European Journal of Human Genetics (2003) 11, Suppl 2, S123–S142

www.nature.com/ejhg

REVIEW

# Genetic information and testing in insurance and employment: technical, social and ethical issues

Béatrice Godard[1,6], Sandy Raeburn[2], Marcus Pembrey[3], Martin Bobrow[4], Peter Farndon[5] and Ségolène Aymé[*,1]

[1]*INSERM SC11, Paris, France;* [2]*Department of Medical Genetics, Nottingham, UK;* [3]*Institute of Child Health, London, UK;* [4]*Department of Medical Genetics, University of Cambridge, UK;* [5]*Department of Medical Genetics, Birmingham, UK*

**The present paper examines the professional and scientific views on the social, ethical and legal issues that impact on genetic information and testing in insurance and employment in Europe. For this purpose, many aspects have been considered, such as the concerns of medical geneticists, of the insurers and employers, of the public, as well as the regulatory frameworks and unresolved issues. The method used was primarily the review of the technical, social, economical and ethical aspects of advances in genetics and the concerns of parties who are involved, that is, the insurers, the employers and the public. The existing guidelines and legislation on this topic were also reported. Then, the method was to examine the issues debated by these parties in Europe, as well as by 47 experts from 14 European countries invited to an international workshop organized by the European Society of Human Genetics Public and Professional Policy Committee in Manchester, UK, 25–27 February 2000. The result of this was that the most important issues raised by genetic information and testing in insurance and employment in Europe include a need for clear definitions of terms used in genetics, declaring the grounds on which genetic information is or is not used, and promoting confidence between the public and the insurance industry. There is currently very little use of genetic information in relation to employment, but the situation should be kept under review.**
*European Journal of Human Genetics* (2003) **11,** Suppl 2, S123–S142. doi:10.1038/sj.ejhg.5201117

**Keywords:** genetics; insurance; employment; ethics; guidelines; regulation; genetic testing

## Introduction

Genetic information or genetic test results can be used to prevent the onset of diseases, or to assure early detection and treatment, or to make reproductive decisions. This information can also be used for nonmedical purposes, such as insurance and employment purposes. Insurers might wish to use a genetic test result for underwriting, just as other medical or family history data. Employers might wish to ensure that an individual does not have a genetic risk which might affect his ability to work or which might lead to problems of safety to the individual or to others. Applicants might wish to voluntarily disclose their genetic status in order to pay cheaper premiums; or applicants who are prone to disease might wish to seek out the companies with the best benefits. The impact of the use of genetic information for nonmedical purposes justify special attention. The issues which could arise need to be very carefully assessed. Being denied insurance or charged higher premiums on the basis of genetic traits could have serious consequences and could affect individuals, families, or groups who may be already disadvantaged. The choices of the present may affect future generations.

A number of international and national committees have developed recommendations for policy-makers to protect individuals against genetic discrimination. The UNESCO Universal Declaration on the Human Genome and Human Rights (1997) states that 'no one shall be subjected to discrimination based on genetic character-

*Correspondence: Prof S Aymé, Hôpital Broussais, INSERM SC11, 102 rue Didot, F-75014 Paris, France. Tel: +33 1 56 53 81 37; Fax: +33 1 56 53 81 38; E-mail: ayme@orpha.net
[6]Current address: Faculty of Law and Department of Social and Preventive Medicine, University of Montreal, Montreal, Canada.

istics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity'. The 1997 Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Applications of Biology and Medicine specifies in Article 11: 'Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited'. At the national level, the approaches used vary greatly.[a] In respect to insurance, three solutions are usually proposed: (1) prohibition of any use of genetic information by insurers outright; (2) legislation prohibiting this below a certain amount of coverage; and (3) moratoria; the adoption of moratoria on the use of genetic information has been a widespread response of the insurance industry throughout Europe. Among the countries where there is no regulation, bills have been presented or states that have ratified the 1997 Council of Europe's Convention are bound by it.

Despite the desire to protect individuals against genetic discrimination and consequently to restrict the use of genetic information for nonmedical purposes, it seems necessary to find a balance between the interests of insurers, those of applicants, as well as those of other policy holders. This appears especially relevant and sensitive under health-care systems and welfare sectors with increasing budgetary restrictions.

The present paper aims to examine the professional and scientific views on the social, ethical, and legal issues that impact on Genetic Information and Testing in Insurance and Employment in Europe. For this purpose, many aspects have been considered, such as the concerns of medical geneticists (II), of the insurers (III), of the employers (IV) and of the public (V), as well as the regulatory frameworks (VI) and unresolved issues (VII).

## Methods

The method used for analyzing the professional and scientific views on the social, ethical, and legal issues that impact on genetic information and testing in insurance and employment in Europe was primarily the review of the technical, social, economical, and ethical aspects of advances in genetics and the concerns of parties who are involved, that is, the insurers, the employers, and the public. The existing guidelines and legislation on this topic were also reported. Then, the method was to examine the issues debated by these parties in Europe, as well as the results of discussions held during an international workshop. This workshop was organized by the European Society of Human Genetics Public and Professional Policy Committee in Manchester, United Kingdom, February 25–27, 2000.

The purpose of the workshop was to identify, from a professional viewpoint, the most important/pressing/burning ethical issues raised by genetic information and testing in insurance and employment in Europe. The formal workshop presentations covered the following themes: the fundamentals of genetics, of insurance, family histories, actuarial relevance and genetic testing and employment issues. Small multidisciplinary groups were convened to take these discussions further, in particular to consider the specific issues involved in employment, life insurance, private medical insurance, long-term care and critical illness insurance, and total permanent disability and income replacement insurance. Their initial task was to explore the insurance needs and rights in the countries represented and to consider the extent to which these needs were currently being met. Following the small group sessions, conclusions were fed back to the whole group where there were opportunities for further discussion.

A group of 47 experts from 14 European countries was invited. These experts were representatives of the seven following sectors:

(1) Medical Genetics
(2) Human Genetics Societies
(3) Ethical, Legal and Social Issues
(4) Support Groups
(5) Biotechnology/Pharmaceutics
(6) Insurance/Employment
(7) European Union Institutions

A first background document was discussed during the workshop. A second document, including discussions of the workshop, was sent for comments to representatives of the human genetic societies and European experts in the fields of insurance and genetics, as well as to all ESHG members. This document was also put on the ESHG website (www.eshg.org) for public consultation and discussion. The final document was approved by the ESHG board.

## Concerns of medical geneticists

### Complexity of genetic tests

Genetic tests are available for two forms of genetic diseases: monogenic and multifactorial diseases. Monogenic

[a]This paper addresses the issues raised by the use of genetic information by insurers in Europe. Comparisons between the European and American norms ought to be undertaken with caution given the health-care funding differences between the two. Despite the range of developments in relation to genetic information and insurance in both Europe and the United States, the question of the appropriate policy response remains an open one. In Europe, the debate on genetic and insurance has centered upon potential restrictions on the availability of life insurance and related products which are closely linked to the acquisition of primary modern socioeconomics goods (eg homes, cars, loans, etc). In the United States, much of the legislation has developed within a privacy or discrimination paradigm due to the absence of universal healthcare.

disorders are rare but highly penetrant; the genetic test will indicate whether a person has or will 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. 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. 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. In these situations, the most that the genetic test can do is to show a propensity to a disease.[1,2]

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. Genetic disorders show different degrees of severity and diverge with respect to the age of onset. Some genetic disorders affect people with near-certainty but others not. Predictions are therefore complicated by these phenomena.

Finally, our ability to identify individuals at risk for genetic diseases often exceeds our ability to prevent or treat the diseases.[3,4] This has been described as the 'therapeutic gap' and as a reason for tension between policy-makers and health professionals.[5] 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.[6,7]

We are forced to note that genetic tests present some limits, including the possibility of uninformative results, the inability to predict the exact age of onset or the severity of symptoms and, in the case of multifactorial diseases, the inability to predict if the individuals will develop the disease in question. In fact, genetic tests cannot account adequately for the external factors, which can be as important as inborn characteristics.[3,6,8] 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.

### Calling ethical principles into question

Different arguments suggest that there is something special about genetics, and yet ethical principles in medical genetics are the same in medicine, even if this has been questioned. These principles are: respect for the autonomy of persons, beneficence, non-maleficence, and justice. At present, in regard to medical genetics, these principles are not applied with equal force around Europe. The principle of nonmaleficence 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 nonexistent, the possible use of genetic information in insurance and employment has gradually generated debate and increasingly causes concern.[9–15]

Furthermore, medical geneticists' concerns extend beyond the traditional ethical guidelines in medicine. For instance, genetic testing for insurance and employment purposes could disturb family relations. Family cooperation is often necessary to detect genetic problems, but genetic information may affect an entire family rather than only one individual, and the choices of the present may affect future generations. 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.[6,16,17]

## 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 according to family history. Nevertheless, the progress made in predicting diseases alters the information available with regard to the risk of disease. Genetic information contains more certainty than information traditionally gathered by insurers to investigate the existence of diseases running in the family.[6,18] This may have important consequences for insurance industry.

### Goal of insurers

The insurers' goal is to maximize their profits. This is usually reached with an increased number of people under coverage. In this regard, developments in medical science have resulted in an increase of life insurance sales.[19] In other respects, everyone carries some potentially abnormal genes and insurers will not wish to deny coverage to a significant segment of the population. However, the insurance industry would like to use genetic information as just part of the (predictive) information that they should be able to use less for deciding to accept a private, voluntary application, than for setting the premium level according to the individuals' risk, and for avoiding the possibility of adverse selection.

### Underwriting

Underwriting is the method used to classify people according to their risk. 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.[20,21]

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.[7] 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. Individuals in the third group are excluded because the cost of their coverage is unquantifiable or would exceed any reasonable premium.

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. Requesting genetic tests from insurance applicants could then 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. Genetic testing would enhance equity by allowing a precise calculation of which people are really in the same situation and which are not.[6,18] 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.

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 certain tests and on the costs of diseases.[1,6,22] But that does not mean that insurers are not using genetic information. Insurers can currently make genetic inferences from routine and well-accepted questions on family history. Insurers can use genetic information available in medical files; the registered information in medical files is usually more accurate and complete than what is known by the insurance applicants.[15] Since genetics is integrated in medical practice, insurers will have access more and more to genetic information. This will allow insurers, among other things, to know whether applicants have neglected to mention that they are carriers of genetic disorders or that these run in the family.

### Adverse selection

Adverse selection occurs when people have undergone testing and conceal positive test results from insurers.[16] 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. Insurers require symmetry of information. 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.[19] The consequences of a lack of symmetry in information between insurers and applicants or insured persons could force insurers to adjust premiums. In this way, in the Netherlands, after the Medical Examination Act has been in force (1998), 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.[23] 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. Sweden (1999) has the same policy. In the United Kingdom (2000), the Genetics and Insurance Committee stated that the reliability and relevance of the genetic test for Huntington's Disease was sufficient for insurance companies to use the result when assessing applications for life insurance. But in October 2001 the UK government reached an agreement with the Association of British Insurers (ABI) to institute a 5-year moratorium on the use of genetic tests results up to a certain value.

## Concerns of the employers

Concerns of employers and of insurers are 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.

### Goal of employers

It is in employers' interests to have a healthy workforce. Some 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.[23,24]

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. Different sources of information can be used to assess whether an individual has a risk of either sickness or death: medical examination, medical history, family history, age, lifestyle. Genetic testing might confirm the risk of developing a genetic disease, for which some jobs could make the person unacceptable.[23,25] 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.

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.[23] The prospective employees are simply asked to make a declaration about their state of health.

### Constraints imposed on employers

The costs of any health investigation by employers are significant: if employers investigate every prospective employee, 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.[21,23]

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.[21,23]

Although the use of genetic information might conceivably be of some benefit for employers, it runs counter to the fundamental rights of workers to nondiscrimination 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. In those countries that do not have specific regulations prohibiting or limiting employer access to, and use of, genetic information, existing antidiscrimination and privacy legislation may provide individuals with some protection.

## Concerns of the public

### Right to underwrite

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.

Private insurance is based on mutuality and consequently discriminates in setting premiums. 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.[26] 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.[13,25,27,28]

### Duty of disclosure

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.[6] If the applicants have neglected to mention that they are carriers of genetic disorders or that these run in the family, this could be invoked to prove that the applicants have made a false declaration and that the contract is invalid.

The duty of disclosure raises many questions: (1) Are genetic test results 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; (2) 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? (3) Insurers may have access to confidential information that applicants do not want to know, thus infringing on their right not to know. (4) The duty of disclosure may also generate social pressure on a would-be applicant to have a genetic test and disclose a negative result to show that their family history does not put them at increase risk.

### Fear of discrimination

The fear of genetic discrimination by insurers or employers may tip the scales against somebody seeking testing to obtain improved medical management and reassurance.[29] 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.[29] People may also be encouraged not to share the result with their general practitioner for fear of disclosure to insurance companies.[30] 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. The practice of some clinicians to advise people to

buy insurance before having a predictive DNA-test highlights the current perception that people at high genetic risk of late-onset disease face the additional social disadvantage of higher premiums or application rejection.[31]

## Regulatory frameworks

In regard to the above, two principles govern the use of genetic information and testing in insurance and employment; firstly, no one should be subjected to discrimination based on genetic characteristics; secondly, the disclosure of information to a third party or accessibility to personal genetic data should be allowed only with the individual's informed consent. These principles can be found in all international and regional texts. There is a general consensus that applicants should not undergo genetic testing as a condition of obtaining insurance.

On the contrary, national texts (legislation and recommendations) vary greatly. Three solutions are usually proposed: (1) Prohibition of any use of genetic information by insurers outright; such as Austria, Belgium, Denmark, Estonia, France, Luxembourg, and Norway. In Belgium, a notable feature of the legislation is that it prohibits the use of genetic information even in circumstances where it is to the benefit of the applicant. The rationale is to protect privacy. (2) Legislation prohibiting this below a certain amount of coverage, like in Sweden, the Netherlands, and the United Kingdom. In the United Kingdom, the government also set up the Genetics and Insurance Committee (1998) whose role is to assess the actuarial validity of genetic tests that insurance companies would like to be able to take into account in setting insurance premiums. And 3) Moratoria; Moratoria are either indefinite (Finland, Germany), or for a limited number of years (France, Switzerland), or still limited to insurance policies which do not surpass a certain value (Sweden, The Netherlands, the United Kingdom).

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. The Council of Europe's Convention on Biomedicine upholds that the rights and dignity of humans should be respected with regard to the application of biology and medicine and have primary over the goals of science or society.

Table 1 shows the current responses to the use of genetic information by insurers in Europe (dated the 1st January 2003).

The ceiling system (ie 'no questions' asked below a certain amount) of regulation is a policy response that mitigates the problems associated with genetics and insurance. This approach protects the insurance industry against the dangers of adverse selection and, for the applicants, it permits the acquisition of social goods such as healthcare or housing. 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 Association of British Insurers (2001) announced that its members would no longer request results of genetic tests in respect of applications for any type of insurance up to a certain value.

A system of regulation combined with a pragmatic board of examination of ongoing scientifically validated tests, like in the United Kingdom, is also another policy option. The advantage of this approach is that in an area of rapidly developing technology, a responsive system of procedural regulation can react to changing circumstances.[11] Until the moratorium, GAIC had approved only tests for Huntington's disease in respect of life insurance, but a small number of additional tests was under consideration.

A further policy option is the use of moratoria. The adoption of moratoria on the use of genetic information has been a widespread response of the insurance industry throughout Europe. The rationale is that the consequences of the use of genetic information and testing on health and medical research can be studied. This practice affords the

**Table 1**

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

The Oviedo convention refers to the Convention of the 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.

insurance industry time to formulate an alternative policy strategy. However, since moratoria are voluntary, they may only survive for as long as there are no commercial advantages to be gained in using genetic information. For instance, in October 2001 the UK government reached an agreement with ABI to institute a 5-year moratorium on the use of genetic tests results in assessing applications for life insurance policies up to a value of £500 000, and for critical illness, long-term care and income protection policies up to a value of £300 000. For an amount over those limits ABI will be able to use genetic tests results if they have been approved by GAIC. These limits will be reviewed after 3 years.

In the context of employment, there has been some public anxiety that employers may use personal genetic information to discriminate improperly against employees who are seen to be at risk of a particular illness or condition. Yet, it should not be forgotten that employers are bound to protect the health and welfare of their employees. Some countries (Austria, Estonia, France) have adopted legislation which prohibits genetic testing by employers. In other countries, such as Switzerland and the Netherlands, genetic tests can only be used by employers where there is an unambiguous health requirement for the job, or where the protection of the employee's health in the workplace calls for such a test. In the United Kingdom, where there is no legislative prohibition on the use of genetic information in employment, discrimination on the basis of an existing disability of genetic origin would be prevented by the *Disability Discrimination Act* 1995, but there is currently no specific legislation to prevent discrimination against asymptomatic employees.

Finally, in both insurance and employment unless genetic information becomes increasingly normalized (eg blood pressure, cholesterol, etc), the 'consent' of the individual to access to the medical record will limit participation in genetic testing and research, if such 'consented-to' access has more negative economic consequences than access to other medical information. However, the Association of British Insurers (2001) in a joint statement with the British Society for Human Genetics and the UK Forum for Genetics and Insurance, announced that the results of a genetic test taken as part of a research project need not be declared to insurers.

## Issues

The following discussion has been largely inspired by the workshop organized by the European Society of Human Genetics Public and Professional Policy Committee in February 2000 in Manchester (UK) (see Methods). This discussion has then allowed the ESHG: PPPC to issue recommendations on genetic information and testing in insurance and employment (www.eshg.org).

### Need for definition

Insurance contracts laws state that the contract must be written up in utmost good faith otherwise the contract may be void. This means that the applicant is under an obligation to reply honestly, without withholding information. But if the definition of what can be considered genetic information is not clear, how can an applicant reply honestly and how can an insurer ask specific questions which are relevant to risk assessment? There is a need then for clear definitions of terms used in genetics, insurance and employment, so that different professions and their clients have a common understanding of the issues. A genetic test is a test of anything that is, or potentially can be, inherited according to mendelian laws. This covers not only DNA, RNA, and chromosome analysis, but also protein truncation test and clinical examination of a patient for a mendelian condition that is diagnosable in that way.[30] But does the test result have predictive value for the subject or family members? If the answer is no, there are no special features. If it is predictive for the subject but not the family, it is ethically similar to several other medical tests. Only if there are also implications for the family is there a special case. It is also important to distinguish between research and clinical genetic tests. A lot of people's worries concern tests for disease susceptibility, and these are almost always part of research, but only clinically validated tests should be considered for insurance purposes. Legislation without a precise definition of these terms may confuse insurers and applicants when underwriting or renewing an insurance policy.

### Risk pooling and underwriting

A common objection is that classifying policyholders according to risk is an objectionable practice because it amounts to discrimination.[32] The insurance industry argues that it is not engaged in discrimination but in differentiation. 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.

Another objection has to do with the distinction which arise between an industry based on equity and one that is based on equality. 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 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. However, 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 has been argued that if the principle of equity in insurance is replaced by the principle of equality, 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.[33]

### Adverse selection

More and more, people might be able to undergo confidential genetic testing and hide their results.[6,32] Genetic testing will be readily available in doctors' offices and free-standing commercial laboratories. 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. Insurers are concerned that many individuals could attempt to use genetic test results to create an estate when none would have existed prior to testing and for many people, the temptation to buy insurance under these circumstances could be irresistible.[34] Those opposed to sharing genetic information with insurers argue that antiselection will be a rare event. 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.[35]

There is an element of speculation involved in the possibility of adverse selection due to the information provided by genetic tests. Only about 5% of diseases are caused by a single gene. Most are caused by interactions between many genes that are subtle and difficult to determine. Consequently, only individuals with mutations for late onset untreatable diseases will be able to deceive the industry. The number of such diseases will probably also be reduced as treatments will be available for these diseases.

There is controversy about the ruling by insurance companies that genetic test results have to be disclosed by people seeking new policies. 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[7] while 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.[33] Although insurance companies may vary in the stringency with which they scrutinize medical record or use research data to determine insurability, one denial may have far-reaching effects on the individual's opportunities from other insurers. Critics fear that people could be deterred from taking tests whose outcome may be vital for determining their need for prophylactic treatment, or from participating in research involving genetic testing. They are also concerned that the duty of disclosure may infringe on individuals' privacy and violate their right not to know.[12,36]

### Predictive genetic information in insurance

There is an issue surrounding the boundary between predictive genetic information and other health-relevant data. A person's sex is genetic information predictive of health outcomes, but being overt and covered by its own anti-discrimination legislation would not normally be included within 'genetic information' for insurance purposes.

Family history is also predictive genetic information, although it is recognized that the self-reported family history may be inaccurate. There is a need to resolve inconsistencies in current attitudes and policies on use of family history in relation to the use of genetic test results. If the ceiling for life insurance cover, without use of genetic information is intended to allow all healthy people to obtain this basic cover without disclosure of their genetic risk of late onset disease, then it is illogical to still take family history into account.[7] Most of the high risks relevant to life insurance that are contained in genetic test results are revealed by an accurate family history. Thus it would be of little benefit to the genetically disadvantaged if a company agreed to forego the use of genetic test results, but would still require family history information.

In other respects, it is difficult to predict the extent to which genetic tests might become relevant for health prediction in multifactorial diseases, and even more difficult to predict the extent of their influence and timing of such advances in knowledge. A predictive DNA test cannot be regarded as a diagnostic test but rather as a prognostic factor because, at the time the genetic test is performed, there is not yet a disease established. However, one can compare how many tested persons have a positive result and how many a negative result and how many will develop a certain disease during a period. The final result is a likelihood of disease and not a predictive value which can then be expressed as a relative risk. Therefore, as with all genetic information used in an insurance context, sound knowledge of the real predictive value of the information needs to be accrued and validated before being put into practice. It is important that insurance applicants should be clearly aware of the limits of genetic information that is required and utilized by the insurance industry in relation to these complex diseases.

### Types of insurance product affected by predictive medicine

Some argue that genetic test results will not affect all types of insurance product in the same manner. Genetic test results may almost exclusively affect individuals insurance as members of groups usually not individually underwritten.[19] In the same way, genetic test results may only concern individuals applying for high levels of coverage, for which a medical examination is usually requested,[20] or for personally purchased insurance in general.[37]

It is recommended that insurance product which should be exposed to restrictive legislation are those which are perceived as necessary to guarantee a service considered as a basic need, such as health and social insurance.[19,38] There is a clear case for a solidarity-based system for basic needs, with optional extras being provided through a system based on mutuality. Insurance with respect to basic needs has often been compulsory (state or private). There is an issue as to how much 'solidarity for basic needs' can be incorporated into private, voluntary insurance without serious threat to the industry (through adverse selection for example). If it is considered that a substantial solidarity element can be provided by the private sector, the questions arise as to who should finance this solidarity and whether guidelines or legislation are required to regulate this insurance.

### Requesting genetic tests

In the future, could applicants be asked to undergo a genetic test in order to obtain any type of insurance? Insurers may therefore have access to information that applicants do not want to know. Furthermore, 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.

Some published works indicate that despite the significant scientific progress, there are currently not sufficient grounds for requiring individuals to undergo genetic testing and to disclose genetic test results to insurers. This is because the current state of knowledge about patterns of genetic test results does not generally support good predictions of the incidence, timing and severity of disease or of time of death.[3,31] Further research is needed in order to yield useful information. Well-described conditions such as Huntington disease have yielded such information, but this has been gathered over periods of several years. Nevertheless, in the United Kingdom for instance, there had been public disquiet following the ABI report and personal experience had shown increased anxiety regarding testing in Huntington disease clinics.[12] Some of the public found that negative genetic test results could be used to their advantage in lowering already high premiums.[12]

## In employment

At least two types of employment discrimination based on genetic testing have been identified.[26,39] 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 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.[40] The Human Genetics Advisory Committee (1999) said 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. Also, genetic tests are unlikely to identify susceptibility to disease with any precision as it might be aggravated by the workplace environment.[27] Now even if 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,[26,41] prevention of most genetically determined defects that may lead to illness and disability seems an unattainable goal. Consequently, 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; employment decisions should not be based on genetic factors.[42–44] However, there is a range of ethical issues with which the occupational health professional may be confronted as genetic technology advances.[44,45] Genetic testing could be used to improve preventive medicine but also to reduce the costs of sickness in the workplace.[23]

Finally, 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.[2,46]

## Education

The fear of genetic discrimination by insurers and employers has spread throughout society.[4,33,45] It is likely that many people who might benefit from such testing will be reluctant to be tested unless laws are in place to protect them. However, a law is not enough to provide a comprehensive solution to genetic discrimination in insurance. One cannot be certain in the present economic context, that pressure might not be put upon applicants for

an insurance contract in order to obtain genetic information about them. Nor can one exclude the possibility that the candidates themselves might wish to produce the information spontaneously if it were in their favor. Education is needed. Insurance decisions are sometimes made by inexperienced people, or because of a lack of knowledge about particular genetic conditions. 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.

## Conclusion

Insurers and employers are told that unreliable genetic tests must be ignored. Ultimately, objections to the use of genetic information will be subsumed by economic and scientific realities: individually underwritten insurance cannot be sold without risk classification, and some of the medical information needed to classify risks will be genetic.[36] It will become increasingly difficult to distinguish genetic from nongenetic diseases, genetic information from nongenetic information, or to talk of medical and genetic tests as separate categories.

However, in attempting to develop practice fair to both insured and insurer, it is widely accepted that there is a need for clarification of the best means for determining the extent of increased genetic risk of late onset disease, so that there is demonstrable evidence of validity and consistency in the use of any genetic information in underwriting. It is accepted that in time when more reliable actuarial data are available for single gene disorders, genetic test results may be used but it is felt strongly that for multifactorial diseases the results should not be used. Most susceptibility genes are already shared by many people currently insured at standard rates. The unfolding of such results would stratify society in an unacceptable way.

Clear definitions of the terms used in genetics and insurance are revised for the transparency of the process by which genetic information is incorporated into insurance decisions, and for ensuring that genetic information is not used to the detriment of other family members. There is a broad consensus that insurance or employment considerations should not unduly influence the uptake of appropriate clinical care, which may increasingly involve genetic tests. There is also a broad consensus that applicants should not be asked to undergo genetic tests, in order to obtain insurance or employment.

At present, the fear of genetic discrimination remains intense; perhaps because there are very little data to support or refute that discrimination is actually taking place. How to reassure people and protect them? Can a law provide a solution to the problems of insurance, employment and genetics? There are diverging approaches among the various states which have sought to establish binding norms. The legislative activities in several countries show a growing consensus on the need to define the use of genetic information for insurance purposes. Some restrictions on the use of genetic information may be found and be compatible with the continued existence of the insurance industry, such as a ceiling below which no genetic information (genetic test results or family history) has to be disclosed. A valid explanation for selecting a particular ceiling also needs to be provided and should relate to the point where basic economic security (basic house purchase, necessary provision for dependants, and protection for the self-employed) gives way to personal investment. As to genetic testing by employers, it should stay limited to screening individuals at risk for developing diseases that may result from certain exposures that exist in the workplace.

## References

1 Evans JP, Skrzynia C, Burke W: The complexities of predictive genetic testing. *BMJ* 2001; **322**: 1052–1056.
2 Holtzman NA: Are we ready to screen for inherited susceptibility to cancer? *Oncology* 1996; **10**: 57–64.
3 Holtzman NA: Putting the search for genes in perspective. *Int J Health Serv* 2001; **31**: 445–461.
4 Reilly PR: Genetic Risk Assessment and Insurance. *Genet Test* 1998; **2**: 1–2.
5 Kumar S, Gantley M: Tensions between policy makers and general practitioners in implementing new genetics: grounded theory interview study. *BMJ* 1999; **319**: 1410–1413.
6 Lemmens T, Bahamin P: Genetics in life, disability and additional health insurance in canada: a comparative legal and ethical analysis. In: Knoppers BM (ed): *Socio-Ethical Issues in Human Genetics*. Montreal: Les Editions Yvon Blais Inc: 1998, pp 107–276.
7 MacDonald AS: How will improved forecasts of individual lifetimes affect underwriting? *Philos Trans R Soc London* 1997; **352**: 1067–1075.
8 Murthy A, Dixon A, Mossialos E: Genetic testing and insurance. *J R Soc Med* 2001; **94**: 57–60.
9 Chadwick R, ten Have H, Hoedemaekers R *et al*:: Euroscreen 2: towards community policy on insurance, commercialization and public awareness. *J Med Philos* 2001; **26**: 63–72.
10 Harmon C, Nolan B: Health insurance and health services utilization in Ireland. *Health Econ* 2001; **10**: 135–145.
11 McGleenan T, Wiesing U, Ewald F (eds): *Genetics and Insurance*. Oxford: BIOS Scientific Publishers Ltd; 1999.
12 Morrison PJ: Genetic testing and insurance in the United Kingdom. *Clin Genet* 1998; **54**: 375–379.
13 Morrison PJ, Steel CM, Vasen HF *et al*:: Insurance implications for individuals with a high risk of breast and ovarian cancer in Europe. *Dis Markers* 1999; **15**: 159–165.
14 Nys H, Nederveen-Van de kragt CJM, Roscam-Abbing HDC *et al: Predictive Genetic Information and Life Insurance: Legal Aspects. Towards European Policy?*. University of Limburg, Department of Health Law, Maastricht; 1993.
15 Rosén E: Genetic information and genetic discrimination how medical records vitiate legal protection. *Scand J Public Health* 1999; **27**: 166–172.

16 Sandberg P: Genetic information and life insurance: a proposal for an ethical European policy. *Soc Sci Med* 1995; **40**: 1549–1559.
17 Weijer C, Emanuel EJ: Ethics. Protecting communities in biomedical research. *Science* 2000; **289**: 1142–1144.
18 Association of British Insurers: Insurers will Use Genetic Test Result Responsibly. New Release, 12 October: 2000.
19 Chuffart A: *Genetics and Life Insurance: A Few Thoughts*. Zurich, Swiss Re; 1997.
20 Le Grys DJ: Actuarial considerations on genetic testing. *Philos Trans R Soc London* 1997; **352**: 1057–1061.
21 Roscam-Abbing HDC: Predictive genetic knowledge, insurance and the legal position of the individual. in Swiss Institute of Comparative Law (ed): *Human Genetic Analysis and the Protection of Personality and Privacy, International Coloquium*. Lausanne: Swiss Institute of Comparative Law; 1994.
22 Ross T: The likely financial effects on individuals, industry and commerce of the use of genetic information. *Philos Trans R Soc London* 1997; **352**: 1103–1106.
23 Goedvolk VI: The Medical Examinations Act: practical experience from the Netherlands. International Conference on Genetics and Private Life/Health Insurance, Paris, 11–12 February: 1999.
24 Schill AL: Genetic information in the workplace. Implications for occupational health surveillance. *AAOHN J* 2000; **48**: 80–91.
25 Bonn D: Genetic testing and insurance: fears unfounded? *Lancet* 2000; **355**: 1526.
26 Ewald F, Lorenzi JH (eds): *Encyclopédie de l'assurance*. Paris: Economica, 1998, 1780 p.
27 Hall M, Rich S: Laws restricting health insurers' use of genetic information: impact on genetic discrimination. *Am J Hum Genet* 2000; **66**: 293–307.
28 The Human Genetics Advisory Committee: *The Implications of Genetic Testing for Insurance*. London: Office of Science and Technology, 1997.
29 Williams JK, Schutte DL, Evers CA, Forcucci C: Adults seeking presymptomatic gene testing for Huntington disease. *Image J Nurs Sch* 1999; **31**: 109–114.
30 Kaufert PA: Health policy and the new genetics. *Soc Sci Med* 2000; **51**: 821–829.
31 Lapham EV, Kozma C, Weiss JO: Genetic discrimination: perspectives of consumers. *Science* 1996; **274**: 621–624.
32 EUROSCREEN Insurance Sub-Group. Insurance, Newsletter 7, Spring: 1997.
33 British Society for Human Genetics. Statement on Genetics and Life Insurance, May 1998.
34 Pokorski RJ: Insurance underwriting in the genetic era. *Am J Hum Genet* 1997; **60**: 205–216.
35 Zick CD, Smith KR, Mayer RN, Botkin JR: Genetic testing, adverse selection, and the demand for life insurance. *Am J Med Genet* 2000; **93**: 29–39.
36 Kmietowicz Z: Health put at risk by insurers' demands for gene test results. *Br Med J* 1997; **314**: 625.
37 Hauser G, Jenisch A: Laws regarding insurance companies. *J Med Genet* 1998; **35**: 526–528.
38 The Human Genetics Commission. The use of genetic information in insurance: interim recommendations, May: 2001.
39 Natowicz MR, Alper JK, Alper JS: Genetic discrimination and the law. *Am J Hum Genet* 1992; **50**: 465–475.
40 Rothenberg K, Fuller B, Rothstein M *et al*:: Genetic information and the workplace: legislative approaches and policy challenges. *Science* 1997; **275**: 1755–1757.
41 Jacobs LA: At-risk for cancer: genetic discrimination in the workplace. *Oncol Nurs Forum* 1998; **25**: 475–480.
42 Nunes R, Pereira de Melo H: Genetic testing in the workplace. Medical, ethical and legal issues. *Law Hum Genome Rev* 2000; **13**: 119–142.
43 Rothstein MA, Knoppers BM: Legal aspects of genetics, work and insurance in North America and Europe. *Eur J Health Law* 1996; **3**: 143–161.
44 Lemmens T: Genetic testing in the workplace. *Polit Life Sci* 1997; **16**: 57–75.
45 Mossialos E, Dixon A: Genetic testing and insurance: opportunities and challenges for society. *Trends Mol Med* 2001; **7**: 323–324.
46 Tauer CA: Genetic testing and discrimination. How can we protect job and insurance policy applicants from negative test consequences? *Health Prog* 2001; **82**: 48–53, 71.

## Appendix A
### National and international regulatory frameworks (dated the 1st January 2003)
### 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*)*

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 the Directive 95/46/EC in order to harmonize the protection of data privacy in the EU. The Directive was implemented in national laws and regulations by October 24, 1998. The Directive was designed to establish minimum standards for the processing and use of personal data throughout the EU, 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*)*

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'. 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'. Article 4.9 stipulates that for purposes other than those provided for in Principles 4.7, '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.

*European Union, Charter of Fundamental Rights of the European Union (December 18, 2000) (*http://www.europarl.eu.int/charter/default_en.htm*)*

Article 21 of the Charter apply to insurance and states that 'any discrimination based on any ground such as sex, race, color, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited'.

## European Countries

***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. 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.

***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.

***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 may only ask for HIV test and family history when the sum insured is high and over a certain level.

***Estonia*** *Estonian Parliament, Human Gene Research Act, 2001 (*http://www.genomics.ee/genome/act1312.html*)*

This Act has been enacted to protect persons from misuse of genetic data and from discrimination based on interpretation of the structure of their DNA and the genetic risks arising therefrom.

Article 25 on Prohibition on discrimination states that (1) 'It is prohibited to restrict the rights and opportunities

of a person or to confer advantages on a person on the basis of the structure of the person's DNA and the genetic risks resulting therefrom; (2) It is prohibited to discriminate against a person on the basis of the person being or not being a gene donor'.

Article 26 is devoted to discrimination in employment relationships: (1) 'Employers are prohibited from collecting genetic data on employees or job applicants and from requiring employees or job applicants to provide tissue samples or descriptions of DNA; (2) Employers are prohibited from imposing discriminatory working and wages conditions for people with different genetic risks'.

Article 27 is devoted to discrimination in insurance relationships: (1) 'Insurers are prohibited from collecting genetic data on insured persons or persons applying for insurance cover and from requiring insured persons or persons applying for insurance cover to provide tissues samples or descriptions of DNA; (2) Insurers are prohibited from establishing different insurance conditions for people with genetic risks and from establishing preferential tarif rates and determining insured events restrictively'.

Under Article 31, the Criminal Code is amended as follows: 'unlawful restriction of the rights of a person or conferral of unlawful preferences on a person based on the genetic risks of the person is punishable by a fine, detention or up to one year imprisonment'.

***Finland*** 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.

***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*)*

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'.

*Law n. 94-654 of July 29th regarding the donation and use of elements and products of the human body, medically assisted procreation and prenatal diagnostic (*http://www.cnrs.fr/SDV/loirespectcorps.html*)*

Article L1131-1 states that the Genetic characteristics of a person or his identification through the use of genetic prints, when not performed for a judiciary procedure can only be done for medical or scientific goals after having obtained that person's consent.

In *1994, the French Federation of Insurance Companies (*http://www.ffsa.com/pub/pub.htm*)* announced that for a period of 5 years, which coincided 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. 2000-548 date June 15, 2000 Predictive Medicine, Genetic Identification and Genetic Research (*http://www.legifrance.gouv.fr*)*

This decree states that the examination of genetic characteristics of a person, when not done for a judiciary procedure can only be performed for medical purposes or scientific research after having obtained the consent of that person.

***Germany*** 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).

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

This 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.

***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.

***Iceland*** There is no legislation dealing specifically with the issue of genetic discrimination in life insurance and employment. However, discrimination based on genetic characteristics might be prevented by the following regulation and Act.

*Ministry of Health and Social Security, Government Regulation No 32/2000 on a Health Sector Database (2000)*

According to Article 14, 'providing information on individuals from the Health Sector Database is prohibited. Only statistical information involving groups of individual may be provided'.

*Ministry of Health and Social Security, Act on the Rights of Patients No 74/1997 (1997)*

Article 1 stipulates that 'It is prohibited to discriminate against patients on grounds of gender, religion, beliefs, nationality, race, skin color, financial status, family relation or status in other respect'.

***Ireland*** *Irish Insurance Federation, Code of practice on genetic testing, 2001*

1. Applicants must not be required to undergo a genetic test in order to obtain insurance

2. 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 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.

***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.

***Luxembourg*** *Insurance Contracts Act of 27th July 1997*

This law stipulates that the prohibition on the use of genetic test by insurers is of public matter and cannot be bypassed, even with the consent of the insurance applicant.

***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.*

***Portugal*** The Ratification of the 'Convention for the Protection of Human Rights and Dignity of the Human Being and the additional protocol on the prohibition of cloning human beings' was published in January 2001.

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

***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).

*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 known genetic predisposition or to future monogenic illnesses also known without any type of symptom at 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.

***Sweden*** *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.

***Switzerland*** *The Federal Code of Obligations*

The federal Code of Obligations stipulates 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@fwsrvg.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).

***The Netherlands*** *Verzekeraars verlengen moratorium erfelijkheidsonderzoek, December 1990 (1995)*

The moratorium, originally for 5 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).

***United Kingdom*** In May 2001, the Human Genetics Commission (HGC) recommended a three-year moratorium on the use of genetic information by insurers, except in respect of policies over £500 000 in value. In the case of these high-value policies, the HGC says insurers should be permitted to use only the results of tests approved by the Genetics and Insurance Committee (GAIC). GAIC has so far approved only tests for Huntington's disease in respect of life insurance, but a small number of additional tests is currently under consideration. The HGC recommends that the moratorium on the use of genetic information in insurance should be enforced by legislation. The HGC recommendation follows a report by the House of Commons Select Committee on Science and Technology on Genetics and Insurance (April 2001), which found that the current system of self-regulation by the insurance industry was not satisfactory. On the same day that the HGC released its recommendations, the Association of British Insurers announced that its members would no longer request results of genetic tests in respect of applications for any type of insurance up to a value of £300 000. For policies above this value, only the results of tests approved by GAIC would be used. The ABI also announced in a joint statement with the UK Forum for Genetics and Insurance and the British Society for Human Genetics, that the results of a genetic test taken as part of a research project, rather than in the context of a clinical consultation, need not be declared to insurers.

In October 2001 the UK government reached an agreement with ABI to institute a 5-year moratorium on the use of genetic tests results in assessing applications for life insurance policies up to a value of £500 000, and for critical illness, long-term care and income protection policies up to a value of £300 000. For an amount over those limits ABI will be able to use genetic tests results if they have been approved by GAIC. These limits will be reviewed after 3 years.

*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.a-bi.org.uk*)*

In its Code of Practice, the ABI 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 mortage 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. In the interim before further applications are put to GAIC, ABI member companies may continue to require disclosure of the results of certain tests that had been identified by its Genetics Adviser as at November 1998. These are tests for myotonic dystrophy, multiple endocrine neoplasia, hereditary motor and sensory neuropathy, familial Alzheimer's disease, familial adenomatous polyposis, and BRCA1/2-associated familial breast cancer. 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.

*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 2 years while these arrangements were being put in place.

*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. In November 1998, the British Government set up the Genetics and Insurance Committee, a nonstatutory, advisory body whose role is to assess the actuarial validity of genetic tests that insurance companies would like to be able to take into account in setting insurance premiums.

*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.

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

*Genetic tests and future need for long-term care in the UK, A report of a work group of the Continuing Care Conference Genetic Tests and Long-term Care Study Group, July 1999 (with update published January 2000)* http://www.medinfo.cam.a-c.uk/phgu/info_database/Policy/cccreport.asp*)*

The group's report concentrates mainly on Alzheimer's disease, for which an actuarial model is presented to predict the costs of long-term care depending on levels of

risk as predicted by apoE genotype. The report also contains information about the genetic and environmental basis of other adult-onset conditions including cancers, diabetes, ischaemic heart disease and stroke, osteoarthritis, rheumatoid arthritis and some psychiatric conditions, and preventive options.

*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) was asked to examine the actuarial evidence for using individual genetic tests. The insurance industry, through the main trade body the Association of British Insurers, has agreed to abide by GAIC decisions. If GAIC decides that the evidence on the reliability and relevance of a particular test is insufficient to justify its use, the Association have agreed to stop using them and retrospectively reassess affected individual insurance premiums. The broader social and ethical issues surrounding the use of genetic tests in insurance and employment have been referred to the new Human Genetics Commission.

An application for approval of two genetic tests for Huntington's Disease was submitted to GAIC by the Association of British Insurers (ABI) in July 2000. The application was sent to a clinical geneticist and an independent actuary for expert review and also to support groups for Huntington's Disease and to the Genetic Interest Group (GIG) for their comments. At their meeting in September, GAIC considered the application, in the presence of observers from the ABI, GIG and Huntington's Disease Association.

The committee recognizes that this complex subject is an important issue to the public, industry and government alike. GAIC will work closely with the new Human Genetics Commission when they begin their inquiry into the use of genetic data including in insurance and employment.

*House of Commons Select Committee on Science and Technology, 5th report, Genetics and Insurance, HMSO, London, 2001 (*http://www.publications.parliament.uk/pa/cm200001/cmselect/cmsctech/174/17404.htm*)*

The House of Commons Select Committee in its report on genetics and insurance recommends a two-year moratorium on the use of positive genetic test results by insurers, to allow time for further research on the actuarial relevance of test results.

*UK Forum on Genetics and Insurance, Association of British Insurers, British Society for Human Genetics, Joint statement on Genetics and Insurance, 24 April 2001 (*http://www.ukfgi.org.uk/joint%20statement%20abi,%20bshg,%20ukfgi%2024%2004%2001.htm*)*

The UK Forum on Genetics and Insurance said that 'it would continue to work to ensure the use of genetic information is handled appropriately by all parties'. The Association of British Insurers said that 'results from genetic testing arising from research projects will not be used for underwriting policies. Also, if someone already has an insurance policy it will not be affected by the policyholder participating in a research project concerned with genetic testing'. The British Society for Human Genetics 'welcomes the ABI's confirmation that research genetic tests will not affect any insurance proposal and do not need to be declared in any insurance application. This removes one source of anxiety for people asked to take part in genetic research, and should help avoid the risk that research will be hampered because of people's worries about insurance'.

*Human Genetics Commission, The use of genetic information in insurance: Interim recommendations of the Human Genetics Commission, May 2001 (*http://www.hgc.gov.uk/business_publications_statement_01may.htm*)*

In the HGC's view the moratorium should embrace the following features: 'No insurance company should require disclosure of adverse results of any genetic tests, or use such results in determining the availability or terms of all classes of insurance. The moratorium should last for a period of not less than three years. This will allow time for a full review of regulatory options and afford the opportunity to collect data which is not currently available. The moratorium should continue if the issues have not been resolved satisfactorily within this period. (…) An exception should be made for policies greater than £500 000. This will address concerns about adverse selection, the process by which persons having a known risk set out to acquire substantial insurance cover. (…) We recommend this upper financial limit on the basis of the industry's own tables and information as a protection from significant financial loss. Only genetic tests approved by the Genetics and Insurance Committee (GAIC) should be taken into account for these high-value policies'.

*Association of British Insurers, Insurers Confirm Decision To Extend Moratorium On Use Of Genetic Test Results, 1 May 2001 (*http://www.abi.org.uk/HOTTOPIC/nr415.asp*)*

'The (industry's) 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. Following very careful consideration within the industry, we propose to extend this moratorium to cover all classes of insurance up to £300 000. This will have the effect of excluding genetic test results from underwriting other than for a very small number of high value policies. The House of Commons Select Committee on Science and Technology called for a 2-year moratorium. The advantage of this will be to provide a period of stability while new and more permanent arrangements can be put in place. We continue to be keen to work with you and the Government to bring this about'.

*Government Response to the Report from the House of Commons Science and Technology Committee: Genetics and*

*Insurance, (October 2001) (*http://www.doh.gov.uk/genetics/gaicgovrespoct2001.pdf*)*

**International Organizations**

*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*)*

In its Declaration of the Human Genome Project, the World Medical Association considers that 'Medical secrecy should be kept and information should not be passed on to a third party without consent. (…) 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'.

*UNESCO, The Universal Declaration on the Human Genome and Human Rights, (November1997) (*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'. And according to article 7, 'genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions foreseen set by law'.

*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'

*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.

*The World Health Organization, Cloning in Human Health, (1st April 1999) (*http://www.who.int/gb/EB_WHA/PDF/WHA53/ea15.pdf*)*

Article 8 stipulates that 'Genetic information should not be used as the basis for refusing employment or insurance. Exceptions would have to be legally defined'.

## Appendix B
### Contributions

This document was reviewed by the ESHG Public and Professional Policy Committee (PPPC). Members of the PPPC are:

Ségolène Aymé (Paris, France) Chair
Martin Bobrow (Cambridge, UK)
Jean-Jacques Cassiman (Leuven, Belgium)
Domenico Coviello (Modena, Italy)
Gerry Evers-Kiebooms (Leuven, Belgium)
Peter Farndon (Birmingham, UK)
Helena Kääriäinen (Helsinki, Finland)
Ulf Kristoffersson (Lund, Sweden)
Marcus Pembrey (London, UK)
Sandy Raeburn (Nottingham, UK)
Joerg Schmidtke (Hannover, Germany)
Leo ten Kate (Amsterdam, The Netherlands)
Lisbeth Tranebjaerg (Tromso, Norway) Secretary

The first draft of this document was sent out to a wide range of people and organizations for consultation. It was reviewed critically by the following consultants:

***Australia*** Agnes Bankier, Institute Royal Children's Hospital, Parkville Victoria

***Austria*** Gertrud Hauser, Institute of Histology & Embryology, University Vienna, Vienna

***Belgium*** Herman Nys, Center for Bio-medical Ethics and Law, Catholic University Leuven

Myriam Welkenhuysen, Psychogenetics Unit, Centre for Human Genetics, Leuven

***Cyprus*** Kyproula Christodoulou, The Cyprus Institute of Neurology and Genetics, Nicosia

***Denmark*** Jane Emke, Danish Insurance Association, Copenhagen

Lene Koch, Institut of Public Health, University of Copenhagen, Copenhagen

***Eastern Countries*** Vladislav Baranov, Institute of Obstetrics and Gyneaecology, Russian Academy of Medical Sciences, St. Petersburg, Russia

Georges Kosztolanyi, National Institute of Hygiene, Department of human Genetics and Teratology, Budapest, Hungary

Maria Kucerova, Genetics Department, Thomayer University Hospital, Prague, Czech Republic

Astrida Krumina, Department of Medical Biology and Genetics, Medical Academy of Latvia, Riga, Latvia

***Finland*** Kaija Holli, Tampere University Central Hospital, Tampere

Pekka Koivisto, Retro Life Assurance Company Ltd, Helsinki

Veikko Launis, Department of Philosophy, University of Turku, Turku

Nina Meincke, Medical Law Project, University of Helsinki, Helsinki

Minna Poyhonen, The Family Federation of Finland, Department of Medical Genetics, Helsinki
Riitta Salonen, Department of obstetrics and Gynecology, Helsinki University Central Hospital, Helsinki

***France*** Yves-Jean Bignon, Department of Oncology and Genetics, Jean Perrin Centre, Clermont-Ferrand
François Ewald, French Federation of Insurance Companies, Paris
François Eisenger, Institut Paoli Calmettes, Marseille
Josué Feingold, Laboratoire d'Anthropologie Biologique - Paris XII University, Paris
André Klarsfeld, Centre National de la Recherche Scientifique, Institut Alfred Fessard, Gif-sur-Yvette
Dominique Stoppa-Lyonnet, Department of Oncology and Genetics, Curie Institute, Paris

***Germany*** Achim Regenauer, Munich Reinsurance Company, Munich

***Ireland*** David Barton, National Centre for Medical Genetics, Ous Lady's Hospital for Sick Children, Dublin
Tony McGleenan, Faculty of Law, Queen's University, Belfast
Peter Whittaker, Biology, National University of Ireland, Maynooth

***Israel*** Ariella Oppenheim, Hebrew University-Hadassah Medical School, Jerusalem

***Italy*** Bruno Dallapiccola, Medicina Sperireniato, La Spapienza University, Roma
Giovanni Neri, Instituto di Genetica Umana, Universita Cattolica, Roma

***Norway*** Kare Berg, Institute of Medical Genetics, University of Oslo, Oslo
Erik Rosaeg, Scandinavian Institute of Maritime Law, University of Oslo, Oslo

***Portugal*** Maria Cristina Rosamond Pinto, Department of Human Genetics, Faculdty of Medicine, Lisboa
Heloisa Santos, Department of Medical Genetics, De Santa Maria Hospital, Lisboa
Yorge Sequeiros, UmiGENE, IBMC, University of Porto, Porto

***Spain*** Maria Ramos, Department of Genetics, Virgen Del Camino Hospital, Pamplona

***Sweden*** Goran Flood, Swedish Skandia Life, Stockholm
Jan Wahlström, Department of clinical Genetics, Sahlgrenska University Hospital/East, Göteborg

***Switzerland*** Suzanne Braga, FMH medizinische Genetik, Bern
André Chuffart, Swiss Re Life & Health, Zurich
Christian Kind, Ostschweizer Kinderspital, St Gallen
Olivier Guillot, Institut de droit de la santé, Neuchatel University, Neuchatel

***United Kingdom*** Peter Brett, Peridontology, Eastman Dental Institute, London
Jerry Brown, Swiss Re Life & Health Limited, London
Ruth Chadwick, Center for Professional Ethics, University of Central Lancashire, Preston
David Cook, The Whitfield Institute, Oxford
Stephen Diacon, Centre for Risk and Insurance Studies, University of Nottingham, Nottingham
Robert Dingwall, Genetics and Society Unit, University of Nottingham, Nottingham
Bethalee Jones, Association of British Insurance, London
Beryl Keeley, Genetics Science Policy, Department of Health, London
Alastair Kent, Genetic Interest Group, London
Doris Littlejohn, Central Office of Industrial Tribunals, Glasgow
Angus MacDonald, Department of Actuarial Mathematics & Statistics, Heriot-Watt university, Edinburgh
David Muiry, Swiss Re Life & Health Ltd, International Financial Center, London
D. Paul, British United Provident Association Ltd, BUPA House, London
Andrew Read, Department of Medical Genetics, St Marys Hospital, Manchester
Virginia Warren, Group Medical, UPA, London
Pamela Watson, Genetics & Society Unit, University of Nottingham, Nottingham

***United States of America*** Dorothy Wertz, The Eunice Kennedt Shiver Center for Mental Retardation, Waltham, MA

This document forms part of a BIOTECH program financed by the Commission of the European Communities (CEE BIO4–CT98–0550).