

## INFORMED DEMOCRATIC CONSENT? THE CASE OF THE ICELANDIC DATABASE

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**Abstract.** The rapid rise of genetics and the unprecedented tensions between public and commercial interests in this type of scientific research create new problems and magnify old ones concerning the role of government in defending public interests and the efficacy of democratic procedures in securing such ethical requirements as privacy and confidentiality of medical records and genetic material. The question of democratic consent will be of particular interest: We argue that the debate about the Health Sector Database (HSD) in Iceland does not exemplify well democratic community consent, and that the procedure through which the HSD was made possible was seriously flawed. Informed democratic consent has to meet both procedural and substantive criteria. We argue that it would fail on both accounts because the free, reasoned and informed public dialogue which is a necessary condition for such consent never took place.

**Keywords:** Icelandic Health Sector Database, democratic consent, population genetics, medical data, public debate, public and private interests, biobanks

### 1. Introduction

The following discussion is about plans currently being carried out in Iceland to create a single health sector database for the whole nation, intended in part for research in human genomics and genetic epidemiology. The rapid rise of genetics and the unprecedented tensions between public and commercial interests in this type of scientific research create new problems and magnify old ones concerning the role of government in defending public interests and the efficacy of democratic procedures in securing such ethical requirements as privacy and confidentiality of medical records and genetic material. The question of democratic consent will be of particular interest: We are not concerned with the question of whether community consent is at all possible<sup>1</sup>, but we argue that the debate about the

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<sup>1</sup> The discussion about community consent has mainly focused on the possibility of obtaining consent of “ethnic” populations with tribal social structures, cf. Reilly (1998) and Foster et al (1998). It seems to us that the notion of democratic consent is appropriate for a discussion of community consent in modern Western societies.

Health Sector Database (HSD) in Iceland does not exemplify well community consent, and that the procedure through which the HSD was made possible was seriously flawed.

The Health Sector Database will contain information gathered from medical records and it will be linked with two other databases, one containing genealogical data for every Icelander alive and, going centuries back, most of those deceased, and the other containing genetic information. A private company, deCODE genetics,<sup>2</sup> has been granted exclusive rights for 12 years to construct the database, maintain it and sell access to the information.

We shall first, in subsection 2, briefly describe the database project and some of the main ethical issues involved. In subsection 3 we discuss democratic community consent in the context of the Icelandic HSD debate. In subsection 4 we analyse the political procedures and the debate, which led to a controversial bill being passed by the Icelandic parliament on December 17th 1998. The bill contained the changes to Icelandic laws required for the HSD project to go ahead. We conclude that informed democratic consent has to meet both procedural and substantive criteria, and that in this case it failed on both accounts.

## 2. The Icelandic Health Sector Database

The Health Sector Database will contain information taken from medical records in Iceland. The data gathered for the database includes most medically relevant data that are codable, such as symptoms, test results, diagnosis, stage and duration of disease, medication, treatment, results, side-effects and cost of treatment, who provides treatment, where and for how long, and some personal information, such as the patient's age group. Patients' narratives will not be included, nor personal information that is not medically relevant. It is not clear whether information about diet, life-style (other than smoking and drinking habits), sexual orientation, race, vocation or income bracket will be included, all of which can be medically relevant.<sup>3</sup>

The database laws, as they were approved by the parliament, make clear that the Health Sector Database may only include data from medical records, but it can be linked with other databases containing genealogical and genetic data (with the approval of the Data Protection Commission). These two types of data are at opposite ends with regard to sensitivity and privacy. Genealogical information is considered public information in Iceland, no privacy restrictions apply to it and it is frequently published in books and newspapers. In order to keep individuals unidentifiable, genealogical information will only appear in query results from the database as degree of kinship, not as family trees. Genetic data, however, are considered as private in Iceland as in other Western countries and, according to

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<sup>2</sup> For more information about Decode genetics, see their website at [www.decode.com](http://www.decode.com).

<sup>3</sup> The words quoted are from an English translation of parts of the booklet obtained from decode's web site (Íslensk erfðagreining 1999).

ethical codes established by deCODE itself, they will only be entered in the database if the individual has given his or her explicit consent.<sup>4</sup>

There are two worries here concerning the handling of genetic data. One is the claim that no one can give informed consent for providing genetic data for the database as there are no specific research plans available. It is not possible to know how exactly the genetic data will be used or what risks it may involve, hence the consent obtained is an open one. The second worry is an act on tissue banks (i.e., banks containing samples of blood, tissue or other biological material from which genetic information can be gathered), which became law on May 13, 2000.<sup>5</sup> This act proposes somewhat paradoxically: 1) that tissue collected for scientific studies can only be kept after the study or passed on to a tissue bank if the provider of the sample gives informed consent, and 2) that samples collected for clinical tests or treatment can be passed on to tissue banks as long as the provider of the sample does not object (i.e., presumed consent).

As the data in the Health Sector Database is to be “non-personally identifiable”, informed consent is not required from the individual when his or her medical information is transferred to the database. It is, however, possible to opt-out by signing a non-consent form, which will prevent any future information about the individual being entered in the database. According to a recent agreement between deCODE and the Icelandic Medical Association, participants in the database will also have the right to withdraw their information when they so wish. Parents can sign non-consent forms for their children, but many of those most vulnerable of adults who are not able to inform themselves and tend to paperwork, because of mental illness, drug addiction etc., will, as a matter of course, have their medical information entered in the database. Following a recent judgement by the Icelandic Supreme Court, medical information about the dead can be prevented from being entered in the database.<sup>6</sup>

Once the Health Sector Database has been constructed, it will be possible to query it for “statistical information on health, disease and treatment” (Íslensk erfðagreining 1998:5, Íslensk erfðagreining 1999), but it will yield no information about single individuals or groups of fewer than 10 individuals. Like an oracle, it

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<sup>4</sup> It is claimed that the consent obtained is informed consent but we don't think that it meets the requirements of informed consent for participation in particular research. We cannot discuss this point further here. Vilhjálmur Árnason (2004) discusses the issue of consent for all three databases in his “Coding and Consent. Moral Challenges of the Database Project in Iceland”.

<sup>5</sup> The act referred to is Act on Biobanks No. 110/2000. It is available in English translation at <<http://ministryofhealth.is/interpro/htr/htr.nsf/pages/Act-biobanks>>.

<sup>6</sup> A young woman sent a request to the Directorate of Health, asking that health information about her deceased father not be entered in the HSD. When the Directorate of Health refused, the woman sued the Icelandic State in the local court, asking that the refusal be stricken down. The local court judged in favour of the State. The woman then appealed to the Supreme Court, which decided on November 12, 2003, that her request to the Directorate of Health must be honoured. The Supreme Court's judgement is available (in Icelandic only) at <[http://www.haestirettur.is/ifx\\_hr/?MIval=h\\_domar&nr=2566](http://www.haestirettur.is/ifx_hr/?MIval=h_domar&nr=2566)>. It is likely that this judgement will require, or lead to, changes to the Act on a Health Sector Database.

will merely answer the questions posed to it and the questions must be asked in the right way. The company plans to run a consultancy service, helping clients formulating questions and interpreting the answers.

Icelandic health authorities will have unlimited access to the database, to get information that may facilitate management, monitoring and report making for the Icelandic health care system, but the main purpose of the database is to provide data for genetic research. This includes finding genetic factors for disease and for drug and treatment response. Linking medical data with genealogical and genetic data will make it possible to find quickly the most likely locations for genotypes linked with such phenotypes as disease symptoms and efficacy of drugs or treatment. Genotypes linked with drug efficacy and side effects might make it possible (at least in theory) to tailor-make drug treatments according to the genetic profile of the individual.

Here we are almost exclusively concerned with the genetic uses of the databases. It is often pointed out, correctly, that the Health Sector Database is only partially meant for genetic research, but Kári Stefánsson and the deCODE literature make it very clear that genetic research is the main purpose of the database. Its purpose seems to go even beyond genetic research, to a thorough geneticization of medicine.<sup>7</sup> In a paper presented at the first IFFC-Roche Conference<sup>8</sup> in Singapore in March 1998, Kári Stefánsson said that the “ultimate goal of the database [is] to usher in an era of preventive health care and individual-based disease management practices based on human genetics”. A little later he adds: “The goal of the database is to bring the genetics together with medical phenotypes and outcomes to create a totally informative population with which to search for drug targets and to model both disease and host-drug interactions” (Gulcher and Stefánsson 1998:526).

### 3. Democratic procedures and democratic consent

A database of the sort envisaged by deCODE genetics could not have been constructed in Iceland in the legal framework – or lack of legal framework – at the time. The company took the initiative of presenting to the Ministry of Health ideas about the database and what legal framework would be needed for it. It is not known to what extent deCODE was involved with the drafting of the resulting bill for a Health Sector Database, but it was drafted at least in close co-operation with the company.<sup>9</sup>

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<sup>7</sup> The term “geneticisation” is borrowed from Abby Lippman (1991:19).

<sup>8</sup> IFFC stands for “International Federation of Clinical Chemistry and Laboratory Medicine”. “Roche” refers to Roche Diagnostics, a Hoffman-La Roche subsidiary.

<sup>9</sup> According to historian Gudni Th. Jóhannesson, the very first draft of the HSD legislation was faxed from deCODE genetics to the Ministry of Health on September 3, 1997. The first HSD bill was a revised version of that first draft, but the basic ideas were the same. Although organisations, institutions and even individuals may contribute in various ways to the drafting of legislation, it is highly unusual that a company provides the first draft of legislation. See Jóhannesson (1999:170–178).

The first version of the bill for a health sector database was circulated in the Icelandic parliament on April 6, 1998, and a second extensively revised version of it was passed the same year on December 17. Our purpose in recounting the debate taking place between these two dates is to question the claim that what took place can properly be called “democratic consent”. Paul Rabinow and Gísli Pálsson (1999:17), for instance, have claimed that the decision to pass the bill “was clearly the product of informed democratic consent”. They point to the nine months of intense public debate preceding the vote, vocal opposition from doctors and biologists, decisive vote in the parliament (“37 to 20 with 6 abstentions”<sup>10</sup>) and opinion polls indicating high support by the general public for the bill. According to Gallup poll conducted at the time when the bill was passed 58% were in favour of the bill, while only 13% of population claimed to have a good grasp of the issue (Zoëga and Andersen 2000:44).<sup>11</sup>

Spokesmen of deCODE have also made similar arguments about presumed consent, referring to strong support in the polls. They even define presumed consent in this context as “the consent of society to use health care information according to the norms of society” (Gulcher and Stefánsson 2000:1827). This is a rather odd notion of presumed consent, but even if it was correct, it would not provide sufficient reasons for waiving the requirement of obtaining consent from those participating in research. As Ruth Macklin (1999:203) writes: “When a society’s norms and customs diverge from the basic principles of research ethics, researchers are obligated to adhere to the research ethics and not to local or cultural customs.”

The idea of democratic consent seems to serve a key function in this case. It is argued that because of the extensive debate that took place in Iceland and the overwhelming support for the HSD shown in Gallup polls, it is fair to collect data under the assumption of presumed consent. But the notion of community consent must be used very carefully and it can never be used to replace individual consent. As George Annas (2000:1831) correctly points out, “a community can approve a research project. It cannot legally or ethically require individual members of the community to participate”. These two things were conflated in the Icelandic HSD debate. It is reasonable to argue that the community approval for the deCODE project was an important backup for the parliament act on the central databank. But it cannot be referred to as an argument for presumed consent of any individual. It can also be argued that the national debate, though flawed, provides an important background for the decisions of competent adults to opt in or out of the database. Nevertheless, members of marginalised groups (e.g. mentally ill, poor, illiterate, children), the protection of whom should be the primary concern of research regulation, are likely to be exactly those people who have not participated in or even followed the national debate over this issue, however intensive and extensive that debate may have been.

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<sup>10</sup> This requires correction: There were no abstentions, but six Members of Parliament were absent.

<sup>11</sup> Gallup and other polls most often showed that about three quarters of the population were in support of the bill.

It still remains a question, however, what the idea of an “informed democratic consent” implies. On the surface it may seem to be obvious: Iceland is a democratic country, the bill did get extensive debate both in the parliament and in the society (although considerably less than nine months before the bill was passed as law), the parliament solicited views from a great number of institutions and individuals, and a decision was reached through ordinary democratic procedures, which furthermore reflected the majority view of the Icelandic public.<sup>12</sup> But even if the debate, and the entire procedure, is democratic in the formal sense, it does not follow that it amounts to “informed democratic consent”. Although the HSD debate was certainly often informing, much of the debate was uninformed, misleading and prejudicial. The quantitative facts about extensive debate and overwhelming majority opinion must not be confused with the qualitative notion of consent to participation in the database which implies an understanding of the issue consented to.

It might be helpful in this context to invoke the distinction between the “aggregative” and the “deliberative” models of democracy. On the former view, the emphasis is on the majority view as a set of preferences which needs to be transformed into public decisions. This view is primarily quantitative and “vote-centric” and thus goes hand in hand with the strategies which are best suited for “winning the game” of power politics (Kymlicka 2002:290). On the second view, on the other hand, the focus is on how the preferences of the citizens can be formed in processes of public deliberation or practical reasoning which precedes voting and public decisions.<sup>13</sup> In line with this “talk-centric” view, democracy has been defined as the rule of the free dialogue: “An essential feature of democratic government ... is that it is government through discussion, by persuasion instead of by force” (Raphael 1970:150). Democratic discussion takes time, especially when new and complicated issues, which concern crucial interests of every citizen, are dealt with for the first time. Arguments need to be carefully weighed and evaluated in light of the best professional and scientific knowledge available. Attempts have to be made to activate the citizens in rational deliberation and to institutionalise the conditions of political will formation.

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<sup>12</sup> A letter to the editor of *Nature* from Kári Stefánsson and Jeffrey Gulcher, responding to a news story in *Nature* (Abbott 1999), claimed that “deCODE obtained its license to construct and run the health-care database through democratic process” (Gulcher and Stefánsson 1999). Two outspoken critics of the Database bill objected in letters to the editor, one pointing out that “important changes were made to the bill in parliament, without debate [...] The warnings of nearly all the independent expert groups that were asked to comment on the bill were ignored. Our small society was not able to withstand deCODE's expensive information campaign” (Hauksson 1999). The other commented that to “assert that the law was approved through a democratic process underestimates the steamrolling power of a large government majority. Warnings from the Icelandic Medical Association, local and international geneticists, and privacy experts were ignored. The speed of the Icelandic legislative process precluded balanced and informed analysis of a complicated issue. It is sheer spin-doctoring to suggest that this over-speedy, ill-thought-through legislation expresses informed community consent” (Sigurdsson 1999).

<sup>13</sup> Cf. Bohman and Rehg (1997): “Introduction”.

#### 4. From corporate presentation to law: The question of democratic process

In the remainder of this article, we will focus on the parliamentary procedure which we take to be indicative of the type of democratic consent at issue. Evaluated in the light of the “ideal type” of “aggregative” democracy, the HSD certainly won the majority vote as we have already described. On the “deliberative” democracy view, however, the political handling of the case was seriously flawed. The HSD bill was rushed through parliament and informed well-reasoned criticism was largely ignored, even regarded as irrelevant. Moreover, in a democratic state, the legislators have the obligation to give shape to the general rules of society with the interest of all in mind. These rules are supposed to guarantee the general interest, but not to give an advantage to a limited group of people. For this reason, it seems very questionable, at least from the viewpoint of deliberative democracy, that the very company, which has most at stake in the matter, was influential in drafting the law itself. Yet this seems to have happened in the HSD affair. Throughout the process, in fact, the ties between the private company and the public sector were suspiciously close. Such working procedure is not conducive to “informed democratic consent”. In order to substantiate these claims, we shall now take a closer look at the debate and the events that led to the establishment of the HSD.

Kári Stefánsson, a former professor of neurology at Harvard, founded deCODE genetics Inc. in August 1996. The company was incorporated in Delaware, U.S.A., and a wholly owned subsidiary (Íslensk erfðagreining) was soon established in Iceland with a capital of \$12 million (U.S.) provided by seven American venture funds.<sup>14</sup> In February 1998, before the database bill was introduced in the Icelandic parliament, deCODE signed a \$200 million (U.S.) deal with the pharmaceutical giant Hoffman-La Roche, at the time it was the largest deal ever made in genomics. The details of the deal are naturally a corporate secret, but it is focused on linkage studies of 12 diseases: Heart attack, peripheral vascular disease, high blood pressure, stroke, schizophrenia, anxiety disorder, Alzheimer's, manic-depressive disorder, osteoarthritis, osteoporosis, non-insulin dependent diabetes and emphysema (Kunzig 1998:96). Hoffman-La Roche gets the right to use the studies to develop diagnostic tests and drugs.

The competitive edge of deCODE over other genomics companies depended on the proposed Health Sector Database, which, at the time of the signing of the contract, was legally impossible to create in Iceland. The company started marketing (or at least publicising) its unique asset, the HSD, long before the laws making its construction possible were passed. Already in October 1997, *Science* published an article about deCODE's plans to construct the Health Sector Database, quoting Kári Stefánsson saying that he had forged an agreement with the Icelandic

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<sup>14</sup> The venture funds are Advent International, Alta Partners, Atlas Venture, Arch Venture Partners, Falcon Technologies, Medical Science Partners and Polaris Venture Partners. As is usual, the investors got members on the company's board of directors and have therefore considerable control over the company. This issue was largely ignored in the debates in Iceland, where deCODE was strongly presented as an Icelandic company.

government and academics, who almost all support his project (*Science* 1997:566). An article in the Swiss business magazine *Cash* from March 1998 discusses the deal between deCODE and Hoffman-La Roche, noting that apparently the Icelandic parliament were to pass laws that same spring giving deCODE exclusive rights to marketing the genetic data (Peter 1998:34). An article published in the May 1998 issue of another business magazine, *Red Herring*, discusses deCODE's database as if it already existed:

*“DeCODE has taken advantage of this homogeneity [of the Icelandic population] to compile a database comprising hundreds of years of Icelandic genealogy as well as more recent information about the medical history, disease symptoms, resource use, and treatment outcomes of the country's families. The company asserts that its database gives researchers a depth of understanding about gene-based diseases that tools companies cannot match. DeCODE claims that it proved the value of the Icelandic population database when it took just three months – instead of an industry average of 15 years – to locate the gene for familial essential tremor...”* (Red Herring 1998)

This article was published about eight months before the Health Sector Database bill was passed as law, and now when this is written, almost six years after the publication of the article, the HSD still does not exist. DeCODE corporate literature supported the sentiment that the Icelandic parliament would, as a matter of formality, pass the required laws for the HSD and give deCODE the exclusive rights to it.<sup>15</sup> The database law seemed to be a done deal when in early April 1998, about a month after the deal with Hoffman-La Roche was signed, a bill was circulated in the Icelandic parliament proposing new laws about a central health sector database. Ten days later, on April 16, the bill was to be introduced and debated in the parliament. Only a few weeks were left of the 122nd parliament session. Prime Minister Davíð Oddsson had told the media that the bill required a speedy process and would be passed before the end of the session. The first round of debates, before Health Minister Ingibjörg Pálmadóttir even got a chance to formally present the bill, started with a discussion whether the governing coalition planned to force the bill through the parliament before the end of the session. Opposition MPs complained that it had been their understanding that the bill was introduced for review only and would be debated in the subsequent session in the autumn. They had not been given a chance to do their homework for the debates. The Health Minister promised that the bill would get the debate needed, but emphasised the importance of a speedy process.<sup>16</sup>

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<sup>15</sup> According to a flyer from Mannvernd (the “Association of Icelanders for Ethical Science”, established specifically to fight the Health Sector Database bill), a corporate brochure deCODE sent in June 1998 to a number of prospective international “corporate partners” boasts “deCODE genetics will be in a position to offer its corporate partners access to the Icelandic population for clinical trials of drug candidates.” (Mannvernd 1998).

<sup>16</sup> Parliament speeches are available (in Icelandic only) at [www.althingi.is](http://www.althingi.is). An overview of the process of the first database bill is available at <<http://www.althingi.is/dba-bin/ferill.pl?ltg=122&mnr=661>>, and for the second (which was passed) at <<http://www.althingi.is/dba-bin/ferill.pl?ltg=123&mnr=109>>. For a very interesting discussion of “speed” in genomics research, see Fortun (1998).



Health Minister Ingibjörg Pálmadóttir introduced the bill in the parliament. After pointing out the slow and expensive development of information technology in the health care system, she noted that when the CEO of deCODE genetics expressed interest in establishing a health sector database containing medical information about all Icelanders, the possibility arose of speeding up the development of information systems in the health sector. The company would pay for computers and software in health care institutions, as well as all required medical data entry and processing. She reports that the medical information gathered from medical records and entered into the database would be separated from all personalised information, and that the medical information would be anonymous and “presumably” include not only information about health and disease, but also efficacy, side effects and cost of treatment. She also notes that the database would be dynamic (new information would constantly be added), and that deCODE would require exclusive rights to Icelandic medical records (excepting already established databases, such as the Heart Association database and the cancer registry of the Cancer Foundation). Furthermore, health authorities would have unlimited access to the database for the purpose of making reports, planning and decision-making. According to the Minister, the benefits of the database would be marvellous: It would be of great use to Icelandic health authorities for management and policy-making in the health sector, and it could also be useful to other health systems for constructing models. It was hoped that information from the database could be used to find new medications and develop new and improved methods for predicting, diagnosing and treating disease. She also noted that foreign pharmaceutical companies and health care institutions might want health information from the database. No risks were mentioned.

The Minister is remarkably silent about many crucial issues of the matter: what exactly the purpose of the law is and why deCODE would want to construct a database for the government. She did not say what would go into the database, nor that (if the bill were to pass into law) no one could prevent his or her confidential information from being entered into the database. There was no mention of whether the HSD could be linked with genealogical and genetic databases (as deCODE had indicated) or whether any other options had been considered (such as a network of local databases and/or public financing and managing of the database). The Minister did not say whether anyone other than deCODE and legal institutions had been consulted, and she did not mention that the company would not be expected to pay anything beyond the cost of constructing the database (in return for the potentially profitable access to the nation’s medical records). There was no clarification of how exactly a health sector database could be profitable and scientifically beneficial.

In the parliamentary debates that followed, opposition MPs criticized the database bill on many of the above issues, as well as the secrecy surrounding its drafting, lack of consultation (the Minister of Health claimed there had been wide consultation, but no formal views or comments had been sought and many institutions concerned officially declared they had not been consulted). There was criticism of the poor preparation of the bill, since it was circulated without any supporting documents, external reviews or comments, or drafts of Ministry regulations, all of

which are strictly not required but often accompany the more significant bills. The close involvement of the “prospective licensee” deCODE genetics was criticised. Some MPs were first informed about the contents of the database bill by Kári Stefánsson. Further criticism was directed at the great haste in which the bill was to be approved by the parliament: The Prime Minister had publicly said that it would be passed before the end of the session.

Vocal opposition to the bill, both in the parliament and from doctors, scientists and academics, in addition to growing media attention, prevented a quick and quiet approval of the bill as it was. A vote in the parliament on April 22 sent the bill to second debate and for discussion in the parliamentary Committee for Health and Insurance. Instead of having the bill rubber-stamped in the committee and taken up for second debate right away, the Minister of Health decided to postpone it until the 123rd session in the fall of 1998. This would give the Ministry of Health time to revise the bill, seek external views and comments and find ways to conciliate at least the medical opposition, if not scientists and opposition MPs, and deCODE time to win – or rather maintain – the trust of the public.

This was not the end of the debate about the database bill in the 122nd session of the Icelandic National Parliament. On April 28, shortly after the database bill debate had been postponed, a short debate was allowed under the rubric “Remarks on Parliament Activities” (which is one way to bring into parliament matters that require immediate attention). The media had reported that an agreement had been reached to put the database bill aside until autumn, then it would be re-introduced in the first days of the 1998–1999 session with final vote by October 20th. Opposition members declared that no such agreement had been made, except for postponing the bill until fall, and objected to “tying the hands of the parliament”.<sup>17</sup> There was obviously considerable pressure on the Ministry of Health and the government to get the bill quickly through parliament.

Proponents of the database bill, in particular the Prime Minister (who wisely kept a low profile during the debates) and the conservative MP Tómas Ingi Ólrich, stressed that a speedy process was imperative because the market opportunities which made the database project a feasible undertaking for a private company might suddenly evaporate in the volatile and fast paced world of biotechnology and genetics. Critics objected that speed was required only in order to minimise criticism and debate.

During the spring and summer months the bill was revised, not in the Committee for Health and Insurance, as would normally be the case, but in the Ministry of Health. It is not uncommon for bills to be drafted in a Ministry and then taken up in parliamentary committees for review after the first debate in parliament.<sup>18</sup> What is

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<sup>17</sup> See <<http://www.althingi.is/altxt/122/04/128151317.shtml>>.

<sup>18</sup> Critics claim it would be better to seek comments and views from experts, those concerned and the public while a bill is drafted. That way different options can be discussed and the bill can take shape through democratic discussion. Otherwise the debate is determined at the outset to be merely on details of the bill and whether to pass it into law, with no regard to other options. (See Thórhallsson 1998a).

uncommon and democratically suspect is letting a Ministry (which is a part of the executive branch of the state) have so much control over the lawmaking process after the bill has been circulated. The Committee consists of regular MPs, including members from the opposition, and their work is relatively transparent, while the Ministry staff working on the draft of the bill are largely appointed by the Health Minister or her party and their work takes place behind locked doors. The Health Minister and her staff could consult with deCODE representatives in a more open and informal manner, not to say more closely, than would have been the case in the Committee. Furthermore, during spring and summer of 1998, Kári Stefánsson increasingly became the spokesperson for the database bill, a trend which culminated in his trip around Iceland where he held open community meetings, usually in local health care centres, to gather public support for the database project.

By the end of July, a new draft of the database bill was sent to 40 institutions and individuals for comments, and posted on the Health Ministry web site with a call for comments and views.<sup>19</sup> This was the first time that the Internet was used in Iceland to publicise parliament bill and seek feedback. Debates in the media gathered new force and a flurry of articles appeared in newspapers and magazines. Important changes had been made in the revised draft of the database bill. The most important addition was the opt-out clause, giving individuals the right not to have their medical information entered in the database. Other changes included stricter coding requirements, giving the government a right to negotiate fees for the licensee's access to medical records in excess of the costs incurred for the state, and a clarification of who will have access to medical records for scientific research apart from the licensee. Most commentators believed the bill had improved considerably, but they also pointed out that it was fundamentally the same bill and the larger issues had not been solved, namely those of privacy, confidentiality, consent, scientific freedom and corporate monopoly of medical information.<sup>20</sup>

Much of the discussion, both in the parliament and in society, focused on legal and technical problems concerning privacy and consent, such as the coding system, the relative merits of central versus local databases and potential conflicts with Icelandic and European law.<sup>21</sup> In the process, some of the most important ethical aspects of the HSD were smothered by technical issues, for instance forcing the discussion about consent and privacy of medical data into the mould of encryption and coding technologies.

The revised database bill was circulated in the parliament on October 13, 1998. On the same day a rival database bill was circulated in the parliament, drafted by three opposition MPs. It would not allow the construction of one health sector database with a *carte blanche* for scientific research, but it would allow a single

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<sup>19</sup> The database laws are available in Icelandic and English, and so is some information about the database, at the web site of the Ministry of Health <<http://www.ministryofhealth.is>>.

<sup>20</sup> See for instance Thórhallsson (1998b), Björnsson and Einarsson (1998), Guttormsson (1998) and Guðmundsson (1998).

<sup>21</sup> *Cf.* Árnason and Stefánsdóttir (1998).

licensee to centrally process information from medical records and construct temporary databases for specific studies, requiring the licensee to request a permit for each database which would only be given after a review of the study proposal by a committee appointed by the Minister of Health. Once a study would be finished, the respective database was to be destroyed. The information would be personally identifiable, but people would be allowed to opt out at any time (in which case no information, or all but specified information, from their health records would be entered in a central database). A third draft concerning health sector databases was also circulated in the parliament on October 13, it was a draft of a parliamentary resolution calling for a careful consideration of local health sector databases in lieu of a central database. The resolution draft was supported by a discussion paper on the issue and a great number of documents, including a recent and very thorough report from Norway on access to medical records and articles on the database issue written by lawyers, doctors, computer scientists and laymen.

There was an informal agreement between the parliament parties to discuss the two database bills and the resolution draft together, as is often the case with closely related issues, but the Minister of Health vetoed a common debate for all three drafts. Immediately preceding the database bill debate on October 15, the Minister's veto was discussed in the parliament. Opposition MPs demanded an explanation for the veto from the Minister and she explained that her database bill had been discussed for seven months in the society and that the other two drafts were not the same as her draft bill. It was quickly pointed out that all three drafts had been circulated in the parliament on the same day, that they did deal with the same issue and that they obviously did not have to be identical but merely sufficiently related to merit a parallel debate. It should also have been pointed out that the seven-month discussion in society was not irrelevant to the two new drafts but rather the three drafts represented different positions within the same debate.

The veto made it clear at the beginning of the parliamentary debate that the database bill would go through the parliament with or without the support of opposition MPs and practically regardless of what the debate would reveal. The government had shown it had no interest in criticism of the bill or alternatives to it, the MPs knew then that they could debate this bill as they pleased, it would pass into law regardless. And it did, on December 17, 1998.

## **5. Conclusion**

In light of the preceding description, we conclude that the parliamentary and public debates in the Icelandic society about the Health Care database do not amount to a democratic consent. Informed democratic consent has to meet both procedural and substantive criteria. The procedural requirements have to do with issues such as the time allowed for the debate, the unhindered access of the public to relevant information about the case, and the independence of the legislature

with respect to interests groups in society. The substantive requirements have to do with the subject matter of the debate, whether the public and members of parliament were well informed about the relevant issues and the principles needed to assess them. We argue that it would fail on both accounts. The prior, free, reasoned and informed public dialogue which is a necessary condition for a democratic community consent never took place.

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