genetic test results. Any requirement for disclosure should be restricted to evidence that the company can show, on the basis of published and actuarially validated data, as being likely to affect the risk insured, over the timescale insured. Also, preferred life insurance at below standard premium on the basis of genetic test results should not be offered. The British Human Genetics Advisory Committee (1998) also suggests that the insurance industry should stop using tests results, until the Genetics and Insurance Committee has validated them. Regarding genetic testing for employment, the Human Genetics Advisory Committee (1999) say that individuals should not have to disclose the results of previous genetic tests without clear evidence that the information was needed to assess whether they could do the job safely.

The WHO (1997) proposes that results of carrier tests, presymptomatic tests, susceptibility tests and prenatal tests be kept confidential from employers, insurers, schools and government agencies. People should not be penalized or rewarded for their genetic constitutions. Information about a symptomatic condition may be disclosed as part of general medical information, in accordance with laws and practices in different countries.

VI- Delineation of important topics for insurers, employers and the public

6.1- Insurers

6.1.1- Risk pooling and underwriting

The EUROSCREEN Insurance Subgroup (1997) reported that there tends to be an under appreciation of the importance of risk classification in insurance. A common objection is that classifying policyholders according to risk is an objectionable practice because it amounts to discrimination. The insurance industry argues that it is not engaged in discrimination but in differentiation. Further, it differentiates between risk categories rather than between individuals. To date, legislators have reacted to the claim that since an increased use of genetic information will mean that some people will be refused insurance premiums, this amounts to an unjustified form of discrimination. This could then lead to the conclusion that legislation should be passed to limit the use of genetic information by insurers.

There also seems to be a misunderstanding of the distinctions which arise between an industry based on equity and one that is based on equality. Insurers argue that their system is based on the principles of equity, mutuality and actuarial fairness. The insurance industry does not claim to be based on equality - as a social insurance system would - but rather the principles of equity, mutuality and actuarial fairness combine to produce a system whereby the individual consumer pays a premium which seeks to reflect the risk which she/he brings to that mutuality or risk pool. Genetic testing skews the fairness principle because 1) some will be aware of their risk status whereas others will not and 2) because the risks associated with particular genotypes are not voluntarily assumed by individuals, but are rather the result of the luck of the draw. It is argued that if the principle of equity in insurance is to be replaced by equality in an era that sees a widespread use of genetic tests, then this could signal the end of the involvement of the insurance industry in certain sectors of the market, notably life insurance and perhaps medical expenditure insurance. If legislators decide to intervene in this area and alter the balance of the insurance industry, efforts might be directed at finding an alternative method of producing the social benefits currently provided by the insurance industry (EUROSCREEN Insurance Subgroup 1997).

6.1.2- Adverse selection

Adverse selection is a classical problem in insurance theory (Sandberg 1995). Adverse selection occurs when people have undergone testing and conceal positive test results from insurers. Insurers require symmetry of information. If the insured person does not disclose information which the insurer needs to know, then this disrupts the equilibrium of the relationship and the possibility of adverse selection arises. If insurers are prohibited from having access to pertinent information at the time of underwriting or when the policy is renewed, the applicants could use genetic information to abuse the insurance system, taking advantage of private knowledge of the risks they are submitting for coverage (Chuffart 1997). The consequences of a lack of symmetry in information between insurers and applicants or insured persons could force insurers to adjust premiums. In the Netherlands, after the Medical

Examination Act has been in force, insurers have taken measures to prevent the risk of adverse selection by implementing premium increases in advance, by prescribing a maximization of the pension pay-out or basing payments on a maximum salary, or by including an option to increase the premium in the policy. Dutch insurers have also introduced waiting times for existing illnesses when issuing the insurance. This means that if, within a term stipulated in the waiting time, the insured becomes disabled or dies as a result of an illness that he had when he took out the insurance, no payment will be made. This measure does not apply for life insurance (Goedvolk 1999).

In the future, people might be able to undergo confidential genetic testing and hide their results (Lemmens & Bahamin 1998). Those who will know that they are at high risk might start buying substantial amounts of insurance and insurance companies would be overwhelmed by claims (Pokorski 1997). Still, a recent study assessing the potential for adverse selection in the life insurance market when tested individuals know their genetic test results but insurers do not, shows that women who test positive for the BRCA1 gene mutation do not capitalize on their informational advantage by purchasing more life insurance than those women who have not undergone genetic testing (Zick et al 2000).

There is an element of speculation involved in the possibility of adverse selection due to the information provided by genetic tests. Genetic testing is in its infancy: a high degree of uncertainty is involved in many genetic diseases and the specificity of many tests is not optimal (Ross 1997). Some restrictions on the use of genetic information may be found and be compatible with the continued existence of the insurance industry. The Association of British Insurers (1997) agrees that potential applicants should not have to undergo a genetic test as a pre-condition of obtaining an insurance policy, but anyone who has previously had a genetic test should disclose the results. Some life insurance companies in the UK believe that some tests could be used appropriately to stratify the risks to which they are exposed (Wilkie 1998). For the British Human Genetics Advisory Commission (1997), the life insurance industry could currently withstand limited adverse selection that might occur as a result of non-disclosure of genetic test results for life insurance.

6.1.3- Types of products affected by genetic issues

Genetic test results will not affect all types of products in the same manner. Genetic testing may almost exclusively affect individuals insurance as members of groups usually not individually underwritten (Chuffart 1997). In the same way, genetic testing may only concern individuals applying for high levels of cover, for which a medical examination is usually requested (Le Grys 1997), or for personally purchased insurance in general (Hauser & Jenisch 1998).

Products which should be exposed to restrictive legislation are those which are perceived as necessary to guarantee a service considered as a social good such as access to health care or credit (Chuffart 1997, Wilkie 1998).

6.2- Employers

At least two types of employment discrimination based on genetic testing have been identified (Natowicz et al. 1992). First, an employer may not hire someone who is likely to

develop a genetic disease. An at-risk individual may be viewed as someone who would frequently be absent from work, would be less productive than others, or might require more healthcare services. Second, an employer may not permit an individual to work in an area in which (s)he would be exposed to a toxic chemical if that individual is known to have a susceptibility to its toxic effects. It might be proved easier to test for genetic susceptibility than to remove whatever environmental health hazards there are in the work place. Genetic testing in this situation may increase productivity by reducing absenteeism caused by illness linked to susceptibilities to occupational hazards. However, it has been argued that, at least for multifactorial diseases, there is no scientific evidence yet to link unexpressed genetic factors and the ability to perform a job function (Rothenberg et al. 1997). Genetic tests are unlikely to identify susceptibility to disease with any precision as it might be aggravated by the workplace environment (The Nuffield Trust 2000). Therefore, employers cannot prove that the use of genetic information is job related.

An improvement in health would be beneficial to employers and employees. Sickness is expensive, both in time spent not working and the cost of treatment. Genetic testing could be used to improve preventive medicine and to reduce the costs of sickness (Ross 1997).

6.3- Public

It has been argued that giving insurers and employers access to genetic information through medical files could discourage people from being tested or infringe on their privacy and violate their right not to know (Miller 1994, Morrison et al 1999, Park & Dickens 1995). It has been also argued that allowing insurers and employers to require genetic testing removes genetics from the medical context and increases the pressure for genetic conformity (Lemmens & Bahamin 1998).

6.3.1- Genetic information

Genetic information includes DNA, chromosome analysis and clinical tests, as well as family history. Giving insurers access to genetic information in medical files raises two questions: 1) How relevant is it, when people neglect to inform their insurer about medical problems or conceal health information from them, if their death has nothing to do with the missing information? 2) Are the results of genetic tests always relevant for insurers? Applicants who test positive for genetic mutations in a context of research might not have health problems that are relevant for insurance purposes (Lemmens & Bahamin 1998).

As for insurance, the fear of employment discrimination through employers access to medical files might discourage at-risk individuals from undergoing medically indicated genetic testing (Holtzman 1996).

6.3.2- Genetic tests

Should applicants be asked to undergo a genetic test in order to obtain any type of insurance? Insurers may therefore have access to confidential information that applicants do not want to know. The perceived threat of discrimination will tip the balance against somebody seeking testing to obtain improved medical management and reassurance. In the

United Kingdom, the ruling by life insurance companies that results of ten specified, previously voluntarily taken genetic tests have to be disclosed by people seeking new policies worth more than £100,000, might deter people from having tests that could save or prolong their lives and jeopardize research into genetic testing (Kmietowicz 1997). People may also be encouraged not to share the result with their general practitioner for fear of disclosure to insurance companies. This fear has been observed among people with a family history of Huntington disease who requested presymptomatic gene identification: people attempted to avoid insurance or employment discrimination by withholding the decision to seek testing from their primary care providers (Williams et al 1999). Genetic testing could then cause insurance applicants and their relatives to be rated up or denied insurance and lead to social exclusion, especially since genetic information would not only be used for insurance purposes but also employment purposes. Finally, requesting genetic tests from insurance applicants could create problems if counseling services are missing and if social pressure increases on those affected by genetic disorders.

Several factors represent significant issues for insured persons and insurers: inheritance mode of the disease, treatment costs, age at death... For untreatable monogenic diseases with an early onset, there is no relevance for life insurance; for those with late onset, there is maybe the chance to reduce the risk to near normal (Bodmer 1996). In multifactorial inheritance, the question arises whether genetic information can be used to help the individuals at risk to overcome their susceptibility. However, the level of risk may be insufficient to have relevance for life insurance (Bodmer 1996, Morrison et al 1999). It may well be relevant to health insurance.

Genetic testing in the workplace may lead to individuals with an increased susceptibility to the effects of workplace toxins being banned from working in these areas (Jacobs 1998). Prevention of most genetically determined defects that may lead to illness and disability is an unattainable goal. It has been argued that genetic testing by employers should be limited to screening individuals at-risk for developing diseases that may result from certain exposures that exist in the workplace and employment decisions should not be based on genetic factors (Jacobs 1998, Rothstein 1995). The employee's main reason for joining the employer is to get a job, not to exploit a benefits package (Ross 1997).

VII- International comparisons: legislation, policy statements, professional guidelines

In recent years a significant number of states have enacted legislation to prevent the acquisition of genetic information by insurers such as Austria, Belgium, Denmark, France, Norway, and the Netherlands. Or insurance companies have chosen to impose a moratorium. This is the case in Finland, France, Germany, Sweden, Switzerland, and the Netherlands. Among the countries where there is no regulation, bills have been presented, like in Iceland and Switzerland, or states that have 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 are bound by it. This Convention is the first internationally-binding legal text designed to protect people against the misuse of biological and medical advances. This text has legal effect in the Council of Europe's member States that have ratified it. Each state then has to bring its laws into line with the Convention. Austria, Belgium, Germany, Ireland, and the United Kingdom have not yet signed the Convention and it has no force until it is signed and implemented into the national law.

There are Two main legislative responses to genetic testing and insurance in Europe: the first is that of countries which prohibited the use of genetic information by insurers outright, such as Austria, Belgium, France, Norway, and Denmark. The second legislative approach is that of countries which authorize access to genetic information under certain conditions: for instance if the amount of coverage exceed a certain limit. It is assumed that the risk of adverse selection only truly comes into play with large amounts of capital. This is the case in the Netherlands where insurance companies are prohibited by the Medical Examinations Act from seeking disclosure of the results of any genetic test where the amount being sought is less than 300.000,00 guilders. Although it is not a legislative decision, in the United Kingdom, the insurance industry is able to take into account genetic tests that are validated as actuarially sound by the independent Genetics and Insurance Committee.

The adoption of moratoria on the use of genetic information 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, Switzerland), or still limited to insurance policies which do not surpass a certain value.

The table below shows the current responses to the use of genetic information by insurers in Europe:

Country	Legislation	Moratorium	No regulation
Austria	+		
Belgium	+		
Denmark	+		Has ratified the Oviedo Convention
Finland		+	
France	+	+	
Germany		+	
Greece		+	Has ratified the Oviedo Convention
Iceland			Bill
Ireland			
Italy			
Norway	+		
Portugal			
Spain			Has ratified the Oviedo Convention
Sweden		+	
Switzerland		+	Bill
The Netherlands	+	+	
United Kingdom			

7.1- European Institutions

- *European Union, Resolution on the Ethical and Legal Problems of Genetic Engineering of the European Parliament (March 16, 1989, n. R89, 2, n. R89, 14) (<http://europa.eu.int>), in which two principles refer to insurance:*

Principle 19: "Insurance companies have no right to demand that genetic testing be carried out before or after the conclusion of an insurance contract nor to demand to be informed of the results of any such tests which have already been carried out and that genetic analysis should not be made a requirement for the conclusion of an insurance contract"

Principle 20: "The insurer has no right to be notified by the policyholder of all the genetic data known to the latter"

The Resolution has no legal authority; it sensitizes people to the arisen problems of the developments in genetics.

- *Council of Europe, Recommendation on genetic testing and screening for health-care purposes of the European Committee of Ministers (1992, n. R92, 3) (<http://www.coe.fr/cm/ta/rec/1992/92r3.htm>)*

Principle 7 refers to insurance: "Insurers should not have the right to require genetic testing or to inquire about results of previously performed tests, as a pre-condition for the conclusion or modification of an insurance contract"

All members of the Council of Europe adopted this Recommendation, except the Netherlands.

- *European Union, The Data Protection Directive, 1995 (http://www.privacy.org/pi/intl_orgs/ec/eudp.html)*

In 1995 the Council and Parliament of the European Union adopted Directive 95/46/EC to harmonize the protection of data privacy in the EU. The Directive was to be implemented in national laws and regulations by October 24, 1998. The Commission's proposed Directive was designed to establish minimum standards for the processing and use of personal data throughout the Community, for two reasons: (1) to ensure that the Member States protect the "fundamental right" to privacy with respect to the processing of personal data, and (2) to prevent Member States from restricting the "free flow of personal data" among Member States on grounds of privacy protection.

- *Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (April 1997, DIR/JUR 96, 14) (<http://www.coe.fr/fr/txtjur/164fr.htm>), in which three articles refer to insurance:*

Article 11: "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited"

Article 12: "Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling"

Article 26: "No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others". It is mentioned that these restrictions may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

- *Council of Europe, Recommendation on the Protection of Medical Data of the European Committee of Ministers (1997, n. 97, 5) (www.coe.fr/cm/ta/rec/1997/97r5.html)*

Article 4.7 states that "Genetic data collected and processed for preventive treatment, diagnosis or treatment of the data subject or for scientific research should only be used for

these purposes or to allow the data subject to take a free and informed decision on these matters". According to Article 4.8, "Processing of genetic data for the purpose of a judicial procedure or a criminal investigation should be the subject of a specific law offering appropriate safeguards. The data should only be used to establish whether there is a genetic link in the framework of adducing evidence, to prevent a real danger or to suppress a specific criminal offence. In no case should they be used to determine other characteristics which may be linked genetically". Article 4.9 stipulates that for purposes other than those provided for in Principles 4.7 and 4.8, the collection and processing of genetic data should, in principle, only be permitted for health reasons and in particular to avoid any serious prejudice to the health of the data subject or third parties. However, the collection and processing of genetic data in order to predict illness may be allowed for in cases of overriding interest and subject to appropriate safeguards defined by law".

- *European Union, The Data Protection Act of the European Committee of Ministers, 1998* (europa.eu.int/comm/dg03/publicat/)

The Data Protection Act 1998 implements the EU Data Protection Directive and provides a system of general protection and security for personal data which covers, amongst other things, medical data.

7.2- European Countries

7.2.1- Austria

- *The Gene Technology Act (1994)*
(http://www.gentechnik.gv.at/gentechnik/B1_orientierung/gen_10084.html)

This Act regulates work with genetically modified organisms, the release and marketing of genetically modified organisms, and the use of genetic testing and gene therapy in humans and amending the Product Liability law:

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 genetic analyses on their employees, candidates, policyholders or insurance applicants. In practice, the state insurance system does not refuse cover to any applicant, but the private insurance companies are able to refuse to grant cover or only grant it at the cost of an increased premium (Hauser & Jenisch 1998). Inquiries made about applicants to the private insurance companies indicate that the latter 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 a negative test result (Ibid). 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 advantage.

7.2.2- Belgium

- *Law on terrestrial insurance contracts, 1992*

Article 95 prohibits the use of genetic testing that enables to predict the future state of health while Article 5 states that "genetic data may not be declared". Applicants are

prohibited from subletting the results of genetic testing to insurers, whether these results are positive or negative.

7.2.3- Denmark

- *Danish Council of Ethics, Protection of Sensitive Personal Information - A Report, Copenhagen, 1992* (www.etiskraad.dk/english/publications.htm)

The Council recommends very strict control on the use of medical records and medico-biological "banks". The Council recommends that the individual is given full control of the gathering and use of "person-sensitive" data and biological material. The Council also recommends legislation to secure individual autonomy, integrity and the right to know about and control the use of person sensitive data.

- *Danish Council of Ethics, Genetic Testing in Appointments. Copenhagen, 1993*

- *Law No. 286 of 24 April 1996 on the Use of Health Information on the Labor Market (Intl. Dig. Hlth. Legis., 47, 1996:371-72)*

This Act strictly limits employers' rights to ask potential employees for health information including information based on genetic testing.

- *Act No. 413 of 10 July 1997, Act to Amend the Insurance Agreement Act and Act on the Supervision of Company Pension Funds* (<http://www.forsikringenshus.dk/htmm/eng/annualr.htm>)

The way insurers used to get health information when the law was passed is not prohibited and this means that the insurer is allowed to ask for information on blood samples e.g. HIV test. Insurers only ask for HIV test and family history when the sum insured is high and over a certain level.

7.2.4- Finland

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 principles, such questions include those about genetic tests. 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).

About the occupational aspects, there is a law on the privacy in occupational life that is under preparation. The proposal states that genetic tests in occupational settings can be used only with a permission of The National Board of Medical Legal Affairs and that permission could be attained only if the test is for protecting the individuals health.

- *Acts and Decrees Concerning Protection of Personal Data and Confidentiality of Medical Data, 1987*

The Personal Data Files Act contains the right to know whether a file includes 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 regarding him/herself, how that information is used and to whom that information is given.

- *Personal Data Act, 523/1999 (<http://www.tietosuoja.fi/uploads/hopxtvf.HTM>)*

The Personal Data Act 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.

7.2.5- France

- *Law of December 1989 related to the protection of persons against discrimination on the basis of their state of health or of their handicap, J. O. of January 3, 1990*

- *Law n. 94-653 of July 29, 1994 on respect for the human body (Article 16-10 of the Civil Code) (<http://www.cnrs.fr/SDV/loirespectcorps.html>) stipulate that:*

- According to the Article 16-10, "the genetic study of an individual's characteristics can only be carried out for medical purposes or scientific research".

- Article 226-26 of the *Code pénal* states that "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 FRF 100,000"

- In 1994, the *French Federation of Insurance Companies* (<http://www.ffsa.com/pub/pub.htm>) announced that for a period of 5 years, which coincides with the 5-years period upon expiry of which the law n. 94-653 of July 29, 1994 was to be revised, its members would not use genetic information to determine applicants' insurability. This moratorium has been extended for another period of 5 years (2004).

- *National Consultative Ethics Committee, Opinion and Recommendations on Genetics and Medicine: from Prediction to Prevention, Reports, Paris, 1995 (<http://www.ccne-ethique.org/english/avis/>)*

The report recommends prohibiting insurers from using genetic information, even if that information is voluntarily provided by applicants.

- *Decree n. 2000-570 dated June 23, 2000 fixing the conditions of prescription and implementation of genetic characteristics and genetic identification investigations of a person for medical reasons and modifying the Public Health Code.*

This decree fixes 5 conditions for prescribing and implementing genetic testing for medical purposes: 1) Condition of prescription; 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 purpose.

7.2.6- Germany

The use of genetics for insurance purposes is not regulated under German law. Contractual liberty allows insurers to ask 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 which could be important for the acceptance of a risk. This includes the results of a genetic test. However, a moratorium exists since 1988, according to which insurers neither make genetic tests a prerequisite for insurance contracts nor do they ask for the results of genetic tests performed in the past. This moratorium has been renewed in 1999 by the German insurers' association (Lauth & Schmidtke 1999).

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

- *Enquete-Kommission des Deutschen Bundestages, Chancen und Risiken der Gentechnologie, Dokumentation des Berichts an den Deutschen Bundestag, Frankfurt, 1987*

The document recommended a new criminal offence where an employer discriminates against an employee on the basis of the results of his genetic test. In most instances the report did not recommend that legislation be enacted but rather that these matters be supervised by authoritative professional bodies (McGleenan 1999).

- *The German insurers' roof organization, Moratorium on genetic tests, 1988*

This moratorium states 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.

7.2.7- Greece

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.

7.2.8- Iceland

There is as yet no legislation prohibiting insurance companies from using genetic information when people take out insurance. A bill has been presented. The intention is that genetic testing should be used for medical research, for the benefit of the public (Federation of Finnish Insurance Companies, 1999).

7.2.9- Ireland

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

Health Insurance (but not life insurance) must by law be "community rated". That is, every person is entitled to insurance at the same rate, regardless of medical history or status. Thus, discrimination on the grounds of genetic status is prohibited in health insurance.

The Irish Insurance Federation proposed in October 2000 to implement a code of practice for life insurance modelled on that adopted by the British Insurance Federation. This Code forbids insurers to require applicants to take a genetic test to obtain insurance, and does not require insured persons to disclose results of tests taken after a policy comes into force. However, any tests results known at the time of application for insurance must be revealed. Discussions between Government Departments and stakeholders are ongoing as of January, 2001.

7.2.10- Israel

- Law on Protection of Personal Genetic Information, 13 December 2000

The law follows the guidelines for protection of genetic information as issued by HUGO and other organizations. The section regarding the issues of Insurance and employment are as follows:

Insurance: Israel has a National Medical Insurance, with coverage of basic health needs. The outcome in the law on protection of personal genetic information is as follows: The insurer may not request genetic testing under any circumstances. They may, however, ask whether the person requesting insurance had a genetic test, with the following restrictions: 1. It will apply only to recent genetic testing in the last 3 years (prior to requesting the insurance); 2. It will apply only to cases where the requested insurance rate is high (the limiting rate will be determined by the Minister of Finance); 3. The list of diseases will be determined by the Minister of Health; 4. It will not apply to people asking for life insurance which is required for mortgage when buying a home.

Employment: It is prohibited for employers to ask employees for genetic testing or genetic information, or to use such information in any way related to hiring, promotion, firing, etc. The only exception is in special workplaces where it is well established that certain genetic make-up may predispose the worker to health risks. In such cases: 1. The decision about which jobs or places are allowed to ask for genetic testing/information will be made by the Minister of Health in consultation with the Minister of Welfare, and require the approval of the Parliament Committee of Science and Technology (the committee that worked

on the law). 2. Employers permitted to ask for genetic testing/information will do so only after hiring the employee, and before starting the job (in order to avoid a situation where the genetic information will be used to discriminate in hiring). If the employee is found to be genetically susceptible, the employer must make all efforts to facilitate his/her employment at the same place by eliminating the risk factor (i.e. transfer the employee to another job in the same facility or provide special protection). 3. The details (which genetic tests, how they will be performed, what is needed to protect the health of employees) may be determined by the Minister of Health, as under (1) above.

It was decided (in the Science Parliament Committee) at this stage NOT to allow genetic testing for the 'protection of the public'. The reasons were two: first, there was no practical example of genetic testing available that may justify such exception. Therefore it was decided to leave this door closed, and to make the amendment in the future if the need arises and it is scientifically justified. Second, the general feeling was that the law should be as tight as possible, and that even narrow exceptions may open the door to wider discrimination.

7.2.11- Italy

- *Law n. 675, 31 December 1996, D.P.R. n. 318, 28 July 1999, on Medical Information Privacy*

There is no specific legislation on the use of genetic information by insurers and employers in Italy, but the Law n. 675 states the privacy of all medical information.

- *The Italian Committee on Bioethics, Orientamenti bioetici per i test genetici, 19 November 1999 (<http://www.palazzochigi.it/bioetica/orientamenti%20biomedici.htm>)*

These recommendations 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.

7.2.12- Norway

- *Act Relating to the Application of Biotechnology in Medicine, Law n. 56 of 5 August 1994 (http://www.helsetilsynet.no/htil/avd2/bio_act.htm)*

Chapter 6 states that genetic testing can only be performed for medical diagnosis and/or therapeutic purposes. (...) It is forbidden to request, receive, possess or use information resulting from a genetic test on any person. It is also prohibited to ask whether such a test has been carried out previously.

Chapter 8 stipulates that anyone violating this law will be punished with an economic fine or will be sentenced to prison for three months.

- *Norwegian Biotechnology Advisory Board, Genetic Testing: When & Why? Oslo, March 1996.*

- *Norwegian Biotechnology Advisory Board, The Use of Genetic Information about Healthy People by Insurance Companies. Oslo, April 1997.*

7.2.13- Portugal

There is no legislation concerning genetic testing in Portugal; however some important guidelines prepared by the 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 counseling.

- *Act No 10/95 related to the Protection of Personal Information*

7.2.14- Spain

- *The Spanish Constitution of 1978*

The Spanish Constitution forbids any kind of discrimination on grounds of any personal or social circumstance or condition. This prohibition should be concerned 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).

- *General Health Law of 25 April 1986*

There is no specific rule in Spanish General Health Law concerning the submission to genetic tests by adults.

- *The Organic Law regulating the automated processing of personal data of 29 October 1992*

This law provides special measures of protection for personal health data (articles 7.3 and 8).

- *Labor Risk Preventive Act of 8 November 1995*

Article 25 "Protection of the specially sensitive workers to determined risks" stipulates that employers will guarantee the protection of the workers who will be specially sensitive to the risk derived from work. This article does not refer to the situations of susceptibility to know genetic predisposition or to future monogenic illnesses also known without any type of symptom in the moment of entering the work post (Karlic & Horak 1998). There is no provision for applicants to a job.

- *The Organic Law regulating the automated processing and protection of personal data of 13 December 1999*

This law includes automated data and any type of personal data.

7.2.15- Sweden

- *Data Storage in Health Care Act (1985:562):*

This act address patients personal files.

- *Health Care Act 182:763 (1992:567):*

This Act states that health care should be provided to all members of the Swedish society on an equal basis.

- *Law 114 of March 1991 on the Use of Certain Gene Technologies within the Context of General Medical Examinations (1993)*

This law examines the use of certain genetic technology in medical screening. There must be a permission from the National Board of Health and Welfare. Authorization from this body is required before DNA testing can be carried out. This requirement extends to the use of genetic screening techniques for diagnostic purposes.

The use of information about an individual which has been obtained by studying his genetic characteristics other than for medical purposes is prohibited.

Genetic discrimination can be subject to penalties in the form of fines or prison sentences up to a maximum of 6 months.

- *The Agreement between the Swedish State and the Swedish Insurance Federation concerning genetic testing, 1999*

According to this agreement, insurance companies have undertaken not to start requiring insurance applicants to undergo genetic investigations, nor – as a condition of individual life and health policies up to an inflation-indexed once-only lump sum – to ask them to submit the findings of previous genetic tests, if any. The state is entitled to cancel the agreement with immediate effect if any insurance company disregards what the Insurance Federation has undertaken. This agreement is valid to the year 2002.

7.2.16- Switzerland

- *The Insurance Contract Act*

Under the Act on Insurance Contract, applicants have a duty to inform insurers of whatever they know or should know that could influence the contract (Lemmens & Bahamin 1998). The insurance companies have unofficially agreed not to request any genetic tests until the year 2000 at the earliest.

- *The Federal Code of Obligations*

The federal Code of Obligations stipulate the nullity of any contract against the law or against common morality (art. 20). Read in connection with article 27 II of the Civil Code which protects the individual against excessive commitments, this article speaks for the nullity of a contractual clause in an insurance contract which would release the applicant physician altogether from his obligation of confidentiality. Article 321 of the federal Criminal Code punishes the professionals who reveal confidential information.

Article 328b of the Code of Obligations stipulates that employers may only use data regarding the employee if they concern the employment relationship or if they are necessary to carry out the employment contract. This rule concerns existing or imminent diseases, thus excluding presymptomatic investigations (Karlic & Horak 1998).

- *The Swiss Federal Constitution, 1992*

Article 119 (introduced in 1992 as article 24novies, old numbering) paragraph 2 states that the genetic heritage of an individual may be analyzed, registered or divulged only with his consent or on the basis of a legal prescription.

- *The Swiss Academy of Medical Sciences, Medical-ethical Guidelines for Genetic Investigations in Humans, Approved by the Senate of the Swiss Academy of Medical Sciences on 3rd June 1993 (http://www.samw.ch/e/richtlinien/richtlinien_fs.html)*

Paragraph 3.7 states that "medical doctors may make the medico-genetic findings available to third parties only with the consent of the person investigated or of his legal representative, and only after the implications of such disclosure of information have been explained to them".

Paragraph 3.8 states that "genetic investigations must not be carried out for the purpose of assessing the suitability of a person for certain activities or work, unless the investigation is performed in order to detect factors which, if present, would render a particular activity a considerable risk to the health of the individual or for other persons".

Paragraph 3.9 recommends "particular reservations when the results of a requested genetic investigation are to be used in connection with the taking out or the revision of an insurance policy. The results are to be communicated exclusively to the person investigated or his legal representative, after the implications of the passing on of such information to third parties have been explained to them".

The Swiss Academy of Medical Sciences guidelines about genetic investigations in humans have been included into the Code of Deontology of the Swiss Medical Association and apply directly to all the physicians who are members of the Association. These guidelines are not legally binding, unless cantonal legislation gives them binding force.

- *Bill regarding Genetic Investigations in Humans, 1998*
(<http://www.admin.ch/cp/d/384b8f91.0@fwsrv.g.bfi.admin.ch.html>)

This bill has not yet been debated in Parliament. Section 3 stipulates that when establishing an employment relationship, or during employment, the industrial doctor may order a presymptomatic investigation only if all of the following conditions are met (Art. 19 § 1): The workplace represents a risk for an industrial disease or a serious damage to the environment or an extraordinary risk of accidents or health hazard for third parties. Safety measures according to the law are not sufficient to eliminate this risk. The workplace is put under the regulation of preventive industrial medicine by order of the competent authority or by law. The specific risk for the employee or the imminent and serious risk for third parties or the environment cannot be evaluated in another way. A federal panel for genetic investigations has pronounced the method safe and reliable on detecting a risk. The employee agrees to the investigation. The employee shall inform the industrial doctor, on the latter's initiative, of the results of former presymptomatic investigations relevant to the ability to perform the specific work (Art. 19 § 2).

Section 4 stipulates that insurers are not allowed to demand a presymptomatic or prenatal investigation as a condition of insurance (Art. 22 § 1). As for the results of former investigations, the Bill differentiates: As a rule, insurers are not allowed to ask for or use the results of former presymptomatic or prenatal investigations or investigations for family planning (Art. 22 § 2). The competent federal authority, however, can make an exception in the case of non-compulsory insurance (Art. 23 § 2). The applicant is obliged to answer the medical examiner's questions on the results of a former presymptomatic investigation, if this investigation is reliable and if the scientific value of the result for calculating the premium is shown (Art. 23 § 2). The applicant may inform the insurer of the results of former presymptomatic or prenatal investigations in order to demonstrate that he has wrongly been classified in a high-risk group (Art. 23 § 1). The competence to specify which genetic information can be requested by insurers must rest in the hands of a federal authority (Art. 24 § 1). The questions must be relevant to evaluating the insured risk (Art. 24 § 2).

7.2.17- The Netherlands

- *Health Council of the Netherlands, Report: Heredity, Science and Society: On the possibility and Limits of Genetic Testing and Gene Therapy, The Hague, 1989*

The Council takes a strong position on autonomy, suggesting that every individual owns his or her genetic material and therefore informed consent is necessary for any use of it. However, the doctor-patient relationship is regarded as one in which the doctor's role cannot be specified entirely in terms of satisfying the interests of the patient. The doctor has his or her own responsibilities (e.g. to other parties), which lead to a potential conflict between beneficence and autonomy. The council is of the view that unauthorized disclosure may be permissible under limited circumstances when serious harm can be avoided and has noted that relatives' right to privacy should be a consideration when deciding whether or not a disclosure should be made.

- *Verzekeraars verlengen moratorium erfelijkheidsonderzoek, December 1990 (1995)*

The moratorium, originally five years, became indefinite in 1995. Insurers must abstain from using existing genetic test results for life applications up to NLG 300,000 and for disability applications up to NLG 60,000. Insurers must abstain from requesting genetic tests for all applications.

- *Medical Examination Act, 1 January 1998*

The basic principle of the Act is that individuals must have unimpeded access to socially important facilities such as work and certain insurances; employers and insurers may not discriminate people with some blemish. The legislature was of the opinion that in a number of cases this principle could only be achieved by a prohibition of the medical examination. The Medical Examination Act prohibits employers and insurers from requiring medical tests that could indicate that the applicant may be suffering from a severe incurable disease. 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. Insurers may not ask whether any blood relatives have any hereditary, serious, untreatable diseases, not even if the illness has already manifested itself or the blood relative has died from it. Finally, insurers may not ask about the results of previous genetic tests among blood relatives or the prospective insured himself. However, these prohibitions apply only for life policies below NLG 300,000 and for disability policies below NLG 60,000 (Goedvolk 1999).

7.2.18- United Kingdom

The present position in UK is that insurance applicants are not forced to undergo genetic tests but the results of certain genetic tests, to be defined by the new Committee on Genetics and Insurance, will be taken into account by insurers within certain guidelines. This Committee has already approved the use of Huntington's predictive test for insurance purposes. The ABI Code of Practice (see below) is accepted as the basis of good practice and is to be developed and adapted as new genetic knowledge comes to light. The ABI imposed a moratorium in 1997 on the use of results of genetics tests from new applicants for life insurance up to £100,000 linked to cover the purchase of a principal residence with a mortgage. This moratorium has been lifted in 2000.

- *Nuffield Council on Bioethics, Genetic Screening Ethical Issues, 1993* (<http://www.nuffield.org/bioethics/publication/pub0006739.html>)

The report called for the establishment of a central co-ordinating body to monitor genetic screening programmes once they are in place to make sure that they are: 1) following proper standards and criteria in providing information to people; 2) not introducing an element of compulsion; 3) protecting the data; 4) following any guidelines and rules that have developed in relation to the release of data for insurance. The co-ordinating body should also assess and recommend to government the value of establishing a screening program before its inception. The conclusions of the report have been widely endorsed.

- *House of Commons Select Committee on Science and Technology, Human Genetics: the science and its consequences, 3rd report, HMSO, London, 1995* (<http://www.parliament.the-stationery-office.co.uk/pa/cm199899/cmselect/cmsctech/489/48902.htm>)

The House of Commons Select Committee in its report on human genetics recommended that the insurance industry should find ways to avoid a conflict between their interests and the medical interests in genetic testing. The Association of British Insurers subsequently issued a Code of Practice on Genetic Testing (see below) and the Government appointed the HGAC, who took on insurance as one of their first projects.

- *Government Response to the Third Report of the House of Commons Select Committee on Science and Technology, Human Genetics: The science and its consequences, Department of Trade and Industry, 1996* (<http://www.parliament.the-stationery-office.co.uk/pa/cm/cmsctech.htm>)

- *Association of British Insurers, Code of Practice on Genetic Testing, November 1997 (revised August 1999)* (<http://www.abi.org.uk>)

This Code of Practice states that ABI members will in future only be able to take into account genetic tests that are validated as actuarially sound by the independent Genetics and Insurance Committee. As specified in the previous code of practice, insurance companies may not require applicants to undergo a genetic test, but an applicant who has received a test result must disclose it in relevant insurance applications. There is no requirement to disclose the results of a test taken by another family member, and insurers may not use genetic test results for one person in the assessment of an application from any other person. A person who undergoes a genetic test after taking out an insurance policy is not required to disclose the results to an insurer but must have honestly answered any questions in the policy application regarding medical and family history. Insurers may not 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. Best practice recommendations are included in the Code of Practice to ensure that information about individuals is kept secure and confidential.

- *Human Genetics Advisory Committee, The implications of genetic testing for insurance, November 1997* (www.dti.gov.uk/hgac/papers/papers_b.htm)

The HGAC report made a number of recommendations of which the three most important were that insurers should not be allowed to use any genetic tests results unless they had satisfied an independent body that there was a good factual actuarial basis for using these results; that there should be a transparent, open and independent appeals process; and that

there should be a moratorium on all testing for two years while these arrangements were being put in place.

- *British Society for Human Genetics, Statement on Genetics and Life Insurance, 1998* (<http://www.bshg.org.uk/insuranc.htm>)

This statement recognizes 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 (BSHG 1998).

The BSHG statement will be reviewed not later than summer 2003.

- *Department of Trade and Industry, Genetic Testing and Insurance, Government formal response to the HGAC report, 5 November 1998* (www.hgc.gov.uk/about_regulatory.htm)

The British Government accepted all of the HGAC recommendations apart from the moratorium. While not agreeing to the moratorium, they suggested that the insurance industry should immediately stop using test results, until the Genetics and Insurance Committee (GAIC) had validated them. The ABI did not take up this suggestion but declared in February 1999 that if a particular genetic test result was not validated for insurance use by the GAIC, their members would re-underwrite all policies taken out from November 1998 and review all relevant declinations from that date.

The mechanism for evaluating genetic tests and their relevance to insurance products, the setting up of a Genetics and Insurance Committee to do that and to monitor the industry's compliance to its recommendations, was established in 1999; the application form for industry use was issued in June 2000. The Genetics and Insurance Committee in June 2000 published its criteria for the assessment of applications for approval to use genetic test results for insurance risk assessment. The Genetics and Insurance Committee is now considering applications for approval of specific genetic tests, against these criteria.

- *Human Genetics Advisory Committee, The implications of genetic testing for employment, June 1999* (www.dti.gov.uk/hgac/papers/papers_ff_03.htm)

The HGAC report does not recommend a total ban on the testing of employees for genes that might predispose them to various conditions. The report suggests that employers could be allowed to ask for tests to detect a potentially dangerous illness, in the way that pilots are currently tested. In effect, testing should only be for the employees' benefit and not for the benefit of shareholders. The Commission also said that genetic tests should not play a part in recruitment. The Commission concluded that an individual's right not to know his or her genetic pre-dispositions should be upheld. Individuals should not have to disclose the results of previous genetic tests without clear evidence that the information was needed to assess whether they could do the job safely. Finally, the report recommends that testing be covered by the principles of data protection.

The Government's response to the HGAC report has now been published. This accepts all the main findings of the HGAC report and agrees that this issue should be kept under review. It asks the Human Genetics Commission to include this issue in the Commission's wider study of the uses of genetic information and to provide advice to Ministers in due course.

- *The Genetics and Insurance Committee, Decision of the Genetics and Insurance Committee Concerning the Application for Approval to Use Genetic Test Results For Life Insurance Risk Assessment in Huntington's Disease, October 2000* (<http://www.doh.gov.uk/genetics/gaichuntington.htm>)

The Genetics and Insurance Committee (GAIC) has approved a predictive genetic test for use by insurance companies. The test is a predictive test for Huntington's disease. This follows the Government's decision not to accept the recommendation of the Human Genetics Advisory Commission that there should be a moratorium on the use of predictive genetic tests by insurers. Instead, the Government set up GAIC to assess the actuarial validity of tests the insurance companies would like to use. The Huntington's application is the first GAIC has considered after issuing an application form setting out the information insurers must provide when applying for permission to use a test.

7.3- International Organizations

- *HUGO, Statement on the DNA Sampling Control and Access (February 1998)* (<http://www.gene.ucl.ac.uk/hugo/conduct.htm>)

Unless authorized by law, there should be no disclosure to institutional third parties - such as employers, insurers, schools, and government agencies because of possible discrimination - of participation in research, nor of research results identifying individuals or families. Like other medical information, there should be no disclosure of genetic information without appropriate consent.

- *UNESCO, The Universal Declaration on the Human Genome and Human Rights, (November 1997)* (<http://www.unesco.org/ibc/uk/genome/project/index.html>)

Article 6 states that "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity".

- *The World Medical Association, World Medical Association Declaration on the Human Genome Project (September 1992, doc. 17.S/1)* (www.wma.net/e/policy/17-s-1_e.html)

The disclosure of information to a third party or the accessibility to personal genetic data should be allowed only with the patient's informed consent.

- *The World Medical Association, Proposed international guidelines on ethical issues in medical genetics and genetics (1998)* (<http://wwwlive.who.ch/ncd/hgn/hgnethic.htm>)

"Genetic data should not be given out to insurance companies, employers, schools or governments, other than after the full informed consent of the person tested. In some countries it may be possible or necessary to protect both confidentiality and non-discrimination through legal means"