

**The European Group on Ethics
in Science and New Technologies
to the European Commission**

**Opinion on the ethical aspects of
genetic testing in the workplace**

- Opinion N° 18 -

- 28th July 2003 -

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¹ By Jutta Buyse, a Trainee with the Secretariat of the European Group on Ethics in Science and New Technologies, from March to July 2003.

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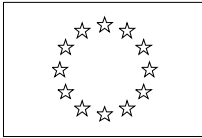
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ETHICAL ASPECTS OF GENETIC TESTING IN THE WORKPLACE

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**Delivered by the European Group on Ethics
in Science and New Technologies
to the European Commission**

On 28th July 2003



OPINION OF THE EUROPEAN GROUP ON ETHICS
IN SCIENCE AND NEW TECHNOLOGIES
TO THE EUROPEAN COMMISSION

No 18

Final – 28th July 2003

Original in English

ETHICAL ASPECTS OF GENETIC TESTING IN THE WORKPLACE

Reference: Initiative of the Group
Rapporteurs: Peter Whittaker and Nicos C. Alivizatos

The European Group on Ethics in Science and New Technologies (EGE),

Having regard to the Treaty on European Union as amended by the Treaty of Nice, and in particular Article 6 of the common provisions, concerning the respect for fundamental rights;

Having regard to the EC Treaty and in particular Article 137 concerning the working conditions and health and safety at work;

Having regard to the Charter on Fundamental Rights of the European Union, approved by the European Council in Biarritz on October 14th 2000 and proclaimed solemnly in Nice by the European Parliament, the Council and the Commission on December 7th 2000, in particular Article 8 on the "Protection of personal data", Article 15 on the "Freedom to choose an occupation and right to engage in work", Article 21 prohibiting discrimination based, among others, on genetic features, and Article 31 on "Fair and just working conditions";

Having regard to the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data;

Having regard to the Directive 2000/78/EC of the European Council of 27 November 2000 establishing a general framework for equal treatment in employment and occupation;

Having regard to the Directive 2002/14/EC of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community;

Having regard to the Council of Europe's Recommendation R(89)2 of 1989 on the protection of personal data used for employment purposes;

Having regard to the Council of Europe's Recommendation R(92)3 of 1992 on genetic testing and screening for health care purposes and, in particular, Principles 6 and 8, allowing genetic testing and screening only exceptionally and the collection and processing of personal data thereof only for the purposes of healthcare, diagnosis and disease prevention;

Having regard to the Council of Europe's Recommendation (97)5 of 1997 on the protection of medical data and, in particular, Principle 4.9 providing that the collection and processing of genetic data should in principle only be permitted for health reasons;

Having regard to the Council of Europe's Convention on Human Rights and Biomedicine, signed on 4th April 1997 in Oviedo, in particular Article 11 on "Non-Discrimination" and Article 12 on the "Predictive genetic tests";

Having regard to the International Labor Office (ILO) Code of Practice on the Protection of Workers' Personal Data (1997) and, in particular, Article 3.20 providing that "genetic screening in relation to work is a disproportionate infringement of individual rights" and that "current scientific knowledge is not sufficient to warrant its use for an occupational health purpose".

Having regard to the Round Table organised by the Group on 6th March 2000 in Brussels with members of the European Parliament, jurists, philosophers, scientists, representatives of employees and employers, representatives of religions, representatives of patients' associations and other groups of interest, and of international and European organisations (UNESCO, Council of Europe, WHO, OECD);

Having regard to the hearings of experts in Brussels on 18th March, 15th April and 17th June 2003, and in Athens on 27th May 2003;

Having heard the rapporteurs Peter Whittaker and Nicos C. Alivizatos;

WHEREAS :

DEFINITIONS

For the purposes of this Opinion:

- (a) “undertaking” means a public or private enterprise, carrying out an economic activity, whether or not operating for gain, which is located within the territory of a member State;
- (b) “workplace” means a unit of business defined in accordance with national law and practice, whether in the public or in the private sector, located within the territory of a Member State, where an economic activity is carried out on an ongoing basis with human and material resources;
- (c) “employer” means the natural person or legal entity, whether public or private, party to employment contracts or employment relationships with employees, in accordance with national law and practice; moreover, the term employer comprises employment agencies, temporary employment agencies, personnel selection consultants and agencies that dispose of employees to other natural or legal entities (“personnel lending”).
- (d) “employee” means any person who, in the Member State concerned, is protected as a worker or as an employee under national law and practice; moreover, the term employee comprises candidates for a post whatsoever, as well as former employees;
- (e) “genetic testing” in this context means the use of a scientific test to obtain information on some aspects of the genetic status of a person, indicative of a present or future medical problem. In the context of employment, “genetic testing” incorporates “genetic screening” and “genetic monitoring”;
- (f) “genetic screening” in this context means the use of a scientific test to determine whether a person possesses particular variant forms of one or more genes in his/her genome;
- (g) “genetic monitoring” in this context means the examination, at regular intervals, for chromosomal abnormalities in samples of cells from a person who may be at risk, in their employment, of exposure to agents which cause genetic damage;
- (h) “personal data” in this context refers to data, however obtained, containing information that might give an indication of either the present health or predicted future health status of a person.

SCIENTIFIC BACKGROUND

1.1 Genetic Testing

1.1.1 Introduction

A person's DNA comprises the genetic information that, within the constraints imposed by all the environmental influences to which that person is exposed, governs the growth, development and resulting characteristics of that person. It is becoming increasingly easy to obtain information regarding particular aspects of someone's genetic status by testing for the presence of particular variant forms of genes or by microscopic examination of their chromosomes. The information obtained from such genetic tests may sometimes be used to anticipate the onset of certain genetically determined diseases and to initiate appropriate early therapy or other anticipatory action. Genetic testing is also being used at the present time, in the investigation of crime and in paternity identification. The predictive value of some genetic information means, however, that some insurance companies would like to access this, in order to obtain what they believe to be a more accurate assessment of risk for life and health insurance purposes. This Opinion focuses in particular on employers' interest in genetic testing as a way to predict an employee's future health or their susceptibility to particular hazards in the working environment (genetic screening). They might also wish to monitor the genetic status of an employee who is at risk of exposure to agents known to cause genetic damage (genetic monitoring).

1.1.2. Non-DNA based Genetic Screening

The definition of genetic screening need not be restricted to tests carried out directly on an individual's DNA. Many genes are coded instructions for making particular proteins. Others may regulate the timing or quantity of protein synthesised. Consequently it may be possible in some cases to access indications of genetic status by measuring the activity of a protein or some of its products. For the purposes of this Opinion, any test that evaluates specific genes or gene products that may be indicators of a person's genetic status are considered to be genetic tests.

1.1.3. Family Medical Histories

Family medical histories can give an indication of possible genetic status with regard to susceptibility to some diseases and are routinely used by some insurance companies for persons applying for health insurance. In so far as family medical histories can provide information on a person's genetic status, which may have a predictive value for future health as significant as a laboratory performed genetic test, these are included within our definition of genetic tests.

1.2 Applications of genetic testing in the context of employment

1.2.1. Genetic Screening as an Indicator of future health

It is clear that a person's genetic constitution plays a role in their susceptibility to a variety of diseases. That is not to say that genes are the sole determinant of disease susceptibility as this may be modulated by environmental, lifestyle, dietary and perhaps other serendipitous factors. Nevertheless, it is possible that investigation of an individual's genetic constitution for the presence or absence of particular gene variants might provide some indication of the likelihood of the individual contracting, in the future, a particular disease.

Employers, either current or prospective, could have an interest in the results of such genetic screening in so far as these might be a predictor of the future health of an employee, particularly if they were to imply possible levels of future absenteeism or low work rate which might impact on profitability. An employee who develops heart disease, for example, would certainly be likely to require periods of absence from work and, in certain occupations, might not be able to sustain a normal work rate. There is also the possibility that sudden onset of a disease condition might result in a hazard for the employee, other employees or the public. An employer could use the results of such tests to exclude job applicants on the basis of predicted future health.

This type of genetic testing, where there is no reason to suspect that the employee might possess any particular genetic constitution, is generally referred to as genetic screening.

1.2.2. Genetic Screening as an indicator of susceptibility to occupational hazards

Employers could also have an interest in whether the genetic profile of an employee might endow them with greater or lesser susceptibility to occupational hazards, such as the presence of toxic, mutagenic or carcinogenic materials in the workplace environment at levels below those that are recognized as acceptable. Variants of genes that affect the metabolism of such genotoxic agents can result in variations in individual's ability to activate or inactivate these. Other genes may control the repair of genetic damage. Occupational factors have been shown to be associated with 10% of cases of adult asthma. Asthma is a polygenic disease in which many gene-environment interactions are involved. Other diseases having an occupational component and with a known genetic basis include beryllium allergy and chronic obstructive pulmonary disease resulting from α -1-antitrypsin (AAT) deficiency.

An employer might wish to use such information to deploy workers in areas appropriate to their particular genetic make up or to exclude them from employment.

Information from this type of genetic screening might also be of value to the employee. Being aware of the likely level of their own susceptibility to a particular workplace hazard would permit them to make informed decisions with regard to the type of work they would seek for their own long-term health and safety.

1.2.3. Genetic Monitoring

Even in the best regulated employment environment, it may not be possible to ensure total elimination of the presence of all traces of chemicals or irradiation that could damage a person's genetic material. In such circumstances it is possible to monitor cells of a potentially exposed person for genetic damage. Such tests may impact not only on the well-being of the individual, but also on the next generation. The results of genetic monitoring could reveal a hitherto unappreciated risk to health and hence is of public health relevance. In this Opinion this type of genetic testing is referred to as genetic monitoring.

1.3 Genes and Disease

1.3.1 Monogenic and Polygenic Diseases

Although there are many diseases with a recognized genetic component resulting from a defect in a single gene (monogenic diseases), as a general rule the incidence of such diseases is low. Monogenic diseases include cystic fibrosis, sickle cell anaemia, Huntington's Disease and haemophilia.

Cystic fibrosis and sickle cell anaemia are examples of autosomal recessive diseases, where the relevant genes are carried on one of the 22 pairs of human chromosomes that are not sex-specific. This means that a copy of the defective gene must be inherited from both parents if the disease is to be manifest. A person carrying a normal copy of the gene from one parent and a defective copy from the other are carriers of the disease gene but do not usually manifest symptoms of the disease.

Huntington's Disease is an example of an autosomal dominant disease. In this case only a single copy of the defective gene coming from either parent is required for development of the disease.

Haemophilia is an example of a disease resulting from a defect in an X-linked gene. The sex-specific chromosome pair comprises two X chromosomes (female) or an X and a Y chromosome (male). As males have only a single X chromosome, they are more likely to develop such a disease than females with two X chromosomes, as the recessive gene variant on one of the X chromosomes will not be expressed in the presence of the normal gene on the other X chromosome.

In contrast to the above examples of diseases resulting from defects in a single gene, other human diseases with a genetic component are thought to result from interactions between several genes (polygenic diseases). The incidence of some polygenic diseases is very high. In most of these cases the genetic basis is incompletely understood and is complicated by influences of environment, diet and lifestyle. Examples of such polygenic diseases are heart disease, several cancers and some allergies.

1.3.2 Factors affecting development of hereditary disease

The possession of one or more genetic defects does not necessarily dictate that the person possessing the defect will develop the disease. For example, a woman with the BRCA1 breast cancer susceptibility gene has an 80% risk of developing breast cancer by age 65. The "expressivity" of a genetic defect describes the different severities of disease from which various possessors of the defect may suffer. Both penetrance and expressivity, as well as the timing of disease onset, may be affected by environmental factors, life style or the presence of a range of other genes.

1.4 Methodology for Genetic Testing

1.4.1 Methodology for Genetic Screening

Defective versions of a gene may be altered only very slightly in DNA sequence from the normal version of the gene. Genetic screening aims to identify such small changes in the gene in question. Only a very small amount of DNA is required for genetic screening. As an example, the DNA region required is usually amplified thousands of times using the polymerase chain reaction (PCR). A fluorescent label is then attached to the amplified DNA. The fluorescence-labelled DNA is then passed through a filter to which is attached a small length of DNA (the “probe”) containing a sequence characteristic of the version which is being screened for. If the version in question is present in the fluorescent amplified DNA then this will bind to the probe, showing up as fluorescence on the filter. By attaching several different probes at different points on the filter it is possible to screen for the presence of several different versions of the gene at the same time. Developments in DNA microarray technology are likely to make it possible to screen for large numbers of genes with variant forms simultaneously.

Where a genetic screen involves identification of a protein altered in concentration as a result of a particular defective gene, the strategy used varies with the protein in question. It may be recognised using electrophoretic identification, an antibody probe or by an enzyme assay for example.

1.4.2 Methodology for Genetic Monitoring

In contrast to genetic screening, genetic monitoring usually involves microscopic examination of the karyotypes (chromosome patterns) of white blood cells. Indication of unacceptable levels of exposure to genotoxic agents comes from observations of changes in chromosome structures including chromosome breakage, inversion or deletion of sections of chromosomes or translocation of a part of a chromosome to a different chromosome. Recently developed technology permits the observation of quite small alterations in chromosome structures.

1.5 Validity, Reliability and Predictability of Genetic Tests

1.5.1 Validity of Genetic Tests

At the present time, very few genetic tests are available that give information to either an employer or an employee which could validly be used in the context of decisions concerning employment. It is likely that this situation may change in the future although it is difficult to predict the pace of such change. Where employment is linked to health or life insurance, employers may come under pressure from insurance companies to implement genetic screening to assess the level of risk to which the employee might be exposed. Validity of a genetic test would require demonstration of

- 1) its relevance to health protection of workers,
- 2) the reliability and reproducibility of the test and
- 3) the level of predictive value for the test.

In some countries, there are statutory bodies that may be asked to rule on the validity of genetic tests in particular circumstances.

1.5.2 Relevance of Genetic Tests

At the present time, it is difficult to make a case for any genetic tests to be carried out as indicators of future health in terms of their relevance to employment. Genetic screening for susceptibility to workplace environmental hazards clearly has some precautionary relevance but in many cases the link between a particular genetic status and susceptibility to a particular hazard has only a theoretical basis at present.

In the general debate there have been exaggerated beliefs about the predictive value of genetic tests, perhaps based on the concept of genetic determinism, which have been proved to lack foundation. On the other hand, where there is a possible risk of genetic damage to an employee resulting from exposure to workplace contaminants, genetic monitoring for chromosomal changes resulting from this exposure may have a very clear relevance for the health of an employee.

1.5.3 Reliability of Genetic Tests

In such a sensitive area, it is obviously extremely important that procedures for genetic testing are as reliable as possible, as provision of incorrect information to an employer or employee could have far reaching consequences. All stages of a scientifically satisfactory testing procedure should have built in negative and positive controls to ensure the reliability of the test result. Good laboratory practice would be observed at all times, including detailed documentation of procedures and results. Even when testing procedures are optimised, false negatives and false positives will emerge and validation procedures for the tests may be required.

1.5.4 Predictive value of Genetic Tests

Even for monogenic diseases, predictive value of genetic testing may be limited. There is always a possibility that the disease in question might not manifest itself during the working life of the individual and it is not always possible to predict the severity of the future disease.

The situation is even more complex where diseases with a polygenic basis are concerned. At the present time it is virtually impossible accurately to predict, using genetic tests, either whether the disease will develop at all or, if it does, its timing and severity. Even if the genetic basis of such diseases becomes fully understood, environmental and lifestyle factors, which may themselves be unpredictable, will limit the predictability of disease development.

Testing protocols that are less than 100% accurate (most of the cases) will reduce predictive value still further. False negatives would result in possible exposure of a susceptible individual to unacceptable levels of occupational hazard whilst false positives could result in unjustified exclusion of non-susceptible individuals from employment.

1.6. The Practice: Employer Utilisation Of Genetic Testing

It is far from clear what is the actual present and anticipated usage of genetic testing by employers. There has been more interest in genetic testing in the United States than in Europe. This appears to be related to the more widespread practice in the USA than in Europe for employers to contribute to health insurance. Perhaps for this reason there have been more studies of genetic testing in the workplace in the USA. The results of such surveys should be viewed with caution as some studies have shown that some of the employers surveyed did not have a full understanding of what a genetic test was.

1.6.1 Genetic Testing in Employment in Europe

Increasing globalisation in industry and trade suggest that U.S. models for health insurance in employment might start to apply in Europe. In this situation it is probable that there might be pressure to widen preemployment medical examinations to include genetic tests. A study of genetic testing in the workplace carried out by the School of Health and Related Research at Sheffield University suggests that the surveys that have been carried out in Europe have tended to ask employers whether they are carrying out genetic tests. In a situation where the technology is not widely available, it is hardly surprising that very few examples of genetic testing in the workplace could be found. It might have been preferable to have asked employers about their attitudes to genetic testing in the future.

As far as can be determined at present, there is still only the single case of genetic screening in the workplace previously referred to in reports from the Nuffield Council on Bioethics and the Human Genetics Advisory Committee in the United Kingdom. This is the screening of aircrew by the UK Ministry of Defence for sickle cell trait. The worry has been that carriers of the sickle cell gene might be adversely affected by low oxygen pressures in an aircraft. This strategy has been criticised on the basis that it is not founded on sound evidence and also that it could be viewed as discriminatory in view of the fact that there are much greater numbers of sickle cell allele carriers in the Afro-Caribbean population than in the general population. The UK Ministry of Defence is reported to have discontinued this practice.

A survey carried out by the Institute of Directors in the UK in August 2000 recorded that 2 out of 353 directors reported that their companies routinely used genetic tests. A further 4 directors stated that genetic tests were used by their companies, but only if they were concerned about specific employees. The particular types of genetic tests used were not recorded. The report also sought information on directors' attitudes to genetic screening for particular reasons. 34% of 353 directors approved of genetic screening for the likelihood of developing heart disease as long as the employee consented. A further 8% would be in favour of compulsory testing if it was considered to be in the employee's best interests. 50% approved of genetic tests, with employee consent, to see whether employees were at risk of developing an occupation-related disease due to exposure in the workplace. A further 16% thought that this should be compulsory.

1.6.2. Genetic Testing In Employment In USA

In the 1970s, the US Air Force Academy did not permit sickle cell gene carriers to participate in pilot training. Subsequently, courts have found that tests for sickle cell trait disproportionately impact on African-Americans and many states now prohibit employers from testing for the disease. A 1991 survey of Genetic Monitoring and Screening in the Workplace carried out by the US Congress Office of Technology Assessment examined both practices and attitudes. Only 1% of company health officers at that time reported that their company had a formal policy either on preemployment genetic screening or on genetic monitoring. Despite this, a majority of personnel and health officers suggested that their companies considered the use of genetic screening tests for job applicants as generally acceptable to inform the latter of their level of susceptibility to workplace hazards. Well over one third of both health officers and personnel officers felt that it would be acceptable to exclude employees with increased susceptibility to risk situations. Surprisingly, a majority of both felt that it would be unacceptable to monitor chromosomal changes associated with workplace exposure. The survey showed that 1% of companies claimed to have used genetic screening to identify persons with increased health risks. 12% of companies reported genetic monitoring or screening of employees. Most of these involved genetic monitoring in companies where workers might be exposed to chemicals or ionising radiation.

With the enormously expanded knowledge of the human genome and improvements in genetic technology it is likely that usage and potential usage of genetic testing in the USA will have expanded significantly since that survey. According to a 1996 poll of members of families with perceived genetic risk carried out by Georgetown University, 13% had been dismissed from their jobs because of this perceived risk. A 1998 survey by the American Management Association suggested that 10% of employers routinely test employees for genetic predispositions to diseases and that this figure is growing.

In 2001 the US Equal Employment Opportunity Commission (EEOC) settled its first court action involving workplace genetic screening against the Burlington Northern Santa Fe Railway. This company had carried out genetic screening without the knowledge or consent of its employees. The genetic testing had been carried out in response to claims from some employees for work-related injuries based on carpal-tunnel syndrome. At least one worker had been threatened with dismissal for non-provision of a blood sample. EEOC required that the company completely and immediately stop its programme of genetic testing and asserted that it would “respond aggressively to any evidence that employers are asking for or using genetic tests in a manner which violates the Americans with Disabilities Act of 1990”.

LEGAL BACKGROUND

1.7. Introduction

As a general rule, standing instruments at national, community and international level do not specifically address the issue of genetic testing at the workplace. While there exist rules purporting to forbid such testing for reasons other than health care and to prohibit discrimination thereof, there are no binding provisions barring genetic screening in the employment sector and addressing the threats that such screening may constitute for both the privacy and the dignity of the weakest party involved, that is workers and employees. On the other hand, save some scattered regulations, there exist no special rules on the collection and processing of genetic personal data. The lack of adequate protection in this field may hurt trust, mutual respect and professionalism in the relationship between employers and employees, which could adversely affect not only the latter, but also employers and the business as a whole.

1.8. At national level

Some Member States have enacted rules on human genetics:

- In France, a 2002 amendment to the *code civil* and to the *code pénal* prohibits discrimination based on one's genetic characteristics or on predictive genetic tests "having as an object a disease which has not yet manifested or a genetic predisposition to a disease".
- In a similar way, in Sweden, standing legislation requires that genetic testing may only take place if it has a medical aim or serves a research purpose.
- In Finland, a 2001 law provides that employers shall not require employees to participate in genetic testing either at the time of recruitment or during employment, nor do employers have the right to obtain information as to whether an employee has undergone such testing.
- In Denmark legislation from 1996 regulates the Use of Health Information on the Labour Market. The aim is to ensure that health checks focus on the actual/present health conditions and that those conditions are relevant to the employee's work. Thus the Act widely limits the employer's possibilities to ask potential employees for health information including information based on genetic testing. The employer is for example not allowed to collect information concerning the probability of the employee suffering from diseases in the future, but is for example allowed to obtain information about the employee's health if conditions in the working environment make it reasonable and desirable in relation to the employee himself or other employees.
- In Austria, both genetic screening and the collection, demand, acceptance or any other utilisation of genetic data on the employees by the employers are explicitly prohibited.
- Restrictions to the collection and processing of genetic data at the workplace are also provided in the Netherlands, in Luxembourg and in Greece.
- In Italy, according to the data protection law of 1996, genetic data may only be processed under the circumstances referred to in an ad-hoc authorisation to be granted by the national supervisory authority. The genetic data expressly referred to in that authorisation may be processed with regard to such information and operations as are indispensable to protect the bodily integrity or health of either the subject, a third party or the community as a whole - on the basis of the subject's written consent.

Failing the subject's consent, the processing may be started and/or continued if it is aimed at protecting the bodily integrity or health of either a third party or the community as a whole - exclusively on the basis of a prior ad-hoc authorisation to be granted by the national data protection supervisory authority.

1.9. At Community level

In June 2000, the Commission published the Social Policy Agenda, which provided for a consultation with social partners on the protection of personal data in the employment context. The Commission believed that employees (during and post employment) and prospective employees may not have sufficient protection of their fundamental rights and personal data, processed by employers and/or transferred to third parties. More concretely, consent, which is admitted by the Data Protection Directive as a means for legitimising data collection and processing, may not be really free in the employment context, in which employees and prospective employees are either subordinate or dependent. In other words, employees often find themselves in a position where it is virtually impossible for them to refuse, withdraw or modify consent, due to the employer's position and power, and to their own fear of loss of job offer, promotion and so on. Since the Data Protection Directive does not, in principle, expressly address data protection issues in the workplace, the Commission considered that it should be duly particularised and complemented. Although it does not directly address the relevant issues, Council Directive 2000/78/EC of 27 November 2000, establishing a general framework for equal treatment in employment and occupation, contains useful rules, such as the obligation to treat equally persons with disabilities. Presently, the Commission considers a specific community action which can take the form of a specific Directive providing for a European framework on the protection of employees' personal data. Based on the fundamental principles of the Data Protection Directive, this framework aspires to cover all kinds of employees' personal data, including medical data and data deriving from genetic tests.

1.10. At International level

A number of international instruments in the field of data protection exist which have some relevance to the issue of genetic testing in the workplace. The Council of Europe 1981 Convention No 108 for the protection of individuals with regard to automatic processing of personal data and the 1997 Recommendation (97)5 on the protection of medical data are relevant, but neither of these instruments relate expressly to employment. The International Labour Office (ILO) Code of Practice on the protection of workers' personal data (1997) is a useful source of inspiration for Community action. Both this instrument and the 1989 Recommendation No R(89)2 of the Council of Europe on the protection of personal data used for employment purposes recognize that different traditions exist among countries in regard to the regulation of employers and workers. Such traditions, though, should not be used to obstruct enforcement of widely recognized fundamental principles in this field.

ETHICAL BACKGROUND

Ethical issues can be related either to the performance of the genetic testing itself, or to the use of the data which have been obtained by genetic testing.

1.11. Ethical Aspects Relating to Performance of Genetic Tests

1.11.1 Autonomy of Employees or Applicants for Work

The performance of genetic tests makes available personal data of great sensitivity. Particular attention must be given to the interests of the person to be tested and to the question of whether the benefits that might accrue from the testing will warrant any personal intrusion that the test imposes.

In particular, the autonomy of the person to be tested, whether prior to or during employment, must be carefully balanced against the duties of employers to provide protection for members of the work force, including the person to be tested, and third parties.

In the context of genetic testing, autonomy implies for the person to be tested, fully informed consent to the test(s). Full information, as well as incorporating understanding of the testing procedures, would also involve information about the possible test outcomes and the significance of these, and appropriate counselling when the test results are delivered. It is often the case that the position of an applicant for employment is rather weak compared with that of an employer and that this might result in a self imposed pressure to consent to tests that could be unnecessary.

1.11.2 Duties of Employers to Employees and Other Parties

Employers have a duty to protect members of their workforce and other parties that might possibly be harmed as a result of either sudden or progressive sickness of an employee. It is possible that in some cases, genetic testing of an employee might be the only way of ensuring that this duty is carried out. Employers also have a primary duty to ensure that employees are provided with a safe working environment and are not exposed to harmful occupational hazards.

1.11.3. Employee's Ability to Carry Out Work

Employers have the right to expect their employees to be capable of carrying out the work required. This would normally be judged by an employer using the traditional approaches of *curriculum vitae*, interview, aptitude tests and references. An applicant's ability to carry out the work is sometimes also assessed during a medical examination. Working contracts are often subject to a probationary period – an additional safeguard for the employer. A genetic test of limited predictive value would add nothing to knowledge of an applicant's ability to carry out the work at the outset and would give very little information on how this might change in the future.

1.11.4 Validity of Genetic Tests

Another ethical issue is the validity of a test, its relevance, reliability and predictive value. At the present time very few tests would achieve a high score in all of these categories. It would be manifestly unfair to base important decisions regarding employment or promotion on the results of tests either of dubious relevance or with low reliability or predictive value. Any benefits emerging from such tests in terms of protection of employees or third parties could be greatly offset by suffering resulting from false negatives and false positives.

1.12. Ethical Aspects Relating to Use of Genetic Information

1.12.1. Confidentiality and the Right Not to Know

The sensitive nature of data obtained from genetic testing raises the question of confidentiality. The data will initially become available to the health professional responsible for requesting the test. The question arises of whether the raw genetic data should ever be made available to an employer or if the medical professional should merely communicate their relevant professional opinion to the employer. In this respect, the independence of the medical professional is an important consideration. Genetic data are clearly the property of the person who has been tested but the latter may wish to exercise their right not to know their genetic status.

Another issue with respect to confidentiality is that genetic information on one individual might also give an indication of the genetic status of one or more of the individual's family members.

1.12.2. Discriminatory Use of Genetic Test Results

Data from genetic screening could be used to the disadvantage of an applicant for employment or an employee. It could be used to discriminate unfairly between applicants for employment or for promotion within a company. It could have serious implications for a person's career prospects.

2. OPINION

The Group focuses in this Opinion on the ethical issues related to genetic testing, with particular reference to genetic screening. Nevertheless, the ethical dilemmas and conflicts of interest to be considered in regard to genetic testing including genetic monitoring can be viewed in the general context of medical data at the workplace.

The Group submits the following opinion:

2.1.

Employers have the duty to protect the health of their employees and to prevent risk to third parties. On the other hand, employees and candidates for employment have a right to privacy and to the protection of their personal data.

2.2.

Employers have the duty to adapt the workplace in order to limit the risk of health damage for the employees.

2.3.

During recruitment, employers must guarantee fair treatment for all applicants and avoid any discrimination.

2.4.

Employees have the duty to prevent risk to third parties.

2.5.

Employees or potential employees must realise that a medical examination may be part of the assessment of aptitude for the position.

2.6.

The medical examination should not be a criterion of selection . It should take place after the phase of selection.

2.7.

Where there is a possible risk of genetic damage to an employee resulting from some component of the working environment, the employer must take every possible step to eliminate that risk. If such a risk cannot be totally excluded, genetic monitoring, which aims at evaluating chromosomal abnormalities induced by exposure to agents in the context of employment, may be valuable but requires properly informed consent.

2.8.

Genetic screening is a type of medical testing. It concerns the potential future health status of the individual screened.

As a general rule, the Group considers that only the present health status of the employees should be considered in the employment context.

2.9.

Furthermore, there is, up until now, no proven evidence that the existing genetic tests have relevance and reliability in the context of employment. They still have uncertain predictive value.

2.10.

The Group considers that, in general, the use of genetic screening in the context of the medical examination, as well as the disclosure of the results of previous genetic tests, is not ethically acceptable. The legitimate duties and right of employers concerning the protection of health and the assessment of ability can be fulfilled through medical examination but without performing genetic screening. Thus, employers should not in general perform genetic screening nor ask employees to undergo tests.

2.11.

In exceptional cases, the use of genetic screening could be considered when it may be necessary to guarantee health protection of workers or protection of third parties.

2.12.

In these exceptional cases, genetic testing could be considered provided that, among others, the following conditions are fulfilled:

- the performance of the test is necessary for guaranteeing the protection of the employee's health and safety or those of third parties,
- there is scientifically proved evidence that the genetic test is valid and is the only method to obtain this information,
- the performance of the test does not prejudice the aim of improving conditions in the workplace,
- the principle of proportionality is respected regarding the motivations involved to perform the test,
- the principle of non-discrimination is not violated.

2.13.

The definition of exceptional cases for proposing and performing genetic screening at the workplace should be explicitly regulated by law.

2.14.

For a specific application, the prior assent of the appropriate labour organisation and a specific *ad hoc* authorization by an independent committee should be required.

2.15.

The applicant or the employee should receive full information from an independent health professional on the testing procedure, the reasons for performing such tests, the potential outcomes and their implications and consequences, as well as the conditions of storing and access to data. They should also, if requested, be provided with access to independent legal counselling.

2.16.

The applicant or the employee should consent to the genetic test.

2.17.

When the test reveals a genetic condition which is incompatible with the protection of the health of the employee or the applicant or with the safety of third parties, the information given to the employers should only concern the inappropriateness of the applicant for the specific job, without specification of the cause.

2.18.

The genetic data as other medical data remain confidential; such personal attributable data should only be accessible to the applicant and to the health professional, and transfer without consent of these data to third parties, including the employer, should be strictly prohibited.

2.19.

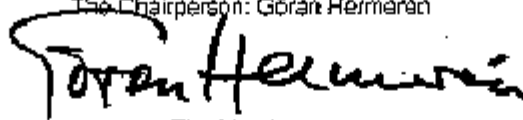
Genetic screening or monitoring conducted at the workplace should not be considered as a genetic test to be disclosed for the purpose of insurance.

2.20.

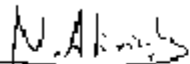
Legal measures should be taken at EU level to preserve the confidentiality of these genetic data also in case of transborder movement of the employees/employers, namely in the context of free circulation of workers within the EU.

The European Group on Ethics in Science and New Technologies

The Chairperson: Göran Hermerén



The Members:



Nicos C. Alivizatos

Inez de Jong



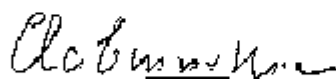
Rafael Caputo



Yvoni Engler




Catherine Labrousse-Nou



Anne Mc Laren



Linda Nielsen



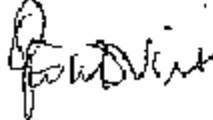
Flore Fulgdomenach Rosell



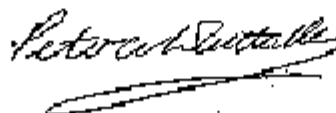
Stefano Rodota



Günter Vint



Peter Whittaker





STELLUNGNAHME DER EUROPÄISCHEN GRUPPE FÜR ETHIK
DER NATURWISSENSCHAFTEN UND DER NEUEN
TECHNOLOGIEN BEI DER EUROPÄISCHEN KOMMISSION

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ETHISCHE ASPEKTE VON GENTESTS AM ARBEITSPLATZ

Bezug: Initiative der Gruppe

Berichterstatter: Peter Whittaker und Nicos C. Alivizatos

gestützt auf den durch den Vertrag von Nizza geänderten Vertrag über die Europäische Union, insbesondere auf Artikel 6 der gemeinsamen Bestimmungen über die Achtung der Grundrechte;

gestützt auf den EG-Vertrag, insbesondere auf Artikel 137 über die Arbeitsumwelt und die Gesundheit und Sicherheit am Arbeitsplatz;

gestützt auf die vom Europäischen Rat in Biarritz am 14. Oktober 2000 angenommene und vom Europäischen Parlament, vom Rat und von der Kommission am 7. Dezember 2000 in Nizza feierlich verkündete Charta der Grundrechte der Europäischen Union, insbesondere auf Artikel 8 über den "Schutz personenbezogener Daten", Artikel 15 über "Berufsfreiheit und Recht zu arbeiten", Artikel 21 über Nichtdiskriminierung, unter anderem wegen genetischer Merkmale, und Artikel 31 über "Gerechte und angemessene Arbeitsbedingungen";

gestützt auf Richtlinie 95/46/EG des Europäischen Parlaments und des Rates vom 24. Oktober 1995 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten und zum freien Datenverkehr;

gestützt auf Richtlinie 2000/78/EG des Rates vom 27. November 2000 zur Festlegung eines allgemeinen Rahmens für die Verwirklichung der Gleichbehandlung in Beschäftigung und Beruf;

gestützt auf Richtlinie 2002/14/EG des Europäischen Parlaments und des Rates vom 11. März 2002 zur Festlegung eines allgemeinen Rahmens für die Unterrichtung und Anhörung der Arbeitnehmer in der Europäischen Gemeinschaft;

gestützt auf die Empfehlung Nr. R(89)2 des Europarates von 1989 über den Schutz personenbezogener Daten im Arbeitsbereich;

gestützt auf die Empfehlung Nr. R(92)3 des Europarates von 1992 über Gentests und genetisches Screening für Zwecke der Gesundheitsfürsorge, insbesondere auf die Grundsätze 6 und 8, nach denen Gentests und genetisches Screening nur in Ausnahmefällen und die Erhebung und Verarbeitung der entsprechenden personenbezogenen Daten nur zu Zwecken der Gesundheitsfürsorge, der Diagnose und der Krankheitsvorbeugung zulässig sind;

gestützt auf die Empfehlung Nr. R(97)5 des Europarates von 1997 zum Schutz medizinischer Daten, insbesondere auf Grundsatz 4.9, wonach die Erhebung und Verarbeitung genetischer Daten grundsätzlich nur für Gesundheitszwecke zulässig ist;

gestützt auf das am 4. April 1997 in Oviedo unterzeichnete Übereinkommen des Europarates über Menschenrechte und Biomedizin, insbesondere auf Artikel 11 über "Nicht-Diskriminierung" und Artikel 12 über "Prädiktive Gentests";

gestützt auf den Verhaltenskodex der Internationalen Arbeitsorganisation (ILO) für den Schutz von Beschäftigtendaten, insbesondere auf Artikel 3.20, wonach "genetisches Screening in Verbindung mit dem Arbeitsplatz eine unverhältnismäßige Verletzung der Personenrechte ist" und "der gegenwärtige Stand der Wissenschaft nicht ausreichend ist, um seine Durchführung zu Zwecken der Gesundheit am Arbeitsplatz zu garantieren".

gestützt auf das Rundtisch-Gespräch der Gruppe vom 6. März 2000 in Brüssel mit Mitgliedern des Europäischen Parlaments, Rechtssachverständigen, Philosophen, Naturwissenschaftlern, Arbeitnehmer- und Arbeitgebervertretern, Vertretern der Religionsgemeinschaften, Vertretern von Patientenvereinigungen und anderen Interessengruppen sowie von internationalen und europäischen Organisationen (UNESCO, Europarat, WHO, OECD);

gestützt auf die Sachverständigenanhörungen in Brüssel vom 18. März, 15. April und 17. Juni 2003 sowie in Athen vom 27. Mai 2003;

nach Anhörung der Berichterstatter Peter Whittaker und Nicos C. Alivizatos;

1. IN ERWÄGUNG NACHSTEHENDER GRÜNDE:

DEFINITIONEN

Für den Zweck dieser Stellungnahme:

- (a) bedeutet "Unternehmen" ein staatliches oder privates Unternehmen, das, gewinnorientiert oder nicht, eine Wirtschaftstätigkeit ausübt und seinen Sitz auf dem Hoheitsgebiet eines Mitgliedstaates hat;
- (b) bedeutet "Arbeitsplatz" eine entsprechend nationalem Recht und Gebräuchen definierte Unternehmenseinheit im öffentlichen oder privaten Sektor, die sich auf dem Hoheitsgebiet eines Mitgliedstaates befindet, und wo ständig eine Wirtschaftstätigkeit mit Human- und Sachressourcen ausgeübt wird;
- (c) bedeutet "Arbeitgeber" eine natürliche Person oder Rechtspersönlichkeit im öffentlichen oder privaten Bereich, die Beschäftigungsverträge oder Beschäftigungsverhältnisse mit Arbeitnehmern entsprechend nationalem Recht und Gebräuchen eingeht; ferner umfasst der Begriff "Arbeitgeber" Arbeitsvermittler, Zeitarbeitsvermittler, Personalberater und Agenturen, die Arbeitnehmer an andere natürliche Personen oder Rechtspersönlichkeiten vermitteln ("Personalvermittlung").
- (d) bedeutet "Arbeitnehmer" eine Person, die in dem betreffenden Mitgliedstaat als Arbeiter oder Angestellter nach nationalem Recht und Gebräuchen geschützt ist; ferner umfasst der Begriff "Arbeitnehmer" Bewerber um einen Arbeitsplatz sowie ehemalige Arbeitnehmer;
- (e) bedeuten "Gentests" in diesem Zusammenhang die Durchführung eines wissenschaftlichen Tests, um Angaben über einige Merkmale der genetischen Veranlagung einer Person zu erhalten, die auf ein gegenwärtiges oder künftiges Gesundheitsproblem hinweist. Im Zusammenhang mit der Arbeitswelt beinhalten "Gentests" "genetisches Screening" und "genetisches Monitoring";
- (f) bedeutet "genetisches Screening" in diesem Zusammenhang die Durchführung eines wissenschaftlichen Tests, um zu bestimmen, ob eine Person über besondere Varianten eines oder mehrerer Gene in ihrem Genom;
- (g) bedeutet "genetisches Monitoring" in diesem Zusammenhang die regelmäßige Prüfung auf Chromosomenabweichungen in Zellproben einer Person, die an ihrem Arbeitsplatz genschädigenden Stoffen ausgesetzt ist.
- (h) bedeuten "personenbezogene Daten" in diesem Zusammenhang jegliche Art von Daten, die entweder auf den gegenwärtigen oder voraussichtlich künftigen Gesundheitszustand einer Person schließen lassen.

WISSENSCHAFTLICHER HINTERGRUND

1.2 Gentests

1.2.1 Vorbemerkung

Die DNA eines Menschen enthält die genetischen Informationen, die unter Berücksichtigung aller Umwelteinflüsse, denen eine Person ausgesetzt ist, das Wachstum, die Entwicklung und die sich daraus ergebenden Merkmale dieser Person bestimmen. Es wird zunehmend leichter, Informationen über Einzelaspekte des genetischen Zustandes einer Person zu gewinnen, indem man das Vorhandensein bestimmter Genvarianten prüft oder ihre Chromosomen unter dem Mikroskop untersucht. Die Ergebnisse dieser Gentests können zum Teil benutzt werden, um den Ausbruch gewisser genetisch bestimmter Krankheiten vorherzusehen und geeignete Frühtherapien oder andere vorbeugende Maßnahmen einzuleiten. Gentests werden gegenwärtig auch in der Forensik und bei Vaterschaftstests verwendet. Die Präzision genetischer Daten führt jedoch dazu, dass Versicherungsgesellschaften in ihren Besitz gelangen möchten, um die Risiken ihrer Lebens- und Krankenversicherungen ihrer Meinung nach genauer abschätzen zu können. Diese Stellungnahme konzentriert sich insbesondere auf das Interesse der Arbeitgeber an Gentests als Möglichkeit, den künftigen Gesundheitszustand eines Arbeitnehmers vorherzusagen bzw. seine Anfälligkeit für gewisse Risiken am Arbeitsplatz ist (genetisches Screening). Sie könnten auch ein Interesse daran haben, die genetische Veranlagung eines Arbeitnehmers zu überprüfen, der genschädigenden Stoffen ausgesetzt ist (genetisches Monitoring).

1.1.2. Nicht-DNA-basiertes genetisches Screening

Die Definition des Begriffs "genetisches Screening" beschränkt sich nicht allein auf DNA-Tests. Bei vielen Genen handelt es sich um kodierte Anweisungen zur Herstellung bestimmter Proteine. Andere können den Zeitpunkt oder die Menge der Proteinsynthese steuern. Es kann daher in einigen Fällen möglich sein, Anzeichen für einen genetischen Status zu erhalten indem man die Tätigkeit eines Proteins oder seiner Erzeugnisse misst. Zum Zwecke dieser Stellungnahme werden alle Tests zur Beurteilung bestimmter Gene oder Gernerzeugnisse mit Hinweisen auf die genetische Veranlagung einer Person als Gentests angesehen.

1.1.3. Erb- und Familienkrankheiten

Erb- und Familienkrankheiten können Hinweise geben auf eine mögliche genetische Veranlagung im Hinblick auf die Anfälligkeit für bestimmte Krankheiten und werden von einigen Versicherungsgesellschaften bei der Prüfung von Krankenversicherungsanträgen herangezogen. Insofern Erb- und Familienkrankheiten Hinweise auf die genetische Veranlagung einer Person geben können, die ebenso aussagekräftige Hinweise auf die zukünftige Gesundheitsentwicklung liefern wie ein im Labor durchgeführter Gentest, werden diese in unsere Gentest-Definition einbezogen.

1.2 Durchführung von Gentests in der Arbeitswelt

1.2.1. Genetisches Screening als Indikator für die zukünftige Gesundheitsentwicklung

Unbestreitbar spielt die genetische Verfassung einer Person eine Rolle im Hinblick auf ihre Anfälligkeit für bestimmte Krankheiten. Die heißt nicht, dass Gene allein über die Krankheitsanfälligkeit bestimmen, da diese auch durch Umwelteinflüsse, Lebensstil, Ernährung und eventuell durch andere günstige Umstände abgewandelt wird. Gleichwohl können Untersuchungen zum Nachweis bestimmter Genvarianten Hinweise darauf bieten, mit welcher Wahrscheinlichkeit eine Person in Zukunft eine bestimmte Krankheit entwickelt.

Gegenwärtige oder künftige Arbeitgeber könnten ein Interesse an den Ergebnissen derartiger genetischer Screenings haben, da sie Hinweise auf die künftige Gesundheitsentwicklung eines Arbeitnehmers bieten können, insbesondere auf die für die Rentabilität relevante Wahrscheinlichkeit künftiger Fehlzeiten oder niedriger Arbeitsproduktivität. Beispielsweise benötigt ein Arbeitnehmer, der eine Herzkrankheit bekommt, mit großer Wahrscheinlichkeit Arbeitsunterbrechungen und ist in einigen Berufen wahrscheinlich nicht in der Lage, eine normale Arbeitsproduktivität zu erbringen. Es ist ebenfalls möglich, dass das plötzliche Ausbrechen einer Krankheit zu Gefahren für den Arbeitnehmer, andere Arbeitnehmer oder die Öffentlichkeit führt. Arbeitgeber könnten diese Testergebnisse verwenden, um Bewerber aufgrund ihres erwarteten zukünftigen Gesundheitszustands abzulehnen.

Diese Art von Gentest, bei der kein Grund für die Annahme vorliegt, dass der Arbeitnehmer über eine bestimmte genetische Verfassung verfügt, wird allgemein genetisches Screening genannt.

1.2.2. Genetisches Screening als Indikator im Hinblick auf die Anfälligkeit für

Berufskrankheiten

Arbeitgeber können ebenfalls ein Interesse daran haben, herauszufinden, ob Arbeitnehmer aufgrund ihres genetischen Profils anfällig sind für berufliche Risiken wie das Vorhandensein von giftigen, mutagenen oder karzinogenen Stoffen am Arbeitsplatz unter den allgemein zulässigen Werten. Genvarianten, die den Stoffwechsel derartiger genotoxischer Stoffe beeinflussen, können die Fähigkeit einer Person zu ihrer Aktivierung bzw. Inaktivierung verändern. Andere Gene können für die Behebung genetischer Schäden sorgen. Berufsbedingte Faktoren sind in 10 % aller Fälle verantwortlich für Asthma bei Erwachsenen. Asthma ist eine polygenetische Erkrankung, an der viele Wechselwirkungen zwischen Genen und Umwelt beteiligt sind. Zu den anderen Erkrankungen, die ebenfalls berufsbezogen sind, und bei denen eine genetische Grundlage bekannt ist, gehören die Beryllium-Allergie und eine chronisch obstruktive Lungenerkrankung aufgrund eines α -1-Antitrypsin (AAT)-Mangels.

Ein Arbeitgeber könnte daran interessiert sein, diese Informationen zu nutzen, um Arbeitnehmer in Bereichen einzusetzen, die ihrer besonderen genetischen Verfassung entsprechen, oder sie von einer Beschäftigung auszuschließen.

Informationen dieser Form eines genetischen Screenings können auch für den Arbeitnehmer von Wert sein. Kennt er seine Anfälligkeit für ein bestimmtes Berufsrisiko, kann er im Hinblick auf seine Gesundheit und Sicherheit bewusste berufliche Entscheidungen treffen.

1.2.3. Genetisches Monitoring

Selbst in einer wohlregulierten Arbeitsumgebung dürfte es nicht möglich sein, alle Spuren chemischer Stoffe oder Strahlungen auszuschalten, die das Erbgut eines Menschen schädigen können. Es ist in solchen Zusammenhängen möglich, die Zellen einer potenziell gefährdeten Person im Hinblick auf Genschäden zu überwachen. Solche Tests haben nicht nur Auswirkungen auf die Gesundheit der betreffenden Person, sondern auch auf die Folgegeneration. Die Ergebnisse des genetischen Monitorings könnten auf ein bisher nicht erkanntes Gesundheitsrisiko aufmerksam machen und sind somit von Bedeutung für die öffentliche Gesundheit. In dieser Stellungnahme wird diese Art von Gentest genetisches Monitoring genannt.

1.3 Gene und Krankheit

1.3.1 Monogenetische und polygenetische Krankheiten

Obwohl es zahlreiche anerkannte Erbkrankheiten gibt, die auf einen Defekt in einem einzelnen Gen zurückzuführen sind (monogenetische Krankheiten), so kommen solche Krankheiten doch im Allgemeinen selten vor. Monogenetische Krankheiten sind etwa zystische Fibrose, Sichelzellenanämie, die Huntington-Krankheit und Hämophilie.

Zystische Fibrose und Sichelzellenanämie sind Beispiele autosomal-rezessiv vererbter Krankheiten, bei denen sich die relevanten Gene auf einem der 22 nicht geschlechtsgebundenen menschlichen Chromosomenpaare befinden. Dies bedeutet, dass die Krankheit nur ausbricht, wenn das defekte Gen von beiden Elternteilen geerbt wurde. Ein Mensch, der von einem Elternteil eine normale Kopie des Gens und vom anderen eine defekte Kopie geerbt hat, ist Träger des Krankheitsgens, zeigt aber normalerweise keine Symptome der Krankheit.

Die Huntington-Krankheit ist ein Beispiel einer autosomal-dominant vererbten Krankheit. In diesem Fall ist nur eine einzige Kopie des defekten Gens von einem der Elternteile erforderlich, damit die Krankheit ausbricht.

Hämophilie ist ein Beispiel einer Krankheit, die auf einen Defekt in einem X-gebundenen Gen zurückzuführen ist. Das Geschlechtschromosomenpaar besteht aus zwei X-Chromosomen (weibliche Person) oder einem X- und einem Y-Chromosom (männliche Person). Da Personen männlichen Geschlechts nur ein einziges X-Chromosom besitzen, entwickeln sie eine solche Krankheit mit höherer Wahrscheinlichkeit als Personen weiblichen Geschlechts mit zwei X-Chromosomen, da die rezessive Genvariante auf einem der X-Chromosomen in Gegenwart des normalen Gens auf dem anderen X-Chromosom nicht zur Expression kommt.

Im Gegensatz zu den genannten Krankheiten, deren Ursache ein einziges fehlerhaftes Gen ist, wird bei anderen menschlichen Krankheiten mit genetischer Komponente davon ausgegangen, dass sie auf Wechselwirkungen zwischen mehreren Genen zurückzuführen sind (polygenetische Krankheiten). Einige polygenetische Krankheiten treten sehr häufig auf. In den meisten dieser Fälle ist die genetische Grundlage noch nicht ganz geklärt, das Verständnis

wird außerdem durch mögliche Einflüsse der Umwelt, der Ernährung und des Lebensstils erschwert. Beispiele für solche polygenetischer Krankheiten sind Herzkrankheiten, mehrere Krebsformen und einige Allergien.

1.3.2 Faktoren, die die Entwicklung einer Erbkrankheit beeinflussen

Der Besitz eines oder mehrerer genetischer Defekte diktiert nicht notwendigerweise, dass sich bei der Person, die diesen Defekt besitzt die Krankheit entwickeln wird. So besteht etwa bei einer Frau mit dem Brustkrebsrisikogen BRCA1 ein 80 %iges Risiko, dass sie bis zu Ihrem 65. Lebensjahr an Brustkrebs erkrankt. Die „Expressivität“ eines genetischen Defekts beschreibt die unterschiedlichen Schweregrade der Erkrankung, unter der die einzelnen Träger des Defekts leiden können. Sowohl die Penetranz und Expressivität als auch der Zeitpunkt des Krankheitsausbruchs können durch Umweltfaktoren, den Lebensstil oder die Anwesenheit einer Reihe anderer Gene beeinflusst werden.

1.4 Methodik für Gentests

1.4.1 Methodik für das genetische Screening

Die DNS-Sequenz eines fehlerhaften Gens unterscheidet sich vielleicht nur sehr wenig von derjenigen der Normalvariante des Gens. Das genetische Screening soll solche kleinen Abweichungen beim fraglichen Gen aufdecken. Hierfür ist nur eine sehr geringe Menge an DNS erforderlich. Beispielsweise wird der erforderliche DNS-Abschnitt normalerweise durch die Polymerase-Kettenreaktion (PCR) mehrtausendfach vervielfältigt („amplifiziert“). Dann wird die amplifizierte DNS fluoreszenzmarkiert. Anschließend leitet man die fluoreszenzmarkierte DNS durch einen Filter, auf den ein kleines Stück DNS (die „Sonde“) aufgebracht ist, das eine Sequenz enthält, die charakteristisch für die Variante ist, auf die hin man untersucht. Ist die fragliche Variante in der fluoreszenten amplifizierten DNS vorhanden, wird diese sich an die Sonde binden, wodurch die entsprechende Stelle des Filters fluoreszent aufscheint. Durch das Aufbringen mehrerer unterschiedlicher Sonden an verschiedenen Stellen des Filters ist es möglich, gleichzeitig auf die Anwesenheit mehrerer verschiedener Varianten des Gens zu untersuchen. Die Entwicklung DNS-Microarray-Technik dürfte künftig die gleichzeitige Untersuchung auf eine große Zahl von Genvarianten hin ermöglichen.

Wenn beim genetischen Screening nach einem Protein gesucht wird, dessen Konzentration aufgrund eines bestimmten fehlerhaften Gens verändert ist, so hängt die verwendete Strategie vom fraglichen Protein ab. In Frage kommen zum Beispiel eine Identifizierung durch Elektrophorese, eine Antikörpersonde oder ein Enzymtest.

1.4.2 Methodik für das genetische Monitoring

Im Gegensatz zum genetischen Screening umfasst genetisches Monitoring normalerweise die mikroskopische Untersuchung der Karyotypen (Chromosomenmuster) weißer Blutzellen. Änderungen der Chromosomenstruktur - einschließlich Chromosomenbruch, Inversion oder Verlust von Chromosomenabschnitten oder Übertragung („Translokation“) eines

Chromosomenstückchens auf ein verschiedenes Chromosom - bilden einen Hinweis auf die Einwirkung gentoxischer Stoffe in unannehmbare hoher Konzentration. Neu entwickelte Techniken erlauben die Aufspürung ziemlich kleiner Veränderungen der Chromosomstruktur.

1.5 Validität, Reliabilität und Aussagekraft von Gentests

1.5.1 Validität von Gentests

Gegenwärtig gibt es nur sehr wenige Gentests, die Informationen für Arbeitgeber oder Arbeitnehmer beinhalten und aussagekräftig sind für Entscheidungen in der Arbeitswelt. Es ist möglich, dass sich diese Situation in der Zukunft ändert. Allerdings ist es schwierig, vorherzusagen, wann diese Veränderung eintritt. Besteht ein Zusammenhang zwischen dem Arbeitsplatz und einer Kranken- oder Lebensversicherung, könnten Versicherungsgesellschaften gegenüber Arbeitgebern darauf drängen, genetische Screenings durchzuführen, um Risiken abzuschätzen. Die Validität eines Gentests erfordert den Nachweis

- 4) seiner Relevanz für den Gesundheitsschutz der Arbeitnehmer,
- 5) der Reliabilität und Reproduzierbarkeit des Tests und
- 6) der Aussagekraft des Tests.

In einigen Ländern gibt es gesetzliche Einrichtungen, die unter bestimmten Umständen die Validität von Gentests kontrollieren.

1.5.2 Relevanz von Gentests

Gegenwärtig kann man kaum befürworten, dass Gentests als Indikatoren für die künftige Gesundheitsentwicklung im Hinblick auf ihre Bedeutung für das Beschäftigungsverhältnis durchgeführt werden. Genetisches Screening im Hinblick auf die Anfälligkeit für Arbeitsplatzrisiken ist natürlich relevant für die Vorbeugung, aber in vielen Fällen ist die Verbindung zwischen einer besonderen genetischen Veranlagung und der Anfälligkeit für ein besonderes Risiko zur Zeit nur theoretisch.

In der allgemeinen Debatte wurden übertriebene Auffassungen über die Aussagekraft von Gentests geäußert, die wahrscheinlich auf dem jeglicher Grundlage entbehrenden Konzept genetischer Vorbestimmung beruhen. Unterliegt ein Arbeitnehmer dem Risiko eines Genschadens, weil er am Arbeitsplatz Schadstoffen ausgesetzt ist, kann andererseits das genetische Monitoring von Chromosomenveränderungen aufgrund dieser Gefährdung für die Gesundheit eines Arbeitnehmers von großer Bedeutung sein.

1.5.3 Reliabilität von Gentests

In einem derart sensiblen Bereich ist es selbstverständlich äußerst wichtig, dass die Verfahren für Gentests so reliabel wie möglich sind, da die Bereitstellung unzutreffender Informationen an einen Arbeitgeber oder Arbeitnehmer weitreichende Konsequenzen haben könnte. Alle Stufen eines wissenschaftlich zufriedenstellenden Prüfverfahrens sollten eingebaute negative und

positive Kontrollen beinhalten, um die Reliabilität der Testergebnisse zu gewährleisten. Bewährte Laborverfahren sind jederzeit zu verwenden, wozu auch die genaue Dokumentation der Verfahren und Ergebnisse gehört. Auch wenn die Prüfverfahren optimiert sind, gibt es falsche Negative und falsche Positive, und eine Validierung der Prüfungen kann erforderlich sein.

1.5.4 Aussagekraft von Gentests

Selbst bei monogenetischen Erkrankungen kann die Aussagekraft von Gentests begrenzt sein. Es ist immer möglich, dass die betreffende Erkrankung während des Arbeitslebens einer Person gar nicht auftritt, und es ist nicht immer möglich, die Ernsthaftigkeit der künftigen Krankheit vorherzusagen.

Dieser Sachverhalt ist bei Krankheiten mit polygenetischer Basis noch komplizierter. Gegenwärtig ist es fast unmöglich, mit Hilfe genetischer Tests genau vorauszusagen, ob die Krankheit überhaupt ausbricht, oder, falls ja, wann und wie schwer. Selbst wenn die genetischen Grundlagen dieser Erkrankungen vollständig erforscht sind, wird die Vorhersehbarkeit der Krankheitsentwicklung durch die selbst unvorhersehbaren Umwelt- und Lebensstilfaktoren begrenzt.

Prüfprotokolle, deren Genauigkeit unter 100 % liegt (wie in den meisten Fällen), führen zu einer weiter reduzierten Aussagekraft. Falsche Negative könnten möglicherweise dazu führen, dass eine gefährdete Personen einem inakzeptablen Gesundheitsrisiko ausgesetzt wird, während falsche Positive dazu führen könnten, dass nicht anfällige Personen ungerechtfertigterweise von einer Beschäftigung ausgeschlossen werden.

1.6. Die praktische Nutzung von Gentests durch die Arbeitgeber

Es ist bei Weitem nicht klar, inwieweit Gentests gegenwärtig und in Zukunft von Arbeitgebern benutzt werden. In den Vereinigten Staaten bestand ein größeres Interesse an Gentests als in Europa. Dies scheint damit zusammenzuhängen, dass die Arbeitgeber in den Vereinigten Staaten einen stärkeren Beitrag zur Krankenversicherung leisten als in Europa. Dies ist wahrscheinlich der Grund dafür, dass es in den USA mehr Untersuchungen über Gentests am Arbeitsplatz gibt. Die Ergebnisse dieser Untersuchungen sollten mit Vorsicht betrachtet werden, da sich herausgestellt hat, dass einige der untersuchten Arbeitgeber gar nicht genau wussten, was ein Gentest ist.

1.6.1 Gentests am Arbeitsplatz in Europa

Die zunehmende Globalisierung von Industrie und Handel deutet darauf hin, dass das US-amerikanische Vorbild bei der Krankenversicherung in Europa angewendet wird. Es ist daher wahrscheinlich, dass Druck ausgeübt wird, damit die ärztlichen Untersuchungen vor Beschäftigungsaufnahme auch Gentests beinhalten. Eine von der School of Health and Related Research der Universität Sheffield durchgeführte Studie über Gentests am Arbeitsplatz

deutet an, dass bei den in Europa durchgeführten Untersuchungen die Arbeitgeber gefragt wurden, ob sie Gentests durchführen. Angesichts der Tatsache, dass die Technik nicht vollständig zur Verfügung steht, überrascht es kaum, dass es nur sehr wenige Beispiele für Gentests am Arbeitsplatz gab. Es wäre besser gewesen, wenn die Arbeitgeber über ihre Einstellung gegenüber Gentests in der Zukunft befragt worden wären.

Gegenwärtig kann lediglich festgestellt werden, dass es bis jetzt nur den einzelnen bekannten Fall eines genetischen Screenings am Arbeitsplatz gibt, auf den sich die Berichte des Nuffield Council on Bioethics und des Human Genetics Advisory Committee im Vereinigten Königreich beziehen. Hierbei handelt es sich um das Screening von Flugzeugbesatzungen durch das britische Verteidigungsministerium auf Sichelzellen. Es bestand die Sorge, dass jemand, der über das Sichelzellen-Gen verfügt, durch den niedrigen Sauerstoffdruck in einem Flugzeug Schaden nimmt. Die Strategie wurde deshalb kritisiert, weil sie sich nicht auf solide Tatsachen gründet, sondern als diskriminierend angesehen werden konnte, da es in der afro-karibischen Bevölkerung viel mehr Sichelzellen-Allelträger gibt als in der Gesamtbevölkerung. Das britische Verteidigungsministerium hatte dieses Verfahren nicht weiter angewendet.

Eine vom Institute of Directors im Vereinigten Königreich im August 2000 durchgeführte Untersuchung ergab, dass zwei von 353 Direktoren berichteten, dass ihre Unternehmen routinemäßig Gentests verwendeten. Weitere vier Direktoren gaben an, dass Gentests von ihren Unternehmen verwendet werden, aber nur, wenn sie Bedenken im Hinblick auf bestimmte Arbeitnehmer haben. Welche besonderen Arten von Gentests verwendet wurden, wurde nicht angegeben. In dem Bericht ging es auch um Informationen über die Einstellung der Direktoren zu genetischen Screenings aus bestimmten Gründen. 34 % der 353 Direktoren waren für ein genetisches Screening, um die Wahrscheinlichkeit späterer Herzkrankheiten festzustellen, solange der Arbeitnehmer einverstanden war. Weitere 8 % befürworteten Pflichtuntersuchungen, wenn dies im Interesse des Arbeitnehmers war. 50 % waren für Gentests mit Zustimmung des Arbeitnehmers, um das Risiko der Angestellten, eine berufsbezogene Erkrankung aufgrund einer Gefährdung am Arbeitsplatz zu entwickeln, zu ermitteln. Weitere 16 % glaubten, dass diese Untersuchung Pflicht sein sollte.

1.6.2. Gentests am Arbeitsplatz in den USA

In den 70er Jahren untersagte die US Air Force Academy Trägern des Sichelzellen-Gens die Teilnahme an der Pilotenausbildung. In der Folge stellten die Gerichte fest, dass Sichelzellenträger tests Afroamerikaner unverhältnismäßig benachteiligten, und in vielen Staaten ist es den Arbeitgebern mittlerweile untersagt, Tests im Hinblick auf diese Erkrankung durchzuführen. In einer vom Office of Technology Assessment des US-Kongresses 1991 durchgeführten Untersuchung des genetischen Monitorings und des genetischen Screenings am Arbeitsplatz wurden sowohl Verfahren als auch Einstellungen überprüft. Nur 1 % der Gesundheitsbeauftragten der Unternehmen gaben damals an, dass ihre Unternehmen ein routinemäßiges genetisches Screening bzw. ein genetisches Monitoring vor Aufnahme des Beschäftigungsverhältnisses durchführen. Dennoch gab die Mehrheit der Personal- und Gesundheitsbeauftragten an, dass ihre Unternehmen die Durchführung genetischer Screenings für Bewerber für allgemein akzeptabel halten, um letztere über den Grad ihrer Anfälligkeit für Arbeitsplatzrisiken zu informieren. Gut ein Drittel der Gesundheits- und Personalbeauftragten hielt es für akzeptabel, Arbeitnehmer mit einer erhöhten Anfälligkeit für Risikosituationen abzulehnen. Überraschenderweise hielt eine Mehrheit beider Gruppen es für

inakzeptabel, genetisches Monitoring für Chromosomenveränderungen in Verbindung mit Gefahren am Arbeitsplatz vorzunehmen. Aus der Untersuchung ging hervor, dass 1 % der Unternehmen angab, genetische Screenings verwendet zu haben, um Personen mit erhöhten Krankheitsrisiken zu identifizieren, obwohl 12 % über genetisches Monitoring oder Screenings von Arbeitnehmern berichteten. Bei den meisten von ihnen handelte es sich um genetisches Monitoring in Unternehmen, in denen Arbeitnehmer möglicherweise chemischen oder ionisierenden Strahlungen ausgesetzt sind.

Aufgrund des enorm fortgeschrittenen Wissens über das menschliche Genom und den Verbesserungen der Gentechnologie dürften Verwendung und potenzielle Nutzung von Gentests in den USA seit dieser Untersuchung beträchtlich zugenommen haben. Den Ergebnissen einer 1996 von der Universität Georgetown durchgeführten Umfrage bei Familienmitgliedern mit erhöhten Genrisiken zufolge wurden 13 % aufgrund dieses erhöhten Risikos aus ihrem Arbeitsverhältnis entlassen. Aus einer 1998 von der American Management Association durchgeführten Untersuchung geht hervor, dass 10 % aller Arbeitgeber ihre Arbeitnehmer routinemäßig auf eine genetische Veranlagung für Erkrankungen testen, und dass diese Zahl weiter zunimmt.

Im Jahre 2001 führte die Equal Employment Opportunity Commission (Kommission für Chancengleichheit in der Beschäftigung, EEOC) ihren ersten Rechtsstreit im Zusammenhang mit genetischen Screenings am Arbeitsplatz gegen die Burlington Northern Santa Fe Railway. Dieses Unternehmen hatte genetische Screenings ohne das Wissen oder die Zustimmung seiner Arbeitnehmer durchgeführt. Die Gentests waren aufgrund von Klagen einiger Arbeitnehmer im Hinblick auf arbeitsbezogene Krankheiten auf der Grundlage des Karpal-Tunnel-Syndroms durchgeführt worden. Mindestens einem Arbeitnehmer war wegen Nichtabgabe einer Blutprobe mit Entlassung gedroht worden. Die EEOC forderte, dass das Unternehmen sein Gentestprogramm vollständig und mit sofortiger Wirkung einstellt und betonte, dass sie "aggressiv reagieren würde auf jeden Hinweis, dass Arbeitgeber Gentests auf eine Weise verlangen oder verwenden, die gegen den Americans with Disabilities Act von 1990 verstößt".

RECHTLICHER HINTERGRUND

1.7. Einleitung

In der Regel beschäftigen sich die üblichen Instrumente auf nationaler, Gemeinschafts- und internationaler Ebene nicht ausdrücklich mit Fragen von Gentests am Arbeitsplatz. Während es Vorschriften gibt, die solche Tests aus Gründen außerhalb der Gesundheitsfürsorge und eine Diskriminierung auf deren Grundlage untersagen, gibt es keine verbindlichen Vorschriften, die ein genetisches Screening am Arbeitsplatz verbieten und sich mit den Bedrohungen auseinandersetzen, die ein solches Screening sowohl für die Privatsphäre als auch für die Würde der Schwächsten, d.h. der Arbeitnehmer, darstellt. Andererseits gibt es außer verstreuten Verordnungen keine besonderen Vorschriften für die Erhebung und Verarbeitung persönlicher Gendaten. Das Fehlen eines angemessenen Schutzes in diesem Bereich kann das Vertrauen, den gegenseitigen Respekt und die Professionalität in den Beziehungen zwischen Arbeitgebern und Arbeitnehmern erschüttern und nicht nur für die Arbeitnehmer, sondern auch für die Arbeitgeber und die Geschäftswelt insgesamt von Nachteil sein.

1.8. Auf nationaler Ebene

In einigen Mitgliedstaaten wurden Vorschriften im Bereich Humangenetik erlassen:

- In Frankreich verbietet eine Änderung von 2002 des *code civil* und des *code pénal* eine Diskriminierung im Hinblick auf die genetischen Merkmale einer Person oder aufgrund prädiktiver Gentests, "die eine Krankheit, die noch nicht ausgebrochen ist, oder eine genetische Veranlagung für eine Krankheit zum Gegenstand haben".
- Ähnlich verlangt das ständige Recht in Schweden, dass Gentests nur zu medizinischen oder Forschungszwecken durchgeführt werden dürfen.
- In Finnland sieht ein Gesetz von 2001 vor, dass Arbeitgeber von Arbeitnehmern vor Aufnahme oder während des Beschäftigungsverhältnisses weder Gentests verlangen dürfen noch das Recht haben, Informationen darüber zu erlangen, ob ein Arbeitnehmer an einem derartigen Test teilgenommen hat.
- In Dänemark reguliert die Gesetzgebung von 1996 die Verwendung von Gesundheitsinformation auf dem Arbeitsmarkt. Das Ziel ist zu sichern, dass Gesundheitsuntersuchungen sich auf den tatsächlichen/heutigen Gesundheitszustand konzentrieren und dass dieser Gesundheitszustand relevant ist für die Arbeit des Beschäftigten. Der Arbeitgeber ist nicht berechtigt, Informationen zu erheben die die Wahrscheinlichkeit betreffen, dass der Arbeitnehmer in Zukunft von einer Krankheit betroffen sein wird. Er ist jedoch berechtigt, Informationen über die Gesundheit des Arbeitnehmers zu erhalten wenn es aufgrund der Arbeitsbedingungen es wünschenswert und redlich ist in Hinblick auf den Beschäftigten oder andere Beschäftigte.
- In Österreich sind sowohl genetisches Screening als auch die Erhebung, Beantragung, Entgegennahme oder sonstige Verwendung genetischer Daten von Arbeitnehmern durch den Arbeitgeber ausdrücklich verboten.
- Die Erhebung und Verarbeitung genetischer Daten am Arbeitsplatz ist auch in den Niederlanden, in Luxemburg und in Griechenland eingeschränkt.
- In Italien dürfen Gendaten laut Datenschutzgesetz von 1996 nur verarbeitet werden unter den Umständen die in einer ad-hoc Genehmigung die von der nationalen Überwachungsinstanz beschrieben werden.
Die Gendaten auf die sich diese Genehmigung explizit bezieht dürfen verarbeitet werden

im Hinblick auf Information und Unternehmungen die unerlässlich sind zur Beschützung von körperlicher Integrität und Gesundheit der Person, um deren Gendaten es sich handelt, eines Dritten oder der Gemeinschaft als Ganzes – auf Grundlage der Zustimmung der Person, um deren Gendaten es sich handelt.

Sollte die Person, deren Daten verarbeitet werden, nicht zustimmen, darf die Verarbeitung nur begonnen oder weitergeführt werden wenn sie dem Ziel der Beschützung der körperlichen Integrität und der Gesundheit eines Dritten oder der Gemeinschaft als Ganzer dient – allerdings ausschliesslich auf Grundlage einer vorhergehenden ad-hoc Genehmigung die von der nationalen Datenschutzbehörde erlassen werden muss.

1.9. Auf Gemeinschaftsebene

Im Juni 2000 hat die Kommission die Sozialpolitische Agenda veröffentlicht, die unter anderem eine Konsultation mit den Sozialpartnern über den Schutz personenbezogener Daten im Arbeitsbereich vorsah. Die Kommission war der Ansicht, dass Arbeitnehmer (während und nach Beendigung des Beschäftigungsverhältnisses) und zukünftige Arbeitnehmer über keinen ausreichenden Schutz ihrer Grundrechte und personenbezogenen Daten, die von Arbeitgebern bearbeitet und/oder an Dritte weitergegeben werden, verfügen. Konkret bedeutet dies, dass die in der Datenschutzrichtlinie als Mittel zur Legitimierung der Datenerhebung und -verarbeitung verlangte Zustimmung bei einem Arbeitsverhältnis, in dem Arbeitnehmer und künftige Arbeitnehmer entweder in einer untergeordneten oder abhängigen Position sind, nicht unbedingt freiwillig zustande kommt. Arbeitnehmer befinden sich mit anderen Worten häufig in einer Position, in der es für sie praktisch unmöglich ist, aufgrund der Position und Machtbefugnisse des Arbeitgebers und aufgrund ihrer eigenen Angst, auf ein Stellenangebot, eine Beförderung usw. verzichten zu müssen, ihre Zustimmung zu verweigern, zurückzuziehen oder abzuändern. Da sich die Datenschutzrichtlinie im Prinzip nicht ausdrücklich mit Datenschutzfragen am Arbeitsplatz beschäftigt, war die Kommission der Auffassung, dass sie entsprechend präzisiert und ergänzt werden sollte. Obwohl sie sich nicht unmittelbar mit den einschlägigen Fragen befasst, enthält die Richtlinie 2000/78/EG des Rates vom 27. November 2000 zur Festlegung eines allgemeinen Rahmens für die Verwirklichung der Gleichbehandlung in Beschäftigung und Beruf nützliche Vorschriften wie die Verpflichtung zur Gleichbehandlung von Behinderten. Gegenwärtig prüft die Kommission eine besondere Gemeinschaftsmaßnahme, die die Form einer besonderen Richtlinie zur Schaffung eines europäischen Rahmens zum Schutz personenbezogener Daten von Arbeitnehmern annehmen kann. Auf der Grundlage der Prinzipien der Datenschutzrichtlinie soll dieser Rahmen alle Arten personenbezogener Daten von Arbeitnehmern, einschließlich medizinischer und Daten, die aus Gentests stammen, umfassen.

1.10. Auf internationaler Ebene

Es gibt eine Reihe internationaler Instrumente im Bereich des Datenschutzes, die eine gewisse Bedeutung für die Frage von Gentests am Arbeitsplatz haben. Einschlägige Dokumente sind das Übereinkommen Nr.108 des Europarates zum Schutz des Menschen bei der automatischen Verarbeitung personenbezogener Daten und die Empfehlung des Europarates Nr. R(97)5 zum Schutz medizinischer Daten, sie befassen sich jedoch nicht ausdrücklich mit der Arbeitswelt. Der Verhaltenskodex der Internationalen Arbeitsorganisation (ILO) für den Schutz von Beschäftigtendaten (1997) bildet eine wertvolle Inspirationsquelle für Maßnahmen

der Gemeinschaft. Sowohl dieses Instrument als auch die Empfehlung Nr. R(89)2 des Europarates von 1989 über den Schutz personenbezogener Daten im Arbeitsbereich verweisen auf die verschiedenen Traditionen der einzelnen Länder hinsichtlich des Verhältnisses zwischen Arbeitgebern und Arbeitnehmern. Diese Traditionen sollten jedoch nicht benutzt werden, um die Durchsetzung weitgehend anerkannter Grundprinzipien in diesem Bereich zu behindern.

ETHISCHER HINTERGRUND

Ethische Fragen können sich entweder auf die Durchführung von Gentests selbst oder die Nutzung der durch Gentests erzielten genetischen Daten beziehen.

1.11. Ethische Aspekte im Zusammenhang mit der Durchführung von Gentests

1.11.1 Autonomie von Arbeitnehmern oder Stellenbewerbern

Die Durchführung von Gentests führt zur Erhebung sehr sensibler persönlicher Daten. Ein besonderes Augenmerk ist zu richten auf die Interessen der zu testenden Person und auf die Frage, ob die Vorteile, die sich durch den Test ergeben, den persönlichen Eingriff, den dieser Test darstellt, rechtfertigen.

Insbesondere muss die Autonomie der zu testenden Person vor Aufnahme oder während des Beschäftigungsverhältnisses sorgfältig gegenüber den Pflichten des Arbeitgebers, seine Mitarbeiter, einschließlich der zu testenden Person, und Dritte zu schützen, abgewogen werden.

Im Zusammenhang mit Gentests bedeutet Autonomie für die zu testende Person, dass sie vollständig aufgeklärt wurde und dem Test zustimmt. Zu einer vollständigen Aufklärung gehören neben dem Verstehen der Testverfahren auch eine Unterrichtung über die möglichen Testergebnisse und deren Bedeutung sowie eine angemessene Beratung bei Vorlage der Testergebnisse. Häufig befinden sich Stellenbewerber gegenüber dem Arbeitgeber in einer eher schwachen Position, was dazu führen kann, dass sie unter selbst auferlegtem Druck möglicherweise unnötigen Tests zustimmen.

1.11.2 Pflichten des Arbeitgebers gegenüber Arbeitnehmern und anderen Parteien

Arbeitgeber sind verpflichtet, ihre Mitarbeiter und Dritte vor ausbrechenden oder fortschreitenden Erkrankungen eines Arbeitnehmers zu schützen. In einigen Fällen ist ein Gentest unter Umständen die einzige Möglichkeit, dieser Pflicht nachzukommen. Arbeitgeber sind auch vorrangig verpflichtet, den Arbeitnehmern ein sicheres Arbeitsumfeld zu gewährleisten und sie keinen Gesundheitsrisiken am Arbeitsplatz auszusetzen.

1.11.3. Eignung von Arbeitnehmern zur Durchführung von Arbeiten

Arbeitgeber haben das Recht von ihren Arbeitnehmern zu erwarten, dass sie in der Lage sind, die verlangte Arbeit auszuführen. Dies wird normalerweise von einem Arbeitgeber anhand der üblichen Mittel wie *Lebenslauf*, Einstellungsgespräch, Eignungstest und Referenzen überprüft. Die Eignung eines Bewerbers für die Durchführung einer Arbeit wird manchmal auch anhand einer ärztlichen Untersuchung beurteilt. Arbeitsverträge enthalten häufig Klauseln über eine Probezeit - eine zusätzliche Absicherung für den Arbeitgeber. Ein Gentest mit begrenzter Aussagekraft erhöht keineswegs das Wissen über die Fähigkeiten des Bewerbers zur Durchführung der Arbeit zu Beginn des Beschäftigungsverhältnisses und vermittelt nur wenig Informationen über künftige Entwicklungen.

1.11.4 Validität von Gentests

Eine weitere ethische Frage betrifft die Validität eines Tests, seine Relevanz, Reliabilität und Aussagekraft. Derzeit würden sehr wenige Tests alle diese Kriterien in großem Maße erfüllen. Es wäre offensichtlich ungerecht, wichtige Entscheidungen im Hinblick auf Beschäftigung oder Beförderung auf der Grundlage von Testergebnissen zu treffen, deren Relevanz zweifelhaft und deren Reliabilität bzw. Aussagekraft gering ist. Sämtliche Vorteile, die solche Tests im Hinblick auf den Schutz von Arbeitnehmern oder Dritten bieten, würden dem Schaden, der durch falsche Negative und falsche Positive entsteht, die Waage halten.

1.12. Ethische Aspekte im Zusammenhang mit der Verwendung genetischer Informationen

1.12.1. Vertraulichkeit und das Recht auf Nichtwissen

Die Sensibilität der auf der Grundlage von Gentests erhaltenen Daten führt zu der Frage der Vertraulichkeit. Zunächst stehen die Daten dem medizinischen Mitarbeiter, der den Test beantragt hat, zur Verfügung. Es stellt sich die Frage, ob die genetischen Rohdaten dem Arbeitgeber überhaupt zur Verfügung gestellt werden sollten, oder ob der medizinische Mitarbeiter ihm nur seine einschlägige professionelle Stellungnahme übermitteln soll. In diesem Zusammenhang ist die Unabhängigkeit des medizinischen Mitarbeiters von großer Bedeutung. Gendaten sind eindeutig das Eigentum der Person, die getestet wurde, aber vielleicht von ihrem Recht Gebrauch machen möchte, nichts über ihre genetische Verfassung zu erfahren.

Ein weiteres Problem im Hinblick auf die Vertraulichkeit besteht darin, dass genetische Informationen über ein Individuum auch Hinweise auf die genetische Verfassung eines oder mehrerer Familienmitglieder dieses Individuums geben könnten.

1.12.2. Diskriminierender Umgang mit Gentestergebnissen

Genetische Screeningdaten könnten zum Nachteil von Stellenbewerbern oder Arbeitnehmern verwendet werden. Sie könnten zur unzulässigen Diskriminierung von Bewerbern um einen Stelle oder eine Beförderung innerhalb eines Unternehmens führen. Dies könnte ernsthafte Folgen für die zukünftigen beruflichen Chancen einer Person haben.

2. STELLUNGNAHME

Die Gruppe konzentriert sich in dieser Stellungnahme auf ethische Fragen im Zusammenhang mit Gentests unter besonderer Berücksichtigung genetischer Screenings. Gleichwohl können die ethischen Dilemmas und Interessenskonflikte, die im Hinblick auf Gentests, einschließlich eines genetischen Monitorings, zu untersuchen sind, im allgemeinen Zusammenhang medizinischer Daten am Arbeitsplatz gesehen werden.

Die Gruppe gibt folgende Stellungnahme ab:

2.1.

Arbeitgeber sind verpflichtet, die Gesundheit ihrer Mitarbeiter zu schützen und Risiken für Dritte vorzubeugen. Andererseits haben Arbeitnehmer und Stellenbewerber ein Recht auf eine Privatsphäre und den Schutz ihrer persönlichen Daten.

2.2.

Arbeitgeber sind verpflichtet, den Arbeitsplatz so zu gestalten, dass die Gefahr von Gesundheitsschäden für die Arbeitnehmer begrenzt wird.

2.3.

Während des Einstellungsverfahrens muss der Arbeitgeber eine gerechte Behandlung für alle Bewerber gewährleisten und jegliche Diskriminierung vermeiden.

2.4.

Auch Arbeitnehmer sind verpflichtet, Risiken für Dritte vorzubeugen.

2.5.

Arbeitnehmer oder künftige Arbeitnehmer müssen wissen, dass eine ärztliche Untersuchung Teil der Eignungsprüfung für die Stelle sein kann.

2.6.

Die ärztliche Untersuchung darf kein Auswahlkriterium sein. Sie sollte nach Abschluss des Auswahlverfahrens stattfinden.

2.7.

Besteht das Risiko einer genetischen Schädigung eines Arbeitnehmers aufgrund eines Bestandteils des Arbeitsumfelds, muss der Arbeitgeber alles in seiner Macht Stehende tun, um dieses Risiko zu beseitigen. Kann ein solches Risiko nicht vollständig ausgeschlossen werden, kann genetisches Monitoring, das darauf abzielt, Chromosomenanomalien aufgrund von Stoffen, denen der Arbeitnehmer im Arbeitsumfeld ausgesetzt ist, zu evaluieren, sinnvoll sein, eine ordnungsgemäße Unterrichtung und Zustimmung ist jedoch vorausgesetzt.

2.8.

Ein genetisches Screening ist eine Form medizinischer Untersuchung. Es steht im Zusammenhang mit der möglichen künftigen gesundheitlichen Verfassung der Person, an der dieses Screening vorgenommen wird.

Grundsätzlich ist die Gruppe der Ansicht, dass im Zusammenhang mit Beschäftigungsfragen nur die gegenwärtige gesundheitliche Verfassung von Arbeitnehmern zu berücksichtigen ist.

2.9.

Darüber hinaus gibt es bislang keinerlei Beweise für die Relevanz und Reliabilität der bestehenden Gentests im Zusammenhang mit Beschäftigungsfragen. Ihre Aussagekraft ist nach wie vor zweifelhaft.

2.10.

Die Gruppe ist grundsätzlich der Ansicht, dass die Durchführung von genetischen Screenings im Rahmen der medizinischen Untersuchung sowie die Freigabe der Ergebnisse vorausgegangener Gentests aus ethischer Sicht inakzeptabel sind. Der Arbeitgeber kann seinen legitimen Pflichten und dem Recht im Hinblick auf den Schutz der Gesundheit und die Beurteilung der Eignung durch eine medizinische Untersuchung genügen, bei der allerdings kein genetisches Screening durchgeführt wird.

Arbeitgeber sollten daher grundsätzlich weder genetische Screenings durchführen noch ihre Mitarbeiter zur Teilnahme an Tests auffordern.

2.11.

In außergewöhnlichen Fällen könnte die Durchführung genetischer Screenings in Betracht gezogen werden wenn sie notwendig sind, um dem Gesundheitsschutz von Arbeitnehmern oder den Schutz Dritter zu gewährleisten.

2.12.

In diesen Ausnahmefällen können Gentests angemessen sein, sofern die folgenden grundlegenden Bedingungen erfüllt sind:

- die Durchführung des Tests ist notwendig, um den Schutz der Gesundheit und der Sicherheit des Arbeitnehmers oder Dritter zu gewährleisten,
- es ist wissenschaftlich erwiesen, dass der Gentest valide und die einzige Methode ist, um diese Informationen zu erhalten,

- die Durchführung des Tests gefährdet nicht das Ziel einer Verbesserung der Bedingungen am Arbeitsplatz,
- der Grundsatz der Verhältnismäßigkeit wird im Hinblick auf die Motivation zur Durchführung des Tests gewahrt,
- der Grundsatz der Nichtdiskriminierung wird nicht verletzt.

2.13.

Die außergewöhnlichen Fälle, in denen genetische Screenings am Arbeitsplatz vorgeschlagen und durchgeführt werden dürfen, sind ausdrücklich gesetzlich festzulegen.

2.14.

Bei besonderen Anwendungen ist die vorherige Zustimmung der einschlägigen Arbeitsorganisation und eine besondere *Ad-hoc*-Genehmigung eines unabhängigen Ausschusses notwendig.

2.15.

Der Stellenbewerber bzw. der Arbeitnehmer ist von einem unabhängigen medizinischen Mitarbeiter umfassend über das Testverfahren, die Gründe für die Durchführung solcher Tests, die möglichen Ergebnisse und ihre Auswirkungen und Folgen sowie über die Bedingungen hinsichtlich der Aufbewahrung und des Zugangs zu den Daten zu informieren. Ihm ist ebenfalls eine unabhängige Rechtsberatung zu gewähren. Er sollte auch, wenn er es ersucht, unabhängige juristische Hilfe erhalten.

2.16.

Der Stellenbewerber oder der Arbeitnehmer muss dem Gentest zustimmen.

2.17.

Ergibt der Test eine genetische Kondition, die unvereinbar ist mit dem Schutz der Gesundheit des Auftragnehmers bzw. Stellenbewerbers oder mit der Sicherheit Dritter, dürfen die dem Arbeitgeber bereitgestellten Informationen nur enthalten, dass der Bewerber für die spezielle Stelle ungeeignet ist, ohne dass hierfür ein Grund angegeben wird.

2.18.

Die Gendaten bleiben wie andere medizinische Daten vertraulich; solche personengebundenen Daten dürfen nur dem Bewerber und dem medizinischen Mitarbeiter zugänglich sein, und ihre Weitergabe ohne Zustimmung des Betroffenen an Dritte, einschließlich des Arbeitgebers, muss streng verboten sein.

2.19.

Am Arbeitsplatz durchgeführtes genetisches Screening oder Monitoring darf nicht als Gentest betrachtet werden, der zu Versicherungszwecken freigegeben werden kann.

2.20.

Auf EU-Ebene müssen gesetzliche Maßnahmen getroffen werden, um die Vertraulichkeit dieser Gendaten auch in Fällen grenzüberschreitender Mobilität von Arbeitnehmern/Arbeitgebern, namentlich im Zusammenhang mit der Freizügigkeit der Arbeitnehmer innerhalb der EU, zu wahren.

Die Europäische Gruppe für Ethik in Naturwissenschaften und neuen Technologien

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SUMMARIES OF STATEMENTS

ON GENETIC TESTING IN THE WORKPLACE

BY NATIONAL AND INTERNATIONAL BODIES²

² By Jutta Buyse, a Trainee with the Secretariat of the European Group on Ethics in Science and New Technologies, from March to July 2003.

A. DEFINITIONS

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Definitions

Most of the opinions summarised hereafter use very similar definitions for the key terms in the field of genetic testing. Nevertheless, some differences exist. In the summaries of opinions hereafter, the technical terms were kept in the sense that they were used in the original documents. For complete reference on the definitions, the reader is referred to the original documents. This brief information sheet merely alerts to existing differences and serves as a guide to interpretation.

In the European Group on Ethics' opinion, *genetic testing* is defined as 'the use of a scientific test to determine whether a person possesses particular variant forms of one or more genes in their genetic complement'.

For purposes of the EGE opinion, the term 'genetic testing' includes both *genetic screening* and *genetic monitoring*. Many of the other opinions summarised here do not make specific reference to genetic monitoring and do not specify whether it is included in the term genetic testing. This is the case for example for the Greek opinion. The American SACGT however specifies that biological monitoring is not included in the scope of its opinion. Other opinions choose to discuss genetic monitoring as a different category and hence, when stating a principle related to genetic monitoring, use the term explicitly.

The EGE opinion furthermore specifies that its definition of *genetic testing* for opinion no. 18 includes the analysis of gene products, insofar as they reveal characteristics of a person's genetic disposition. For example, non-DNA based genetic screening is also considered a form of genetic testing.

This procedure is not followed by all opinions. For example, the Italian opinion limits the scope of 'genetic tests' strictly to DNA-based tests.

The EGE's opinion also views the analysis of *family history* as a genetic test, again insofar as it reveals characteristics of an individual's genetic disposition. Some opinions choose to treat it as a different category. Others choose other solutions. For example, the Greek opinion extends its scope to *genetic data* which is 'any information collected or resulting from genetic tests or analysis of the genetic material of one or more persons'. The majority of the opinions summarised here do not specify whether the analysis of family history and gene products are part of their definition of genetic tests. Therefore, in the summaries that follow, it is specified when an opinion includes family history or gene products in its definition of genetic testing.

Genetic testing encompasses *presymptomatic* and *susceptibility testing*. Whereas presymptomatic tests identify a mutation in a gene that is guaranteed to cause a disease at one point in the life of person (e.g. Huntington's disease), susceptibility tests identify mutations that imply a strong risk, but not a certainty, that a disease will develop. These terms are not explicitly defined in the EGE's opinion, as the EGE makes no distinction between these two types in the scope of its recommendations. The WHO-document however issues recommendations specific to either one of these categories.

Presymptomatic tests are associated with monogenic diseases, and susceptibility tests with polygenic or multifactorial diseases. In addition to the term *polygenic diseases* defined in the EGE opinion, some opinions use the term *multifactorial diseases*. It designates diseases caused by a combination of genetic and environmental factors and is often used synonymously with the term polygenic diseases, as they share the main characteristics..

In addition, the term *penetrance* is used in some of the existing opinions on the topic. It refers to the proportion of true false versus true negatives in diagnosis, i.e. the proportion of those who are diagnosed with a defect gene whose gene is not actually defective versus those who have a defective gene but were erroneously not diagnosed as such. Penetrance is distinct from *predictability*, which refers to the likelihood that a person who was correctly diagnosed as having a defective gene will actually develop the associated disease in the future.

B. EU and NON-EU NATIONAL BODIES



BELGIUM

Advisory Committee on Bioethics

Overview of the Committee

The Belgian Advisory Committee on Bioethics was established in January 1993. Its duties are twofold. First, it provides advice on the problems raised by research and research applications in the fields of biology, medicine and health care; these problems are studied from the ethical, social and legal points of view, particularly from the angle of the respect for human right. Second, it informs the public and the authorities about these problems.

The interdisciplinary Committee is composed of 43 members, out of which there are 26 ordinary members with the right to vote. It is required to give its opinion at the request of the chairs of the various parliaments or of any member of their governments, as well as at the request of a research institute, a hospital, a higher-education establishment and of the local ethical committee of either a hospital or a university or an ethical committee approved by any of the Communities. The Committee may also give advice on its own initiative.

Context and scope of the Committee's opinion

The Belgian Senate requested an opinion from the Advisory Committee on Bioethics in the context of a legal proposal on medical examinations within work relations and a legal proposal on medical examination within recruitment that both aim at prohibiting the application of predictive genetic and HIV-tests, but allowing some exceptions. The Committee issued its '**Opinion n° 20 on predictive genetic tests and HIV-tests in work relations**' on 18th November 2002.³ Its conclusions apply to predictive genetic tests and HIV-tests (their commonality being that they all predict future health status). Excluded from this opinion are genotoxicity tests, i.e. tests that diagnose genetic mutations that are not of hereditary character, but acquired.

Recommendations of the Committee

The Committee stresses the role of the occupational health physician who is to assist the employee and the currently low statistical predictive power of the existing tests. It underlines that to its knowledge, there are no tests known to be currently available which could be suited for testing in the workplace. Furthermore, it stresses that the question of workers' consent is a complicated one in light of the unequal relationship between workers and employers.

There is a need for specific legislation in this field.

³ The text is available at www.health.fgov.be/bioeth/

Given the validity and penetrance of currently available tests, genetic tests during recruitment and during employment should not be allowed.

The committee does not adopt a unanimous opinion on whether exceptions should be made to this general rule in the future. Committee members' opinions can be divided into two distinct positions. However, not all members agree with the entirety of either one of the positions summarized below.

- **Position one : no exceptions**

Supporters of the opinion not to make any exceptions stress that since the nature of these tests is that they are predictive, they do not say anything about the current capacity of the worker to fulfil his functions – and so, even if a test reveals such a genetic condition that there is a 100% occurrence of the disease, the tests could never be the cause of a declaration of aptitude or inaptitude since the timing of the appearance of the symptoms of the disease remains uncertain. The risk of excluding workers who may well be able to fulfil their obligations for the next ten years to come exists, as do the risk of discrimination (particularly in light of the debated link between some genetic disorders and the belonging to certain ethnic groups) and a move towards a selective medicine, aimed only at the most productive workers.

Genetic and HIV-testing is a flagrant intrusion into workers' personal life, and in contradiction with the 1989 resolution of the European Parliament that individuals have a 'right not to know' their genetic makeup. This type of testing is furthermore unacceptable because it provides information about the tested person's relatives. For the same reason, supporters of this opinion also find that it is not legitimate to ask questions about family history.

Instead, members stress the importance of the currently existing approach of protective occupational medicine. Workers must be protected collectively, i.e. risk factors in the workplace must be avoided in general and for all workers. The right approach is the construction of the workplace to fit the worker, not the inverse.

- **Position two : possible exceptions in the future**

The other part of the members does not want to exclude the possibility that exceptions be made to the general rule of prohibition in the future under well-defined conditions, and if predictability of the tests improves.

These conditions would include a high statistical pertinence and a careful risk analysis with regard to the implication of the results. Risk analysis must take into account the risk of appearance of a disease, the risk of an accident after the apparition of a disease and the amplitude of the consequences of the accident after the disease.

Exceptions are acceptable if they are in the worker's benefit, as defined by the following criteria : an irrefutably strong risk, a high test reliability, clinical pertinence in the work field considered, the advantage of prevention/protection compared to possible negative consequences of such a test result, the respect of privacy, and the absence of other means of sanitary surveillance. Some members also want to include the additional condition that prevention or treatment of the disease exists.

If these conditions could be met, predictive genetic tests could be compulsory for the **entirety** of the concerned workers in order to preserve the principal of collective solidarity. To only obtain one worker's consent could give rise to a discriminatory policy founded on workers' economic potential or intellectual abilities.

Furthermore, with regard to the application of such test, some members also consider the possible risk posed to third parties.

UNITED KINGDOM

1 Nuffield Council on Bioethics

Overview of the consultative body

The Nuffield Council on Bioethics was established in 1991 to identify, examine and report on the ethical questions raised by recent advances in biological and medical research. The Council is funded jointly by the Nuffield Foundation, the Medical Research Council and the Wellcome Trust.

Members of the Council include clinicians, lawyers, scientists, philosophers, anthropologists, journalists, political scientists and theologians. Once the Council has identified a major ethical issue for consideration, it establishes a multidisciplinary Working Party with the relevant expertise to examine and report on ethical, social, legal and practical issues. Each Working Party produces a Report, which, once approved by the Council, becomes a publication of the Council.

Context and scope

The extensive and widely-cited '**Genetic screening. Ethical issues**' is the first report by the Nuffield Council, issued in December 1993.⁴ It includes a specific section and recommendations on genetic testing in the workplace, and deals with the question of genetic screening in a variety of contexts, issuing general as well as specific recommendations.

Nuffield recommendations

The Council acknowledges the possible interests of the three parties involved, i.e. employers, employees and the public. It notes the possibility of a restriction of job opportunities to those who, with few employment prospects, or for personal reasons, were prepared to assume the risk of health. It also notes the risk that available testing could provide a convenient excuse for employers to refuse either to take the reasonable steps necessary to accommodate those at higher risk or to employ certain categories of people able to work normally for an indefinite period. It stresses the responsibility of the employer to provide a safe workplace – no genetic screening programme may serve as an excuse for failing to do so. There would be a public interest in employees' test results only if the individual concerned were at risk for a condition with a sudden and unpredictable onset as well as being in an occupation that puts third parties at risk. The danger of discrimination based on irrational grounds against those with a genetic disease poses a particular concern.

⁴ The text is available at www.nuffieldbioethics.org/publications/index.asp

Based on these considerations, and following the principle that people should be excluded from employment opportunities only where this is shown to be absolutely necessary, the Council concludes that employers should only require individuals to undergo genetic screening when the illness or condition will present a serious danger to third parties. Should a worker not be able to be employed as a consequence of the results of a screening programme, official steps have to be taken to ensure fair treatment and make available procedures to assist and facilitate employment in other areas. By the same token, the onset of a genetically conditioned disease should not be used for dismissing an employee; instead a transfer to another position should take place. When only individual employees' health is at stake, they themselves should make the decision whether to participate in the screening programme.

Existing genetic information should not be used to exclude people from employment unless the genetically determined condition has already onset and can affect performance on the job. The Council is concerned that discrimination could occur if genetic information had to be disclosed on job applications or on medical reports that are made available to employers.

The Nuffield Council issues a series of general recommendations on genetic screening. With regard to confidentiality, it recommends that the accepted standards of the confidentiality of medical information should be followed as far as possible. Effective arrangements for the preservation of confidentiality, particularly in relation to genetic registers, should be considered. Individuals should be fully informed of the results of genetic screening and the implications of these results for the family.

Adequately informed and voluntary consent (preferably in written and oral form) should be a requirement for all genetic screening programmes, and genetic counselling should be available for those being genetically screened or tested.

Detailed criteria for introducing genetic screening programmes should be stipulated, and programs should be adequately reviewed and monitored. Relevant criteria include: the aims and purposes of the entire programme; the predictive power and level of accuracy of the particular screening test; the value to those being screened of the knowledge gained; the availability of therapy for the particular condition (lack of treatment should however not necessarily mean that screening is not worthwhile); the potential social implications, and the resource costs.

Despite extensive enquiries, the Working Party was unable to identify any employer in the UK making use of genetic screening with the exception of the Royal Air Forces. The Ministry of Defence has implemented programs screening for sickle cell disease and sickle cell trait for those who apply to join occupational categories of the Forces which involve exposure to atypical atmospheric conditions (for example aviation).

2 Human Genetics Advisory Commission

Overview of the consultative body

The Human Genetics Advisory Commission (HGAC) was operational from December 1996 until December 1999, after which it was subsumed into the newly launched Human Genetics Commission (HGC). Commissioned by the British Government, it offered independent advice on issues arising from developments in human genetics, including genetic testing and insurance, cloning, and genetic testing and employment. Its governmental mandate specified that it was to keep under review scientific progress at the frontiers of human genetics and related fields; to report on issues arising from new developments in human genetics that can be expected to have wider social, ethical and/or economic consequences and to advise on ways to build public confidence in, and understanding of, the new genetics. Answering to a request from the Government, the Human Genetics Advisory Commission issued its report 'The implication of genetic testing for employment' in June 1999⁵.

HGAC recommendations

The HGAC-conclusions are to a large extent in accordance with the Nuffield Council on Bioethics recommendations: The Commission concludes that the use of genetic testing in employment should be restricted to specific circumstances. Any genetic test used for employment purposes must be subject to assured levels of accuracy and reliability, reflecting best practice. Furthermore, it should be evidence-based and consensual. The results should always be communicated to the person tested and professional advice should be available. As for the treatment of results, the HGAC recommends that they be treated in accordance with the existing data protection principles and carefully interpreted, taking into account how they might be affected by existing working conditions. It should not be used to provide information about a condition or predisposition to a condition that might lead to an increase in levels of absence for sickness. It is not acceptable that genetic tests be used for employee selection, on the grounds that they have a predisposition to future ill health.

Again paralleling the Nuffield Council's conclusions, the HGAC assesses that individuals cannot be required to take a test for employment purposes, their 'right not to know' their genetic condition must be upheld. Similarly, previous test results cannot be required to be disclosed, unless there is clear evidence that the information it provides is needed to assess either current ability to perform a job safely or susceptibility to harm from doing a certain job.

⁵ The text is available at www.doh.gov.uk/hgac/papers/paperg1.htm

Like the Nuffield Council, the HGAC pays great attention to the risk possibly posed to third parties. The HGAC goes further than the Nuffield Council in stating that where questions of public safety arise, an employer should be able to refuse to employ a person who refuses to take a relevant genetic test.

The HGAC encourages genetic testing in employment contexts under one specific condition: Employers should offer a genetic test (where available) if it is known that a specific working environment or practice, while meeting health and safety requirements, might pose specific risks to individuals with particular genetic variations.

Currently, employers do not use genetic tests because most tests currently available are used to confirm diagnosis of current conditions, which are already recorded in medical records. It will take major developments before genetic testing becomes a serious issue for employment practice. The introduction of DNA chip technology will raise wider ethical issues, as it might render possible easy genetic testing for multiple disease susceptibility: consent for multi-tests, collection of irrelevant information, access to third parties, and testing for characteristics or predispositions without medical significance. Like the Nuffield Council, the HGAC finds that no UK-employer other than the Ministry of Defence is using genetic testing or screening methods.

DENMARK

The Danish Council of Ethics

Overview of the Council

The Danish Council of Ethics was established in 1988 to provide the Danish Parliament, official authorities and the public with ongoing advice and information about ethical problems raised by developments within the national health service and the field of biomedicine. It is the successor to a committee set up in 1984 by the Danish Minister for Interior Affairs to examine the ethical problems arising in areas such as genetic engineering, assisted reproduction and foetal examination. The Council submits reports and statements in specified areas and promotes public discussion by e.g. public enquiries and debate days, publishing of debate books, anthologies, videos and teaching material, and extensive lecturing activities. The Council's 17 members are appointed because of their interest of bioethical dilemmas. 9 of the members are appointed directly by the Minister of Health, and 8 are appointed by a committee designated by the national parliament. This committee may also place requests for specific topics for the Council to work on.

Recommendations from the Danish Council of Ethics

Two texts from the Danish Council of Ethics are relevant to the topic of genetic testing in the workplace:

'Genetic screening' and **'Genetic testing in appointments etc.'** (1993)⁶. The latter is a response to the Danish Minister of labour's November 1991 bill to prohibit the use of genetic testing in appointments and in underwriting pensions and insurance. The Council supports the initiative for legal action in this field and shares the fear of possible discrimination or differential treatment of citizens in recruitment and placement (or pension and insurance schemes) on the grounds of hereditary traits.

The Council stresses the need to counter discrimination on the labour market and in insurance matters. DNA-analysis should not be allowed to have any influence on individuals' employment, pension and insurance status. These considerations are particularly important in contemporary societies with a large amount of social segregation and high unemployment.

However, prohibiting DNA analysis is not sufficient to guarantee respect of the principle of equality before the law. It has been possible for a long time to predict certain elements of individuals' future health, including genetic predispositions, by means other than DNA-analysis. Possibilities range from tissue-type analysis and analysis for the serum protein α_1 -antitrypsin to analysis of a more or less specific nature such as determination of cholesterol level. Therefore, genetic test data and other health-related information should be treated as one with regard to the goal of protecting individuals against the detrimental use of data regarding personal biological characteristics on the labour market or in society at large.

⁶ Both texts are extracts from *Ethics and the Mapping of the Human Genome* (1993), pp. 43-76 and 79-87. They are available at www.etiskraad.dk

The Council recommends absolute confidentiality regarding information on genetic conditions towards employers, insurance companies and pension funds. This implies an extended form of professional discretion that should be applied not only by doctors and other practitioners/therapists but also by other personnel groups or private companies conducting the same analysis and having access to individuals' genetic and similar health-related information. An upholding and intensification of confidentiality is particularly necessary in light of the constantly mounting exchange of data among personnel groups in the modern hospital and the recording of medical records on social administration services.

As a direct comment on the proposed Danish bill, the Council states that it considers the modalities to prevent employees of presenting employers with their genetic data on their own initiative potentially dubious. This precludes those employees who have a certain susceptibility confirmed by a DNA-analysis from attempting to influence their work situation themselves.

Regarding genetic screening programs in general, the Council recommends that each project be assessed individually and contain a pilot project which should be evaluated thoroughly.

Equality before the law regardless of sex, race and religion, is a fundamental principle in the Danish legal system. The Danish welfare system is organised around the concept that the communality – the societal community – is obliged to redress geographical, social and health-related inequalities that present an obstacle to equal access to education and training, work and well-being.

The Council of Ethics regards these principles as a high ethical standard, which should also encompass the compensation of the individual for any possible negative consequences of naturally occurring biological differences between individuals. It supports any step in the direction of acceptance of this concept.

Genes are on the one hand a fundamental element of a person's biology, and on the other a 'public domain' shared with relatives and other fellow citizens. In connection with genetic diseases, the individual can be said to be in an exposed situation, and public authorities have a 'duty to help'. At the same time, genes are part of the personal sphere which must be respected, and personal autonomy must remain. A balance must be found between the utilitarian approach of seeking benefit that is greater than possible harm for *all* population members and the respect for personal autonomy. In contrast to the procedures involved when an individual requests specific medical advice about a condition, screening is an initiative of the public health system.

The Council also emphasises the possibilities of the enhancement of personal autonomy as a consequence of increased knowledge about one's personal genetic constitution, which can lead to increased options for life choices.

FRANCE

National Consultative Ethics Committee

Expert hearing of Prof. Anne Cambon-Thomsen

June 17th 2003, Brussels

Anne Cambon-Thomsen is Director of Research at the CNRS, the French national institute for scientific research, member of the Inserm unit 558 for Epidemiology and public health. She has been a member of the French National Consultative Ethics Committee since 2002. The hearing took place at the EGE meeting on June 17th 2003 in Brussels. In this hearing, Prof. Cambon presented principles and recommendations agreed at the French National Consultative Ethics Committee relevant to the topic of genetic testing at the workplace and also in her personal capacity as an expert in the field. A discussion followed the presentation.⁷

Overview of the Committee

The National Consultative Ethics Committee for Health and Life Sciences (CCNE) was established by a Presidential decree in February 1983. The Committee's mission is to issue opinions on ethical problems raised by progress in the fields of biology, medicine, and health, and publish recommendations on this subject. It is an independent and purely consultative body linked to the Ministries of Research and Health.

The Committee is composed of the President, nominated by the President of the Republic, an Honorary President, and 39 members. 5 of these members are drawn from the main philosophies and religious faiths and are designated by the President of the Republic, 19 members are chosen because of their qualifications, competence, and their interest in ethical issues, and 15 members are engaged in scientific research.

Next to the Plenary Committee, on which all members sit, cases are investigated by the Technical Section which is composed of 12 of the committee members. Working groups are also set up to document given subjects and prepare draft of opinions.

Requests to the Committee may be made by Presidents of Parliamentary Assemblies, members of the Government, an establishment for higher education, a public institution, or an officially recognised foundation whose main activity is research, technological development, or the promotion and protection of health. The Committee may also take on matters upon its own initiative.

⁷ This summary was prepared by Jutta Buyse, a Trainee with the Secretariat of the EGE from March to July 2003 on the basis of a presentation submitted by Prof. Anne Cambon-Thomsen as well as the discussion that followed it.

Recommendations from the CCNE

The key ethical questions raised by genetic testing in the workplace relate to the use of the results of these tests – whether they are used for an informed choice by the worker, or whether there is a risk of discrimination by the employer – who prescribes the test, who counsels the tested employee/applicant, and who makes the decision on the professional consequences and implications of the test results for the employees or applicants.

The CCNE has addressed these questions specifically in two opinions: **opinion n°25 on ‘The application of genetic tests to individual studies, family and population studies (Problems of DNA banks, cell banks and electronic data processing)’**, issued in June 1991, and opinion n°46 on **‘Genetics and medicine : from prediction to prevention’**, issued in October 1995. These opinions are complementary and in agreement on a variety of statements.⁸

The CCNE acknowledges that ethical issues of selection and discrimination are of central importance to society. Genetic testing intensifies these issues. Besides the risk of stigmatisation based on a trait or susceptibility to a disease, there is a risk of anticipatory or prospective discrimination.

In the field of employment, employers may have an interest in using genetic testing for selecting applicants or considering existing employees' career prospects. They could hope to lower absenteeism or prevent lowered productivity by eliminating at-risk individuals. In such a context, testing would be no more than a further means of selection made available to employers. Though genetic testing results may in fact not be very useful to predict the productivity of employees (due to possible erroneous interpretation of test results or bias or misunderstandings or unreliable analyses), the risk that employers may turn to them does exist, given that employers use even more questionable methods on occasions.

The possible benefits for employers stand in stark contrast to workers' fundamental rights to non-discrimination for health reasons and to the protection of their privacy. An employer may only ask an applicant or an employee for information that is directly connected to and necessary for the post or for an evaluation of vocational abilities. Few genetic tests, if any, would meet such conditions. The evaluation of aptitude at a medical examination before recruitment and during further periodic examinations concerns only the aptitude at the time the test is taken and not the evaluation of future risks. As long as a disease has not broken out, there is no inaptitude for work and a decision based on such a diagnosis would be discriminatory. However, when a workplace-related risk is particularly high for individuals with a particular genetic disposition and the risk factor cannot be eliminated by other measures, it may be acceptable for the occupational health physician to suggest a test to detect susceptibility to a disease. The Committee acknowledges that the 'right not to know' is difficult to respect in the context of a test result that indicates a strong risk for an employee in his current workplace.

⁸ These texts are available at: www.ccne-ethique.fr

Extracting DNA for analysis must remain a medical undertaking and only examine medically recognised indications. Use of the results of a study of genetic characteristics for purposes other than medical or scientific, i.e. employment and insurance, is prohibited, even if the tests may have been requested by the concerned applicants/workers or if they have given their consent. No result on the characteristics of an individual's genome is to be communicated to his relatives, to third parties or to any public or private party without the individual's prior consent. The communication of results as part of a medical diagnosis has to take place with the intermediary of a medical professional able to give all the information on their significance.

By the same token, it should be prohibited for any third party, notably employers or insurance companies, to have access to the information contained in a register, as well as to ask the concerned party to provide the information concerning them in the register.

Any determination of an individual's genome's characteristics should be undertaken only having made sure of his or her complete understanding of the possible implications of knowledge of the results, with a delay for reflection. The CCNE stresses the importance of genetic counselling. Consent is given for specific analyses. The extension of the investigation to a characteristic of the genome other than the one for which consent has been given will have to be the object of new information and new consent. Every individual, in principle, has to be informed of the possible results of the investigation and their significance, the right not to be informed must however exist as well.

With regard to data processing, the Committee stresses that registers must be reserved to a limited number of centres that are agreed upon by a public authority and that present all the necessary scientific and ethical guarantees. Any interested person must give an agreement to this transmission of data and must be previously informed about their right not to have to consent. The person must also have access at all times by the intermediary of a chosen medical professional to the registered information and must be aware of their right to ask for the deletion the information concerning him or her.

Future debates are likely to concentrate on the challenge of balancing individual rights and the common good, the right to choose to be tested or not to be tested, the question of who initiated the tests and who gets their results, and how genetic data obtained in the context of employment can be protected from further use in a different context.

GREECE

National bioethics commission

Overview of the organisation

The National Bioethics Commission is an independent advisory body of experts, established in 1998. Its mission is to explore the ethical, social and legal impact of the possible applications of biological sciences. Specifically, the Commission investigates the ethical, social and legal aspects that arise from scientific advances in biology, biotechnology, medicine and genetics. It outlines proposals of general policy and provides specific recommendations on related issues. The Commission collaborates with international organisations and related bodies and represents Greece to international forums. It also informs the public on issues related to biotechnological advances and the impact of their applications. Finally, it co-ordinates related governmental advisory bodies in the field of bioethics.

The Commission is composed of nine members, all academic personalities, appointed by the Prime Minister for a term of five years.

Recommendations from the National Bioethics Commission

The jointly published '**Recommendation on the collection and use of genetic data**' and '**Report on the collection and use of genetic data**' (September 2002) contain recommendations on genetic testing and screening in general that are applicable to questions regarding genetic testing in the workplace as well as recommendations specific to the question of genetic testing in the workplace.⁹

Concerning genetic information in a general context, the Commission states that every person has the right to determine whether their genetic information should be disclosed to third parties, and if so, at which time, and with which specific content.

In the context of labour relations however, the disclosure of genetic information to employers is unacceptable, even with the consent of employees or applicants. This is due to the unequal position of employees and employers.

Two exceptions are granted to this principle. Should specific working conditions trigger the development of genetic disease, employers may be allowed access to related genetic information with the consent of employees or applicants provided there are no alternative protective measures. Or, should a third person be put at risk in a given occupation, employers may ask for a genetic test and the communication of its results in order to guarantee the safety of the third parties involved.

⁹ The texts are available at www.bioethics.gr

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

The Commission stresses that genetic data is of a special nature as it characterises identifiable person and the undesirable social consequences, in particular discrimination, which may arise from the current technological capacity for rapid collection and extensive diffusion of genetic data.

The disclosure of genetic data is a main area of ethical concern. Genetic data are 'sensitive' data. They reveal the genetic profile of a person and as such constitute a framework of basic specifications on whose basis people may plan their lives. They also reveal in part the genetic identity of third persons. These characteristics raise the question of whether and in which specific situations information resulting from genetic tests may or should be transmitted to other parties and whether the tested person should have the right not to know their own test results. A specific question is whether particular circumstances exist where a test result should be transmitted to third persons, for example with the goal of preventing the onset of a disease; and whether organisations such as insurance companies, employers and foundations should be informed of the test results.

Where the testing of population groups is concerned, the consent of each individual member is required. A collective consent may be sought in a first step, but every member should have the right not to participate in such a program. Accordingly, any hierarchical orders or pressures by supervising authorities to ensure participation in population research should be ruled out.

The National Bioethics Commission recognises both the 'right to know' and the 'right not to know'. When the results of genetic tests involve the health of third persons, any person exercising their right to know must also assume responsibility for informing any third persons involved.

Next to disclosure, consent – and specifically free and informed consent – is one of the main ethical issues with regard to genetic tests. It is strongly linked to the principal ethical principle of autonomy. It is of crucial importance that those tested are able to make independent and free decisions. The Committee distinguishes between 'formal' and 'substantive' informed consent – only the latter can be regarded as truly autonomous. Free and informed consent is to be obtained from any person on whose sample a test is to be performed. If possible, consent should be obtained before the taking of the sample in order to ensure genuine conditions of free will. Consent must be written, specific and revocable at any time before the onset of sample or data processing. The use of confidential samples or genetic data in future research unrelated to the object for which the initial consent was given requires a new consent.

The question of consent as far as population genetic tests are concerned is complex. Arguments for and against are located around the question of whether a population as an entity can ever truly consent, what the authority over the group (and its interests) over the individual is, and the risk of social discrimination of a specific group.

The National Bioethics Commission stresses that the fact of being able to obtain very precise information on individuals' DNA does not mean that diseases can be predicted just as accurately. Confusion at this level is the main cause of the overestimation of genetic information. The idea of genetic determinism is associated with the risk of a neglect of social solidarity and equity measures and principles since intervention in the socio-economic environment becomes neglected.

Genetic testing in the workplace creates the risk of adverse categorisation of employees or applicants. On the other hand, the issue remains open with regard to professions that may contribute as environmental factors to manifestation of genetic disease that could be avoided if the genetic data of the employee were known in time. The disclosure of genetic data of employees or applicants seems particularly justified when a possible manifestation of the genetically based disease could directly affect third persons.

ITALY

National Bioethics Committee

Overview of the Committee

The National Bioethics Committee was established by a decree signed by the President of the Council of Ministers on March 28th 1990. The Committee's mandate includes the issuing of opinions and suggestion of solutions that address the ethical and legal problems which may emerge as a result of the progress of research and the emergence of possible new applications of clinical interest.

Furthermore, the Committee is responsible for proposing solutions for control over both the safeguarding of human and environmental security in the production of biological material and the protection from all risk of all patients treated with products produced by genetic engineering or who are subjected to gene therapy. The Committee promotes the drafting of codes of conduct for practitioners in the various fields concerned and awareness-raising initiatives to keep the public properly informed. It is also expected to produce an outline summary of the programmes, objectives and results of research and experimentation in the field of the life sciences and human health.

Members of the Government, the Parliament and other institutions may consult the National Bioethics Committee and ask it to issue an opinion on a specific topic. Associations, research centres, local ethics committees, scholars and single individuals can address themselves to the Committee for information regarding Bioethics.

Recommendations from the Committee

The opinion on '**Bioethical Guidelines for Genetic Testing**', adopted in November 1999, is the result of the current bioethics committee and its predecessor, as the work spanned over a period of two years.¹⁰

The opinion addresses the question of workplace screening for susceptibility to types of cancer in combination with the possible exposure to carcinogenic substances in the workplace. The Committee states that genetic screening intended to identify any predisposition to illness in the workplace is ethically permissible only if aimed at protecting the worker's health and if it satisfies the ethical criteria of autonomy of decision, benefits accruing, and justice. Autonomy of decision implies the freedom to decide whether or not to take the test, and freedom to choose a compatible job after complete information has been obtained concerning the nature of the potentially cancer-causing exposure and the limitations of the test. Benefits accruing implies the moral obligation of the employer to avoid using carcinogenic substances in the workplace – the employee would obtain greater benefits from not being exposed to the hazard in the first place.

The Committee specifies ethical criteria for the identification of genetic tests that safeguard the workers' rights: an achievable aim must be guaranteed, the active participation of the workforce to be tested must take place, equal opportunity of access and effective executive protocols have to be guaranteed. Access to information, counselling and follow-up services must be provided. Individuals must have a right to confidentiality of their test results.

¹⁰The texts are available at www.palazzochigi.it/bioetica/eng/opinions.html

Any form of genetic discrimination should be prohibited. Confidentiality of genetic data is to be guaranteed and any genetic testing requires prior free and informed consent.

The Committee makes a series of recommendations regarding genetic screening in general, i.e. not only in the workplace: The 'principle of equality' is to be respected at all times in access to screening. The distribution of possible 'benefits' from screening investigations must be guaranteed at least for every group and each population selected. This implies their active and informed participation. No screenings should be proposed on which the international scientific community has not expressed sufficiently broad and converging conclusions on reliability. Test specificity and test sensitivity, i.e. the percentage of false positives and false negatives, have to be indicated. Correct information must be guaranteed, so that informed consent can be given. In addition, the consent for screening should be free and independent of the choices the individual may want or decide to make after being informed of the results. A cost-benefit analysis must take place.

The authors emphasise the need for sound scientific research and the rigorous control of genetic testing. Counselling must always be provided before indicating any genetic tests in a continuous dialogue between potential beneficiary and consultant. The Committee stresses the need for well-trained genetic counsellors.

The Committee stresses that the growth in knowledge of the human genome will bring with it an extension and acceleration of genetic research. The determination of 'genetic predisposition' to polygenic or multifactorial pathologies will increasingly be possible; hand in hand with the identification of genetic predisposition to the action of pathogens present in the home or in the workplace for late onset diseases.

DNA-analysis of late onset genetic diseases, i.e. diseases where the clinical signs will appear at the adult age, raises a series of serious problems. When a suitable therapy is available or when it is possible to modify the course of the disease to reduce any complications, the prescription of genetic test at a pre-symptomatic stage is perfectly appropriate. However, when these conditions are not fulfilled, it is dubious to undertake such tests. The 'right not to know' is particularly important in those cases where a prior knowledge of the disease would only anticipate suffering without any concrete advantage in therapeutic terms.

The prognoses that may be inferred from genetic investigations are quite different from those offered by other diagnostic tests, as they identify a risk, as opposed to a disease in its early stages. A large psychological and social cost can be associated with the knowledge of such a predisposition. The individual may be discriminated against in the various arenas of his everyday life, including the workplace, but also insurance companies, or even by his/her own partner on the basis of a mere probability (as opposed to a certainty). Correct and widespread information must be given to the public in order to counteract the risk of genetic determinism associated with the implementation of screening programs.

UNITED STATES

1 US Congress, Office of Technology Assessment

Overview of the consultative body

The Office of Technology Assessment (OTA), installed by the US Congress, operated from 1972-1995. The non-partisan analytical agency's mandate consisted of assisting Congress with anticipating, understanding, and considering existing and emerging national problems which arise as a consequence of technological applications – giving early indications of their probable beneficial and adverse impacts. It was to secure competent, unbiased information concerning the physical, biological, economic, social, and political effects of such applications. The basic function of the Office was to provide early indications of the probable beneficial and adverse impacts of the applications of technology and to develop and co-ordinate information to assist Congress.¹¹

Highlights from the OTA-report

'Genetic monitoring and screening in the workplace' was published in October 1990, after a number of Senate and House Committees had requested a recent report on the topic, following up on OTA's 1983 report on the application of genetic tests to the workplace.

The OTA identifies three main ethical issues with regard to the application of genetic tests for employment: the implementation of monitoring and screening tests in the workplace and the use of the information they generate; the dissemination and storage of information gained from genetic monitoring and screening, and the role of genetic counselling for both employers and employees in genetic monitoring and screening programmes.

The OTA states that these issues vary according to whether the test performed is genetic monitoring for chromosomal damage, genetic screening for susceptibilities to occupational illness, or genetic screening for inherited conditions or traits that are unrelated to the workplace. Whereas genetic screening at the workplace for conditions that are not workplace-related seems hardly justifiable, a series of cases can be made for and against genetic screening for susceptibilities to occupational illness. One of the main ethical problems for this type of screening is that it is invasive to workers' or applicants' privacy, because genes provide much of the basis of human individuality.

¹¹ The texts are available at www.wws.princeton.edu/~ota/.

Genetic screening appears to be more controversial than genetic monitoring, because monitoring is more closely related to the observation of genetic damage that has already been caused by workplace or other exposure. The OTA however points out that it is not correct to classify only genetic screening as predictive. Genetic monitoring is of a predictive nature as well – even though monitoring observes changes in the genetic material that have actually taken place, these changes nevertheless remain predictors of adverse health effects that could occur in the future.

Results obtained from screening or monitoring must be accompanied by appropriate interpretation. They furthermore need to be placed in context, because unless their significance is properly communicated, there is much room for misunderstanding.

Employers' and applicants' respective rights to autonomy stand in opposition to each other with regard to the application of genetic tests. The autonomy of job applicants and employees will be limited if employers are free to implement and enforce genetic monitoring or screening policies. Giving the applicant or employee complete freedom to protect his or her own interests would restrict the freedom of the employer and possibly present a risk to co-workers or family.

Based on these and other considerations, OTA stipulates a series of guidelines for screening and monitoring in the workplace:

Employers should demonstrate the need for a genetic monitoring or screening program. The purposes for monitoring or screening should be clearly stated in advance and be realistic. Any workplace screening should have the goal of reducing the burden of occupational illness to workers, employers, and society. The tests used must be scientifically valid, and they must provide relevant health information for protecting employee health. Workers should decide for themselves whether they want to participate in a program. At the same time, participation in programs must be equally possible for all workers. Workers and applicants must give informed consent prior to any screening or monitoring. They should also have access to results. Professional interpretation of genetic monitoring and screening results should be provided for both workers and employers. All results should be confidential. Ideally, employers would only have access to them with the worker's explicit consent, or if results have previously been anonymised.

The report addresses the question whether employees who are found to be genetically susceptible to workplace exposure should be allowed to accept or remain in jobs that increase the risk of disease. It notes that the possibility of making such a choice can be considered being a part of personal autonomy, as it can be argued that susceptible workers are responsible for their own health as long as they are informed of risks, even if alternative employment is available.

In 1989, OTA commissioned a US-national survey that was targeted at the 500 largest US-industries. Results indicate that only a small minority of US-companies use genetic screening or monitoring.

According to the OTA, the available policy options at the government level relate to two central issues: the appropriate role of the Federal Government in the regulation, oversight, or promotion of genetic tests (which includes both monitoring and screening), and the adequacy of federally sponsored research on the relationships between genes and the environment.

2 Secretary's Advisory Committee on Genetic Testing, National Institutes of Health

Overview of the consultative body

The mandate of the Secretary's Advisory Committee on Genetic Testing (SACGT), chartered in 1998, consisted of advising the government about all aspects of the development and use of genetic tests, including the complex medical, ethical, legal, and social issues raised by genetic testing. Part of the National Institutes of Health, the SACGT's recommendations were made to the US Secretary of for Health. SACGT's charter recently expired and a new Secretary's Advisory Committee on Genetics, Health, and Society has been created.

SACGT recommendations

The SACGT was asked in June 1999 to assess the adequacy of oversight of genetic tests and, if necessary, make recommendations for additional oversight and for ensuring public access to quality genetic tests. A public consultation process was part of this assessment. The resulting 'Preliminary recommendations on the adequacy of oversight of genetic tests' were published in 2000.¹²

The document addresses the question of genetic testing at the workplace directly. It states the need for federal legislation to prohibit discrimination in employment and insurance based on genetic information. It furthermore states that additional federal legislation is needed to protect the privacy of genetic information in medical records.

Potential exclusion from health insurance and employment is one of the potential risk resulting from a positive genetic test result. Many of the comments received from the public during the consultation process relate to the fear that the inappropriate disclosure of genetic test results could lead to stigma and discrimination in a series of settings, for example in employment.

The SACGT issues a series statements aimed at the oversight of genetic testing in general (i.e. also outside the workplace) that are also applicable to policy questions regarding workplace genetic testing: Informed consent must be obtained and documented prior to genetic testing.

¹² The texts are available at www4.od.nih.gov/oba/sacgt.htm

Education of the public as well as health providers is necessary in light of the importance of the appropriate use, interpretation, and understanding of genetic test results. Genetic education and counselling should be required for any genetic test that is predictive (as opposed to diagnostic), that has a low penetrance (i.e. predictive value) and where little or no treatment is available. The major criteria for assessment of the benefits and the risk of a genetic test should be analytical validity, clinical utility, and social consequences.

Privacy and confidentiality are issues of major concern in the question of adequate oversight of genetic testing. This also applies to DNA-samples and test results collected as part of a research process. Here also, the fear of possible later discrimination should privacy not be safeguarded applies.

The SACGT furthermore stresses that genetic test results have psychological and emotional risks, and predictive testing in particular, can have important psychological and social impacts.

GENETIC DATA AND CONFIDENTIALITY

The Estonian Experiment

Expert hearing of Prof. Ismini Kriari-Catranis

May 27th 2003, Athens

In the context of the Greek presidency of the European Union during the preparation of this opinion, the EGE held its May meeting in Athens. During this visit, the EGE was also invited to a joint meeting with the Greek National Committee on Bioethics. The Greek National Committee on Bioethics had asked Prof. Ismini Kriari-Catranis to speak about the results of her research on the Estonian gene bank to assist the EGE in its general deliberations for this opinion.

Prof. Kriari-Catranis is an Associate Professor at the Panteion University of Social and Political Sciences in Athens. ¹³

Estonia is the first state that founded a gene bank by collecting the genetic material and health data of its entire population in order to make it available to the scientific community for genetic research. Iceland has undertaken a similar initiative, but Estonia is the first country in which this bank operates under public control.

Examining how confidentiality of genetic data is assured in the Estonian case is thus of particular interest.

The respect of confidentiality – a vital principle in European legal systems – expresses the general due respect for patients' privacy and autonomy. This right to informational self-determination guarantees every individual the freedom of decision as to what medical and genetic data will be given to whom, at what time and under which conditions. It is also crucial for preserving patients' confidence in the medical profession and in the health services in general.

Guaranteeing confidentiality of data is all the more pertinent when it comes to genetic data. First, individuals must be protected from genetic discrimination, which is based on risk potential and not on the factual appearance of a disease, resulting in unfitness for a particular occupation or job. Genetic discrimination does not operate by assessing *who one is*, but rather by estimating *who one is likely to be* in the future, given their DNA and external conditions (i.e. environmental exposure, life style etc). Second, genetic data is of particular interest to third

¹³ This summary was prepared by Jutta Buyse, a Trainee with the Secretariat of the European Group on Ethics in Science and New Technologies from March to July 2003 on the basis of a presentation submitted by Prof. Kriari-Catranis.

parties such as employers, insurers, research institutions and state agencies for a variety of reasons. Third, genetic information reveals the genetic pattern not only of the person tested but also of his/her entire family and (future) descendants.

As a response to these genetic challenges, Estonia has established specific provisions about gene data protection. It is one of the few countries that have already drafted specific regulations concerning the protection of the individual in the workplace. The January 2001 Human Genes Research Act states in its paragraph 26 on “discrimination in employment relationships” that employers are prohibited from collecting genetic data on employees or job applicants, as well as requiring employees or job applicants to provide tissue samples or descriptions of DNA. Employers are prohibited from imposing discriminatory working and wages conditions on people with different genetic risks. ¹⁴

This general prohibition does not exclude a differentiated approach in cases where working conditions could be harmful to those with a certain predisposition. The European Court of Human Rights has made it clear that not every distinction or difference in treatment can be regarded as discrimination: “A difference of treatment is discriminatory” if “it has no objective and reasonable justification”, that is “if it does not pursue a legitimate aim or if there is not a reasonable relationship of proportionality between the means employed and the aim sought to be realised” (Abdulaziz, Cabales and Balkandali v. United Kingdom of 1985). Exceptions from the general rule could thus be tolerated, if they are intended to serve the health of the individuals concerned (e.g. in the case of a toxic working environment that would have adverse consequences on an employer with asthma predisposition) or the health of third persons (e.g. in the case of pilots).

The creation of a Gene bank is motivated by a series of expectations by the Estonian population. Estonians expect a better organised health care system, based on the results obtained from genetic research, in terms of better electronic databases and genetic information in diagnostics, in the treatment and prevention of diseases, and an improvement in the individualisation of medical care.

Finally, they want to attract biotechnology and gene technology firms: The Gene Bank may only be used for scientific research, research for and treatment of gene donors, public health research and statistical purposes.

The creation of a gene data bank for research purposes is governed by two main principles. First, its creation is based on the idea that the human genome is a national resource, echoing the recognition enshrined in the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights that the human genome is in a symbolic sense “the heritage of humanity”. Second, it is governed by the idea of ‘genetic altruism’. The latter is hoped to encourage of wide population participation motivated by the contribution to the improvement of diagnostic and therapeutic medicine brought about by the storage and processing of genetic material.

¹⁴ The law also includes a section on genetic testing and insurance, a question closely related to genetic testing and employment. It prohibits insurers from collecting genetic data on insured persons or persons applying for insurance and from requiring insured persons or persons applying for insurance to provide tissue samples or descriptions of DNA. Insurers are prohibited from establishing different insurance conditions for people with different genetic risks and from establishing preferential tariff rates and determining insured events restrictively.

The Estonian solution to the question of data protection was to establish an entity that is positioned between the donors and research/business community. The chief processor, i.e. The Gene Data Bank, entrusted with the collection, storage and processing of the material is funded by the Estonian State.

Research entities can rely on the anonymous tissue and obtained from the chief processor. No private arrangements are allowed between individuals and genetic laboratories in order to avoid competition between fact – interested entities or individual agreements that could lead to different legal protection.

A specially created body, the Supervisory board of chief processor of Gene Bank, supervises the Bank. It establishes an Ethics Committee, which is entrusted with the elaboration of opinions about the processing procedures of the gene bank. The Ethics Committee acts according to generally recognised ethical rules and international conventions.

Supervision over the collection and processing of descriptions of state of health and genealogical data, the coding and decoding of tissue samples, and descriptions of DNA, is exercised by the data protection supervision authority. The chief processor obtains the approval of the data protection supervision authority for the method of generating the codes for the tissue samples, descriptions of DNA etc.

The Estonian Human Genes Research Act confirms widely acknowledged basic ethical and legal principles relating d to human rights. Use of an individual's tissue and health data for genetic research is voluntary and previous informed consent is required. The Act prohibits advocating or influencing an individual to become a gene donor. The gene donor remains anonymous, he has a 'right to know' his gene data maintained in the Gene bank, just as he has the 'right not to know'. He furthermore has the right to allow disclosure of his or her identity. Whether a person is a gene donor or not remains classified.

After the collection of their data, the gene donors still control the data: they have the right to personally access their data stored in Gene bank, the right to submit additional information as well as the right to prohibit the supplementation, renewal and verification of descriptions of state of health stored in the Gene Bank. Gene donors have the right to apply to the chief processor to destroy all coding information, so that their material can never be identified again.

In the case of unlawful disclosure of genetic and medical data by health care professionals or other persons that have had access to this data by way of their their professional activity, the law foresees fines, deprivation of the right of employment in a particular position or operation in a particular area of activity and penal sanctions.

Gene data banks are based on the combination of two powerful technologies: Genetics and Informatics. Comprising an enormous potential for the advancement of science, the development of new technologies and the improvement of medical care, their management raises issues with regard to the ethically responsible treatment of genetic data. It seems that every effort has been undertaken in the Estonian case to safeguard informational autonomy and self - determination, to provide for institutional safeguards and to endorse social acceptance and social sensitivity in this field.

C. INTERNATIONAL BODIES



THE WORLD HEALTH ORGANISATION

Human Genetics Programme

Overview of the Organisation

The World Health Organisation (WHO) – the United Nations' specialised agency for health – was established in 1948. Its objective is the attainment by all peoples of the highest possible level of health, in the sense of a complete physical, mental and social well being and not merely the absence of disease or infirmity. WHO is governed by 192 Member States through the World Health Assembly, which is composed of representatives from WHO's Member States.

The WHO Human Genetics Programme (HGN) aims to develop genetic approaches to control the most common hereditary diseases and those having a genetic predisposition. In addition, it seeks to provide a response for WHO's direction and support to the many questions posed by current genetic challenges. Working together with with various non-governmental and international organisations, the WHO Human Genetics Programme covers areas of medical genetics, as well as community genetic service delivery; the monitoring of human genome research and the ethical, legal and social aspects of its application to practice; education and training aimed at communities and health professionals.

Recommendations from the WHO

The 'Proposed international guidelines on ethical issues in medical genetics and genetic services' were adopted in December 1997 by a group of experts commissioned by the Human Genetics Programme.¹⁵ The resulting document integrates the previous 'Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetics Services' issued by the Human Genetic Programme, and the comments received from all Regions and WHO staff in response to a consultation process on the previous document.

¹⁵ The text is available at www.who.int/ncd/hgn/hgnetic.htm

The Proposed Guidelines state specifically that unfair discrimination or favouritism in employment, in insurance or in schooling based on genetic information must be prevented.

'Informed consent' must be obtained before any genetic testing. Informed consent is only guaranteed by genetic counselling. Generally, counselling is to provide accurate, full and unbiased information, and takes place in an understanding, emphatic relationship. In counselling, privacy of the individuals and families from unjustified intrusions by employers, insurers, and schools must be maintained. Information about possible misuse of the information by employers, insurers, and schools must be provided. As far as this is possible, unbiased presentation of information must be provided. A non-directive approach is recommended.

Susceptibility testing should be voluntary, preceded by adequate information and based on informed consent. Presymptomatic testing should be available for adults at risk, who request it after proper counselling and informed consent, even in the absence of treatment.

Proposed ethical guidelines concerning disclosure and confidentiality of genetic test results, include the respect of the 'right not to know', the communication of all relevant test results, with the exception of information that could cause great psychological or social harm, which may be temporarily withheld. Test results not directly related to health may be withheld as well.

Results of carrier tests, presymptomatic test, susceptibility tests and prenatal tests should be kept confidential from employers, health insurers, schools and government agencies, as individuals should neither be able to be penalised for characteristics of their genome.

UNESCO

(The United Nations Educational, Scientific and Cultural Organisation)

International Bioethics Committee

Overview of the Organisation and the Committee

The United Nations Educational, Scientific and Cultural Organisation (UNESCO) aims to stimulate co-operation among its 188 Member States to promote the human rights and freedoms that are affirmed by the Charter of the United Nations.

The International Bioethics Committee (IBC) of UNESCO was created in 1993.

It drafted the 'Universal Declaration on the Human Genome and Human Rights', which the United Nations Assembly adopted in November 1997. The IBC is a body of 36 independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom. Its members are chosen from a variety of disciplines appointed for a four-year term. Through its sessions and working groups, the Committee produces advice and recommendations on specific issues that are adopted by consensus and are widely disseminated and submitted to the Director-General for transmission to the Member States, the Executive Board and the General Conference.

In 2002, the UNESCO General Conference organisation's Executive Board declared that an *International Declaration on Human Genetic Data* that has due regard for the implications for human dignity, human rights and freedoms should be prepared.

Recommendations from the IBC

The IBC issued a '**Revised Outline of the International Declaration on Human Genetic Data**' in November 2002 for a consultation process and examination by a committee of governmental experts.¹⁶ Revisions to the first draft are the results of the examination by whole group of the original draft produced by the working group. The final result will be a draft Declaration presented for adoption at the UNESCO General Conference in October 2003. The Declaration contains a series of statements on genetic testing policy that are relevant to the question of genetic testing in the workplace.

¹⁶ The text is available at www.unesco.org/ibc

The Declaration upholds the principles of non-discrimination and non-stigmatisation: human genetic data shall not be used for discriminatory purposes, nor shall it be used in a way that may lead to stigmatisation of an individual, a family or a group.

For the collection of human genetic data, prior free and informed consent must be obtained, which may at all times be withdrawn. The declaration stresses the individual's right to decide whether or not to be informed. Genetic counselling has to be available at all times, though participation in counselling should not be mandatory.

Everyone should have access at any stage of the process to their genetic data. Confidentiality of genetic data linked to an identifiable person has to be guaranteed.

Genetic data shall not be disclosed or be accessible to third parties, in particular employers, insurance companies or educational institutions, 'except in cases provided for by national legislation or regulations and subject to the consent of the person concerned, and in compliance with international human rights law'. Human genetic data collected for a specific purpose shall not be used for a different purpose.

With regard to the characteristics of the genetic tests, the IBC states that accuracy, reliability, quality and security must be ensured. The relevant professional bodies shall exercise rigour, caution, intellectual honesty and integrity in the processing and the interpretation of results from genetic data.

The International Declaration applies not only to human genetic data, but also to data that is or might be derived from it, e.g. proteomic data.

THE INTERNATIONAL LABOUR ORGANISATION

(ILO)

Expert hearing of Brigitte Froneberg, MD

April 15th 2003, Brussels

Dr. Brigitte Froneberg is a Senior Occupational Safety Officer and Environmental Health Specialist for the InFocus Programme SafeWork with the International Labour Organisation in Geneva.

The EGE invited Dr. Froneberg to speak about ILO's position and activities related to genetic testing in the workplace, as well as report on the current use of genetic tests by employers in the United States. The hearing took place at the EGE meeting on April 15th 2003 in Brussels. During this hearing, Dr. Froneberg was also free to speak in her personal capacity as an expert in the field. A discussion followed the presentation.¹⁷

Overview of the organisation

The International Labour Organisation, founded in 1919, is a supranational organisation that became a specialised agency of the United Nations in 1946. The ILO currently has 175 member states. It formulates international labour standards mainly through three types of instruments: Conventions, Recommendations and Codes of Practice that set minimum standards of basic labour rights. It also provides technical assistance in several fields, primarily related to training, employment, and social security. Within the United Nations system, the ILO has a unique tripartite structure composed of representatives of workers' and employers' organisations and governments.¹⁸

The 1944 Philadelphia Declaration states the fundamental objectives of the ILO. With reference to this Declaration, the following strategic objectives have been formulated to promote decent work: the promotion and realisation of standards and fundamental principles and rights at work, the creation of greater opportunities for women and men to secure decent employment and income, the enhancement of the coverage and effectiveness of social protection for all and the strengthening of tripartism and social dialogue.

¹⁷ This summary was prepared by Jutta Buyse, a Trainee with the Secretariat of the EGE from March to July 2003, on basis of a presentation submitted by Dr. Froneberg, as well as the discussion that followed it.

¹⁸ The text is available at www.ilo.org

Recommendations from the ILO

The ILO has not issued any separate statement on genetic testing in the workplace. However, previously stated principles from the Philadelphia Declaration, the Fundamental Human Rights Convention and other Conventions represent the position of the organisation on this topic.

The Philadelphia Declaration affirms that 'all human beings, irrespective of race, creed or sex, have the right to pursue both their material well-being and their spiritual development in conditions of freedom and dignity, of economic security and equal opportunity'. The Philadelphia Declaration also advocates full employment under safe and decent working conditions and the use of measures to ensure employability.

ILO's philosophy has consistently focussed on *non-discrimination* and *autonomy*, as expressed in several Fundamental Human Rights Conventions.

Discrimination includes 'any distinction, exclusion or preference made on the basis of race, colour, sex, religion, political opinion, national extraction or social origin, which has the effect of nullifying or impairing equality of opportunity or treatment in employment or occupation' (C111 Discrimination (Employment and Occupation) Convention).

The ILO stresses employers' obligation of providing a safe and healthy working environment that will facilitate optimal physical and mental health in relation to work, and the need for the adaptation of work to the capabilities of workers. It also emphasises the need for fully professional independent personnel of an occupational health service. The latter has the task of 'surveillance of worker's health in relation to work'. All workers must furthermore be informed of health hazards involved in their work (C161 Occupational Health Services Convention, 1985).

Governments are to do everything possible to prevent any discrimination between workers (C169 Indigenous and Tribal Peoples Convention, 1989).

The Code of Practice on Protection of workers' personal data (1997) and the Chapter on 'Biological tests and other investigations' of the Technical and Ethical Guidelines for workers' health surveillance (1989) contain specific references to genetic testing.

The Code of Practice on Protection of workers' personal data states that 'workers and their representatives should be kept informed of any data collection process', and that the 'processing of data should not have the effect of unlawfully discriminating in employment or occupation'. Workers may not waive their privacy rights. Medical personal data may only be collected as needed, i.e. to determine whether the worker is fit for a particular employment, to fulfil the requirements of occupational health and safety, and to determine entitlements to, and grant, social benefits. Specifically, genetic screening should be prohibited or limited to cases explicitly authorised by national legislation. The ILO comments this statement stressing that though genetic screening may appear to be inherently in the interest of workers in order to prevent dangers arising from their genetic constitution, it discloses highly personal data with far-reaching implications for a worker's future. Hence, the subjection of workers to such an examination may not be left to employers' discretion.

The Technical and Ethical Guidelines for workers' health surveillance further state that any detection should take place at a time when intervention is beneficial to individuals' health. The medical professional undertaking the test may help with the placement of a worker in an appropriate position that takes into account his capacity for a particular work, and prevent the total exclusion of any worker from employment. Medical examinations should be regarded as a *baseline* for future health surveillance. Again, any examination should be conducted bearing in mind the possibility of improving the working conditions.

Biological tests and other medical investigations must be carried out with due regard to their sensitivity, specificity and predictive value. Biological monitoring is judged useful, but should not be regarded as a substitute for the surveillance of the working environment. Priority should be given to environmental (environmental exposure limits) over biological (biological exposure limits) criteria. Given the present state of scientific knowledge in this specific field, genetic screening at the workplace is 'a disproportionate infringement of individual rights'.

The ILO recognises the limits of the individual worker's autonomy with regard to the protection of third parties or when the elimination of exposure is impossible. In the case of possible danger to third parties, the management must be informed and take the necessary measures to safeguard other persons. When elimination of exposure is impossible, the only solution may be the removal from exposure or a particular work situation.

Current techniques for monitoring are not exposure-specific, and thus not able to identify the true cause of changes in genetic material. In occupational settings, they may be effectively used to identify recent exposure to a common hazard in groups. They may therefore be regarded as a method of health surveillance.

Employers could use test results for several reasons: to lower exposure levels or to ensure appropriate worksite placement of susceptible employees, but also in order to exclude employees who are likely to develop an occupational or non-occupational disease later in life.

Most diseases are multifactorial. More than one genetic factor usually contributes to a particular trait, and genetic factors often interact with environmental factors, which in turn also often interact with each other. Furthermore, genetic predisposition does not have a continuous effect during the life course, as genetics influence differently at different points in time. The number of currently available genetic tests is limited – approximately 50 tests for increased susceptibility for occurrence of an occupational disease are available – as is their predictive value. The limited sensitivity and specificity of most tests will lead to misclassification, in particular for genetic disorders with low prevalence.

Employers could have an interest in knowing their employees' predisposition to certain behaviours and abilities, in extension of psychological assessment. There appears to be presently more concern about genetic screening at work than there is evidence for such tests actually being performed on a routine basis.

The use of genetic testing in the workplace touches on areas of basic concern to most people: opportunity for employment, job security, health, self-esteem, and privacy. The key ethical principles involved are autonomy, nonmaleficence and beneficence, and justice. Justice, strongly related to equality and fairness, becomes an issue with regard to the carrier of the cost. Nonmaleficence and beneficence translate into a number of employer duties in the workplace setting: not to knowingly subject workers to conditions that are likely to cause injury or diseases, remove harmful substances, and take actions in order to improve worker's health. Further ethical questions relate to information, counselling, record keeping, and privacy.

Survey results indicate little current use of genetic testing in the workplace in the United States. Similar to the results of the OTA survey (see -section 7: United States- in this publication), in the AMA – American Management Association 2001 survey on medical testing, only 2 out of 1 627 respondent firms that use genetic testing.

Further evidence on the use of genetic testing in employment is anecdotal. In 1997 a group of employees at *Lawrence Berkeley laboratories* sued their employer for testing them for sickle cell, syphilis, and pregnancy. The plaintiffs were found to be right by the Court of appeals on privacy and civil rights claims, but not on infringement of the Americans with Disabilities Act because the testing took place post-hire and pre-placement, hereby falling into a statutory window for testing which allows the employers great latitude.

Recently, the *Burlington Northern Santa Fe Railroad* case has received much publicity. Burlington had required thirty-six employees to provide blood samples for a genetic DNA test for chromosome 17 deletion, which is claimed to predict some forms of carpal tunnel syndrome. These employees had previously submitted claims of work-related carpal tunnel syndrome. They were neither informed nor asked for their consent. This case was settled out of court in May 2002 – Burlington paid the damaged employees 2.2 Million USD, settling the case mainly to avoid bad publicity. There is limited federal prohibition with regard to genetic testing in the workplace, and since Burlington did not fire an employee on the grounds of test results, the company did not violate the Americans with Disabilities Act. Relevant Federal American legislation with regard to genetic testing includes: The Occupational Safety and Health Act (OSHA) of 1970, the 1990 Americans with Disabilities Act (ADA), the Fourth Amendment's constitutional prohibition on illegal searches and seizures, Title VII of the 1964 Civil Rights Act. State legislation has developed from early statutes to prevent discrimination on specific genetic conditions to statutes that broadened coverage of 'genetic testing' for all conditions to statutes against genetic discrimination for all conditions no matter how the information is obtained.

No state law exists which prevents employers from collecting non-job-related genetic information about job applicants. The most promising approach is contained in The Minnesota Human Rights Acts. It requires that all medical exams, including pre-placement exams, be strictly limited to measuring the ability to perform job-related functions. In February 2000, President Clinton signed Executive Order 13145 prohibiting discrimination on the basis of protected genetic information in the Executive branch. Applicants and employees are to be judged on their current ability to perform the jobs they seek or hold, and not on the possibility that they might in the future develop a disease or condition. The Executive Order accordingly places stringent limits on the collection, use, and disclosure of protected genetic information.

THE COUNCIL OF EUROPE

Expert hearing of Dr Laurence Lwoff

April 15th 2003, Brussels

Laurence Lwoff is an Administrative Officer/Secretary of the Working Party on Human Genetics and of the Working Party on the Protection of the Human Embryo and Foetus. Dr. Lwoff was invited by the EGE to speak about principles and recommendations agreed at the Council of Europe relevant to the topic of genetic testing at the workplace, as well as ongoing deliberations. The hearing took place at the EGE meeting on April 15th 2003 in Brussels. During this hearing, Dr. Lwoff was also free to speak in her personal capacity as an expert in the field. A discussion followed the presentation.¹⁹

Overview of the Organisation

The Council of Europe (CoE) is an intergovernmental organisation that aims to promote the protection of human rights and democracy in Europe. Its field of activities includes health and education. Created in 1949, the CoE is composed today of 45 states, including the 15 member states of the European Union, the 10 accession countries and the applicant countries Croatia, Turkey, Bulgaria and Romania. All CoE-member states are legally bound to the Convention of Human Rights and Fundamental Freedoms drafted in 1950.

The "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine", known as the "Convention on Human Rights and Biomedicine" or the "Oviedo Convention" was opened for signature in April 1997 in Oviedo (Spain). It is the only legally binding international instrument in this field. On the basis of its principles, additional protocols have been elaborated and are now opened for signature to the signatories to the Convention: The Additional Protocol on the prohibition of cloning of human beings (12.01.1998) and the Additional Protocol concerning transplantation of organs and tissues of human origin (24.01.2002).²⁰

¹⁹ This summary was prepared by Jutta Buyse, a Trainee with the Secretariat of the EGE from March to July 2003, on basis of a presentation submitted by Laurence Lwoff as well as the discussion that followed it.

²⁰ The text is available at www.coe.int/bioethics

Principles and recommendations from the Council of Europe

The "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine", known as the "Convention on Human Rights and Biomedicine" or the "Oviedo Convention" was opened for signature in April 1997 in Oviedo (Spain). It includes several Principles relevant to the field of genetic testing in the workplace. In the explanatory report that accompanies the Convention, the issue of genetic testing in the workplace is addressed directly in relation to predictive genetic tests.

The Oviedo Convention has been signed by all European Union member states, except Austria, Belgium, Germany, Ireland and the United-Kingdom. Finland, France and Luxembourg have signed, but not yet ratified it. All accession/candidate countries have signed this Convention; it has however not been ratified yet in Latvia, Poland and Turkey.

A draft additional Protocol on Human Genetics to the Oviedo Convention is currently being elaborated by a Working Party working under the authority of the Steering committee on bioethics. The first part of the draft Protocol addressed applications of genetics for health purposes.. At the time of this hearing, the preparation of the second part of this Protocol was at its initial stage. This second part will elaborate provisions with regard to the application of human genetics for non-medical purposes.

With applications of genetic for non-medical purposes, a third party might be involved that could have an interest in knowing an individuals' health status, including their genetic status. Employers and insurance companies could be such a third party.

A series of conditions that set the framework for the future CoE-policy on this matter to be elaborated in the new Protocol are established in the Oviedo Convention:

The dignity and identity of all human beings must be protected, and respect for integrity and other rights and fundamental freedoms with regard to the application of biology and medicine must be guaranteed (art. 1). Free and informed consent must be given prior to any intervention (art. 5). Private life must be respected in relation to information about health (art. 10). Discrimination on grounds of genetic heritage must be prevented (art. 11).

Two articles are of particular relevance regarding the question of the application of genetic testing in the field of employment:

Predictive tests may be carried out only for health purposes or scientific research linked to health or research purposes and subject to appropriate genetic counselling (art. 12).

Exceptions to this rules are possible , when prescribed by national law where necessary [...] 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 (art. 26).

Thus, the Convention prohibits genetic testing for employment purposes when it does not serve the health of the individual. In the explanatory report to the Convention, an exception is made when the working environment could have prejudicial consequences to the health of an individual, and cannot be improved in other ways – testing should not be an alternative to the improvement of working conditions.

Genetic tests could also be allowed when the health condition of an employee might pose a serious risk to a third party.

Articles 1-3 of the European Social Charter (revised 1996) represent an additional basis for deliberation. They stipulate the right to work, the right to just conditions of work, and the right to safe and healthy working conditions. Further relevant instruments from the CoE include recommendations (92)3 on genetic testing and screening for health care purposes, (97)5 on the protection of medical data, (89)2 on personal data used for employment purposes of the Committee of Ministers.

Dr. Lwoff highlighted the main issues to be considered in the discussion of genetic testing in the workplace. The main ethical concerns are similar to concerns raised in general by medical examination for employment purposes: the respect for private life, the protection of integrity of the person and non-discrimination. They are increased by the characteristics of genetic information: the predictive nature of genetic tests and the fact that genetic characteristics are shared with family members.

A concern specific to the use of genetic tests for employment purposes is the risk of compromising health care by influencing the free choice of using genetic services or not for health purposes. Individuals may hesitate to use genetic tests for health purposes if the results of such a test could be used for other purposes, such as employment. Furthermore, there might be a risk of compromising access to employment on the basis of genetic characteristics.

The objective of genetic tests in employment should be to assess the applicant's medical fitness for the position concerned, while at the same time protecting their health and safety at work. Dr. Lwoff stressed that the question of 'aptitude' for a specific occupation is a very precise one, answering it requires a prior narrow definition of very exact criteria that will be used.

Accordingly, the information communicated should be limited to the conclusions with regard to the objective of the examination: the assessment of medical fitness for the position, and information on specific working conditions to be respected. The results as such may not be given to the employer.

Occupational doctors must meet professional obligations and standards and should be independent from the employer. Medical data, and in particular genetic data, go hand in hand with a confidentiality requirement.

A further concern is the conservation of obtained genetic data and its possible use for other purposes. This information should not be used for other purposes without the consent of the individual. The question of the conservation of genetic data however remains open. In the employment context, storage of the information could be useful for later genetic monitoring.

There appears to be agreement in Europe that medical examinations have the goal of examining current health status. But in cases where future health status could pose a significant risk to others, a test could be considered.

Further considerations to be taken relate to the quality of genetic tests, i.e. scientific validity, reliability and predictive value. Whether genetic testing is the best way for the assessment of fitness is a subject for discussion; some argue that genetic or medical monitoring are better-suited for protecting individuals' health. In any case, the quality of the laboratory must be assured.

An additional issue to consider is the question of timing. Specifically, this includes the question whether a test should take place at the pre-employment stage, or whether it should constitute a part of monitoring when the person is already in the position.

Appendix:

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