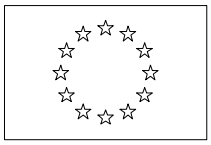

OPINION OF THE EUROPEAN GROUP ON ETHICS

IN SCIENCE AND NEW TECHNOLOGIES

TO THE EUROPEAN COMMISSION

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ETHICAL ASPECTS OF GENETIC TESTING IN THE WORKPLACE

Reference: Initiative of the Group

Rapporteurs: Peter Whittaker and Nicos C. Alivizatos

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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 solemny 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;

1. 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 disproportionally 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.

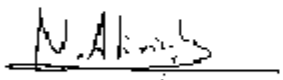
2.20.

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

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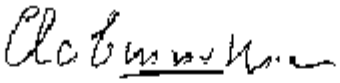
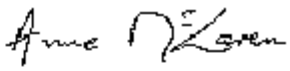
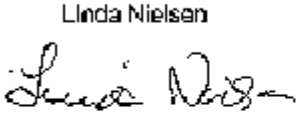


Anne Mc Laren



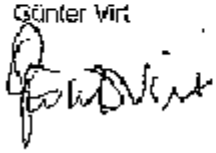
Linda Nielsen



Pere Pulgdomenech Roselt

Stefano Rodota

Günter Virt



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