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An analysis of the Icelandic Supreme Court judgement on the Health Sector Database Act

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Abstract

Six years after the Icelandic Health Sector Database Act came into force, the Supreme Court of Iceland as court of appeal was asked to give a judgement on the constitutionality of the Act. The appellant had unsuccessfully applied to the Director General of Public Health to prevent the transfer of her deceased father's medical records to the Health Sector Database. The court of first instance, the Reykjavik District Court, dismissed the case for lack of legal standing. The Icelandic Supreme Court decided that the appellant had legal standing due to the fact that from the data related to hereditary characteristics of her father information about the plaintiff herself could be inferred. The Icelandic Supreme Court further discussed privacy and data protection issues with regard to the Health Sector Database, coming to the conclusion that the one-way encryption system was a sufficiently safe mechanism for data protection, but that due to the richness of data to be entered into the Health Sector Database, individuals could be identifiable.

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1. Introduction

November 27, 2003 was a triumphant day for the opponents of the Icelandic Health Sector Database project. The legislation passed by the Icelandic government not for the benefit of scientists in general, but for one specific commercial company and enabling deCODE Genetics, a firm registered in the USA and based in Iceland, to set up a database consisting of the medical and genealogical records of the entire Icelandic population, living and dead, as well as tissue samples of every living Icelander, was considered unconstitutional by the Icelandic Supreme Court.¹ This decision could be of considerable international importance, taking into account the fact that genetic databanks are being established in many countries. The Icelandic court decision shows clearly that there are limits as to how far genetic research can intrude into the private lives of participants and how far the government can pass legislation on the scientists' behalf. This article provides an analysis of the decision reached by the Icelandic Supreme Court and determines which of the concerns about the Health Sector Database from various quarters have been addressed by the judgement and which remain unresolved.

2. An outline of the Icelandic Health Sector Database

The history and development of the Icelandic Health Sector Database has been much publicised with a multitude of articles written both in favour of, and in opposition to, the project.² Still, it is important to begin with a short outline of the development of the Health Sector Database from the original idea until the present day to depict the situation on which the Icelandic Supreme Court judgement is based.

In 1996, the biomedical company deCODE Genetics was founded in Delaware, USA by Dr Kari Stefánsson and Dr Jeffrey Gulcher. At the end of 1997, Stefánsson submitted the idea of a genebank to the Icelandic Minister of Health and convinced him of the feasibility and success of such a project. The idea was to utilise the already existing medical and genealogical records of all Icelanders and combine this information with the genetic information gained from tissue samples of the entire population. In effect, this would result in three different databases that could, and

¹ The translation of the judgement into English was provided by Mannvernd. A translation from the Icelandic Supreme Court itself was not available.

² See for example M Fortun "Breaking the code" (2001) *Rensselaer Mag*; J F Merz, G E McGee and P Sankar, "'Iceland Inc.'?: On the ethics of commercial population genomics" (2004) *Social Science & Medicine*; M Fortun "Breaking the code" (2001) *Rensselaer Mag*; S Sigurdsson "Bioethics Lite: Two aspects of the Health Sector Database deCODE controversy" in: T Hornschuch, K Meyer, G Rueve and M Voss: *Schoene gesunde neue Welt? Das humangenetische Wissen und seine Anwendungen aus philosophischer, soziologischer und historischer Perspektive* (2002) IWT –Paper 28; A Kong, J R Gulcher and K Stefánsson "Genealogy certainly matters in for multifactorial genetic disease" (1999) 319 *British Medical Journal*; J R Gulcher, K Kristjánsson, H Gudbjartsson and K Stefánsson, "Protection of privacy by third-party encryption in genetic research in Iceland" (2000) 8 *European Journal of Human Genetics*; S Sigurdsson, "Decoding Broken Promises" (2003) *Open Democracy*; J Potts, "At least give the natives glass beads: An examination of the bargain made between Iceland and deCODE Genetics with implications or global bioprospecting" (2002) 8 *Virginia Journal of Law and Technology*; O Hlodan, "For Sale: Iceland's genetic history" *ActionBioscience.org*, June 2000; N Duncan, "World Medical Association opposes Icelandic gene database" (1999) 318 *British Medical Journal*

would, be linked as well as operate separately: a genealogical database, a genetic one and one consisting of all past, present and future medical records from the entire Icelandic population, both living and dead.³ The reason given for performing the study in Iceland was the relative genetic homogeneity of the Icelandic population,⁴ an issue contested by some scientists as being basically wrong.⁵ Stefánsson drafted and submitted a bill for an enabling piece of legislation. On 31 March, 1998, the Icelandic Minister of Health introduced this first draft bill to the parliament. Finally, after several changes to the bill, the Health Sector Database Act was passed by the Icelandic parliament on 17 December, 1998.⁶ In October 1998, as an opposition to the Icelandic genebank, the organisation Mannvernd was established, consisting of Icelandic physicians and scientists.⁷

In 2000, an exclusive licence to commercial exploitation of the genetic database for 12 years with the possibility of renewal was granted to deCODE to construct the Health Sector Database (HSD) and develop the necessary informatics technology.⁸ As early as 1998, deCODE entered into non-exclusive arrangement with Hoffmann-LaRoche for a duration of 5 years with regard to genetic research and drug development.⁹ In 2002, a new agreement was enacted between deCODE and Hoffmann-LaRoche whereby deCODE agreed to provide Hoffmann-LaRoche with blood samples from the Icelandic project.¹⁰

Based on the fact that the Icelandic population was deemed to be genetically homogenous to a considerable degree as well as easily manageable - taking into account that the population numbers around 288,000 – the Health Sector Database Act provided for the entire population to be encompassed in the genebank. The medical and genealogical records of all citizens were to be used as the foundation for the health sector database. The records were to be obtained from medical practitioners and hospitals and consequently digitalised. Presumed consent was deemed sufficient for these two databases. However, Icelandic citizens could opt out of the medical records database. To do so, they were required to fill in a special form, available in health clinics. On 27 August, 2001, an agreement was executed between deCODE, the Icelandic Medical Association and the Director General of Public Health. In this agreement, deCODE agreed that citizens could have their data removed from this database after they had been collected if they filled in and submitted the opting out

³ M Fortun “Breaking the code” (2001) *Rensselaer Mag*

⁴ M Binyon, “An Icelandic saga unveils life’s secrets” (1999) *The Times*, February 13; J R Gulcher, A Helgason, K Stefansson, “Genetic homogeneity of Icelanders” (2000) *Nature Genetics*

⁵ E Arnarson, “Genetic heterogeneity of Icelanders” (2003) 67 *Annals of Human Genetics* 1; I Arnason, H Sigurgislason, E Benedikz, “Genetic homogeneity of Icelanders: fact or fiction?” (2000) *Nature Genetics*

⁶ Act No. 139/1998

⁷ see <http://www.mannvernd.is/english/index.html>.

⁸ J F Merz, G E McGee and P Sankar, “Iceland Inc.?: On the ethics of commercial population genomics” (2004) *Social Science & Medicine* p. 1202

⁹ S Sigurdsson “Bioethics Lite: Two aspects of the Health Sector Database deCODE controversy” in: T Hornschuch, K Meyer, G Rueve and M Voss: *Schoene gesunde neue Welt? Das humangenetische Wissen und seine Anwendungen aus philosophischer, soziologischer und historischer Perspektive* (2002) IWT –Paper 28

¹⁰ *ibid.*

form.¹¹ Part of the agreement was for the Icelandic Medical Association to drop its opposition to the database project.

Informed consent was to be required for the genetic samples that were to be taken from the entire Icelandic population. However, in May 2000, the Icelandic Biobanks Act was adopted, a piece of legislation that could enable deCODE to negotiate access to clinical samples collected or archived at various institutions. This access would be without express consent of the original donors.¹² If deCODE followed up on this, the company's assurance to secure informed consent from citizens donating samples would not be adhered to.¹³

In an article published in 2000, Stefánsson and Gulcher of deCODE explain the consent and encryption process. According to this article, all participants in the databases were going to remain anonymous, made feasible through one-way encryption.¹⁴ The paper medical records were to be encoded, converting social security numbers to an alphabet-derived character string.¹⁵ From this list the opt-outs would then be removed and the list would be delivered to the laboratory. The government's Personal Data Protection Authority would encrypt the remaining data for use in the final database.¹⁶ Once donors had given their consent, blood would then be taken and stored in containers labelled with a barcode sticker with a number acting as a temporary coded identifier so that the blood sample could be matched with the data regarding the donor already collected from the medical and genealogical records. The final link was then encoded again and sent to the laboratory on a sealed computer disk together with the blood samples.¹⁷

At this time, the Health Sector Database has not yet been initialised; none of the medical records have yet been transferred. In fact, several physicians have stated their intention of refusing outright to hand over any medical records of their patients. Since deCODE Genetics has to contract with each physician and hospital to obtain the records, no estimate can be given as to when the database might become operational.

3. Background of the judgement of the Icelandic Supreme Court

As already touched upon briefly above, one of the disputed aspects of the Health Sector Database Act was the fact that the medical records of deceased Icelanders were to be included in the database without the possibility for relatives to demand the

¹¹ Joint Statement of the Icelandic Medical Association and deCODE genetics on the health sector database, Reykjavik, Iceland: Ministry of Health and Social Security, August 27.

¹² J F Merz, G E McGee and P Sankar, "Iceland Inc.?: On the ethics of commercial population genomics" (2004) *Social Science & Medicine*

¹³ A Kong, J R Gulcher and K Stefánsson, "Genealogy certainly matters in for multifactorial genetic disease" (1999) 319 *British Medical Journal*, p. 578

¹⁴ J R Gulcher, K Kristjánsson, H Gudbjartsson and K Stefánsson "Protection of privacy by third-party encryption in genetic research in Iceland" (2000) 8 *European Journal of Human Genetics*

¹⁵ *ibid.*

¹⁶ J F Merz, G E McGee and P Sankar, "Iceland Inc.?: On the ethics of commercial population genomics" (2004) *Social Science & Medicine* p. 1202, 1203

¹⁷ J R Gulcher, K Kristjánsson, H Gudbjartsson and K Stefánsson, "Protection of privacy by third-party encryption in genetic research in Iceland" (2000) 8 *European Journal of Human Genetics*, p. 741

opting out clause for the deceased. On 30 April, 2001, Birna Þórðardóttir filed a suit before the Reykjavik District Court against the Director General of Public Health on behalf of her daughter, Ragnhildur Guðmundsdóttir, a minor. The claim was for annulment of an administrative decision made by the defendant on 16 February, 2000, rejecting the plaintiff's request not to transfer the medical records of the plaintiff's deceased father to the Health Sector Database pursuant to Act No. 139/1998, the Health Sector Database Act. On 31 October, 2001, the Reykjavik District Court dismissed the case on the grounds that the data were not personally identifiable and that the plaintiff had no standing in the case. That same day, the plaintiff appealed to the Icelandic Supreme Court, who instructed the lower court to take the case for material hearing. On 13 February, 2002, the Reykjavik District Court denied the plaintiff's request to allow expert witnesses in the field of computer science to be heard. On 3 March, 2003, the Reykjavik District Court ruled that the defendant was not guilty of the charges brought by the plaintiff. On 29 April, 2003, the appellant, Birna Þórðardóttir on behalf of Ragnhildur Guðmundsdóttir, referred the case to the Icelandic Supreme Court.

The Icelandic Supreme Court made the following 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.”¹⁸

4. The main aspects of the judgement

The judgement of the Icelandic Supreme Court dated 27 November, 2003 can be divided into several main aspects.

4.1. Legal standing

The first item analysed by the Icelandic Supreme Court was that which had led to the original dismissal of the case by the Reykjavik District Court. While the lower court had based its decision on the finding that the plaintiff had no legal standing, the Icelandic Supreme Court followed a different reasoning, granting legal standing to the appellant. The Supreme Court based its decision on the appellant's right to privacy, stating that information about the plaintiff herself could be inferred from the data related to hereditary characteristics of her father and that these data could apply to herself.¹⁹ This provided the appellant with legal standing and a personal interest in preventing the integration of her deceased father's medical records into the Health Sector Database.

¹⁸ Icelandic Supreme Court, No. 151/2003

¹⁹ Icelandic Supreme Court, No. 151/2003, para. II.

The question of a person's legal standing and personal interest when attempting to refuse the inclusion of a deceased relative's medical data could be seen as a feature which is specific to the Icelandic database. From an international perspective, the Icelandic Health Sector Database Act is the only piece of legislation that expressly provides for the medical data of deceased individuals to be transferred into a database with no provision for opting out, irrespective of the wishes of the relatives. The Estonian Genome Project, for example, requests that citizens fill in a questionnaire which includes genealogical questions, also containing information about deceased relatives and the respective causes of death. However, before filling in these questionnaires, Estonians are provided with detailed information about the questionnaire and what it will be used for. Accordingly, taken from this perspective, the legal standing aspect of the Icelandic Supreme Court's judgement is the one with the least international significance.

However, it depends very much on the characterisation of the circumstances and the definition of 'personal data' whether the Icelandic situation can be seen as unique in this way. The European Data Protection Directive 95/46 provides a definition for 'personal data'. Accordingly, 'personal data' encompasses information that relates to one identified or identifiable person. Identifiable in this respect means that the person can be identified through a list of means, namely by reference to an identification number or to factors specific to the person's physical, physiological, mental, economic, cultural or social identity.²⁰ However, if 'personal data' are considered to be one's own data by virtue of one's blood relationship with a deceased person, 'personal data' encompass a much wider meaning than set out in Directive 95/46/EC. If such a broad meaning were to be considered, the entire data protection legislation would have to be rethought. The Data Protection Directive and associated laws would potentially be under threat. The way in which the Icelandic Supreme Court reached the decision to grant legal standing to the appellant follows along the lines of a broader meaning of 'personal data' and bases the decision on genetic reasoning.

As in many legal systems, under Icelandic law, personal rights end with the death of the individual unless legislation provides otherwise. While the Icelandic Health Sector Database Act provides for the inclusion of the personal information about deceased citizens in the database, there is no provision for descendants or other relatives to execute the right to opt out on their behalf. The Icelandic Supreme Court, however, attempted to find a way to circumvent this prohibition to grant legal standing to the appellant. The Court reached its desired aim through recognising that personal information about the appellant herself could be derived from the personal information related to the hereditary characteristics of her father. As it stands, the genetic background to the way this decision was reached is questionable to a certain degree.

First, it has to be taken into consideration that all humans share 99.9% of their DNA with each other.²¹ What varies is the arrangement of the base pairs of DNA. In this connection, the research described by Cavalli-Sforza needs to be taken into account.²²

²⁰ Directive 95/46/EC, Art. 2 (a)

²¹ K Finkler, C Skrzynia, J P Evans, "The new genetics and its consequences for family, kinship, medicine and medical genetics" (2003) 57 *Social Science & Medicine*

²² L L Cavalli-Sforza, *Genes, peoples and languages* (2000), p. 42, 43

Cavalli-Sforza illustrates how due to genetic drift, populations tend to be homogenous to a high degree. An example given by him is the discovery of “Oetzi”, a bronze-age man in the Austrian/Italian alps. DNA analysis showed that “Oetzi’s” DNA showed a remarkable similarity to the DNA of people living in the same region today.²³ If Icelanders are as genetically homogeneous as proclaimed by Gulcher and Stefánsson, should legal standing then not be given to each Icelander in such a case? And could each Icelander then challenge the inclusion of every other Icelander in the database on the basis that the Icelandic population is supposedly so remarkably homogeneous? Surely this can be classified as an undesired and undesirable result.

Second, following the court’s reasoning, every Icelander could not only object to his/her deceased parent’s data being included in the database, but also those of his/her living parent’s. The genetic connections would be the same and would provide this person with legal standing before court. This means that every Icelander would be able to take his/her parents to court and demand that they opt out of the database, a result that was surely not intended by the Supreme Court. Not only would this have the potential to disrupt family life to a considerable extent, it also focuses on a problem that commentators in legal and ethical studies as well as in social sciences have remarked on, namely the tension between the individual and the family regarding genetic information.²⁴ Modern medicine regards diseases increasingly as founded in genetic inheritance with medical genetics and genetic counselling based largely on knowledge of family and the family history of illnesses.²⁵ In this context, genetic data is difficult to define due to this tension between the individual and the family, taking into consideration that certain family medical records can be classified as genetic data.²⁶ As Heyd points out, genetic testing may affect other persons besides the individual being tested, for example if an inherited disease is determined. Basically, the decision in favour of an inquiry into the genetic make-up will ultimately have an influence on other family members.²⁷ Attempting to find a solution to the tension of family versus individual in the field of genetic information, or even providing an in-depth discussion, however, would be well outside the frame of this paper.

Third, Icelanders have been granted legal standing for requesting that their deceased parents’ medical information not be included in the Health Sector Database. Every individual shares 50% of his/her genetic material with father and mother. These 50% are obviously be deemed to be sufficient by the Icelandic Supreme Court to infer information about the plaintiff could be inferred from the data related to hereditary characteristics of each parent. This allows the question to arise whether grandchildren would be granted legal standing to challenge their grandparents’ inclusion in the database, taken into consideration that they share 25% of their genetic material with their grandparents. Or, similar, whether legal standing would be granted to challenge

²³ *ibid.*, p. 34, 35

²⁴ see for example J Sándor, “Genetic information: science, society and legal norms” in: J Sándor (ed.), “Society and genetic information: codes and laws in the genetic era” (2003), p. 22

²⁵ K Finkler, C Skrzynia, J P Evans, “The new genetics and its consequences for family, kinship, medicine and medical genetics” (2003) 57 *Social Science & Medicine*

²⁶ J Sándor, “Genetic information: science, society and legal norms” in: J Sándor (ed.), “Society and genetic information: codes and laws in the genetic era” (2003), p. 22

²⁷ D Heyd, *Genethics: moral issues in the creation of people*, (1992)

the inclusion of the siblings of their parents in the database. Thus, the judgement opens up many more questions than it provides answers to.

4.2. The consent issue

It is warranted to say that the issue, which aroused most of the criticism regarding the Icelandic Health Sector Database, is the use of presumed rather than informed consent.²⁸ The background to the debate is the internationally accepted standard of requiring informed consent for genetic research carried out on human subjects. This norm is laid down in legal texts and guidelines such as the Helsinki Declaration,²⁹ the CIOMS guidelines,³⁰ the recommendations by HUGO³¹ as well as in European legislation. However, instead of informing the population of Iceland about the Health Sector Database and all that it encompasses, and subsequently asking the citizens for consent to have their medical records entered into the database and to link this database with the genealogical and the genetic database, the Icelandic government adopted national legislation containing the provision of presumed consent. The justification provided by the Icelandic government for this use of presumed instead of informed consent is that the information is supposed to be non-identifiable and that Icelanders can opt out.³² Furthermore, the technophile character of the Icelandic population was mentioned and the assumption that people would act in the interest of the community.³³ Still, obtaining informed consent from the Icelandic population would not have been an insurmountable task. One of the reasons for choosing Iceland to create a population-based database was the very fact that the Icelandic population was relatively small. Also, as deCODE Genetics claims to have overwhelming public support, the danger of citizens not giving their consent would not have been overly large.³⁴

The topic of presumed versus informed consent, however, is only touched upon briefly by the Icelandic Supreme Court. As it stands, the entire judgement dedicates only two sentences to the consent problem, pointing out that Article 7 of the Health Sector Database Act provides private entities, who are neither medical institutions nor health-service workers of any kind, with the possibility to obtain information from medical records without any informed consent given by the individuals to which the information refers. While this simple fact did not constitute a violation of Paragraph

²⁸ see for example D Winickoff, "Biosamples, genomics, and human rights: context and content of Iceland's Biobanks Act" (2000) 4 *Journal of BioLaw and Business*; J F Merz, G E McGee and P Sankar, "'Iceland Inc.': On the ethics of commercial population genomics" (2004) *Social Science & Medicine*; M Fortun, "Breaking the code" (2001) *Rensselaer Mag*

²⁹ <http://www.wma.net/e/policy/b3.htm>.

³⁰ http://www.cioms.ch/frame_guidelines_nov_2002.htm.

³¹ <http://www.gene.ucl.ac.uk/hugo>.

³² D Winickoff, "Biosamples, genomics, and human rights: context and content of Iceland's Biobanks Act" (2000) 4 *Journal of BioLaw and Business*; J Potts, "At least give the natives glass beads: an examination of the bargain made between Iceland and deCODE Genetics with implications for global bioprospecting" (2002) 7 *Virginia Journal of Law and Technology*, p 13; M Fortun, "Breaking the code" (2001) *Rensselaer Mag*

³³ H Rose, *The commodification of bioinformation: the Icelandic Health Sector Database*, (2001), p. 12

³⁴ H T Greely, "Iceland's plan for genomics research: facts and implications" (2000) 40 *Jurimetrics J*, p. 180

1, Article 71 of the Icelandic Constitution, all legislation should take care to ensure that the information could not be traced back to individuals. The Court then proceeds to discuss the issue of encryption of the data so that information cannot be traced back to specific persons and continues to comment on the privacy issue without returning to the consent question.

However, the possibility of identifying individuals through the information contained in the database links directly with the problem of informed consent which can be deducted from international legislation and guidelines, at least some of which are legally binding for Iceland. Regard should be had to guidelines as early as the Nuremberg Code,³⁵ which was established after the Nuremberg trials as a consequence of the unethical medical research performed in Nazi Germany. The Nuremberg Code contains the provision that informed consent is required for medical research, values which were then adopted into the principles of the Helsinki Declaration. However, the Helsinki Declaration does not distinguish between anonymous and identifiable data. Accordingly, any and all medical research, whether with strictly anonymous data or personally identifiable information, requires informed consent from the research subjects. The European Directive 95/46,³⁶ on the other hand, makes this distinction. For data that is not identifiable in any way, presumed consent is sufficient, but according to Art. 8 of the Directive, for personal data from which a person can be identified, explicit consent is required.

The question that needs to be answered with regard to the requirement for informed consent is whether the information contained in the Health Sector Database is personally identifiable. The Icelandic Supreme Court answers this question clearly in the affirmative and argues that due to the richness of the data and the fact that the Health Sector Database would link up with the genealogical and the genetic database, individual persons could be identified without the use of complicated technology and great manpower. Iceland as a member of the EEA has to adhere to Directive 95/46 on Data Protection.³⁷ Following the Icelandic Supreme Court on the issue of personal identifiability, the Health Sector Database Act would violate Directive 95/46 by entering personally identifiable data into the database without previous explicit consent. The Court, however, instead of making this connection, focuses its findings solely on the Icelandic Constitution, especially Paragraph 1 of Article 71, which stipulates that everyone has the right to freedom from interference with privacy, home and family life. While the Court discusses the privacy and data protection issues in this connection, no further mention of the consent issue is made. While consent should provide the threshold mechanism for becoming involved in the database at all, privacy provisions should protect people once they have become involved, i.e. once their data have been entered into the database. The two protection mechanisms are closely linked, as on one hand participants can be involved in the database without their explicit consent if their privacy is guaranteed, i.e. if the data cannot be personally identified. On the other hand, if this is not guaranteed, if the data can be traced back to individuals, explicit consent is required. The Icelandic Supreme Court,

³⁵ <http://www.med.umich.edu/irbmed/ethics/Nuremberg/NurembergCode.html>.

³⁶ OJ L281/31

³⁷ In May 1992 the European Economic Area (EEA) Agreement was signed by Norway, Iceland, Liechtenstein and Switzerland in Oporto and entered into force on 1 January 1994. Directive 95/46/EC was included in the EEA Agreement on 25 June, 1999 through Decision 83/1999.

however, fails to make this important connection. Commentators worldwide on the Icelandic Health Sector Database will be disappointed with this missed opportunity for clarification on the consent question. Taking the diversity of types of consent in account, ranging from broad, open consent to narrow, specific consent for one research project, some guidelines by the Icelandic Supreme Court would have been welcomed.

Considering the present situation in Iceland, however, the significance of asking the population for informed consent to the transfer of medical records to the Health Sector Database now seems rather inconsequential. As Hoeyer and Lynoe point out, the Icelandic citizens have heard the debate about the database through the media in great detail.³⁸ The question that needs to be asked is what further information a consent form could provide, what additional news could be offered. Seeing informed consent as the saving grace in the Icelandic context would seem to be a rather belated effort.³⁹ In this case, the change to informed consent would be too little too late and would only constitute an end in itself.

This could be considered as an argument in favour of the opt-out system. However, an opt-out system can never replace the signing of an explicit informed consent form. For a research project funded by the Wellcome Trust, Rose studied the Icelandic Health Sector Database and also did field work in Iceland.⁴⁰ In interviews with Icelandic citizens it became clear that in order to opt out, people had to actively seek out their physicians' surgeries and request a form, then fill it in and resubmit it, proved to be too much of an effort. People who under other circumstances would not have consented to having their medical records transferred to the Health Sector Database, did not obtain an opt-out form. Rose gives an example of a flight attendant in her late twenties, who proclaimed that she did not want to know whether she would die of a heart attack in her forties, and that she didn't want anybody else to know either. When asked if she was going to opt out, she replied that she wasn't going to bother, because it all "seemed a bit unreal".⁴¹

4.3. Data protection issues

The Icelandic Supreme Court divides the data protection issue into two aspects. First, the Court discusses the security of the one-way encryption system and second, provides an analysis of the privacy provisions of the Icelandic Constitution.

4.3.1. *The one-way encryption system*

In its findings the Icelandic Supreme Court states that the type of one-way encryption as scheduled by the Health Sector Database Act is sufficient with regard to data confidentiality and that the encryption could be carried out in such a way that it would be virtually impossible to read the encrypted information. As elaborated by the Icelandic Supreme Court, the District Court decision regarding the security of the data

³⁸ K. Hoeyer, N Lynoe "Is informed consent a solution to contractual problems? A comment on the article "Iceland Inc.?" On the ethics of commercial population genomics" (2004) 58 *Social Science & Medicine*, 1211

³⁹ *ibid.*

⁴⁰ H Rose, *The commodification of bioinformation: the Icelandic Health Sector Database*, (2001)

⁴¹ *ibid.*, p. 24

was not successfully contested. Instead, the Supreme Court pointed towards the fact that the Health Sector Database Act contained no provision giving any clear instruction as to which information from the medical records was to be encrypted in such a way before being transferred into the database or whether certain information regarding the personal identity of people was not to be transferred at all. Still, from the various comments on the database and the elaborations of Dr Stefánsson, the only data to be encrypted will be the national identity number of each person whose data will be entered into the Health Sector Database, while the name and address will be omitted.⁴²

To understand fully the reasoning behind the issue of one-way encryption, a look back needs to be taken to the time when the first drafts of the Health Sector Database bill were submitted. When Dr Kari Stefánsson drafted the first bill, he included a definition of “personal information” that contained the words “An individual shall not be counted as nameable if a considerable amount of time and manpower would be required in order to name him/her. When an individual is not nameable the information about him/her shall not be considered to be personal information”.⁴³ This draft bill was submitted to the Ministry of Health in September 1997. A modified draft was later presented to the Icelandic Parliament in Spring 1998.

A further addition was made to the original draft, containing the provision that if a key to the data existed, individuals should not be considered personally identifiable when the body in possession of the data did not have access to that key. The sentence “The same applies if the identification could only take place through use of a decoding key, not available to the person having the information” was inserted between the two original sentences. The definition regarding personal identifiability through a “considerable amount of time and manpower” are derived from the Council of Europe Committee of Ministers on the protection of medical data, Recommendation No R(97)5, which was given to the Member States.

After considerable opposition from both the Parliament and the Icelandic public, the bill was amended again. This draft again contained the requirement of “considerable time and manpower” for the data to be considered identifiable. This draft was sent out to several official Icelandic bodies, amongst those the National Bioethics Committee and the Icelandic Data Protection Commission. The response from the Data Protection Commission was a sharp criticism of the draft bill’s definition of personal data and the requirement for identifiability. For the first time, the attention was drawn to the European Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. As already mentioned above, Iceland as a member of the European Economic Area was legally bound to adhere to this Directive. The Directive, however, does not mention the time or manpower needed to identify personal data.

The final draft of the bill was then changed accordingly and contained the definitions of the Directive: “An individual shall be counted as personally identifiable if he can

⁴² see for example: E Arnason, “Personal identifiability in the Icelandic Health Sector Database” (2002) 2 *The Journal of Information, Law and Technology*; R Anderson, “The deCODE proposal for an Icelandic Health Database” (1998) <http://www.l.cam.ac.uk/users/rja14/iceland/iceland.html>; O M Arnardottir, D Björgvinsson and V M Matthiasson, “The Icelandic Health Sector Database” (1999) 6 *European Journal of Health Law*

⁴³ Article 2, draft Health Sector Database bill, dated July 14, 1997

be identified, directly or indirectly, especially by reference to an identity number, or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.”⁴⁴

In concluding that the encrypted data were indeed anonymous and not personal data as defined in Article 2 of the Act, the Icelandic Supreme Court comes to the same conclusion as can be found in the report of the Council of Europe Steering Committee on Bioethics, who performed a study on the Health Sector Database in 1999. This report, which has mistakenly been interpreted as the Council of Europe’s opinion instead of the Icelandic Government’s evidence,⁴⁵ contains the conclusion that the main criterion to be applied was that of reasonableness.⁴⁶ The Steering Committee deduced that an identification of individuals “cannot be regarded as reasonably possible without substantial effort” and continued that the information contained in the Health Sector Database had to be considered to be anonymous according to international law.⁴⁷ This was based on the fact that according to Article 7 of the Health Sector Database Act, the one-way encoding system meant that no key for decoding the information was allowed. Accordingly, the question that needed to be answered was not whether the Health Sector Database Act is in accordance with Directive 95/46, but whether a key existed in direct violation of Article 7 of the Act. It will have to be taken into account, however, that this report was prepared by the Icelandic Ministry of Health and Social Security and is not an official Council of Europe document.

In 2000, Dr Stefánsson gave an interview in the *New Scientist*. When discussing the situation of identifying a family with a certain disease, he mentioned contacting that family and asking for a blood sample as well as for permission to cross-reference their names with the Health Sector Database. When asked how the identification from the Health Sector Database was to be made possible, Dr Stefánsson replied that while the information in that database was to be encrypted, the keys would be kept by the Icelandic Data Protection Commission. Also, deCODE Genetics’ Department of Database explained in an interview in the Icelandic newspaper *Morgunblað* that the encryption would be performed using a special key, which supposedly adhered to the strictest technical security measures. The statement regarding technical security measures that the keys would fulfil is a reference to the requirement of the Council of Europe Committee of Ministers Recommendation No R(97)5, which requires “considerable time and manpower” to decrypt the information. Due to the changes in the Health Sector Database bill, these requirements have become obsolete, since

⁴⁴ Article 2, draft Health Sector Database bill, dated October 1998

⁴⁵ R Chadwick, “The Icelandic database - do modern times need modern sagas?” (1999) 319 *British Medical Journal*, p 442; corrected by: H Rose, “The commodification of bioinformation: the Icelandic Health Sector Database”, (2001) the Wellcome Trust; B Andersen, E Arnason and S Sigurdsson, “Kafkaesque ethics for post-modern vikings” (1999) 319 *British Medical Journal*; also confirmed in a correspondence with Helen Leatherby, Steering Committee on Bioethics, on file with the author

⁴⁶ H Rose, “The commodification of bioinformation: the Icelandic Health Sector Database”, (2001) the Wellcome Trust; B Andersen, E Arnason and S Sigurdsson, “Kafkaesque ethics for post-modern vikings” (1999) 319 *British Medical Journal*; also confirmed in a correspondence with Helen Leatherby, Steering Committee on Bioethics, on file with the author

⁴⁷ Council of Europe Steering Committee on Bioethics, “The Icelandic act on a health sector database and Council of Europe conventions” Strasbourg: Ministry of Health and Social Security, 1999 (CDBI-CO-GT2(99)7 1999)

Directive 95/46 was used as a base for the Health Sector Database Act, meaning that the criterion of “considerable time and manpower” was not applicable. However, the Health Sector Database Act also included the explicit prohibition of any key to decode the data. The fact remains that a key to identify personal data obviously does exist. According to the Health Sector Database Act, it does not matter who has possession of the keys, the person with access to the data or somebody else. Considering the fact that further information is scheduled to be added to the Health Sector Database once it is established, the necessity for a key and therefore the violation of the Icelandic Health Sector Database Act becomes obvious.⁴⁸ The Icelandic Supreme Court, however, does not reach this conclusion. The important question whether a key to decode the information transferred into the database is not touched upon. Accordingly, the fact that with the existence of a key, the Database seemed in obvious violation of a provision of the Health Sector Database Act itself also did not appear in the judgement.

4.3.2. *Identifiability due to richness of data*

The second part of the Icelandic Supreme Court judgement with regard to data protection deals with the variety and multitude of data to be entered into the database. In the annexes to the operating licence for deCODE Genetics it is implied that the name and addresses of the patients and their families would be completely omitted from the database and that the patient’s identity number would be encrypted. All other information, however, such as marital status, education, profession, municipality of residence and age of the person as well as specific diseases would be transferred to the database. From this fact, the Icelandic Supreme Court drew the conclusion that even without having access to the identity number or the name and address of the individual, an identification could be possible and accordingly both the terms of the Constitution and international treaties regarding the handling of personally identifiable data applied. A fact that also needs to be taken into account in this context is the size of the Icelandic population, which results in a very limited number of births a year. Considering that the creation of new jobs for Icelanders was one of the incentives of the Health Sector Database project, it can safely be assumed that the employees of the Health Sector Database will mostly be Icelanders. That, however, increases the probability of an employee recognising individuals from the richness of data entered into the database to a considerable degree, thus making the data in the database personally identifiable.⁴⁹

The Icelandic Supreme Court realises this problem when it discusses the richness and variety of the data that will be transferred into the Health Sector Database, namely

⁴⁸ see Data Protection Commission’s Opinion on the draft Bill on a health-sector database, commissioned 4 September 1998: “In the general notes to the Bill, however, it is assumed that the data on the database will be regularly updated, as new data are added. From this it may be inferred that the Bill assumes that the data will be coded and not disconnected from personal identifiers.”; H Greely, “Iceland’s plan for genomics research: facts and implications” (2000) 40 *Jurimetrics J*, p 185; JPotts, “At least give the natives glass beads: An examination of the bargain made between Iceland and deCODE Genetics with implications for global bioprospecting” (2002) 7 *Virginia Journal of Law and Technology* 8, p 13

⁴⁹ H Greely, “Iceland’s plan for genomics research: facts and implications” (2000) 40 *Jurimetrics J*, p 186, see also Data Protection Commission’s Opinion on the draft Bill on a health-sector database, commissioned 4 September 1998, III. Observations on individual articles of the Database Bill, on Art. 1

information about the age, municipality of residence, education, marital status and profession of an individual. The Court then combines the aspect of data protection with that of access to the data, taking the position that any law must ensure that such information which involves the private affairs of identifiable persons does not fall into the hands of third parties who do not have a legitimate right of access to the information in question. This was to be the case whether the third parties consisted of other individuals or of governmental authorities.

Obviously, the Health Sector Database Act falls short on the data protection issue. While supposedly secure through the encryption of the identity number and omission of the name and address, the Act does not take into account that individuals can be identified through means other than their name and identity number and the Icelandic Supreme Court reaches the conclusion that in this respect, the Act violates the provisions on privacy contained in the Icelandic Constitution, Paragraph 1 of Article 71, which state “Everyone shall enjoy freedom from interference with privacy, home and family life.”

4.4. Open queries into the database

Another problem the Icelandic Supreme Court depicted was that of open queries into the database as regulated by Article 10 of the Health Sector Database Act. While Article 10 prohibits the licensee from providing direct access to the database, queries can be processed and answered with information from the database. However, what type of queries will be permitted and/or what form the replies will have is not regulated. Background to this problem is the fact that deCODE Genetics demanded that the query layer be opened up further, which was refused by the Icelandic Data Protection Authority. By recognising the problem and stating that the information given out has to be limited strictly to anonymous data without any personal identifier, the Icelandic Supreme Court strengthened and supported the position of the Data Protection Authority. Still, as the Court realised, the need for further regulation of the types of queries made to the databases and the types of reply to be given out is in need of further consideration.

4.5. Monitoring of the Health Sector Database

A further remark by the Supreme Court was related to the monitoring of the Health Sector Database.

This aspect of the judgement needs to be considered in light of the change of the National Bioethics Committee.

Both the Health Sector Database Act and the setting up of the genetic databank fall under the control of the National Bioethics Committee, which was originally established in 1997. The 7 Committee members were appointed by the Minister of Health based on nominations from the Faculty of Medicine, the Institute of Ethics, the Institute of Biology and the School of Law, all University of Iceland, the Icelandic Nurses Association and the Icelandic Medical Association. In 1999, however, the

Minister of Health cancelled the regulation on biomedical research and issued a new regulation, reducing the National Bioethics Committee to only 5 members.⁵⁰

For the new Committee, the government nominates all members; 1 each is nominated by the Minister of Education, the Minister of Justice and the Director General of Public Health and the remaining 2 members are appointed by the Minister of Health without any nomination.⁵¹ The duties of the new Bioethics Committee were to be approving research protocols with patient involvement as well as providing the politicians with general advice on ethical aspects of medical treatments. The official argument against criticism of this change was that the new committee members were free to be frank and open concerning their opinions.⁵² However, when attempting to determine the reasoning behind the sudden change in the Bioethics Committee, it has to be taken into account that this change took place after the original Committee began criticising the plans for the Health Sector Database. Furthermore, the Committee had begun establishing guidelines for informed consent in accordance with the Icelandic Act on Patients' Rights and with international conventions and principles. Had these guidelines been established, they would have affected the Health Sector Database considerably. deCODE Genetics would have had to abide by them when connecting the Health Sector Database to the genetic database.⁵³ It is therefore doubtful whether this new Committee will wish to speak their minds with regard to the database, considering what happened to their predecessors. Also, the possibility will have to be taken into account that only those already in favour of the Health Sector Database will be appointed in the first place.

The Court, however, commented on the lack of independent review mechanisms for the Health Sector Database only indirectly. Rather, the remarks were focussed on the fact that the statutory provisions were insufficient in ensuring the privacy provided for in Paragraph 1 of Article 71 of the Icelandic Constitution, which imposes the protection of privacy on all legislation. The Court stated that this constitutional guarantee cannot be replaced by any review and monitoring mechanisms for the Health Sector Database. Moreover, public agencies and committees such as the National Bioethics Committee were supposed to perform their monitoring functions without any statutory norms to regulate them. This part of the judgement refers to the whimsical changes to regulations made by the Icelandic Government such as the change to the regulations setting up the National Bioethics Committee. If there is no security in knowing which monitoring bodies are responsible for overseeing the Health Sector Database and what regulation their monitoring power is based on, the constitutional provision of privacy cannot be guaranteed in a sufficiently reliable way.

⁵⁰ A Abbot, "'Strengthened" Icelandic bioethics committee comes under fire' (1999) 400 *Nature*, p. 602; M Fortun "Breaking the code" (2001) *Rensselaer Mag*

⁵¹ M Fortun "Breaking the code" (2001) *Rensselaer Mag*.

⁵² A Abbott, "'Strengthened" Icelandic bioethics committee comes under fire' (1999) 400 *Nature*, p. 602

⁵³ so also T Zoëga, B Andersen, "The Icelandic Health Sector Database: deCODE and the 'new' ethics for genetic research (2000) in: Nordic Committee on Bioethics, Proceedings of the Conference "Who owns our genes?", October 1999, Tallinn, Estonia

5. Conclusion

An interesting aspect of the Health Sector Database Act is the fact that it received severe criticism from both its opponents and its advocates. As Annas as well as Gulcher and Stefánsson point out, the Health Sector Database Act itself does not provide any information and guidelines on the most vital aspects: neither does it instruct how the database is to be set up, nor does it regulate who should run it, who should have access to the data or what, if any, control Icelandic citizens should have over the samples. Also, the Act does not contain any information with regard to the method or mechanisms of linking the three individual databases.⁵⁴

To summarise, it is now appropriate to provide a synopsis of the aspects of the Health Sector Database that have come under international criticism and to determine which of those the Icelandic Supreme Court judgement has addressed and which were not touched upon.

5.1. Consent Issue

The consent question, undoubtedly the most contested aspect of the entire debate surrounding the Icelandic Health Sector Database, received surprisingly little attention from the Icelandic Supreme Court. In fact, the Court only mentions consent in the context of data protection issues. However, the very fact that the question of consent is linked so closely to the problem of data protection, which the Icelandic Supreme Court dwelled on for a considerable length of time, should have caused the Court to devote more of the judgement to the consent issue. After all, the question of what type of consent would be required depends largely on the anonymity or identifiability of individuals. However, while the Court explains in detail its findings on the encryption mechanism and the fact that the information contained in the database can be traced back to individuals due to the richness of the data, as discussed above, the Court then fails to link these findings with the consent issue. Accordingly, those hoping for a clear statement with regard to the requirement of consent for databanks such as the Health Sector Database in order to set an international precedent may be disappointed.

One very interesting fact in this context is a particular statement made by the Icelandic Supreme Court, in the light of which the entire judgement will have to be seen. Immediately following the description of the appellant's claim before the courts and before the elaborations on the individual points of the judgement, the Court stated that, based on the information that emerged during the proceedings, it seemed dubious whether the Health Sector Database would ever be initiated properly, as the case documents showed that that the formal measures for preparation of the database had not advanced significantly since issuing of the operating licence on 22 January 2000. From this paragraph the Icelandic Supreme Court's opinion on the future of the Health Sector Database can be deduced, namely that the Court seems to believe that the entire project might fail anyway.

⁵⁴ J R Gulcher, K Stefánsson, "The Icelandic Healthcare Database and informed consent" (2000) 324:24 *New England Journal of Medicine*, p 1827 – 1830; G J Annas "Rules for research on human genetic variation: lessons from Iceland" (2000) 324:24 *New England Journal of Medicine*, p 1830 – 1833; see also D E Winickoff "Biosamples, genomics and human rights: context and content of Iceland's Biobanks Act" (2000) 4:2 *Journal of BioLaw and Business*, p. 11 - 17

5.2. Data Protection

The discussion of privacy and data protection takes up the largest part of the judgement. Still, with regard to the data protection issue itself, the Icelandic Supreme Court does not take the relevant European legislation into account. Accordingly, the result is reached through a deduction, which, while not wrong, omits an important legal aspect. The Court reaches two conclusions in connection with the data protection issue:

First, the Court considers the one-way encryption system in itself to be safe and to provide the Health Sector Database with the necessary anonymity. Therefore, one-way encryption is considered an acceptable security mechanism for the Health Sector Database.

Second, the Court continues with an analysis of the information to be transferred into the database and reaches the conclusion that the nature and extent of the data, namely the medical and genealogical records together with the genetic samples, means that an identifiability of individuals is indeed possible. Accordingly, the relevant privacy and data protection laws apply.

In the course of this, the Court omits an important third aspect and does not discuss the issue of the possible existence of a key to decode the database, an issue which, while not in breach of data protection legislation, is in direct violation of the Health Sector Database itself.

5.3. Lack of independent review mechanism

One of the main concerns amongst critics of the Health Sector Database is the fear that the database will not be subjected to sufficient oversight by an independent ethics commission. This concern was emphasised by the way in which the Icelandic government restructured the National Bioethics Committee and altered the regulations with regard to the appointment of a new Committee in 1999, a fact that aroused international criticism.⁵⁵ In its judgement the Icelandic Supreme Court focuses on the fact that monitoring bodies cannot replace the constitutional guarantee of privacy as laid out in Paragraph 1, Article 71 of the Icelandic Constitution. As discussed above, the problem with regard to the new committee was that it could not be considered independent anymore. In this respect, the judgement should satisfy critics of the Health Sector Database, as it clearly calls for independent review of the database.

5.4. An international perspective

Worldwide more and more genetic databanks similar to the Icelandic Health Sector Database are being initiated and are in various stages of their set-up process. Examples are the UK Biobank,⁵⁶ the Estonian Genome Project,⁵⁷ Generation

⁵⁵ see for example A Abbott, "'Strengthened" Icelandic bioethics committee comes under fire' (1999) 400 *Nature*, p. 602; J F Merz, G E McGee and P Sankar, "'Iceland Inc.'?: On the ethics of commercial population genomics" (2004) *Social Science and Medicine*, p. 1204

⁵⁶ <http://www.ukbiobank.ac.uk/>.

⁵⁷ <http://www.geenivaramu.ee/index.php?show=main&lang=eng>.

Scotland,⁵⁸ the Latvian Genome Project⁵⁹ as well as projects in Japan, China, and the USA. The implications of the Icelandic Supreme Court judgement for the other genetic databanks, however, are limited. As mentioned above, the issue of legal standing, which the Supreme Court focuses on first, is very specific to the Icelandic databank. The consent issue, which is being discussed to a great extent for every genetic databank, is almost completely left aside by the Icelandic Court. The only aspect of the judgement of international significance is the discussion regarding data protection. And while Iceland is bound by the European Data Protection Directive, even this issue is only discussed from a point of view of purely Icelandic national law without taking a look beyond Iceland's borders.

One aspect of the judgement is of significant importance for genetic databases worldwide, namely the fact that the removal of personal identifiers such as identification number and name and address may not be enough to provide anonymisation. The Icelandic Supreme Court made it clear that all data entered into a database will have to be taken into account. If the data is of sufficient richness to enable identification of individuals simply by adding the various factors such as education, profession, marital status etc. together to reach an almost certain conclusion with regard to the identity of the person, than this is a direct violation of privacy and data protection legislation. This again has important implications for the type of consent such a project will require.

To summarise the findings, the Icelandic Supreme Court judgement is a considerable step forward for the opponents of the Health Sector Database, but for international legal scholars hoping for a precedent judgement on genetic databanks, the outcome is limited to the privacy and data protection issue.

⁵⁸ <http://www.generationscotland.co.uk>.

⁵⁹ <http://forum.europa.eu.int/irc/rtd/cogene/info/data/pub/Latvian%20Genome%20Project.htm>.