

GENETIC DATA AND CONFIDENTIALITY THE ESTONIAN EXPERIMENT¹

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I. Introduction

The protection of medical data and information about health in general is a vital principle in almost all legal systems in Europe. The interest in protecting the confidentiality of that information is of twofold nature:

- a. It expresses the general respect due to the privacy of the patient. This right to informational self determination² guarantees every individual free decision as to what medical and genetic data will be given to whom, at what time and on what conditions. Article 10 of the European Convention on Human Rights and Biomedicine specifically lays down the principle that everyone is entitled to the right to privacy and confidentiality of personal medical data.
- b. It is a crucial condition in order to preserve the patient's confidence in the medical profession and in the health services in general. The European Court of Human Rights in the case *Z v. Finland* summarized the reasons justifying the protection of medical data in that sense:

«Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even from seeking such assistance, thereby

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² See the landmark case of the German Federal Constitutional Court BVerfGE 65, 1 (63) about the information collected at census. This right is not limited to the automatic data processing, see BVerfGE 78, 77 (64). See also Hondius, Frits W.(1997): Protecting medical and genetic data, *EJHL*, pp. 361-388; Kienle, Thomas (2001): New forms of medical data collection –should be implemented by a new European privacy standard?, *EJHL*, pp. 27 – 39; Taupitz, Jochen (1996): Genetic analysis and the right to self –determination in German Civil Law, *Law and the Human Genome Review*, pp. 77 – 90.

endangering their own health and, in the case of transmissible diseases, that of the community...»³.

Confidentiality related to genetic data is even more important, because of the following reasons:

- a. Genetic discrimination generally is based on risk potential and not on the factual appearance of a disease, resulting in unfitness for a particular occupation or job. The basic question for genetic distinction is not *who* one is but *who one will likely be*, taking into account his or her DNA and external conditions (i.e. the environmental influence, the way of living etc).
- b. Genetic data are of particular importance for employers, insurers, research institutions and state agencies entrusted with the elaboration of policy options in the field of epidemiology, disease prevention etc.
- c. Genetic information reveals the genetic pattern not only of the person tested but also of his/her entire family and of the descendants, that are not already born.

II. Estonia's Response to Genetic Challenges

1. Specific provisions about gene data protection

Many countries have already launched the discussion as to the protection of genetic data, but only a few among them have drafted or enacted specific legislation.

Estonia⁴ belongs to the countries that have already drafted specific regulations concerning the protection of the individual in the workplace. The Human Genes Research Act, which entered into force January 8, 2001, in Paragraph 26 on "discrimination in employment relationships" states that:

1. Employers are prohibited from collecting genetic data on employees or job applicants or from requiring employees or job applicants to provide tissue samples or descriptions of DNA.
2. Employers are prohibited from imposing discriminatory working and wages conditions on people with different genetic risks.

Further it states that complaints concerning discrimination occurring in employment relationship due to genetic risks shall be adjudicated by the Labour Inspectorate, if necessary with the assistance of the chief processor (i.e. the Gene Data Bank) or experts from the data protection supervision authority in investigating or deciding the matter (paragraph 30).

³ European Court of Human Rights, URL:<http://www.dhcour.coe.fr/eng/Z.html>, Case Z v. Finland (9/1996/627/811), Judgement 25 February 1997, p. 18.

⁴ For the legal developments in Estonia see Krawietz, Werner/ Narits, Raul (2001): Gesetzgebung und Rechtspolitik. Internationales Symposium der Estnischen Juristischen Fakultät in Tartu. *Sonderheft Estland*. Zeitschrift Rechtstheorie, 31 Band 2000, Heft 3/4 (p. 303 – 551).

Finally it foresees that unlawful restriction of the rights of a person or conferral of unlawful preferences on a person, based on the genetic risks of the person is punishable by a fine, detention or up to one year imprisonment .(paragraph 31, s. 4).

This general prohibition does not exclude a differentiated approach, if working conditions may be harmful to a certain predisposition. The European Court of Human Rights in the case: Abdulaziz, Cabales and Balkandali v. United Kingdom of 1985⁵ has made it clear that not every distinction or difference of treatment amounts to 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 realized”⁶. So exceptions from the general rule, prohibiting genetic discrimination, could be tolerated, if they are intended to serve the health of the individuals concerned (i.e. 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 (i.e. in the case of pilots).

As far as insurance relationships are concerned the law 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 (paragraph 27).

Complaints concerning discrimination occurring in insurance relationship due to genetic risks shall be adjudicated by the Insurance Supervisory Authority, if necessary with the assistance of the chief processor or experts from the data protection supervision authority in investigating and deciding the matter (paragraph 30, section2).

⁵ European Court of Human Rights Judgement of 28 May 1985 , Series A, No 94, paragraph 72.

⁶ Sild,T./ Mullari,T.: Population Based Genetic Research: Estonian Answer to the Legal Challenge, in: European Journal of Health Law, 2001, 363 – 371 (369).

2. The creation of a central gene data bank

Data and tissue (i.e. umbilical cord) that may be collected for research, medical and/or epidemiological purposes⁷ may become accessible to unauthorized persons and may be used at the evaluation process in employment and/or insurance relationships.

Therefore it is of particular interest to examine the way Estonia tried to solve this problem, given that it is the first state which founded a gene bank with the aim to collect the genetic material and health data of the whole Estonian population in order to make these, subject to certain restrictions, available to the scientific community for genetic research (paragraph 3 of the above mentioned Act). Iceland has undertaken a similar initiative⁸, but Estonia is the first country, where this bank operates under public control (Paragraph 3 of the Human Genes Research Act of 2001).

2.1. The potential benefits associated with the bank

The Estonians do not expect only a better organized health care system, based on the results to be obtained from the genetic research. The national health care provider may improve its effectiveness by 10 per cent through the application of better electronic databases and genetic information in diagnostics, as well as in the treatment and prevention of diseases. This can be translated to better health service for the population for the same amount of money and no tax increase⁹.

Further, they hope that individualized medical care will be possible, given that medical and genetic data stored in the bank may be given to the family doctor, by the stroke of a key, with the consent of the patient (paragraph 16, s.2 of the Act).

Finally they want to attract biotechnology and gene technology firms: The creation of the bank is anticipated to give new impulse to pharmacological and medical research. As paragraph 6, section 1 states: Genetic research related to the gene bank is permitted in order to study and describe the links between genes, the physical and social environment and the lifestyles of people, to find medicinal products or methods of treatment on the basis thereof, to assess individual health hazards and to prevent illnesses. The Gene Bank

⁷ Knoppers, Bartha M./Hirtle, Marie(1996,1997): Banking of human materials, intellectual property rights and ownership issues: emerging trends in the literature and international policy positions, *Law and the Human Genome Review*, No.5 1996, pp. 87 – 107 and No. 6 1997, pp. 63 – 83.- See also *European Group on Ethics in science and new technologies to the European Commission (EGE): The ethical aspects of human tissue banking*, Opinion No 11, 21 July 1998.

⁸ Bl. Arnardottir, O.M./ Björgvinsson, D.T./ Matthiasson, V.M.: The Icelandic Health Sector Database in: *European Journal of Health Law*, 1999, 307 – 362` Roscam Abbing, H.D.C.: Central Health Database in Iceland and Patient`s Rights, *ibid.*, 363 – 371.

⁹ Metspalu, Andres: Biotechnology as an instrument of politics - The example of Estonia, in: Herbert Quandt Foundation, *The foundation of Altana AG*, Sinclair House Debates: Who owns the human genome? Bad Homburg v.d.Höhe, 2002, 43 – 45 (44).

may be used only for scientific research, research into and treatment of gene donors, public health research and statistical purposes (paragraph 16, section 1).

The Estonians are also willing to give their data to be examined and processed in another unity like a European Institute for Complex Diseases, where EU scientists could analyze data from the EGP (paragraph 18, s. 4) and extend our general knowledge about genetics, biology and the very nature of the human being.

In the words of Andres Metspalu, a professor of biotechnology, who proposed the creation of the DNA database in 1999: “This shows that we have a contribution to make towards Europe, instead of just consuming the security and wealth that are provided... Now we feel we can make a major contribution to human genetics and the pharmaceutical industry by creating the world’s biggest health database available for research and development. This is one form of European integration in practice.”¹⁰

2.2. Main principles governing the creation of the gene data bank

a. The creation of a central gene data bank is based on the idea that the human genome is a kind of national resource. This presumption echoes the recognition enshrined in the UNESCO’S Universal Declaration on the human genome and human rights of 1997, proclaiming that the human genome is in a symbolic sense “the heritage of humanity”¹¹.

b. The population is encouraged to participate to this project, which is hoped to provide unique research material and to contribute to the development of individualized medicine. In this context one should mention **the principle of genetic altruism**, which has been developed elsewhere, serving the same idea: As the UK Human Genetics Commission points out: “We all share the same basic human genome, although there may be variations in our individual genome which distinguish us from other people. Most of our genetic characteristics will be present in others. This sharing of our genetic constitution not only gives rise to opportunities to help others but it also highlights our common interests in the fruits of genetic research”¹².

¹⁰ Metspalu, Andres, op.cit. p. 45.

¹¹ Espiell, Hector Gros (1995): The common heritage of humanity and the human genome, *Law and the Human Genome Review*, pp. 89 – 101; Lenoir, Noelle (1998): UNESCO’S Universal Declaration on the human genome and human rights, 11 November 1997, *Law and the Human Genome Review*, pp. 119 – 141.-

¹² Deech, Ruth (2001): The torn veil of ignorance: The deciphering of the human genome and the consequences for societal solidarity in: Herbert Quandt Foundation, The foundation of Altana AG, Sinclair House Debates: Who owns the human genome? Bad Homburg v.d.Höhe, 2002, 46 – 55 (54)

2.3. The function of the bank

The Estonian solution was to establish an entity between the donors and research/business community. The chief processor, i.e. The Gene Data Bank, entrusted with the collecting, storing and processing the material is founded by the Estonian state. All fact gathering will be under control of this single processing entity.

Research entities can rely on the anonymous material (data) obtained from the chief processor. No private arrangements are allowed between individuals and gene labs, in order to avoid competition between fact-interested entities or special deals which would finally result in different legal protection.

So the chief processor will act as interface between single gene donor and researcher. It can decentralize certain operations like accepting the informed consent, taking tissue and completing health status description to the authorized processors who meet certain requirements (paragraphs 5 and 14).. However, it remains responsible for the whole process and it cannot delegate certain operations, including coding/decoding of the material, to third persons (paragraph 5).

The Act expressly provides that the chief processor shall appoint by name the officials who can perform certain operations (paragraphs 22 s.3 and 24, s.1), and will remain criminally responsible for any wrongdoing (paragraph 31).

2.4. Control instruments of the Gene Bank

The Bank is supervised by a specially created body, i.e. the Supervisory board of chief processor of Gene Bank. This board consists of nine members: Three members are appointed by the Parliament, upon proposal of the Social Affairs Committee; three members are appointed by the Government and three members are appointed by the Board of the Estonian Academy of Sciences (paragraph 4)¹³.

The Supervisory board establishes an Ethics Committee, which is entrusted with the elaboration of opinions about the processing procedures of the gene bank. The assessment of the Ethics Committee is not binding, except in one case¹⁴. The Ethics

¹³ The term of authority of a member of the supervisory board is from one year to five.(para. 4 s. 2). The body which appointed a member may remove him/her from the supervisory board with good reason, which includes, i.a. failure to perform his/her duties to a material extent, the causing of significant damage to the interests of the chief processor of Gene Bank or the commencement of bankruptcy proceedings against the member (para. 4, s. 3).

¹⁴ This case is provided for in clause 24, s.2, point 4: This article states down that the chief processor is allowed to decode data only, i.a. in order to identify a gene donor on the proposal of the chief processor and with the consent of the Ethics Committee, with the aim to contact the gene donor and to renew, supplement and verify description of his or her state of health with his or her written consent (Paragraph 29 section 1 in conjunction with paragraph 24, section 2, point 4).

Committee shall act pursuant to generally recognized ethical rules and international conventions (paragraph 29, section 2).

Supervision over the collection of descriptions of state of health and genealogical data, the coding and decoding of tissue samples, descriptions of DNA, descriptions of state of health, genealogical data, and the processing of tissue samples, descriptions of DNA, descriptions of state of health and genealogical data shall be exercised by the *data protection supervision authority* (paragraph 28). The chief processor shall obtain the approval of the data protection supervision authority for the method of generating the codes for the tissue samples, descriptions of DNA etc. (Paragraph 23. Section 1).

2.5. Human rights protection

The act confirms widely acknowledged basic ethical and legal principles¹⁵ related to human rights such as:

1. Contribution of one's tissue and health data for genetic research is voluntary and following the informed consent¹⁶, given to the authorized processor only; the act prohibits advocating or influencing an individual to become a gene donor. There should be no direct or indirect motivation thereto; it is the individual who should launch the process.
2. The gene donor will remain anonymous, anonymity is secured by the chief processor who will give the donated material unique code and replace all identifying data;
3. The gene donor has a right to know his gene data maintained in the Gene bank;
4. The gene donor has a right not to know his gene data. (paragraphs 8, 9, 10,11).
5. A gene donor has the right to permit disclosure of his or her identity (para. 8 s, 2)

¹⁵ Carulla, Santiago Ripol (1996, 1997): The protection of medical and genetic data in the Council of Europe's normative texts, *Law and the Human Genome Review*, 1996 pp.109 – 120 and 1997 pp. 101 – 127; Nielsen, Linda (1996): Genetic testing and privacy: a European perspective, *Law and the Human Genome Review*, pp. 59 – 76, De Sola, Carlos (1994, 1995): Privacy and genetic data- Cases in Conflict, *Law and the Human Genome Review*, 1994 pp. 173 – 184,1995 147 – 156; Ismini Krtiari – Catranis (1999): Genetic technologies and human rights, Athens, pp. 100 et seq (in Greek); the same: . Bioethical Issues and Human Rights in Greece in: *Law and the Human Genome Review*, No. 16 2002, pp. 37 – 57; Hendriks, Aart (2002): Genetic discrimination. How to Anticipate predictable problems?, *European Journal of Health Law*, pp. 87 – 92; Nunes, Rui/ Pereira de Melo, Helena(2000): Genetic testing in the workplace. Medical, ethical and legal issues, *Law and the Human GenomeReview*, pp. 119 – 142; Bompiani Adriano (2001): Current regulations on Treatment of Genetic Data in Italy, *European Journal of Health Law*, pp. 41- 50; see also the No. 3/ 2002 issue of *European Journal of Health Law*, dedicated to the implementation of the Directive 95/46 with contributions about Norway (Sverre Engelschion), Greece (Maria Canellopoulou – Bottis) and the Netherlands (Theo Hooghiemstra) .- For an American point of view see Cutter, Mary Ann G. (1999): Managing genetic testing information: legal, ethical and social challenges, *Law and the Human Genome Review*, pp. 167 – 185.-

Specific regulations refer to persons with restricted active legal capacity and persons without capacity to exercise will, in paragraph 13.

6. The fact of a person being or not being a gene donor shall remain classified. Only a person himself or herself has the right to disclose the fact of being or not being a gene donor and the circumstances thereof (para. 8 s. 3).

After initiating the fact gathering the gene donor still controls the data by following means:

1. Gene donors have the right to access personally their data stored in Gene bank (Paragraph 11, s. 2).
2. Gene donors have the right to submit additional information on themselves to the chief processor and the right to prohibit the supplementation, renewal and verification of descriptions of their state of health stored in the Gene Bank (Paragraph 12, sections 5 and 6).
3. Gene donors have the right to apply to the chief processor to destroy all coding information, so that his/her material can never be identified again (paragraph 21, section 1 in conjunction with paragraph 10).
7. If the identity of a gene donor is unlawfully disclosed the chief processor may be required to organize the destruction of the tissue sample, unless he/she can prove that the disclosure of the identity of the gene donor results from his/her own behavior. The burden of proof that gene donor himself broke the anonymity lies on chief processor. (paragraph 21, s. 2).
8. In the case of unlawful disclosure of genetic and medical data by health care professionals or other persons, which became known to them due to 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 such as detention or up to one year imprisonment (paragraph 31, s. 3)¹⁷.

III. The wisdom of the past

The Estonian project, which has already been imitated by Latvia, is a very interesting step in the effort undertaken worldwide to harness the huge potential of genetic research, although it cannot be transplanted in every country, due to differences in culture and mentality.

The concept of the gene data bank is based on two powerful technologies: Genetics and informatics. It seems that every effort has been undertaken to safeguard informational autonomy and self - determination, to provide for institutional safeguards and to endorse social acceptance and social sensitivity in this field. In this way it marks a definitive breakthrough in the discussion that dates back in the antiquity:

¹⁷ For further information see www.genomics.ee

In Homer's *Odyssey*, when Telemachus visits the palace of Menelaus, the King of Sparta receives him and invites him to dinner, saying:

When you have had your meal, we will ask you who you are... You belong to the race of heaven-protected and sceptred kings; **no lesser parents could have such sons.**

Queen Helen is of the same opinion: "Have we heard already, Menelaus, the names that our guests give themselves? ... Never, I think, have I seen such likeness in man or woman - amazement seizes me as I look. This boy is far too much like Odysseus to be any other than his son; surely he is Telemachus, the child that the hero left behind him, a baby in arms, when you Achaeans went up to Troy..." Menelaus answered her: "... Odysseus had just such feet and hands; his head and his hair were like this boy's; his eyes had the same glance..."

Telemachus reveals his identity in the course of the evening and Menelaus adds: "You are your father's son; your wisdom in speech comes from him. There is no mistaking the child of a man whom the son of Cronos marked out for happiness, both at bed and bridal"¹⁸.

So it seems that already at this early time it was widely recognized that there were good and bad hereditary traits referring both to character and the outer appearance, although the poet does not specify which traits about the phenotype were considered as the "preferred" ones. The presence of the good characteristics was attributed to the intervention of Gods. Further it was assumed that the individuals blessed with desired traits belonged to what would be -in today's vocabulary- the social and political élites.

The Homeric verses bear testimony to the importance bestowed to genetic traits already in these archaic days. Today it remains to be seen if the hopes associated with the establishment of the Estonian gene bank can meet the necessities of the genetic era and contribute to the protection of the individual in this sensitive and challenging field. It remains to be seen if they can stand the merciless scrutiny of time...

¹⁸ Homer, *The Odyssey*, Book IV, 60 et seq., 137 et seq., 208 - 209. Translation: W. Shewring, Oxford University Press, 1980, pp. 36, 38, 39).