Icelandic Supreme Court

Thursday 27 November 2003

No. 151/2003.

Ragnhildur Guðmundsdóttir

(Ragnar Aðalsteinsson, Attorney at Law)

vs.

The State of Iceland.

(Skarphéðinn Þórisson, Attorney at Law)

Protection of privacy. The Constitution of Iceland. Medical records. Personal data.

R appealed for a decision by the Court to overturn the refusal of the Medical Director of Health to her request that health information in medical records pertaining to her deceased father should not be entered into the Health Sector Database. Furthermore, she called for recognition of her right to prohibit the transfer of such information into a database. Article 8 of Act No 139/1998 on a Health Sector Database provides for the right of patients to refuse permission, by notification to the Medical Director of Health, for information concerning them to be entered into the Health Sector Database. The Court concluded that R could not exercise this right acting as a substitute of her deceased father, but it was recognised that she might, on the basis of her right to protection of privacy, have an interest in preventing the transfer of health data concerning her father into the database, as information could be inferred from such data relating to the hereditary characteristics of her father which might also apply to herself. It was revealed in the course of proceedings that extensive information concerning people's health is entered into medical records, e.g. medical treatment, life-style and social conditions, employment and family circumstances, together with a detailed identification of the person that the information concerns. It was recognised as unequivocal that the provisions of Paragraph 1 of Article 71 of the Constitution applied to such information and guaranteed to every person the right to protection of privacy in this respect. The Court concluded that the opinion of the District Court, which, inter alia, was based on the opinion of an assessor, to the effect that so-called one-way encryption could be carried out in such a secure manner that it would be virtually impossible to read the encrypted data, had not been refuted. It was noted, however, that Act No. 139/1998 provides no details as to what information from medical records is required to be encrypted in this manner prior to transfer into the database or whether certain information contained in the medical records will not be transferred into the database. The documents of the case indicate that only the identity number of the patient would be encrypted in the database, and that names, both those of the patient and his relatives, as well as the precise address, would be omitted. It is obvious that information on these items is not the only information appearing in the medical records which could, in certain cases, unequivocally identify the person concerned. Act No. 139/1998 also provides for authorisation to the licensee to process information from the medical records transferred into the database. The Act stipulates that certain specified public entities must approve procedures and process methods and monitor all queries and processing of information in the database. However, there is no clear definition of what type of queries will be directed to the database or in what form the replies to such queries will appear. The Court concluded that even though *individual provisions of Act No 139/1998 repeatedly stipulate that health information in the Health Sector Database should be non-personally identifiable, it is far from adequately ensured under statutory law that this stated objective will be achieved. In light of the obligations imposed on the legislature by Paragraph 1 of Article 71 of the Constitution, the Court concluded that various forms of monitoring of the creation and operation of the database are no substitute in this respect without foundation in definite statutory norms. In light of these circumstances, and taking into account the principles of Icelandic law concerning the confidentiality and protection of privacy, the Court concluded that the right of R in this matter must be recognised, and her court claims, therefore, upheld.*

Decision of the Supreme Court

Presiding in the case are Supreme Court Judges Guðrún Erlendsdóttir, Garðar Gíslason, Gunnlaugur Claessen, Markús Sigurbjörnsson and Pétur Kr. Hafstein.

The Appellant referred the case to the Supreme Court on 29 April 2003, calling for a reversal of the refusal of the Medical Director of Health to her request of 16 February 2000 to the effect that information from the medical records of her father, Guðmundur Ingólfsson, who died on 12 August 1991, should not be transferred into the Health Sector Database. The Appellant furthermore calls for the Court's recognition of her right to prohibit the transfer of the above information into the database. She also claims costs before the District Court, notwithstanding the legal aid provided to her before the present Court.

The Defendant calls for confirmation of the decision of the District Court and payment of costs before the Supreme Court.

I.

The Health Sector Database Act No. 139/1998 entered into force on 30 December 1998. According to Article 1 of the Act, the purpose of the Act is to authorise the creation and operation of a centralised database of non-personally identifiable health data, with the aim of increasing knowledge for the purpose of improving health and health services. Article 4 lays down the condition that authorisation for such operation is subject to an operating licence, for which conditions are laid down in Article 5 of the Act. Article 6 of the Act entrusts a specially appointed committee with the supervision of the creation and operation of the database to the extent that this does not fall within the terms of reference of the Data Protection Authority, which works on the basis of Act No. 77/2000 on the Protection of Individuals with regard to the Processing of Personal Data. Article 7 of Act No. 139/1998 contains instructions on the authorisation of the licensee to obtain data derived from the medical records of health institutions and self-employed health service workers. However, according to Article 8, persons who do not want information on them to be entered into the database can prevent this by a notification to the Medical Director of Health. Article 10 of the Act contains instructions concerning the utilisation of the database, including the purpose, restrictions and supervision, Article 11 provides for the obligation of confidentiality of the employees of the licensee and contractors in his service, while Article 12 contains further instructions on monitoring by the Data Protection Authority, the Committee on the Operation of the Database referred to above, and the so-called Multidisciplinary Ethics Committee. Finally, Chapter VI of the Act contains rules on the withdrawal and revocation of licenses, sanctions and damages.

The Minister of Health and Social Security issued Government Regulation No. 32/2000 on a Health-Sector Database on 22 January 2000. On the same date, the Minister issued a license to Íslensk Erfðagreining ehf. for the creation and operation of the Health Sector Database. The license was accompanied by seven annexes containing, first, General Specifications for Medical records Systems intended for use in medical institutions in connection with the reporting of information to the database, and second, Rules on the Transfer of Data. Third, it contained a summary of the Main Formal and Substantive Aspects of Agreements between the Licensee and Health Institutions and Self-Employed Health Service Workers, concerning access to the information contained in medical records. Fourth, it contained a Status Report on Health Data with the minimum requirements for databases and information systems. Fifth, it contained Terms of Financial Separation in the operation of the licensee between the departments concerned with the Health Sector Database and other departments in his operation, and sixth, a Register of Health-Care Professions permitted to record and process information for transfer into the database. Seventh, and last, the licence was accompanied by a document on the Technology, Safety and Organisation Terms of the Data Protection Commission for the database; the tasks of that Commission, however, have now been taken over by the Data Protection Authority.

The guardian of the Appellant, who was born in 1985, wrote a letter to the Medical Director of Health on 16 February 2000, with an enclosed notification in the Appellant’s name requesting that information contained in her father’s medical records should not be transferred to the Health Sector Database. Furthermore, the request was made that the genealogical or genetic information on the Appellant's father should not be transferred into the database. The Medical Director of Health replied by a letter dated 21 February 2001. Reference was made, *inter alia*, to the fact that Act No. 139/1998 contained no direct provisions on the right of the relatives of a deceased person to prevent information about him/her being transferred into the Health Sector Database. However, in the commentary attached to the legislative Bill which eventually passed into law it had been stated that it was not the intention that people should be able to refuse the transfer of information on their deceased parents into the database. The Medical Director of Health had obtained a legal opinion concerning this matter, which he enclosed with his reply. Based on this opinion he said that he could not comply with the Appellant's request.

Following receipt of the reply of the Medical Director of Health, the Appellant initiated these proceedings on 30 April 2001. Two of Guðmundur Ingólfsson's sons have declared in writing that they consent to the proceedings and there is no evidence from the parties that he left any other children apart from these.

Based on information that emerged in the course of proceedings before the Supreme Court, the compilation of the Health Sector Database has not yet started. There is, furthermore, some doubt that this will happen. The documents of the case do not reveal that formal measures for the preparation of the database have advanced significantly since the operating license was issued on 22 January 2000 to Íslensk Erfðagreining ehf. and the annexes to the license referred to above were ready.

II.

According to the principles of Icelandic law, the personal rights of individuals lapse on their death insofar as legislation does not provide otherwise. The previously mentioned Article 8 of Act No 139/1998 does not provide for the right of descendants or other relatives of deceased persons to request, on their behalf, that information in their medical records should be withheld from the Health Sector Database. No such rule can be inferred from any other sources of law. The Appellant cannot, therefore, exercise the right provided for in this statutory provision as her deceased father's substitute.

As stated in the appealed judgement, the Appellant bases her legitimate interest in the case partly on the fact that she has a personal interest in preventing the transfer of data from her father's medical records to the Health Sector Database, as it is possible to infer, from the data, information relating to her father's hereditary characteristics which could also apply to herself. The Defendant has not submitted to the court any expert testimony to rebut this contention of the Appellant. In light of this, and with reference in other respects to the reasoning of the District Court, the argument of the Appellant is accepted that, for reasons of personal privacy, she may have an interest in preventing information of this sort about her father from being transferred into the database, and therefore her right to make the claims that she is making in the case is admitted.

III.

Paragraph 2 of Article 2 of Regulation No. 227/1991 on Medical records and Reporting of Health Issues, as amended by Article 1 of Regulation No. 545/1995, includes rules concerning the data on the person and circumstances of a patient that should be included in medical records. According to Item 1 of the provision these should include the name of the patient, address, telephone number, identity number, professional title, marital status and next of kin. Item 3 states that entries into the medical record should include medical history, including information on diet, use of medicines, allergies to medicinal products, use of tobacco, alcohol and other intoxicants. According to Item 4 of the provision, an account should also be given of the family and social circumstances of the patient. In addition, there is an itemised list in ten numbered points concerning illness, medical treatment, subsequent course of events and physicians’ reports, which should be accounted for in the medical records at any time. This regulation was passed on the basis of Articles 16 and 18 of the Medical Act No. 53/1988, as current at the time. Those provisions were amended by Acts No. 76/1997 and No. 68/1998, so that they no longer seem to provide any basis for the regulation. In the course of oral pleadings before the Supreme Court, however, the Defendant stated his opinion that the regulation was still in effect, and this contention is supported in part by Article 29 of Act No 74/1997 on Patients’ Rights.

According to Paragraph 1 of Article 7 of Act No. 139/1998, it is permitted, with the approval of health institutions or self-employed health service workers, to provide data processed from medical records to the holder of an operating licence for a health sector database for transfer into the database. Health institutions shall consult with their physicians' council and professional managers before negotiating contracts with the licensee. Paragraph 2 of Article 7 of the Act states that the handling of records, other documents and information shall comply with the conditions regarded as necessary by the Data Protection Authority at any time. Personal identifiers must be encrypted by means of one-way coding, as defined in Items 4 and 5 of Article 3 of the Act, before the information is transferred into the database, in order to ensure that the licensee's staff only work with non-personally identifiable data. Health institution staff or self-employed health service workers must prepare the data for transfer into the database and the data must be transported in encrypted form. The Data Protection Authority is entrusted with the further encryption of personal identifiers using the methods regarded by the Authority as best suited to ensure the protection of personal privacy. Provisions on these matters are also contained in Regulation No. 32/2000, mentioned earlier, particularly Articles 9, 31 and 33, as well as in Article 16 on the form of agreements between the licensee and health institutions and self-employed health service workers. These do not delimit in further detail what information from medical records may be transferred into the Health Sector Database. This, however, is described to some extent in the previously mentioned annex to the operating license issued to Íslensk Erfðagreining ehf., which concerns the transfer of information into the Health Sector Database, although in this respect a distinction is drawn between information entered into medical records prior to the introduction of a harmonised electronic system of medical records and information entered after the introduction of such a system.

Article 10 of Act No. 139/1998 provides that data recorded in the Health Sector Database, or obtained by processing in the database, may be used to develop new or improved methods of achieving better health, prediction, diagnosis and treatment of diseases, to seek the most economic ways of operating health services, and to produce public health reports. The licensee is authorised to process data in the database from the medical records therein, provided that data are processed and connected in such a way that they cannot be traced to identifiable individuals. The obligation is imposed on the licensee to develop methods and protocols that meet the requirements of the Data Protection Authority in order to ensure protection of privacy in connecting data from the Health Sector Database, from a database of genealogical data, and from a database of genetic data. It is stated specifically in the provision that no information on individuals must be given, and this shall be ensured by means which include access restrictions. Also, the licensee is not permitted to provide direct access to data in the database. According to Paragraph 1 of Article 12 of the Act, the Data Protection Authority is responsible for monitoring the creation and operation of the database with regard to the recording and handling of personal data and the security of data in the database, and it is also responsible for monitoring compliance with conditions laid down by the Authority. The Committee on the Operation of the Database, mentioned above, is entrusted, in Paragraph 2 of the same Article, with monitoring the full compliance of the operation of the database with the provisions of the Act, regulations issued thereunder and the conditions of the operating licence. The committee is moreover responsible for monitoring all queries and processing of information from the database and also for reporting regularly to the National Bioethics Committee on all queries processed in the database and the sources of the queries. Moreover, Paragraph 3 of Article 12 of the Act provides for the obligation of the Minister to issue a regulation on an multidisciplinary ethics committee to evaluate licensee's research and queries to the database. According to the Act, the committee's evaluation must show that there are no scientific or ethical grounds for preventing the study in question from being carried out or for preventing the queries from being processed. The issues discussed here are also addressed in provisions in Articles 13, 14, 21, 26, 28 and 32 of Regulation No. 32/2000. However, it is not delimited in any significant further detail what type of queries will be addressed to the database or what form the replies to such queries will take with or without links with the database containing genealogical or genetic data. In the oral pleadings before the Supreme Court the Defendant stated that responses from the database would only have the form of statistical and completely non-personally identifiable data, although no rules had yet been issued and no decisions made concerning the further details of this matter.

IV.

As may be inferred from the above, extensive information is entered into medical records on people’s health, their medical treatment, lifestyles, social circumstances, employment and family. They contain, moreover, a detailed identification of the person that the information concerns. Information of this kind can relate to some of the most intimately private affairs of the person concerned, irrespective of whether the information can be seen as derogatory for the person or not. It is unequivocal that the provisions of Paragraph 1 of Article 71 of the Constitution apply to information of this kind and that they guarantee protection of privacy in this respect. To ensure this privacy the legislature must ensure, *inter alia*, that legislation does not result in any actual risk of information of this kind involving the private affairs of identified persons falling into the hands of parties who do not have any legitimate right of access to such information, irrespective of whether the parties in question are other individuals or governmental authorities.

Article 7 of Act No. 139/1998 opens the possibility of a private entity, who is neither a medical institution nor a self-employed health service worker, obtaining information from medical records without the explicit consent of the person whom the information concerns. Although this alone does not necessarily, in and of itself, violate the provisions of Paragraph 1 of Article 71 of the Constitution, the legislature, having regard to all of the above, must take steps, in the establishment of a rule of this kind, to ensure to the furthest extent that the information cannot be traced to specific individuals. The District Court, where the Bench included an assessor, concluded that the so-called one-way encryption discussed in Item 5 of Article 3 of Act No. 139/1998, could be carried out so securely as to render it virtually impossible to read the encrypted information. This conclusion has not been contested successfully in the course of the proceedings before the Supreme Court. It should be noted, however, that Act No. 139/1998 provides no guidance as to what information from medical records must be encrypted in this manner prior to transfer into the Health Sector Database or whether certain information contained in the medical records relating to the personal identity of the patient will not be transferred. Nor is this issue addressed in Regulation No. 32/2000. The annex to the operating licence issued to Íslensk erfðagreining ehf., mentioned earlier, which concerns the transfer of information to the Health Sector Database, appears to imply that only the identity number of the patient will be encrypted in the database and that the name, both of the patient and his family, together with the precise address will be omitted. It is obvious that information on these items is not the only information appearing in the medical records which could unequivocally identify the individual in question. In this regard, information concerning the age of a person, municipality of residence, marital status, education and profession, together with the specification of a particular disease, either all together or individually, might suffice. The law does not preclude the transfer of detailed information concerning these items into the Health Sector Database.

The provisions of Article 10 of Act 139/1998 discussed earlier do not specify what information from the medical records involving the personal identifiers of a patients which could be transferred into the Health Sector Database might be seen by a person receiving a response to a query submitted to the database. Nor are there any indications what overall picture could be gained in this respect from the connection of information from the Health Sector Database with databases containing genealogical information and genetic information, as discussed in the provision. Instead, it is merely provided that steps should be taken in the processing of information to preclude linking of the information with identifiable individuals. There are no further provisions on this in Regulation No. 32/2000. As mentioned earlier, no further plans are available concerning the actual implementation of this in the operation of the Health Sector Database.

Individual provisions in Act No. 139/1998 refer repeatedly to the fact that health information in the Health Sector Database should be non-personally identifiable. In light of the rules discussed above concerning the issues addressed in Articles 7 and 10 of the Act, however, the achievement of this stated objective is far from being adequately ensured by the provisions of statutory law. Owing to the obligations imposed on the legislature by Paragraph 1 of Article 71 of the Constitution to ensure protection of privacy, as outlined above, this assurance cannot be replaced by various forms of monitoring of the creation and operation of the Health Sector Database, monitoring which is entrusted to public agencies and committees without definite statutory norms on which to base their work. Nor is it sufficient in this respect to leave it in the hands of the Minister to establish conditions in the operating licence or appoint other holders of official authority to establish or approve rules of procedure concerning these matters, which at all levels could be subject to changes within the vague limits set by the provisions of Act No. 139/1998.

Article 8 of Act No. 139/1998 permits those who so wish to issue binding instructions to the effect that information about them should not be transferred from medical records into the Health Sector Database. In this way, those who, *inter alia*, may consider their right to protection of privacy threatened by this treatment of information are given the option of taking measures. It has been recognised above that the Appellant may herself have an interest in preventing the transfer of information from her father's medical records into the Health Sector Database because of the risk that inferences could be made from such information which could concern her private affairs. Based on the above, it is impossible to maintain that the provisions of Act No. 139/1998 will adequately ensure, in fulfilment of the requirements deriving from Paragraph 1 of Article 71 of the Constitution, attainment of the objective of the Act of preventing health information in the database from being traceable to individuals. Article 8 of Act No. 139/1998 neither provides for nor precludes a person in the position of the Appellant requesting that information from the medical records of a deceased parent should not be transferred into a health sector database. In light of this, and taking into account the principles of Icelandic legislation concerning protection of privacy, the Court recognises the right of the Appellant in this respect. Her court claims in this regard are therefore upheld.

In light of this conclusion of the case, the Defendant is ordered to pay the Appellant costs before the District Court and the Supreme Court, which will be determined in one sum as stated in the adjudication. For this reason there is no reason for any ruling on legal aid from the Defendant.

Adjudication:

The decision of the Medical Director of Health to deny the request of Ragnhildur Guðmundsdóttir, dated 16 February 2000, that information from the medical records of Guðmundur Ingólfsson, who died on 12 August 1991, should not be entered into the Health Sector Database, is reversed. The right of the Appellant to prohibit the transfer of this information into the database is upheld.

The Defendant, the State of Iceland, shall pay to the Appellant a total of ISK 1,500,000 in costs before the District Court and the Supreme Court.