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MEDICAL, ETHICAL AND LEGAL ISSUES OF INIDIVIDUAL AND GROUP GENETIC TESTING

Individual and group genetic testing is a set of procedures aimed at discovering real or potential genetic problems of an individual (patient) or his/her family. This paper primarily examines genetic testing for medical purposes, and goes on to investigate the most important ethical and legal issues concerning individual and group genetic testing. This is done both from the standpoint of legal theory and in terms of positive law, primarily the UNESCO Universal Declaration on the Human Genome and Human Rights, Council of Europe Convention on Human Rights and Biomedicine and the regulations of EU member states, USA and Japan. The first question examins is that of the content and significance of genetic information in general; the second one deals with the interests of individuals (probands) being tested, and the interests of his/her family members related to data obtained by genetic testing; the third question concerns genetic testing and labour relations; the fourth question is that of genetic testing and insurance; the fifth question considers state interests related to genetic information and genetic screening.

Key words: *Individual and group genetic testing. – Genetic personal data, i.e. genetic information. – „Right Not to Know". – Genetic privacy. – Interests related to data obtained by genetic testing.*

INTRODUCTION

In the context of progress in medicine and biology, legal protection of fundamental human values, such as life, physical integrity, human dignity and privacy, becomes more topical. Legal regulation of individual and group genetic testing, as one of bioethical domains, is a priority concern for several reasons: in order to identify values and interests the legal order wishes to protect; in order to prevent abuse and prescribe sanctions for violation or rules and in order to clearly regulate the doctor-patient relation regarding new biomedical technologies.[1]

1 See: A. Eser:" Humanity in Face of Modern Endangerments – New Challenges to Law and Ethics by Modern Biomedical Technique", a paper for international sympo-

Individual and group genetic testing (genetic testing and genetic screening) is a set of procedures aimed at discovering a real or potential genetic problem of an individual (patient) or his/her family.[2] The difference between genetic testing and genetic screening is in their *range*: diagnosis, that is, genetic testing, is focused on individuals; genetic screening is a routine check-up of a population or of possible identified subgroups of population, such as, for example, only men or only women, or ethnic groups under increased risk of certain genetic diseases. Social health is the objective and the central function of genetic testing and genetic counselling.

Even though today it is possible to diagnose approximately 95% of the most common genetic diseases, there are very few available remedies. There is no curative treatment for the majority of most serious genetic disorders. Consequently, the control of genetic disorders depends on prevention. As pointed out by the British House of Commons Science and Technology Committee: „Even though genetics probably transforms medicine, it calls for a certain period of time, possibly a very long one, before curative treatments based on genetic knowledge become available. In the short rune, the most common use of medical genetics will be, as it is now, in *diagnosis* and *screening*".[3]

Although individual and group genetic testing (except for prenatal diagnosis) has not yet gained full momentum in our country, it can be expected that in the future it will become an important diagnostic procedure. Legal regulations in this domain should determine the position of individuals subjected to such procedures, and the limits for its acceptability. That is the only way to protect the physical integrity and dignity of an individual, which is at ever growing risk of inadequate use of achievements in biotechnology.[4]

This paper will primarily examine genetic testing for medical purposes, and then investigate the most important ethical and legal issues regarding genetic testing and genetic screening, both from the standpoint of legal theory, and from the standpoint of positive law, primarily the

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sium „Tranpianti tra etica, diritto, economia), Triangulum V, Padova, 1995, 2 (quoted according to: Zorica Kandić-Popović: „Pravna zaštita osnovnih ljudskih vrednosti i moderna biomedicina – postojeće i buduće jugoslovensko pravo", *Pravni život*, vol. 1, No. 9, 1996, 219).

2 Sherman Elias, M.D. & George J. Annas, J.D.: *Reproductive Genetics and the Law,* Year Book Medical Publishers, INC, Chicago, London. Copyright, 1987, 34.

3 House of Commons Science and Technology Committee *Human Genetics: The Science and its Consequences* Third Report, 6 July 1995, pp. 36–37, paras 71, 72 (quoted according to: J.K. Mason, R. A. Mc Call Smith, G. T. Laurie: *Law and Medical Ethics,* Fifth Edition, Butterworths, London, Edinburgh, Dublin, 1999, 149.)

4 Compare: Z. Kandić-Popović, *op.cit*, 231.

UNESCO Universal Declaration on the Human Genome and Human Rights of 1997, *Council of Europe Convention on Human Rights and Biomedicine* from the same year, and the regulations of EU member states, USA and Japan. The first question is that of the content and significance of genetic information in general; the second one deals with the interests of individuals (probands) being tested, and the interests of his/her family members related to data obtained by genetic testing; the third question concerns genetic testing and labour relations; the fourth question is that of genetic testing and insurance; the fifth question considers state interests related to genetic information and genetic screening.

GENETIC TESTING FOR MEDICAL PURPOSES

Human genetics deals with the study of rules of inheriting human characteristics. The main unit bearing hereditary characteristics is a *gene*, whose chemical composition is made up of larger or smaller parts of macromolecular deoxyribonucleic acid (DNA). The total potential of hereditary characteristics (genetic information) of an organism, which is transferred to the offspring, is called a *genome*[5], and the genome, according to the scientist's latest estimates, contains 20,000–25,000 genes.[6] The collection of all hereditary characteristics one organism contains and which, under certain conditions, result in creation of a given individual (organism) is called a *genotype*. Each individual has a single, unalterable and specific genotype.[7] The visible properties of an individual (organism), that is, physical, biochemical and physiological properties, that are produced by the interaction of environment and the individual's genotype is called *phenotype.*[8]

So-called *predictive medicine* largely depends on genetic testing, that is, on gene analysis. This analysis comprises of decoding and isolating certain hereditary traits of a man and their molecular build-up.

5 Milan Vujaklija: *Leksikon stranih reči i izraza,* jubilee edition, Beograd 1996/97, 167 and 169.

6 Stanko Stojiljković: „Čovek s manje gena" and Vladimir Glišin: „Nije kao na papiru", *Politika* daily paper of October 24, 2004, column „Science and Technology" (quoted according to: Jakov Radišić: *Medicinsko pravo,* ed. Fakultet za poslovno pravo and „Nomos", Beograd 2004, 233).

7 M. Vujaklija, *op.cit.,* 169.

8 President's Commission for the Study of Ethical Problems in Medicine and Biomedicine and Behavioral Research, *Screening and Counselling for Genetics Conditions,* Appendix B (Basic Concepts) 109–115, (1983) in: Judith Areen, Patricia A. King, Steven Goldberg, Alexander Morgan Capron: *Law, Science and Medicine,* Minneola, New York, The Foundation Press, INC. 1984, 1335

This is achieved by *direct* and *indirect* procedure of proving hereditary characteristics. Direct proof is given by molecular-biological method, which allows DNA structure to be analysed, whilst the indirect method does not examine the gene itself but its product or even further derived traits.[9] *DNA analysis* (so-called „genetic test") *enables the identification of genes that cause hereditary diseases or that are responsible for predisposition for a disease.* In the latter case, it is possible to predict diseases that will, in a specific individual, manifest themselves in the future, such as malignant, cardio-vascular of psychological diseases.[10]

ON GENETIC PERSONAL DATA, THAT IS, GENETIC INFORMATION IN GENERAL

The progress in medical genetics over the last years enables the *so-called genetic personal data,* that is, *genetic information* to be obtained by genetic testing, relatively easily and cheaply, but, as a result, this possibility gives cause for concern regarding the access to and use of test results. Whilst the sensitivity of medical data is a general concern, which shall be considered in the context of confidentiality, it is particularly complicated in the context of genetics, due to particular characteristics specific for genetic personal data, that is, for genetic information. Genetic data encoded in a person's DNA is a form of personal „future diary".[11] Genetic testing may reveal a set of genetic personal data that is, as has been correctly observed[12], so delicate that even the person tested (the proband)[13] may wish not to learn it. This is understandable, since informing a person of his/her genetic predisposition for a disease may result in a change in self-perception and the change of attitude of the environment towards that person. This dimension of genetic data justifies legal pro-

9 Franziska Schneider, in Heinrich Honsell (editor) Hanbuch des Arztrechts, Zürich, 1992, 412 (quoted according to: J. Radišić, *op.cit.*, 234); Elias/Annas, *op.cit,* 99–100.

10 Zorica Kandić-Popović, in Radoslav Ninković and Zorica Kandić-Popović: *Medicinsko-pravni aspekti vantelesnog oplođenja,* Beograd 1995*, 121.*

11 G.J. Annas – S. Elias, cds: *Gene Mapping: Using Law and Ethics as Guides,* Oxford University Press, New York 1992, 9 (quoted according to Zorica Kandić-Popović: „Pravna zaštita osnovnih ljudskih vrednosti i moderna biomedicina – postojeće i buduće jugoslovensko pravo", *Pravni život,* vol. 1, No. 9, 1996, 229).

12 See. L.B. Andrews: „Genetic Privacy: From the Laboratory to the Legislature", *Genome Research,* 1995, 271 (quoted according to: Z. Kandić-Popović: *ibidem,* 232).

13 „Proband" (index case) – the subject, regardless of sex, owing to whom the family comes in sphere of interest of the researcher, see: Alan H. E. Emery: *Osnovi medicinske genetike,* ed. „Savremena administracija", Beograd, 1986, 296.

tection of a special value – denoted as *genetic privacy*.[14] On the other hand, the nature of genetic data is different when compared to other personal data. It is not so strictly personal, as other data concerning a person. Firstly, the test result bears consequences not only to an individual being tested but also to his/her blood relations who share the same gene pool. Secondly, this information is significant for future relatives, for, genetic diseases are transmitted vertically through generations. Consequently, genetic information directly affects reproductive decisions. Thirdly, genetic test results may reveal the probability of *future* disease of individuals who are presently in good health. Fourthly, since in majority of cases the testing is done by analysing an individual's DNA, which remains unchanged during his/her life, genetic testing may be performed at any age – from cradle to the grave, and indeed, beyond that. Thus, for example, a foetus may be tested *in utero* for conditions such as the Huntington's disease, which cannot be manifested until one reaches middle age.

All these factors underlay an apparent benefit that genetic testing may offer in terms of prediction (forecast, anticipation). There is a number of individuals or bodies that may have an interest in genetic test results. Relatives may wish to know whether they or their offspring will also be affected by the disease. Insurance companies always take family history as the risk index when assessing the insurance cover, but, now, genetic testing seems to offer more precise means, based on scientific prediction of probability. Similarly, employers may have an interest regarding future possibility of employing an individual who is likely to be affected by a hereditary disease. The state itself has unquestionable interest in promoting health of the population by reducing the incidence of genetic diseases. In the context of this series of interests, the possibility of conflict regarding access to and control of genetic personal data, that is, of genetic information, is irrefutable, and it is important to recognise that one may feel the influence of genetic test results on his/her life much before the disease beginns.[15]

The genetics' knowledge on human genome may be used for purposes adverse to individuals' interests, harmful to their freedom and dignity. In order to prevent that, certain limits have been set for examining the genome and genetic diagnostics. Many developed countries have passed special statutes, which determine the conditions under which genetic testing is permitted, whilst other is strictly forbidden. Examples

14 Compare: L.B. Andrews: *op.cit.,* 209 (according to: Z. Kandić-Popović: *ibidem,* 233).

15 See: Mason et al.. op.cit, 167–168.

of such statutes are Norwegian *Act on Medical Use of Biotechnology*[16] and Austrian Federal Genetic Technology Act (Gent G)[17]. These statutes establish various limits: medically indicated genetic testing is allowed only in specialised institutions and with the approval of the Ministry of Health; access to genetic data is restricted; patient's explicit written consent is required. In addition, this matter is regulated by adequate international instruments: *UNESCO Universal Declaration on the Human Genome and Human Rights* of 1997, *Council of Europe Convention on Human Rights and Biomedicine*, from the same year. The laws of mentioned countries and international regulations guarantee a certain balance between the freedom to examine the gene and its application, on the one hand, and the right to protection of human dignity, on the other.[18] Article 6 of the *UNESCO Declaration* expressly states that „No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity".

INTERESTS OF PROBAND AND MEMBERS OF HIS/HER FAMILY RELATED TO DATA OBTAINED BY GENETIC TESTING

As mentioned before, there is a small number of medications for certain genetic conditions. Successful treatments for many genetic diseases still do not exist. Therefore, except in rare cases, genetic personal data, that is, genetic information, does not imply that the genetic disease will be avoided. This is an important notion, since it raises the question of motivation of those demanding access to genetic testing or test results. In the absence of treatment or therapy, it is often said that *readiness* is the justification for offering or seeking genetic testing. Adults and children can prepare for the beginning of the disease psychologically, or in other ways, and couples planning to start a family or expecting a child are able to make more informed reproductive choices based on all available facts. Such justification is, however, a „double-edged sward". It cannot be claimed that preventive knowledge regarding a future disease is necessarily „a good thing". Whilst there is evidence that this can be the case, there is also a growing number of facts

16 Law No. 56 of August 1994 on the Medical Use of Biotechnology (quoted according to Z. Kandić-Popović: *ibidem,* 229).

17 This statute was passed in 1994 (*Bundesgesetzblatt,* No. 510/1994) and has been amended in 2001 *(Bundesgesetzblatt,* No. 98/2001) (quoted according to: J. Radišić, *op.cit.,* 235*).*

18 Compare: Z. Kandić-Popović, *op.cit.* 229; J. Radišić, *ibidem,* 233.

suggesting that the psychological outcome of such knowledge can be negative. For example, *Andrews* notes that the suicide rate among young Caucasians who know that they have the gene responsible for Huntington's disease is four times larger than the national average for a comparable group in the USA.[19]

Right to know and right not to know. Unfavourable data regarding health obtained by genetic testing (gene analysis) can considerably burden the patient's (proband's) life, and if such data is learned by others, the patient is stigmatised by the society. This is particularly true when it comes to predispositions for serious hereditary diseases. Telling a man in advance that, based on his predisposition, he will become ill in the future, is sure to harm him. Lately, this situation has led to the recognition of the „right not to know", which is also denoted as the „right to self-determination in regard to information".[20] It protects a man from „inadmissible examination and disclosure of his genetic base". This right should protect a man from „having to look into his future".[21] In short, the right not to know one's genetic predisposition for a disease is protected by law, and is also supported by legal theory. Thus, for example, provisions of Article 10 (2) of the Council of Europe *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine* recognise the interest of not knowing in relation to oneself, reading: „Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed".[22] Similarly, UNESCO *Declaration* states in Article 5c: „The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected".

The basis of the „right not to know" does not lie either in autonomy or in confidentiality, but rather it lies in *privacy.* Formulation of legal regulations in the sphere of genetic privacy protection has started to take shape fairly recently. However, it can be noted that the concept of

19 A. Andrews: „Legal Aspects of Genetic Information" (1990) 64 *Yale J. Biol. Med*. (quoted according to> Mason et. al., *op.cit.,* 168–169).

20 Erwin Bernat: „Recht und Humangenetik – ein oesterreichischer Diskussionsbeitrag", in: *Festschfirt für Erich Steffen zum 65. Geburtstag,* Berlin 1995, (quoted according to: J. Radišić, *op.cit,* 235).

21 E. Bernat, *ibidem,* 43 (quoted according to: J. Radišić, *ibidem*)

22 Council of Europe *Convention for the Protection of Human Rights and Dignity of Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Medicine,* Oviedo, April 1997 (quoted according to: Mason et. al., *op.cit.,* 171).

legal protection of that value rests on the more general principles concerning the respect of integrity of person, respect of secrecy of personal data, as well as on prohibition of all forms of discrimination, including the base of a disease or genetic predisposition towards a disease. Respect of the right to integrity of person demands that all genetic tests must be an act of will (§ 65, para. 2. Gent G).[23] Privacy has two aspects: informational privacy or the right to privacy in the wider sense and spatial privacy or right to privacy in the narrow sense. *Informational privacy* is related to the control of personal information and preventing others from accessing such information. Violation of informational privacy takes place when any unauthorised disclosure of information occurs.[24] A close connection between informational privacy and professional secret (confidentiality) is essential, but it is formally derived from a number of international and national regulations. The right to informational privacy and secrecy of information on patients is usually regulated in a single article or the same group of articles. The connection between these two rights is clearly visible in Article 10 of the Council of Europe *Convention on Human Rights and Biomedicine* (1997): „Everyone has the right to respect for private life in relation to information about his or her health." *Spatial privacy* protects the individual's feeling of „oneself'. It recognises the interest everyone has in keeping the feeling of distance (separation) from others. The right to spatial privacy is an absolute subjective right of a natural person to independently decide on disclosing to third parties any manifestation of his/her existence. To that effect, right to privacy protects the totality of an individual's existence, that is, the privacy of all manifestations of the existence of an individual, for instance, his/her condition. Violation of individual's psychological privacy happens when unwanted information regarding oneself is received.[25]

Whilst an individual who requested genetic testing may prepare himself/herself to the possibility of learning bad news, there is an unresolved issue of his/her *family*, which may not be aware (does not doubt) that there might be a genetic disease in the family. Data that can be found in literature show that 85% of high-risk couples had no knowledge of their genetic condition.[26] However, the fact remains that in the family context, different individuals have valid requests to certain genetic information because, in essence, it concerns all of them. When an

23 See: Z. Kandić-Popović, *op.cit.* 233; J. Radišić, *op.cit,* 235.

24 Mason et. al., *op.cit.,* 170 – 171.

25 *Leksikon građanskog prava,* ed. „Nomos", Beograd 1996, 567–568; Mason et. al., *ibidem* 171

26 Mason et al., *ibidem*, 169.

effective treatment or therapy is available, it could be argued that family members should be protected from the risk of genetic disease; prevention of genetic disease may be perceived as excellent general medicine. However, the motivation to disclose a genetic disease in a family is particularly questionable in the absence of curative treatment. What should a doctor who is in possession of familiar genetic information do?

Even if the doctor is convinced that a relative would wish to be informed of the diagnosis or prognosis of genetic disease concerning him/her, the disclosure procedure is ethically conditioned by the fact that his patient (proband) objects to the disclosure. Should the doctor violate the obligation of confidentiality (professional secret) he ows to his patient, he can face civil action. In addition, parents who discover that relevant information was at disposal but was not disclosed may initiate civil action against the doctor for the birth of abnormal child that could have been prevented by timely disclosure of information (*wrongful birth action*).[27] Under such circumstances, the limitations imposed by present ethical and legal principles have been examined. Ethical and legal principle of respect of patient's confidentiality help the doctor to a certain degree, in as much as they establish one of his primary duties towards a patient – patient-doctor confidentiality. In spite of that, a doctor can *equally* justify the disclosure of information to relatives by invoking the *no crime (no harm) principle.* If the doctor sincerely believes that the infringement (damage) will be caused to relatives (or even to their offspring) by failure to disclose, *neither ethics nor the law require the doctor to consider the confidentiality principle absolute.*[28] Therefore, if avoiding damage (injury) or the no harm principle is a top consideration, then the prospect of damage (injury) for a relative, *who can be disturbed by disclosure of information* on possible development of genetic disease must also be taken into consideration. In other words, interest or the „right not to know" deserves recognition also when it comes to patient's (proband's) relatives. Since the principle of observance for individual's autonomy demands that the individual be seen as the „moral chooser", there are opinions in legal theory that the efficiency of basing the „right not to know" on *circumstances of the choice* is questionable. In order to make a profound choice, one must have complete information on a series of available options and consequences of any given choice. However, this paradigm is overturned in the context of one interest, that is, of the „right not to know" regarding genetic information. For, here the choice is

27 Compare: Mason et al., *ibidem*, 169 – 170.

28 C. Ngwena and R. Chadwick:" Genetic Diagnostic Information and the Duty of Confidentiality: Ethics and law", (1993) 1 *Med Law Internet* 73 at 77 (quoted according to: Mason et al., *ibidem*, 170).

related to the knowledge itself. The question is, therefore, *how to protect* the interest or the right not to know. In legal theory it is often established that the *concept (notion) of spatial privacy* – which requires that the degree of observance should *prima facie* be adverted to the state of separation of an individual or, in this case, to the state of „ignorance" – provides a feasible mechanism.[29]

Consequently, spatial privacy of the patient (*proband*) can be legitimately violated only if the doctor can provide valid reasons for doing so. When deciding on how to resolve the conflicting requests for genetic information in familiar context, the doctor should be guided by the following criteria:

- availability of treatment or therapy;
- gravity of the condition and probability of beginning of the genetic disease;
- nature of genetic disease;
- nature of any further tests that may be required;
- whether disclosure may promote a legitimate social interest;
- how the individual can be expected to react like if unsolicited information is offered to him/her, for example, whether some preliminary directives/instructions have been made.

It follows from the above said that, on the one hand, it may be justified for the doctor not to respect the wishes of his patient who refuses to inform the relatives of the test results when there is available therapy or effective treatment protecting the family from harm (damage). On the other hand, the doctor can be, justifiably, less inclined to disclose the information on a genetic condition that cannot be remedied or that shows relatively mild symptoms. This balanced approach could be complemented by taking into account the manner in which the testing has been performed among family members. Thus, for example, the need to test younger generation family members may be redundant if the older generation has undergone testing first. If younger generation family members are tested first and found to be positive, this will mean that one or more parents or progenitors also have the genetic disease in some form, even though these individuals are unaware of their condition or have chosen not to know. In one word, it is very difficult to keep the information flow within the family; the problem of control of communication between family members always remains an issue.[30]

29 G. T. Laurie: „Legal and Ethical Aspects of Genetic Privacy", Cambridge University Press (quoted according to: Mason et al., *op.cit*., 172).

30 Compare: Mason et al., *ibidem.*

INTERESTS OF OTHER PERSONS RELATED TO DATA OBTANIED BY GENETIC TESTING

Numerous third parties, outside the family context, show interest for access to genetic information, that is, to genetic personal data. These can be present and future employers, insurance companies and the state itself. What follows is a consideration of the nature of principles in question and an evaluation of their weight in regards to the interest of the proband and his/her family.

Genetic Testing and Employment (Labour Relations)

German legal theory has produced a standing that employees are under the risk of being damaged due to insufficiently controlled analysis of their genes. Even when genetic testing is performed with granted consent, this is not sufficient guarantee in case of first employment or change of job. Some workers who have a predisposition towards a serious genetic disease might lose their jobs. Such danger generates a need for more comprehensive legal protection from other persons.[31] In line with this idea, the Austrian *Federal Gene Technology Act* (§ 67) prescribes a ban for the employers on collecting, demanding, taking or otherwise using genetic data (gene analysis results) of their employees or those seeking employment. The legislator intended this ban to serve for the „protection of the socially weak in legal relations where there is economic dependence". „The objective of the protection in this regulation is individual's genetic private life".[32]

The attitude taken in British legal theory on the relation of genetic testing towards employment is not as clear and determined as the one in German and Austrian legal theory and Austrian and Norwegian legislation. In British legal theory it is pointed out that the employer may have two conflicting reasons for seeking access to genetic information on his employees. Firstly, there is a financial interest consideration when employing individuals who will probably become disabled due to a genetic disease, since this will influence the employer's profit on account of the work days lost. On the other hand, the employer may truly fear that the working environment might have a negative (adverse) effect on the employee's health, with possible deterioration of the existing genetic condition or provocation of symptoms in an otherwise asymptomatic individual. This fear is linked to the fact that an individual so endangered

31 Erwin Deutsch/Andreas Spickhoff: *Medizinrecht*, 2. Auflage, Berlin, 2003, 520 (quoted according to: J. Radišić, *op.cit,* 237).

32 E. Bernat, *op. cit*., 43 and 44 (quoted according to: J. Radišić, *ibidem*); in that sense also the Norwegian *Law on Medical Use of Biotechnology* (§ 6–7) (quoted according to: Z. Kandić-Popović, *op.cit.* 234).

might seek damages from the employer. British legal theory is on the standing that the appropriateness of allowing the employer or future employer to have access to genetic data must be discussed on a case-to-case basis, and not in principle. Access to genetic information may be granted either by virtue of existing test results or by making employment conditional on genetic testing. Moreover, the request for genetic information may be put forward either before or after employment.[33]

Genetic Testing and Insurance

Life and health insurance companies have a legitimate right to assess the risk being insured. It is therefore understandable why, upon concluding insurance contracts, they whish to be informed of the health condition and health prospects of the insured. Genetic information is clearly important for insurance in order to assess the risk of the foreseen cover in general and in order to determine the premium level if one insurance offer has been made. This interest is entirely of financial nature, and the insurance company has a legitimate right to demand that it be protected. In practice this means that any and all information having a bearing on risk assessment should be disclosed to the insurer, or otherwise the realisation of the contract might be avoided any time in the future. When it comes to more substantial sums for life insurance, the person insured must undergo medical examination, and shall be asked to provide data on how long his/her parents have lived and what was the cause of their death.[34]

However, Austrian law demands that care be taken of justified interests of the insured. In short, the insurance company cannot in any way use the results of the insured's genetic testing, nor to make the conclusion of insurance contract conditional on genetic testing of potential insured (§ 67 of the Austrian *Federal Gene Technology Act*). This also limits the insured's statutory obligation to inform the insurance company of all his/her illnesses he/she is aware of prior to concluding the insurance contract. Some Austrian lawyers find that in these provisions the legislator has exceeded the set objective to protect genetic information.[35]

In British legal literature, in the context of genetic information, it is pointed out that, in insurance, two possible ways are open. Primarily, he may demand that all genetic test results be disclosed. Secondly, the insu-

33 Read more on that in: Mason et al., *op.cit.,* 178–179.

34 Deutsch/Spickoff, *op.cit.*, 521 (quoted according to: J. Radišić, *op.cit,* 178–179).

35 E. Bernat, *op.cit.,* 46 and 47 (quoted according to: J. Radišić, *ibidem*).

rance company may require that the future insured undergo genetic testing. In the first case, one could say that there is no difference compared to any other form of medical history. Genetic test results should be disclosed in the same manner as one would disclose the removal of melanoma or familiar history of high blood pressure. However, the British *House of Commons Science and Technology Committee* has certain reservations regarding this interpretation. It says: „We accept that insurance industry collectively tries to deal with genetics in a reasonable manner; however we are concerned because there is real danger that people will decide to refuse genetic testing, even if such test would prove useful for them, because of possible consequences in terms of insurance".[36] In the second case, when the insurers actively demand that future clients undergo genetic testing, there is a concern that increased availability of tests will lead to „development and multiplication of predictable genetic testing". This would have serious consequences to (spatial) private interests of individuals who are asked to be tested and bear unacceptable degree of coercion which would repeal (distort) any „informed consent" to undergoing genetic testing.[37]

Council of Europe has published recommendations on protection of medical data subject to automated processing; genetic data is particularly included. It is on the position that medical data should, in principle, be collected only by health care professionals or their assistants. Genetic information should be used only for preventive treatment, diagnosis of treatment of a given individual or for scientific research, court proceedings or criminal investigation. The authors of recommenddation have made it clear that:"candidates for employment, insurance contract or other activities should not be forced to undergo genetic testing, making employment or insurance conditional on such an analysis, in as much as such conditionality is not expressly provided by national legislation or unless analysis is necessary in order to protect a certain individual or third person". [38]

State Interests Related to Genetic Information and Genetic Screening

Given that the state has a role in the protection and promotion of collective interests of the society as a whole, a question is imposed as to the degree to which it can demand the results of genetic tests or genetic testing.

36 Quoted according to: Mason et al., *op.cit.,* 175.

37 Mason et al., *ibidem.*

38 Quoted according to: Mason et al., *op.cit.,* 175–176.

One of the most obvious state interests concerning health protection is to insure social health. Even if little or nothing can be done for those individuals who are already affected by the genetic disease, disclosure of such fact may prevent the transfer of defective genes to future individuals (offspring). However, this would potentially violate the private interests that would be established by such practice. On the other hand, one could claim that the state has a positive interest to facilitate individual choices. Namely, the protective (*parens patria*) role of the state towards individuals (citizens) offers them information that helps them bring important life decisions, such as the decision whether to have a child or not, if, for instance, both parents are transmitters of cystic fibrosis. In such a way, not only are individuals made more independent as moral choosers, but also the desired social objective to prevent the spread of genetic diseases is realised. This standing was also supported by the *Royal College of Physicians of London*, whose report states that „as long as individuals have a right to decide for themselves whether to have children or not, such individuals should have access to the most complete information possible, including genetic, that is of significance for such decision and information should not therefore be withheld".[39]

This idea implies that, on order to facilitate choices to individuals (citizens), the state should provide comprehensive *screening programmes*, an abundance of genetic tests followed by adequate genetic counselling services and other support mechanisms, such as easy access to abortion. The risk of conflict of interests would almost entirely be eliminated if such programmes were to be offered free of coercive measures, that is, if they would be implemented on *voluntary basis.* In such a case, medical genetics would obtain a new dimension, where genetic diseases are understood as a matter of choice rather then destiny.[40]

Genetic screening or check-up is „searching within population" for individuals who have certain genotypes that are:

- already associated with a disease or susceptibility to a disease;
- may lead their descendants into disease or,
- may produce other variations for which it is not known whether they are associated with a disease.[41]

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39 D. Ball et al.: „Predictive Testing of Adults and Children", in: A. Clarke (ed).): *Genetic Counselling: Practice and Principles* (1994) at 77 refers to the Royal College of Physicians of London: *Ethical Issues in Clinical Genetics: A Report of the Working Group of the Royal College of Physicians' Committees on Ethical Issues in Medicine and Clinical Genetics* (1991) (quoted according to: Mason et al., *ibidem*, 182–183).

40 This opinion is represented by the British *Nuffield Council of Bioethics* (quoted according to: Mason et al., *ibidem*, 183).

41 Elias/Annas: *Reproductive Genetics and the Law,* Year Book Medical Publishers, INC, Chicago, London. Copyright, 1987, 53–54.

Individuals from the first category are recognised for treatment. The second group is also identified in such a manner that individuals in it can receive genetic counselling on their reproductive options and risks. The third group is identified for the purpose of scientific research, particularly to help determine the constitution of the population. It follows from what was said before that genetic screening has different meanings and contexts and may be ranked from testing only selected individuals to testing all individuals, regardless of age or clinical condition.[42] Justification of the request for genetic screening includes several important factors:

- frequency and severity of genetic condition;
- availability of therapy that has proven to be efficient;
- extent to which discovery by screening improves outcome;
- validity and safety of check-up test;
- sufficiency of resources ensuring effectiveness of check-up and follow-up;
- costs and
- social acceptability of screening programmes, including consumers and general practitioners.[43]

In Great Britain there are no screening programmes for adults. There is only routine screening of newborns, which relates to phenylketonuria, haemoglobin diseases and hypothyroidism.[44]

In American law, historically, there has been a lot of wandering when it comes to the issue of genetic screening and state policy. Screening tests are accepted in American society, even though they raise serious questions on autonomy, stigmatization, informed consent and efficiency. The past two decades witness of three waves of Genetic Screening of Newborns Act. Between 1963 and 1968, screening programme for phenylketonuria was introduced in 43 states in the USA, making them mandatory for all newborns. This legislation is characterised as „immature biomedical legislation". From 1971 to 1974 in 17 states laws have been passed to promote screening for sickle-cell anaemia, which was mandatory, and, as of 1986, 48 states and the District of Columbia have laws regulating the screening of newborns. Genetic screening can be carried out in the USA also over potential bearers of genetic diseases, foetuses and genetic donors.[45] It is pointed out in Ame-

42 Elias/Annas, *ibidem.*

43 Elias/Annas, *ibidem.*

44 Mason et al., *op.cit.,* 183.

45 Elias/Annas, *op.cit.,* 53; 77.

rican literature that mandatory screening programmes are more a result of historic coincidence than of reasoned political decision.[46] American legal theory holds the position that *voluntary programmes* should be used for as long as it is possible to obtain sufficient information on effectiveness of both the screening tests and planned interventions; *mandatory laws* should be passed only if there is reasonable medical certainty that the measures prescribed are necessary for social health and capable of achieving their legislative purpose.[47] Similarly, the USA *President's Bioethics Commission,* in its 1983 Report approves voluntary screening programmes, but notes that mandatory programmes „that require execution of low-risk procedures, that are minimally intrusive, may be justified if voluntary testing would fail to prevent serious damage to people – such as children – who are unable to protect themselves."[48]

In Japan, screening test for colour recognition has been carried out in half-coercive manner in schools for a long time. As a result of this screening, some schools have limited the chances of colour-blind individuals for higher education and free choice of subjects, whilst some companies have discriminated against the colour-blind through their employment policies. Because of that, Japanese Ophthalmologic Society has asked the government to abandon the colour recognition screening in schools. The Society has also requested that textbooks for primary school do not mention the hereditary nature of colour-blindness as an example for gender-related recessive inheritance. All medical and anthropological genetics in Japan oppose the idea on application of coercive and administrative genetic screening. They are in favour of voluntary counselling with doctors, for the protection of privacy and for social education and enlightenment on genetic diseases.[49]

The British *Advisory Committee on Genetic Testing* (*ACGT*) holds the position that the objectives of any screening programme should be clearly articulated by the state; all programmes should be subject to strict scrutiny on the part of the *National Screening Committee* and each programme should be followed by unbiased counselling before and after testing. Autonomous and private interests of each individual require

46 Elias/Annas, *ibidem,* 79–90.

47 Elias/Annas, *ibidem,* 77.

48 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research, *Screening and Counselling for Genetics Conditions.* US Government Printing Office, 1983 (quoted according to: Elias/Annas, *ibidem,* 81).

49 K. Takagi: „Genetic Screening – Policymaking Aspects", in: *Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy,* Edited by Bankowski and A. M. Capron, CIOMS, Geneve, 1991, 118–119

prima faciae observance and this should be borne in mind when considering the introduction of genetic screening of a population. The moral grounds for introducing genetic screening programmes is inevitably questioned if no adequate medical intervention is possible in the presence of positive genetic testing result. If the state seeks to promote the interests of its individual citizens rather than those of society as a whole, there is a real possibility of a conflict of interest when future parents whish to know data on the genetic constitution of their relatives in order to make a more complete, informed reproductive choice. Namely, there is the question of whether the interest for genetic information for reproductive purposes is sufficient to justify the violation of private interests of the relatives. According to the opinion of the British *Advisory Committee on Genetic Testing,* it is very difficult to justify any screening programme for children and adults that are not followed by effective therapy or treatment. The strength of state interest in promoting social health is *per se* insufficient to justify the compromising of individual's interests in receiving or not receiving genetic information on themselves.[50]

50 Quoted according to: Mason et al., *op.cit.,* 183–184.