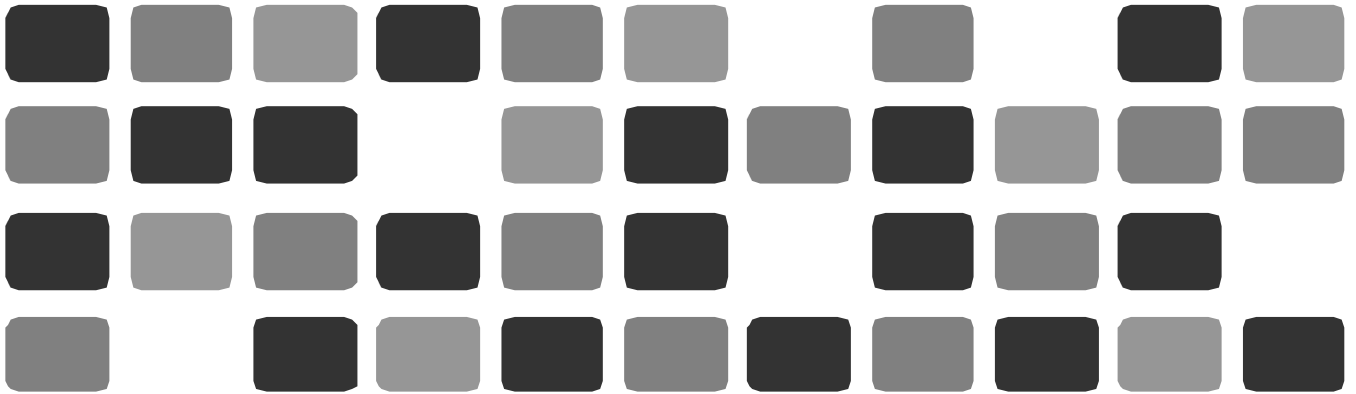

The Commodification of Bioinformation: The Icelandic Health Sector Database



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The Wellcome Trust

Preface

In July 1997, the Wellcome Trust established a programme to fund research into the social, ethical and public policy implications of advances in biomedical research, focusing in particular on the neurosciences and on genetics. The programme, with an initial budget set at £5 million over a period of five years, was intended to fund research. Ultimately, the hope is that the results of research and analysis might feed into rational public policy making.

All researchers who hold grants from the Wellcome Trust are required to file a report at the end of their project. This ethnography includes the report by Professor Hilary Rose on her study of the Icelandic Health Sector Database. As such, it represents Professor Rose's own observations, analysis and conclusions. The Icelandic database has been the focus of public and media interest, so the Trust has decided to disseminate Professor Rose's report in order to further the public debate. Any views expressed in this paper, however, are solely those of the author and do not represent those of the Wellcome Trust or any of its affiliates. The Wellcome Trust takes no responsibility for any factual errors in this document.

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Foreword

This is a piece of history in the making. Many major issues are flagged in these pages – public grasp of the ‘new genetics’, control over personal data, the rush to patent, above all ‘the commodification of nature’ – and they are all meat to the media. But the history I wish to single out is not one that would ordinarily get media attention. This report is also a history of a consultation exercise. It is an account of how a particular biotechnology firm sought to validate its procedures, how public debate did or did not get off the ground, and how it was that a purely market approach to genomics entailed national legislation. The specificities of the Icelandic case which gave the firm its major resource, a small and delimited population, also led to a unique process of interaction with that population. That what happened in Iceland could not happen in the UK is precisely the arresting reflection on which this report ends. The author’s most telling comments are to do with the nature of democratic process and scientific/commercial accountability.

We stand on the brink of biomedical science’s greatest achievements, write Bobrow and Thomas (‘Patents in a genetic age’, *Nature*, 2001, 409:763–4), but to make full use of them we need the backing of the world’s population. As they go on to observe, the world is properly suspicious when all it can see is short-term financial gain. This does neither ‘science’ nor ‘society’ any good. The patent system, for example, at the crucial threshold between scientific result and development of medical applications, has strengths and weaknesses which require urgent re-assessment. In the UK, the problem in their view is failure of political will. The interest of Hilary Rose’s narrative is that it is a real life story of how political will was mobilised, and there are lessons to be learned from the process.

Professor Rose’s study was not planned with this focus – that was an unpredictable outcome. It was funded by the Wellcome Trust’s Medicine in Society (MiS) Programme as a small investigative exercise simply because it was thought important that people in the UK know what was going on. But, as it happens, the MiS Programme is intensely interested in encouraging research on public consultation methods and, as it happens, here we have a fascinating case history. The case is far from the conventional kind of pre-planned and self-conscious consultation exercise which usually goes under that name. But the way in which the Icelandic parliament handled the issue, how opposition to the proposals for a Health Sector Database was formed, the dissemination – or lack of it – of information, and the controversial opt-out reference back to the public at large, all make the crucial period over 1998–9 described here something of a life-size exemplar.

Consultation: whom do you consult, what do they know, and what agendas of their own do they have? And what do you pass on? For people are already caught up in flows of information. The observer might want to consult ‘the public’ (or ‘community people’ in the phrase used here) but she will also want to speak with those who regard themselves as informing – or seeking information – from others. Within a very short space of time, Hilary Rose marshalled a remarkable cross section of data: news reports and websites aimed at national and international audiences; sessions with senior participants in constant communication with the press, in both deCode (the firm) and the civil service; her own experience of lecturing on these topics to university audiences on philosophy and women’s studies; casual conversations; and hour-long, wide-ranging interviews. However, the intimacy which helped also hindered. The involute nature of Icelandic society set her a problem of confidentiality; so she explains that, rather than giving direct quotations which might be all too attributable, she has woven an account out of these people’s narratives, her own encounters and the public record. She also weaves between the two sides to the debate – the supporters and detractors of the database. But the weave isn’t seamless and not everything is in balance: she went out of her way to see if she could detect a distinctive women’s voice, and found some disturbing issues concerning children.

This is a particular version of events which have propagated many versions. And the events themselves will have moved on from the moment captured here. But the interest of this report lies in the question it raises for anyone interested in the consultative process, where consultation is not just a matter of finding out what people think or dealing with public opinion but is itself an organ of government.

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10 March 2001

Introduction

This study of the controversy surrounding the Icelandic Health Sector Database (HSD) began in December 1998. Fieldwork in Iceland took place over three weeks during May and July 1999, and the original research report was submitted in November of that year. Events connected to the controversy moved and continued to move with tremendous speed throughout this time. Initially the debate was confined to Iceland but by the autumn of 1998, the HSD had become a matter of international interest and concern.

It was quite difficult to conclude the original report. I had hoped that there would be some sort of closure or even a predictable end point to the controversy, but this has not been the case. Indeed, as this account of the study makes clear, the speed as well as the way that the innovation was introduced, not least the Icelandic Government's decision to use 'framework' legislation, guaranteed that negotiation and conflict would be almost open-ended. In addition, the question of whether the Health Sector Database can actually work within its own terms can only be judged as and when the system is fully operational. Meanwhile, legal challenges connected to the controversy have already been mounted and others are still being considered.

When I initially approached the Iceland case, I saw it theoretically as an example of the intensifying commodification of the human body, but as the research progressed, I saw it rather differently. What was being traded was not so much nature but information about nature¹. The subsequent Icelandic Biobanks Act passed in May 2000² changes this, as it puts the older form of the commodification of nature firmly back onto the agenda alongside the new commodification of information³. This study of the first phase of the commodification process in Iceland demonstrates the fusion of the two huge technosciences of the 21st century: biotechnology and informatics, creating a new commodity – bioinformation.

The study begins by setting the Icelandic case in the wider context of genomics, which is distinguished by the strong interest of venture capital, major pharmaceutical firms, new biotechnology companies and governments in this fast developing field. With the methodology attached as an appendix, it then follows the chronology of the controversy from the inception of the idea in 1994 by the Harvard clinical neurologist Kari Stefansson, to establish a Health Sector Database bringing together the medical and genetic records for the entire nation. The idea was first introduced to the Icelandic public in March 1998 when the Health Minister presented the first bill to the Althing, the Icelandic parliament. The bill immediately generated intense public debate among Iceland's scientific and clinical communities, but was supported by the public at large. Criticism of this first bill, not least because consent was presumed and universal, led to revisions with the final enactment of the HSD legislation in December 1998. This provided both the right for the individual citizen to opt out of the HSD and also gave the licensee, who was to manage the database, monopoly control for 12 years. The international debate took off in the autumn of 1998 and both the national and international debate has continued since then. This has been reflected by a growing academic commentary published from the several disciplines involved in the ethical, legal and social aspects of the new genetics. I have sought to include these different strands within this account.

1 Current legal and ethical discussions of commodification are focused on the body, and only more recently on this new entity, bioinformatics, cf. Bartha Maria Knoppers, 'Status, sale and patenting of human genetic material; an international survey', *Nature Genetics*, 1999, 22:23–26; Margaret Boyes, 'Whose DNA? Genetic Surveillance, ownership of information and new born screening', *New Genetics and Society*, 1999, 18, 2/3:145–56; Paul Martin and Jane Kay, *The Use of Biomedical Samples and Personal Medical Data in Human Genetic Research* (The Wellcome Trust, 1999); Eurogapp project 1999–2000, European Society of Human Genetics Public and Professional Policy Committee, *Data Storage and DNA Banking: Quality Issues, Confidentiality, Informed Consent, Ownership, Return of Benefits: A Professional Perspective, Background Paper*, 27 March 2000; Eurogapp Project, 1999–2000, European Society of Human Genetics Public and Professional Policy Committee, *Data Storage and DNA Banking: Quality Issues, Confidentiality, Informed Consent, Ownership, Return of Benefits: A Professional Perspective, Background Paper*, 6 April 2000 (this last provides a very useful overview of comparative policies and practices on both samples and information).

2 The Mannvernd website (www.mannvernd.is/english).

3 David E Winnickoff, 'Genomics and Human Rights: Context and Content of Iceland's Biobanks Act'. Mimeo, 7 December 2000.

Lastly the study concludes with some reflections on the Icelandic case. Because the HSD required legislation, this case had the great merit of engendering high visibility and public debate. In contrast, countries such as the UK that have a tradition of leaving such matters to ‘technical’ committees of experts typically introduce similar scale innovations in a socially invisible and democratically unaccountable manner⁴. The demerit of the HSD is that this hugely important innovation has not been given the cultural space or time for calm discussion; instead it has been legislatively steamrolled through, leaving behind a trail of ‘dissensus’ above all among the biomedical research and clinical communities. Yet the Icelandic case casts light on the many historically new ethical, legal and social challenges of the new genomics, particularly in a highly marketised context. And, as so many countries seek to move in this new direction, we will need all the light we can get.

The rise of pharmacogenomics/the Health Sector Database

Most of the public learnt for the first time about Health Sector Databases in 1998 because of the Iceland conflict. The headline of the story ‘Iceland sells its people’s genome’ typifies the media view. To many it read as if *Brave New World* had finally arrived and was now being driven through at high speed⁵. Now, three years later, it is clear that what was happening on this small Nordic island was not some one-off phenomenon, but had to be understood as part of a much wider move by pharmaceutical companies, venture capital, and the state towards predictive medicine and pharmacogenomics.

Although nation states have practised predictive medicine in the past, usually on the basis of public health initiatives to combat or prevent the spread of disease, the new predictive medicine will be founded upon the genetic make-up of the population and will therefore be much more individualistic in its character. In close association with this new development, pharmacogenomics offers the possibility of pharmaceutical researchers and companies tailoring drugs to individual genetic profiles. Correlating particular genetic profiles with characteristic responses to drugs through extensive population genetic research is potentially made possible by the proposed Database. Thus, Iceland may be the first example of pharmacogenomics in action (even though it was never spoken as such in any of the debates and discussions, but always by the softer term, the Health Sector Database – HSD). Unquestionably, it is not going to be the last.

Even while we were reading of the fierce divisions within the Icelandic healthcare and biomedical research communities, and feeling troubled by the proliferating ethical and policy issues, we learnt that global players such as SmithKline Beecham (SB) envisaged very similar scenarios for the UK⁶. There were important differences of approach, not least because George Poste, then the Chief Science and Technology Officer, and Robin Fears, as Director of Science Policy, had had the advantage of seeing the problems generated by the purely market-driven approach of the Icelandic case. The SB proposals differed from the deCode model in two key ways. First, eschewing the raw market model, they suggested that new, hybrid structures between the state and the market were likely to be a more appropriate way of proceeding⁷. Second, seeing the bitter professional fights within Iceland,

4 Arguably this expertocratic tradition is beginning to change as Governments, including that of the UK, begin to recognise the depth of public concern around genetics. The UK Government has established a number of advisory and regulatory bodies, including – after some initial hesitation – the Human Genetics Commission (HGC). These are increasingly including a wider representation than in the past. Thus the membership of HGC includes Bill Albert, a leading figure within the disability rights movement.

5 Icelandic interviewees concerned about the HSD routinely used this *Brave New World* metaphor. It is an indication of the country’s generally high educational level.

6 Robin Fears and George Poste, ‘Building Populations’ Genetics Resources Using the UK NHS’, *Science*, 1999, 284:267–268.

7 Whether cognisant of post-modern analyses such as those of M Gibbons, C Limoges, H Nowotny, S Schwartzmann, P Scott, and M Trow, *The New Production System of Knowledge: The Dynamics of Science and Research in Contemporary Societies* (London: Sage, 1994) or of J Ziman, ‘Postacademic Science; Constructing Knowledge with Networks and Norms’, *Science Studies*, 1996, 1:67–80, Fears and Poste are very conscious that the tectonic plates of the production system of scientific knowledge are shifting.

they emphasised the need to work slowly and consensually, bringing all the constituencies on board. In their emphasis on careful, slow legislation, Poste and Fears echoed the 1999 WHO draft recommendations on genetics and legislation, which spell out the need to move slowly to build consensus⁸. Although their article was published in the US journal *Science*, it envisaged a similar population health database for the UK and carried a reference to Blair's Third Way, indicating SB's willingness to collaborate with New Labour.

Later in 1999 the public learnt from the television programme *Newsnight* of discussions between the Wellcome Trust and the Medical Research Council (MRC) for what appeared to be yet another similar health database for the UK linking genetic profiles with health, illness and indeed behaviour⁹. It seemed that the expert-driven approach to planning was still in command. Were the public and parliament once more to have little input into shaping this research and innovation, despite its immense public policy implications?

With the autumn Labour Party conference, we learnt of the Home Secretary's enthusiasm for and commitment to a crime genetic database. The enthusiasm of the police superintendents for DNA fingerprinting of the entire population is well known, as is the matching hostility of civil libertarians. Steve Bell's cartoon, as usual, captured the geneticised political mood with an image of Prime Minister Blair promising DNA tests for everyone. After the cabinet re-shuffle the public learnt that the recently appointed Secretary of State for Health, Alan Milburn, was to meet the House of Lords Select Committee on Science and Technology to discuss health databases at the end of November. If speed and lack of opportunity for considered reflection is a main reason why the Icelandic case came under such local and international criticism, then these fragments from a speedy UK narrative, which appears scarcely visible politically, should not lead to complacency here.

The issue of Health Sector Databases or pharmacogenomics is of potentially profound significance for the whole shape and direction of healthcare. The promises being made to 'us', both as citizens and patients, are immense, but science and technology have made huge promises before and things have sometimes gone badly wrong. In the immediate post-war period, the physicists persuaded both the state and society that nuclear power could deliver cheap, clean energy. However, the experience of the nuclear industry, with its invisible pollution, its secrecy, and its economic failure, has led to widespread public distrust. For the foreseeable future, no democratic country seems likely to build a nuclear power plant. More positively, like most Northern and Western European countries, Britain has had very good experience of managing and regulating biomedical innovation, particularly in the field of human embryological research and IVF. These matters have been seen to require sensitive management, and have been given the time to develop an ethical consensus between all the stakeholders¹⁰. But culturally sensitive as they are, neither embryological research then (it changes today with the possibility of therapeutic cloning) nor IVF has had the immense significance for economy and society of either nuclear power or the new genetics. The stakes of the current proposals are culturally and economically high.

It is within this fast-changing context that this study of Iceland has to be read. I have tried to identify those features specific to the Icelandic experience and those which will necessarily confront the social market countries of Europe, such as Britain, as they enter the age of pharmacogenomics. My rather bleak hunch is that the new managerial tools produced by health databases, focusing as they do on the individual rather than the social or collective, are likely to intensify the process of exclusion already set in train, for example by the move to health

8 'Hurried and premature legislation in the rapidly evolving field of genetics can be counterproductive...'. Executive Summary Point 6, *Draft WHO Guidelines on Bioethics*, March 1999.

9 The Wellcome Trust and the MRC have committed £25 million to a UK Population Biomedical Collection. Clive Cookson, 'DNA: Searching for Wealth in Genes', *Financial Times*, 27 November 1999. However, no specific plans have yet been announced since then, suggesting that the organisations have encountered technical difficulties, even before they consider the social and ethical aspects. In the interim, the Trust and the MRC have conducted a market research survey of public opinion, available on the Wellcome Trust website.

10 Countries, not least both Iceland and Britain, typically take about four years between initial public discussion and embryology and IVF legislation.

management organisations in the USA. However, my prime consideration is not the marketised healthcare system such as that of the USA, but the still universal if weakened healthcare systems of social Europe.

There is a distinct irony to recent developments in pharmacogenomics. This potentially immense innovation, actively pursued by global pharmaceutical companies and venture capital, requires as its precondition a universal healthcare system¹¹. Only the old welfare states have universal healthcare records; marketised medical care systems exclude many from health insurance. Although those excluded from healthcare insurance may (or may not) receive reasonable emergency care, they are by definition also excluded from cradle-to-grave regular care and their concomitant medical recording systems. Not for the first time the relationship between the organisational structures of healthcare provision and the development of genetics comes into visibility and importance¹². For pharmacogenomics only the old welfare states offer what they speak of, in their depoliticised language, as a ‘good’ population¹³. However, what constitutes ‘good’ remains fluid. Thus, while deCode emphasises the smallness (275 000) and homogeneity of Iceland as ‘good’, SB sees the 59 million of the socially and genetically diverse UK as an even better ‘good’ population. More recently, the joint Wellcome Trust/Medical Research Council expert working group considering the case for a genetic epidemiological study considers that a sample of 500 000 will be appropriate. Again, the ‘good’ population for pharmacogenomics seems remarkably flexible – providing there are universal medical care and recording systems plus well cared for tissue banks.

The chronology of the controversy

Although the conflict over the Icelandic database broke in 1998, its origins go back to the summer of 1994. Then two Harvard-based clinical neurologists – Kari Stefansson, an Icelander, and his US colleague Jeff Gulcher – were visiting Iceland to collaborate in a study of multiple sclerosis (MS) with an Icelandic neurologist, John Benedikz. The research project was to look for a possible genetic predisposition to the disease. Benedikz cared for a number of MS patients and also participated in the MS patients’ association, as is not uncommon for clinicians caring for people with chronic diseases. The setting was ideal: Iceland is a small, easily studied society with universal healthcare provision; the incidence of MS was normal for a North European population; and Benedikz potentially offered links to both patients and their families. In 1994, there was little evidence suggesting that genes were important in the aetiology of MS, so this pursuit of predisposing genes could be read as the increasing geneticisation of clinical disease entities, pioneeringly documented by Yoxen¹⁴. In this process, the explanation of a disease hitherto understood as having some other aetiology, such as a slow acting virus, is now seen, partially or wholly, as lying in genetics.

11 Some commercial firms such as Myriad Genetics in the USA are making similar studies within marketised medicine but they are examining the very distinctive Mormon community where a good deal of genetic information has already been gathered and where genealogy is an intense cultural commitment. (Kari Stefansson is on the Myriad Board.) Other similar commercial studies but where there is social medicine are being made by Gemini Genetics (Cambridge UK) of twins; Signal Gene is examining the genes of the descendants of French settlers in Quebec, and Newfound Genomics the DNA of Newfounders. smartmoney.com, 12 July 2000. Estonia is seeking to establish a similar project and has run into controversy; Frank Lone, ‘Storm brews over gene bank of Estonian Population’, *Science*, 1999, 286, 5443:1262.

12 This was seen in microcosm earlier in London when the reorganisation of the NHS into trusts did immense damage to clinical genetics. Three leading London-based geneticists left for Oxbridge and Australia.

13 The deCode Non-Confidential Corporate Summary puts this clearly, ‘The problem having the greatest impact however, is finding and securing a *good* population’ (my emphasis), 1998, 3.2.

14 E Yoxen, *The Gene Business: Who Should Control Biotechnology?* (London: Crucible, 1982).

In what they spoke of as the ‘helicopter science’ mode¹⁵, the researchers flew in during the summer, secured as many samples as possible from patients and their families, and then returned to the Medical School at Harvard to do the lab work. But if identification of genes associated with disease is difficult in the case of single gene disorders, it is even more difficult in the case of disorders where more than one gene may have an influence. Certainly five years on, there were few signs of progress in their project, over and above oral reports to the Icelandic MS society that they had confirmed the chromosomal positioning already indicated by earlier family studies. A recent authoritative review of the genetic epidemiology of MS points to several difficulties in tying down genetic influences. Among the difficulties are the natural genetic variation of susceptibility in a population; and also the strong role of non-genetic factors indicated, for example, by events which have come to be seen as epidemics, including an Icelandic epidemic between 1945–54 which saw a much younger age of onset¹⁶. Experts debated whether the cause was the earlier presence of British troops or simply better diagnosis. The article concludes by drawing attention to the technical difficulties in the MS field and thence the need for a large sample. It may well be that these pose severe challenges in the Icelandic context.

However, Stefansson’s ambitions and vision were much wider than searching for the genetics of one disease entity. Although not a geneticist by training, he was the first biomedical researcher both to see the potential significance of Iceland and its genome to the genetics of common or complex diseases and also how to exploit the joint interest of the state and of venture capital in modern genetics. MS formed the paradigm case. Because medical care is universal and of high quality, Stefansson could reasonably assume that he had access to all known patients with MS and their families in one population. Having spent two decades in the entrepreneurial culture of first Chicago then Harvard medicine (there is one marvellous quote in the *New Yorker* article where he explains how he did not work at Milton Friedman’s university for nothing¹⁷), Stefansson was uniquely well placed to understand the research and commercial possibilities offered by this small, rich and relatively isolated North European population.

deCode’s twin objectives

It was out of this vision that deCode was born, as a US biotechnology company physically located in Iceland. From its inception, Stefansson had two very different, though interconnected objectives.

The first was to establish a commercial laboratory to carry out biomedical research in Iceland. This, like any other commercial biotechnology company working on human genetics, would seek to collaborate with clinicians interested in specific diseases and, either alone or with other pharmaceutical companies, work to develop new DNA diagnostic tests and drugs. By the autumn of 1999 deCode claimed to have full written consent¹⁸ from no fewer than 10 000 patients. What made deCode different from the routine biotech company was that from the beginning it was aware of the opportunity to link this information into the genealogies. These genealogies have been an Icelandic cultural passion since the time of the Sagas, and constitute a narrative of both personal and national identity. As social scientists and population geneticists are well aware, there is a discrepancy between the biological and the social narrative of family (guesstimated as between 1 and 10 per cent) and this discrepancy may

15 Given the interest in the Icelandic database, helicopter geneticists are being replaced by helicopter social scientists and an array of the world’s journalists. As the key players are few in number, Iceland is getting like the old anthropological joke about how every Hopi family has their own resident anthropologist. Fortunately the non-key actors are less over interviewed.

16 This authoritative review interestingly does not cite either Stefansson’s or Gulcher’s work, though it does cite that of their Icelandic collaborator. A Compston, ‘The Genetic Epidemiology of MS’, *Philosophical Transactions of the Royal Society of London*, 1999, 354, 1390:1623–34.

17 Michael Specter, ‘Decoding Iceland’, *The New Yorker*, 18 January 1999, pp. 43–51.

18 Clinicians who have seen copies of these consent forms are highly critical of their changing character in that they have changed from the normal single analysis consent to a much wider ‘fishing’ consent. Interview, July 1999.

have been more significant in the highly puritanical culture of the past. Nonetheless, access to such genealogical records, especially if they are available in modern computerised form, potentially speeds up the gene hunter's task. To this end, deCode has computerised and coded the genealogies of some 600 000 past and present individuals.

The second and more ambitious objective was to construct the GGPR database. The initials refer to Genetics, Genealogy, Phenotype (as expressed by the personal health record) and Resource (resource use within the Icelandic healthcare system). Iceland's size, high quality universal healthcare, medical records dating back to 1915, purported genetic homogeneity, a large and well documented tissue bank serving as a potential repository for much of the nation's genetic record, plus the presence of the distinctive genealogies, were seen as offering uniquely favourable conditions for turning the hot ideas of preventive medicine into a viable project. During the course of the struggle to secure the legislation, the GGPR became the more anodyne Health Sector Database (HSD). However, under whatever name, the deCode database is self-consciously a project which seeks to construct and commodify bioinformation, as much as one which commodifies the human body through control of the tissue bank or which brings into existence new biotechnological products.

This database also raises the possibility of radically new ways of managing and delivering healthcare. The possibility of tailoring drugs to patients with particular genotypic profiles offers better value for money for the drug budget coupled with less discomfort and danger to patients¹⁹. Given the pressure on healthcare resources, this looks like a win-win promise. DeCode's proposal thus shrewdly positioned itself to be attractive to several powerful players: venture capital; the welfare state; its marketised counterpart in the so-called Health Maintenance Organisations; and the insurance industry. All are potential buyers of this new commodity – bioinformation – although their purposes will be very different²⁰.

Patient groups as a site of conflict

Simultaneously with these two commercial objectives, Stefansson has continued as an active clinical researcher in the field of MS. He has been active within the Icelandic MS society, keeping in touch with the 250 patients and families who have continued to provide many samples over the years. Thus the initial clinical interest in locating a genetic predisposition to MS has been both a springboard and a continuing presence within the deCode story. Currently, the MS society shares Stefansson's view that the emphasis should be on gene hunting, and his belief that this will yield a successful therapeutic intervention for an intractable disease. An alternative objective – that the society should put its main effort into fighting for better health and welfare services for MS patients now²¹ – has been discounted.

It would be a mistake to underestimate the cultural legitimacy that such patient groups and their families can offer research clinicians²². Their attitudes and activities can, for example, increase or decrease the cultural geneticisation of the disease. One can easily identify instances of pharmaceutical companies funding small patient groups representing a genetic disorder (usually one which affects a significant group of the population, particularly where

19 That pharmacological drugs are the fourth largest cause of death in US hospitals realises Ivan Illych's prophetic diagnosis of iatrogenic disease.

20 Given the extent to which genetics is a recurrent theme in the mass media, just one instance of the way in which it permeates contemporary culture, deCode's proposal had heady popular appeal also. There are, however, arguments from within both biology and social science to the effect that this approach may overestimate the significance of genetics in health and disease. Many patients may well receive better treatment as a result of pharmacogenomics, but whether it is prudent to restructure health service provision on the expectation of a 'genetic revolution' remains to be seen.

21 In May 1999 the welfarists challenged the geneticisers at the committee elections. The latter won out, as Stefansson is very much a guru figure within the society.

22 Patients' groups were important in the UK debate at the end of 2000 on therapeutic cloning.

that company has, or has plans to develop, tests or drugs). Funding patient groups is not an intrinsically philanthropic activity, but a pragmatic means of extending and shaping markets. At the same time patient groups frequently need external resources, so they are relieved when companies take an interest and indeed may go out of their way to invite companies in. Their problem is how to manage the relationship so that their interests rather than the company's interests are prioritised²³. In my reading, patient groups are only beginning to be problematised and studied; all too often the genetic literature treats them as if they were not an important site of conflict.

Funding and branding deCode

Stefansson next set out to raise money to establish a research company. He was highly successful, raising US\$12 million in single-dollar shares over a period of a few months. The new firm deCode was registered in Delaware in August 1996. *Red Herring*, a US magazine which seeks to bring together venture capital and would-be scientific entrepreneurs, recognised this achievement by listing him among their 'entrepreneurs of the year'. This listing did him no harm in either the USA or Iceland. The initial venture capital firms were predominantly US-based: Alta Partners; Atlas Venture Partners; Polaris Venture Capital; Arch Venture Partners; Falcon Technologies; Medical Science Partners, together with Advent International which has a UK partner called Vanguard Medica²⁴. New start-ups like this were relatively rare in Europe in 1996, although prolific in the USA, and the registration of the new company in Delaware and its physical location in Reykjavik was a clever combination. (Venture capital in Europe has become more adventurous²⁵ since.) The larger investors joined the board but, other than Sir John Vane²⁶ from Vanguard Medica and Stefansson himself as CEO, there are no researchers on the board. Stefansson also recruited Vigdis Finnbogadottir, the ex-President of Iceland. The ambiguous message about deCode's national identity was thus constructed with some ingenuity. Physically located in Iceland, it was nonetheless a US-registered company with a board dominated by US and British venture capitalists.

The presence of the sometime Head of State unquestionably flagged high-level Icelandic political and cultural support. It is worth noting the parallels with how the British Head of State, Queen Elizabeth, gave her imprimatur to the nuclear project by officially opening the Calder Hall power station²⁷. Above politics, the Head of State can give cultural and political legitimacy to scientific and technological innovation. Even former or future Heads of State can act in this way. An interesting recent development in the UK is when a (future) Head of State refuses

23 My own work on people with familial hypercholesterolaemia studied a voluntary group which was transformed by substantial pharmaceutical company injections from a shoestring operation meeting literally around the vicar's wife's dining table, to a professionally led organisation with its own offices, cars etc. By contrast, an anthropological study of the US 'pockmarked dwarves' – their label not the researchers – showed a patient group with considerable political sophistication collaborating with trusted research clinicians to establish their own sample bank, and thence control the direction of research. Karen Taussig, Rayna Rapp and Deborah Heath, 'Soft Eugenics: Discourse of Perfectibility and Free Choice at the End of the 20th Century', *Wenner Gren Conference: Anthropology in the Age of the New Genetics*, Brazil, June 1999.

24 These companies are very much interlinked and include some of the most powerful venture capital firms. For example, Advent International, Vanguard Medica's partner, is partly owned by Hoffman La Roche, while Atlas Venture Partners partly owns deCode Genetics, deCode, Exelixis Pharmaceuticals and Exelixis. The drug companies themselves continue to make or fail to make mergers. Though my account speaks of deCode as one entity it should be more precisely understood as a group of closely linked companies.

25 'Europe's start-up stampede: US venture capitalists are helping fuel a new boom in new European internet and high technology business', *Economist*, 15 January 1999, 77–8.

26 Sir John Vane was awarded a Nobel Prize for his work carried out at the Wellcome laboratories and represented Vanguard Medica on the deCode board.

27 British Royal Heads of State both current and future have been not uninfluential. Queen Victoria's acceptance of anaesthesia in childbirth unquestionably fostered acceptance of that innovation, while her distaste for animal experimentation, given the widespread popular hostility, might well have blocked the new experimental physiology. The skilled politicking of Darwin and the scientific elite won through, but at the price of accepting animal welfare regulation. This has been much stronger in the UK than is the case for human experimentation and clinical research.

that legitimacy: Prince Charles' comments on GM crops set an intriguing precedent expressive of the UK's ambivalent arrival in the 'risk society'. In Iceland, although the symbolic cultural capital provided by the presence of Finnbogadottir was unquestionably useful, it was the immense energy of the media-skilled six feet five inches Icelandic CEO himself which gave deCode an everyday highly visible Icelandic presence in the national and indeed global media²⁸.

The successful branding of deCode as Icelandic and as Stefansson's personal project is key to its popular acceptability. Social theorists have long regarded the social democratic welfare states as the historic settlement between the two great classes and the state. Forgotten in that account was that all three parties to the settlement took for granted that they had a shared nationalism from which the social democratic project drew its strength. For reasons of geography and of history, progressive nationalism is still vibrant within Icelandic culture and Stefansson has managed entirely brilliantly to locate deCode and the HSD inside a narrative of both scientific and national progress. He commands immense personal loyalty. His reputation is untroubled by accounts of him losing his temper on television. Nor was he damaged by a recent incident in which he denounced Jonathan Knowles of Roche, because he (Stefansson) had not made clear to Icelandic investors that the US\$220 million was conditional on deliverables being delivered. Knowles had also expressed the view that it was unlikely that deCode would be able to generate enough deliverables to secure the full US\$220 million contract. Instead, the general public sees Stefansson's charismatic nationalism and his enthusiasm for scientific innovation as exactly what Iceland needs²⁹.

The 'good population' for pharmacogenomics

The Icelandic population was portrayed by deCode as the ideal 'good population' for pharmacogenomics. Unique as a European nation state in that its small size (275 000 inhabitants mostly living in and around the capital Reykjavik) and watery isolation have left it outside the territorial conflicts which have ravaged (and still ravage) the rest of Europe. It has also historically been a desperately poor country, with only a small elite having anything other than the miserable subsistence existence described so vividly for the early twentieth century in the novels of the Icelandic Nobel Prize Winner Halldor Laxness. Economic growth and social development have been very rapid: hopeful signs flickering in 1914–18, but substantially taking place since 1945, during which time an agricultural and fishing people have become predominantly urban dwellers. Today, the fishing, plus geothermal energy secured by harnessing the volcanoes on the island, has helped generate a high per capita income, low unemployment, a strong welfare state, good healthcare, and high quality education. Iceland's expectation of life and low infant mortality figures are only bettered by those of Japan at the height of her economic boom.

The deCode documents speak of the Icelandic population as not only highly educated but 'cooperative' – by implication with scientific and technological research. Judging by the evident enthusiasm for new consumer technology, from four-by-fours to mobile phones and the Internet, Icelanders are not only a wealthy population but are distinctly technophile. Unquestionably the majority of the population supports the database project, though the opinion polls indicate rather less enthusiasm among the young. This cultural enthusiasm for science and technology and its fruits is more ambiguously shared by most other Europeans, for these have had more than their fair share of the risks as well as the benefits of science and technology. Chernobyl, mad cow disease and GM food have intensified a shared sense of the risks as well as the benefits from science and technology. Indeed, social theorists such as the German Ulrich Beck³⁰ and the British Anthony Giddens³¹ have in recent years developed the

28 I note Stefansson's striking physical appearance not least because he appears in a good deal of journalistic commentary as the embodiment of the tall Viking, while the HSD is frequently represented particularly in US media as being about Viking genes.

29 Nordic press commentary has been quicker to spot what they spoke of as 'genetic nationalism'.

30 Ulrich Beck, *The Risk Society: Towards a New Modernity* (London: Sage, 1992).

concept of ‘the risk society’ to grasp this changed character of risk³². But for those such as Icelanders living in earthquake and volcanic zones and avalanche country it is different: the biggest threats still come from an ever-present, potent nature and not so much culture³³. Thus that scepticism about the fruits of science and technology, born from living in a risk society is not shared by many Icelanders. Science and technology are still seen as friendly: they harness the powers of nature. Technical and social progress are still happily married. Endlessly, Stefansson plugs into the rhetoric of ‘science is progress it cannot and must not be stopped’. Thus, while it has long been the case that biomedical research is both more popular and more trusted than other research fields, this sense of Iceland not being part of the risk society gives the database project a peculiarly friendly niche.

Politically, Iceland is interesting as despite its history of near-subsistence level existence, the islanders also have the longest experience within Europe of parliamentary Government. Their parliament, the Althing, goes back to settlement, that is some thousand years. During this century Iceland was initially under Danish tutelage but during the 1939–45 war came under first British, then US, ‘friendly’ occupation. This occupation was seen as a politically acceptable alternative to Nazi invasion. The occupation of Denmark itself by the Nazis gave the islanders their chance to secure their independence first *de facto* then, with the end of the war, *de jure*. Although territorial war was not part of the formation of nation, war over the sovereignty over the sea was. The Cod Wars have a five-hundred year history³⁴, flaring up in the post-World War II period notably with Britain, and have been as crucial for national survival and identity as any conventional European fight over territory. Extending sovereignty over the seas and thence fishing was thus a major element in the formation of the Icelandic nation state especially following World War II. Unsurprisingly, with 79 per cent of its GNP based on fish, Iceland stayed out of the EU, not least to maintain exclusive access to its waters.

For deCode and genomics the ‘good population’ offered by Iceland lies in the story of settlement, smallness of size and what is endlessly spoken of as the genetic homogeneity of the population. In the deCode Corporate Summary³⁵, the story of the original Viking settlers and their Celtic slaves who settled around 930 AD is updated, and, in the case of the Vikings, socially upgraded, to become ‘Norwegian nobility and Irish slaves’. First, deCode insists on the relative isolation of the island’s inhabitants until the nineteenth century. Thus they set aside the history of Cod Wars first fought by the English against the Hanseatic League just outside the port of Grindavik in the early sixteenth century. Icelanders themselves were at that point too poor to engage in significant fishing, which was controlled by the powerful League. Indeed, without noticing the contradiction of its narrative of isolation, the Summary goes on to note the arrival of the Bubonic plague from Europe in the early fifteenth century which reduced the population by more than half. For deCode this disaster is evidence of a ‘population bottleneck’, a phenomenon which population genetics sees as intensifying founder effects and thence genetic homogeneity. The Summary then notes a second disaster in the famine that followed the huge volcanic eruptions of the early eighteenth century, leading to a similar halving of the population in a second population bottleneck. Lastly it suggests that the mass emigration to North America in the nineteenth century could be seen as a third.

31 Anthony Giddens, *Modernity and Self Identity* (Cambridge: Polity, 1991).

32 The weakness of the theory of the risk society is that it turns on the assumption that the old forms of risk, primarily that of poverty, have been overcome through the welfare state. Now while this may well have been true for Germany in the eighties when Beck initially wrote his book, subsequent German unification and the accelerated rolling back of the welfare state under Thatcher in the UK means that the old risk from poverty is still starkly present. The new risks from science and technology are thus added onto the old poverty risk. By contrast, Iceland still has a strong welfare state and a thriving economy hence its citizens have little currently to fear from poverty. At the millennium Iceland thus offers the perfect antithesis to Beck’s 1980s risk society.

33 Only a few years ago a volcanic avalanche swept away a huge section of the ring road which goes round the entire island and in the spring of 2000 a quite strong earthquake was experienced just outside Reykjavik.

34 The first sea battle being triggered in 1532 by the murder of an Englishman John the Broad in the streets of the fishing station of Grindavik. See Mark Kurlansky’s fascinating book, *Cod: A Biography of the Fish that Changed the World* (London: Cape, 1998).

35 deCode *Non-Confidential Corporate Summary*, Reykjavik: deCode, June 1998.

Thus the language of population genetics is deployed by the deCode Corporate Summary to produce a narrative of ‘strong founder effects’ and ‘genetic homogeneity’. A difficulty with this claim is that, while these were indeed disasters, within the discourse of population genetics even more than halving a population is still not a severe enough reduction to constitute a bottleneck. Indeed, as the distinguished population geneticist Luca Cavalli Sforza notes, Iceland shares the European genetic profile and although a relatively isolated island is much less different from this general pattern than Sardinia. He cautiously observes ‘current research may show that the Icelandic population is not as homogenous as might be expected’³⁶. DeCode’s claim of isolation and homogeneity runs into a second problem which Cavalli Sforza misses because he restricts settlement to a single people, the Vikings. Thus serological studies suggest that the Celtic influence, at 52 per cent, is the stronger biological strand, even though the Vikings were unquestionably dominant culturally and politically. This narrative of homogeneity finds popular echo not only in the deCode literature, but also in the symbolic representation of the nation, whether in the state-commissioned sculptures by the harbour or in the tourist-shop kitsch. The Viking helmet and the long ship predominate. Neither the Celtic slaves nor the North British women abducted or persuaded from the coasts get a place in the symbolic self-representation of the nation³⁷. The quieter work of the serologists and the historians points to a more complex story.

In the furore over the database, stereotypical representation of an island people descended solely from ‘blue-eyed blond Vikings’ frequently spins out of control³⁸. In remarkably racist language, the Icelanders are described as ‘a nation of clones’ because ‘everyone in Iceland is related to everyone else...all of them are descended from the same few Vikings...’. Or the article gets a would-be funny but distinctly inaccurate title: ‘What’s blond and blue-eyed and read all over?’ Another US journalist flew in and declared that the population all ‘looked alike’³⁹. While it is the case that the population is predominantly white (which is, I guess, what ‘looked alike’ actually meant in the mind of the journalist) even this is changing, although still well behind the rate of change of the other Nordic countries. There is, for example, a very small Indian community (about 30) in Reykjavik. There are also children adopted from the Third World by Icelandic couples, together with migrant labourers from the former East Europe, particularly Poland, finding employment in the factories. Since World War II there has been a big US base and, of course, Reykjavik has long been a significant northern port. Raw racism played a part in this story, as for many years the deal with the USA precluded the presence of any black troops. However, while it is true that there has been little formal immigration into the island in the past this is changing subtly, and it is difficult to believe that foreign gametes have not joined the local population in the usual way. Nonetheless, the stereotypical representation and the narrative of national homogeneity is strong and it has suited deCode to play into this.

When US commentary on the HSD began to invoke the stereotype as if it had a robust purchase on reality, the Icelandic Ambassador to the US intervened with a letter to the *Washington Post* to remind the readership of the population’s diverse inheritance⁴⁰. Not only did he gently tease one of the journalists for suggesting that Icelanders were all blond and blue-eyed, but he recounted the story of how Hitler was convinced that securing

36 Luigi Luca Cavalli-Sforza, *Genes, Peoples and Languages* (Harmondsworth: Penguin Press, 2000, p. 31). However his magisterial overview unfortunately fails to take account of the non-Viking settlers, p. 20.

37 Sceptical Icelanders suggest the state-sponsored helmet and longboat iconography is quite recent, possibly satisfying the needs of the tourist industry in an aesthetically pleasing way. They claim that many North Americans want to read their Norse roots as Viking. A similar and perhaps better known phenomenon is the genetically impossible claims by North Americans of Irish ancestry. Some roots are clearly more romantically desirable than others. Such cultural sceptics suggest that trolls with all their fearsomeness are much more Icelandic but that they lack the Viking glamour.

38 Simon Mawer, ‘Nation of Clones’, *New York Times*, 23 January 1999; Eliot Marshall, ‘The answer can be found in Iceland’s mostly blond, blue-eyed, extremely homogenous population’ in ‘Iceland’s Blond Ambition’, *Mother Jones*, May/June 1998, 53–7.

39 Jon Schwartz, ‘For Sale in Iceland: A Nation’s Genetic Code’, *Washington Post*, 12 January 1999.

40 The Ambassador’s letter elsewhere agrees with Schwartz’s characterisation of the Icelanders as a blend of Norse and Celtic stock, but then goes on to say ‘we never thought we looked alike’. Jon Baldvin Hannibalsson, Icelandic Ambassador, letter, *Washington Post*, 29 January 1999.

Iceland would be something like securing Valhalla so that the German representative on the island found it necessary to write a regretful letter explaining that the Icelanders were rather more of a mixed bunch⁴¹.

deCode starts work

Stefansson returned to Iceland in 1997 and by November that same year had established deCode as a commercial research lab in the industrial suburb of Reykjavik. DeCode soon had spent more on research than the Icelandic Government's annual research budget – some US\$65 million. While it was true that some Icelanders were recruited back home from abroad, which had been one of the reasons why deCode was attractive to politicians and public alike, the higher pay scales offered also produced internal movement from the academic and other non-profit research sectors. In a very small country with few scientific migrants flowing through the research system, this could have a big effect on individual laboratories. In Stefansson's strategy, speed was of the essence. Speed first in getting the political and venture capital support in place, then speed in getting the biotechnology company established, and lastly speed in getting the Health Sector Database up and running under exclusive control. Speed was the magic ingredient that would provide the competitive edge for a small new company with huge ambition.

In a small society it was relatively easy for Stefansson, as a member of the well-connected cultural elite, to cultivate the Government politicians concerned with the economy, not least the Prime Minister David Oddsson. As centre-right politicians, they were attracted by Stefansson's highly market-oriented vision that at the same time seemed to offer so many economic and health benefits for Iceland. Oddsson in particular publicly declared himself willing to sweep away ethical constraints that might impede the advance of the new technology. By the autumn of 1997, Stefansson was ready to approach the Ministry of Health with the proposal for the HSD. A book analysing the HSD affair published in Iceland in November 1999, written by postgraduate history student Gudni Johannesson, reports that deCode did rather more than approach the Ministry: the firm faxed a draft copy of the bill to the Ministry in September 1997⁴².

While the discussions with the Ministry were proceeding, deCode realised its ambition to put itself on the global biotechnology map in February 1998. Hoffman LaRoche, then the fourth largest pharmaceutical company in the world, made a US\$200 million, five-year deal with deCode on positional cloning. For LaRoche this reflected a determination to move further into pharmacogenetics, that is using genetic diagnostics to guide the administration of drugs⁴³. For deCode this meant that it was acknowledged by a major pharmaceutical company as a leading-edge biotechnology firm. The deal, as LaRoche emphasises in its publicity, is solely directed toward the first of deCode's two business objectives. It claims to have no connection with the HSD, and instead is composed of up-front investment and payments for the achievement of 'milestones', although neither the exact nature of these milestones nor the size of the payment has been made public⁴⁴. Nonetheless, the deal was big news in Iceland⁴⁵ and in the global world of biotechnology.

41 He could also have reminded them that in the story of Njall, one of the greatest of the Sagas, both that Njall is a Celtic name and also that his sons are described as one having red hair the other being dark. Diversity not homogeneity is present in the founding cultural narrative of Iceland.

42 I am indebted to the Icelandic historian of science Skuli Sigurdson for sending me this information, 22 November 1999.

43 Stephen D Moore, 'Roche Research Chief bets on Future on Genetics', *Wall Street Journal Europe*, 13 July 1998.

44 The deCode *Corporate Summary* suggests that the Roche revenues are anticipated at US\$15–20 million per year. Informed commentators suggest that it is more like US\$10–12 million per year, i.e. calculating US\$1 million per disease and there are 12 diseases. One milestone payment has been made for osteoarthritis. Stephen D Moore, 'Roche and deCode to announce location of osteoarthritis gene', *Wall Street Journal B2*, 26 March 1999.

45 In the same month a group of Icelandic investors made a private placement including venture capitalist Enir Snorrasson who was subsequently to turn against deCode and join Mannvernd.

The Prime Minister, David Oddsson, publicly endorsed the deal, welcoming deCode as wealth creators, as bringing high-tech jobs to Iceland, and as offering the opportunity for young Icelanders working abroad to return home. Vigdis Finbogadottir, who as President had spoken frequently of the need for high-tech jobs to bring young Icelanders home, shared Oddsson's enthusiasm for the new company. DeCode has provided some 250 new jobs of which more than 40 are research positions. As one Icelandic commentator pointed out, 250 such jobs in Iceland would be approximately the equivalent of 250 000 in the USA, so the enthusiasm of Government and public alike is unsurprising. However, others regard the thousand-fold multiplication as absurd: to them a company employing 250 people is the same whether it is located in Iceland or the USA. For such sceptics, the thousand-fold comparison is part of feel-good Icelandic nationalism.

DeCode's Non-Confidential Corporate Summary, published in June 1998, reported that it had started work on 25 common diseases. By December 2000, its website was recording that DNA analysis had started for 28 diseases⁴⁶:

Autoimmune diseases

Atopy/allergy; inflammatory bowel disease; insulin-dependent diabetes; psoriasis; rheumatoid arthritis.

Cardiopulmonary diseases

Asthma; chronic obstructive pulmonary disease; hypertension; myocardial infarction; peripheral arterial occlusive (or peripheral vascular) disease; cerebrovascular disease (stroke).

Cancer

Lung cancer; prostate cancer; melanoma; renal cancer.

Central nervous system diseases

Alzheimer's disease; anxiety disorder; bipolar disease/depression; familial essential tremor; multiple sclerosis; narcolepsy; Parkinson's disease; schizophrenia.

Eye disease

Macular degeneration.

Women's health

Endometriosis.

Metabolic and other diseases

Non-insulin-dependent diabetes; osteoporosis; osteoarthritis.

The Summary claimed that deCode has the capacity to map 12 common or complex – the terms are used more or less interchangeably – diseases each year, and at that point to have fully mapped five. It emphasised the company's ability to take on new disease categories as requested by corporate partners, not least because of the technical ease offered by highly automated systems to run the samples through a battery of DNA analyses.

'Genotyping that is done on patients for a particular disease has value for all subsequent diseases that deCode genetics studies...For example, deCode has a nuclear family that fits into extended family networks for diabetes, familial essential tremor and MS. Hence genotyping this one nuclear family provides information to the solution of all these diseases.'⁴⁷

⁴⁶ Among geneticists the size of the list and the number of research staff produces sardonic jokes... 'everything except the genetics of hanging toe nails etc. etc.'

⁴⁷ deCode *Non-Confidential Corporate Summary*, 1998, 3.2.

Internationally accepted standards of good practice would require not only informed consent for the first DNA analysis, but that the researchers should seek separate consents for each subsequent analysis or secure informed consent to a series of subsequent tests⁴⁸. Thus, deCode's technocratic and commercially driven language of 'has value' appears to set aside consideration of the ethical requirements demanded by human genetics. A similar concern about gene fishing is currently being raised about commercial access to the Swedish tissue banks, as we see from the comments made by the chair of the Research Council's Ethical Advisory Board, Gisela Dahlquist. She observed, 'many people seem to feel that once a blood sample and informed consent is given, they are free to use the blood for any purpose'⁴⁹.

Stefansson similarly sees the information in the health and genetic records as an unexploited resource. What he wants to do is to 'make value' of these untapped resources, in consequence tapping such national information resources becomes a moral and national duty. The bill echoes this thinking and speaks of 'a duty to use the data'.

Legislating for the HSD

Timetable:

First announcement to experts:	23 March 1998
First bill:	31 March 1998
Draft of a new bill:	June 1998
Second bill:	October 1998
Act on Health Sector Database:	22 December 1998

The first time that anyone other than deCode staff, key Health Ministry personnel, and senior members of the Government heard about the proposed HSD was at a meeting on 23 March 1998, six months after deCode had faxed a draft of the bill to the Government. That day, 15 experts were invited at 12 noon to a meeting to take place at 3 p.m. at the Ministry. There they were told about the forthcoming database bill; the participants at the meeting, and in particular the then Director of Public Health, demanded to see the written text.

Two days later the text was made available – in confidence – to the 15 experts. Comments were to be sent to the Ministry before 12 noon the next day, giving the experts less than 24 hours to produce a considered opinion. On a number of occasions, not least in its evidence to the European Steering Committee on Bioethics⁵⁰, the Ministry has claimed wide professional consultation, but there was little evidence of this at the crucial early stages. Neither the Icelandic Medical Association nor the Specialists' Association reported any such consultation among their members.

48 This whole area is under sharp debate. Francis Collins, Chief of National Human Genome Research Institute, has recently warned that if informed consent is required from family members as well as the original subjects, then research will grind to a halt. In this he is challenging the Office of Protection from Research Risks, which has ruled the reverse. Meredith Wadman, 'Geneticists oppose consent ruling', *Nature*, 2000, 403:114–5.

49 News Focus, 'Sweden takes steps to protect Tissue Banks', *Science*, 1999, 286:894.

50 Steering Committee on Bioethics, *Report of Hearing of Icelandic Experts concerning the Law on a Public Sector Database*, Strasbourg: Council of Europe, 4 May 1999. This has been interpreted by ethicist Ruth Chadwick as concluding that the HSD is ethically acceptable: Ruth Chadwick, 'The Icelandic database – do modern times need modern sagas?' *British Medical Journal*, 1999, 319:441–444. However, molecular geneticist Bogi Anderson, evolution geneticist Einar Arnason and historian of science Skuli Sigurdsson subsequently wrote to the journal pointing out that Chadwick had confused the Iceland Government's evidence with the Committee's conclusions, 'Kafkaesque Ethics for Postmodern Vikings?' *British Medical Journal*, 23 August 1999. However, the Eurogapp report (*op. cit.* p. 2), disturbingly ignores this correction and repeats Chadwick's interpretation.

March 1998: The first bill

On 31 March 1998, only eight days after the oral presentation to the expert group, Ingibjorg Palmadottir, Minister of Health, introduced the Health Sector Database bill to the Althing. There the Icelandic public learnt about the database for the first time. As framework legislation, this first draft (and indeed the subsequent bill and final law) left much of the detail to be filled in by negotiation led by the Ministry of Health. The Health Sector Databases, only one of which would be granted a monopoly, were to be constructed from three individual databases: the medical records of the entire population; genetic records; and the genealogies. Universal consent was presumed. Initially the bill offered little protection to patients as, with rather little information, it would be possible to trace individuals. The database was to be funded privately⁵¹. In return, the company that won the licence was to have monopoly access to one of the databases and was to receive the right to market the database for a period of up to twelve years for:

- 1) genetic discovery, diagnostics and drugs and,
- 2) healthcare management.

Both deCode and Stefansson were referred to directly in the gloss to the bill, even though the tender for the licence was to be put out to competition.

A Faroese informant explained that, in the case of the document circulated to residents of the Faroe Islands, the Government went so far as to put a picture of Stefansson on the cover, even though the legislation had not been passed and the contract not awarded. The Faroese decided not to join the HSD, so her interpretation was that this was a counterproductive publicity move. She also claimed that the Faroese church played a big part in criticising the ethics of the HSD project, whereas in Iceland the church was relatively quiescent. Certainly Vilhjalmur Arnason, Professor of Philosophy at Reykjavik University, criticised this silence. It was not, he said, that he thought the church should be for or against the HSD but the ‘deathly silence’ of the church gave no moral leadership⁵². The one criticism took the form of a satirical essay published by a priest in *Morgunblad*, which drew an angry rebuttal from the Prime Minister himself and a mollifying letter from the Bishop.

This first bill proposed that the medical records of the entire Icelandic population were to be entered into the databases on the basis of universal presumed consent. Epidemiological research recognises that there are sometimes intractable ethical or practical problems in getting informed consent. In such cases where it is decided to proceed, the research is accompanied by an ethical and medical rationale justifying such a step on public health grounds and guaranteeing anonymity. (The UK decision to test anonymously all new mothers for HIV status is an example, underlining both the difficulties in coming to such a decision and the ethical problems the process threw up.) In the Icelandic case neither the bill, nor the Minister’s introduction to the bill, offered any such rationale.

Given that there was no prior consultation concerning the core ideas of the HSD, and no equivalent of a UK White Paper or a Warnock Report, the negative reception from much of the clinical and research community was predictable. Thus while the general public was by and large untroubled by the HSD and saw it in the same favourable light as the Government, many of the relevant professional groupings – clinicians, nurses, scientists and patients’ rights lawyers – found the bill ethically unacceptable in principle, and poorly drafted in detail.

51 The licensee was to pay for the licence itself, plus all associated costs with setting up and running the database including the cost of informing the public. And, when the database was functioning to make additional payments, to be agreed, to the Government, these to be ring fenced for health services and health R&D. Act on HSD, 1998.

52 Vilhjalmur Arnason, ‘The Base Cracks and the Deathly Silence of the Church’, *Morgunblad Weekend Review*, 21 November 1998 (translation from Mannvernd website: www.mannvernd.is).

The core ethical, cultural and policy issues concerned consent, privacy and the impact on the healthcare and research systems. The meaning of informed consent in the age of genetics is by no means an easy question. Can encryption offer confidentiality in a very small society? Tomas Zoega, chair of the Icelandic Medical Association, pointed to the threat to the relationship of trust between doctor and patient posed by the database. If patients thought everything they said to the clinician would go into the database, they would stop talking openly. Others thought that putting highly personal material into a record which would enter the database would so trouble clinicians that they would start to keep shadow records.

Peter Hauksson, a psychiatrist and chair of the Iceland Psychiatric Patients' Association, took the view that the supporters of the database were mostly people with no personal history of serious disease and so they did not understand the need for confidentiality in the doctor–patient relationship. Hauksson later became chair of Mannvernd – the association of Icelanders concerned with ethics and responsibility in science. Further, the easy assumption in both the bill and deCode's Summary, that there was no conflict of interest between non-profit and profit-making research, glossed over an obvious problem. Failure to acknowledge and deal with this conflict of interest, not least around intellectual property rights, is a conspicuous weakness in the legislation.

The failure to reflect on the impact of the HSD on the existing research system is most clearly seen in the case of the existing cancer database. Breast cancer is one of deCode's chosen diseases, yet non-profit Icelandic research in the field of genetics, using the meticulous registers of the Cancer Society, had been crucial to the identification and characterisation of *BRCA2* (a gene predisposing to breast cancer) and to improving estimates of the risk deriving from mutations in this gene. Icelandic estimates of risk are considerably lower than those produced by US research, and while the technical debate concerning risk continues, the Icelandic researchers argue that their lower estimates of risk stem from their high quality and comprehensive cancer database.

A serious concern among established researchers in Iceland was whether the generalised new database could ever be as accurate as this specialist register with its careful and expert curation. Would a centralised, and thus an almost certainly poorer-quality, database follow Gresham's law, the non-profit and specialist cancer researchers worried, and drive out the proven high-quality specialist database?⁵³ Further, what damage would the presence of a well-funded commercial biotech laboratory do to the capacity of highly successful non-profit Icelandic research teams to continue to deliver world class genetics? The most able genetics researchers might need to relocate to another country to find a viable research setting. These issues are not yet clear one way or the other. There is no immediate sign of the key team breaking up, but it claims it is losing personnel to the higher wages of the commercial sector. The framework legislation, in its lack of consultation of the research community concerning the impact on the research system, evidently failed to take these issues on board.

The proposal for a monopoly licensee (universally seen as deCode from the first moment the HSD project was made public) potentially raises European competition rules. Did making a monopoly licensee constitute a breach? Meanwhile at least one new biotech firm has been established in competition to deCode's core biotechnology business. Iceland is not a member state of the EU, but does collaborate in EU-funded research and collaborates closely both with other Nordic states and with the European Free Trade Association.

53 This concern has surfaced again in discussions of the UK Population Biomedical Collection of around 500 000 adults currently being considered for the UK by the MRC and the Wellcome Trust. The central technical issue is that medical records created by general practitioners for the purposes of clinical treatment may not be specific and precise enough to permit a true correlation between genotype and phenotype. See David J Weatherall, 'From genotype to phenotype: genetics and medical practice in the new millennium', *Philosophical Transactions of the Royal Society of London*, 1999, 354B:2008, and also, David J Weatherall, 'Single gene disorders or complex traits: lessons from the thalassaemias and other monogenic diseases', *British Medical Journal*, 2000; 321:1117–1120.

Icelandic human rights lawyers saw the HSD legislation as reversing the gains achieved by legislation passed in 1997 setting out patients' rights. In the patients' rights debate in the Althing, the question of the commodification of medical records came up. The Government had proposed that the state owned the medical records but, after intense debate in the Althing where a number of politicians argued that clinical records belonged to the patient, the Government withdrew its proposal. Thus medical records remained where they were, still uncommodified: they were to be held by the medical institutions, but it was the legal responsibility of the clinicians as the professional guardians of the records to maintain confidentiality. The issue of confidentiality is strongly supported by the Icelandic courts and by the medical profession. For example, the memoirs of a retired psychiatrist, which included case material that was felt by patients to be identifiable, were challenged in the courts and led to his being struck off and fined.

For many clinicians, their sense that they held the professional responsibility for patients' records meant that they necessarily had to oppose these being transferred wholesale into the database. So far, some 44 GPs and 109 hospital specialists have signed a statement refusing to submit data unless requested by patients. It is thought by the opposition that more will also refuse but without making their decision public. Meanwhile, the Government and deCode rely on the clinicians eventually giving way as the HSD becomes routine. It is impossible to predict who is right.

June 1998: The second bill

The outrage which greeted the March bill from large sections of the clinical and biomedical research communities led to its withdrawal and the introduction of the second draft in late June. This time the bill was widely circulated in advance. The critics and the intense debate they had conducted in the media had secured three substantial concessions. First, while there was still no rationale from the Ministry setting out the arguments for universal presumed consent, in the July bill this proposal had been modified. To the concern of the critics 'presumed' had not been replaced by 'informed' consent⁵⁴. Instead the possibility of 'opting out' was written into the new bill.

Opting out requires that the patient takes the initiative, picks up the forms held in chemists, surgeries and hospitals, completes the form (which is quite lengthy) then returns it to the Director of Public Health. This enables individuals, and also on behalf of any sons and daughters under 18, to withdraw from the HSD. Early in 1999 all households were sent a pamphlet explaining the HSD and telling them of their rights to opt out. However, the pamphlet did not include a copy of the opting-out form. Thus, although opting out now modestly protects the right of Icelanders not to be included in the database, it has been hedged about with difficulty, thus serving to keep the numbers of those opting out to a minimum. Even so, by mid-June 1999 some 11 000 had opted out and forms have continued to trickle in. By November 2000, 19 437 had opted out, only a few hundred short of Mannvernd's target of 20 000.

The second concession strengthened the privacy and confidentiality of the data. Personal identifiers were now to be encrypted; the licensee would not have a copy of the key; and the information would have a unidirectional flow. In this way, individual patient data could not come back or be attributed to the individual patient. In order to get the bill through, the Government had sacrificed access and re-access. The Data Commission was given the responsibility for separating personal identifiers from the medical information and for making sure that rare or

54 This issue still burns brightly. See Jeffrey Gulcher and Kari Stefansson, 'The Icelandic Healthcare Debate and Informed Consent,' *New England Journal of Medicine*, 2000, 342, 24:1827-30 and George Annas, 'Rules for Research on Human Genetic Variation – Lessons from Iceland' same issue of *NEJM*, pp. 1830-3. This debate was continued very sharply in *Morgunblad* and translated onto the Mannvernd website. As with the later reported attack on UK Cambridge computer specialist Anderson, Stefansson's attack on the health lawyer was ad hominem. This time the US critic was 'only at Boston University' and not at a premier league institution, whereas the UK computer security expert was just a 'hired gun'.

isolated cases would not be featured in database analyses. The minimum group for analysis had to be at least ten.

The third concession reflected anxieties about the impact on the research system. In addition to giving monopoly control of the HSD to the successful tender, the bill also provided for the purchase of access to the data by biomedical researchers from outside the licensee's company. If these researchers worked for the Icelandic health service and thus contributed to the database, they would be charged at a preferential rate. However, this access was still conditional on the researcher's interests not being in conflict with the commercial interests of the company. That the licensee was to be both judge and jury on this matter of commercial interest did not allay the fears of the biomedical professionals, as they saw this as giving the licensee an unreasonable power to control access and thence their freedom to research.

Although the Government had made considerable changes, the difficulty with the *post hoc* approach is that neither the viability nor the desirability of the project can be tested in prospect. Criticism can only modify; rejection of the entire project is not an option. After the second bill, Mannvernd – the association of Icelanders concerned with ethics and responsibility in science – was established, immediately setting up a website both in Icelandic and in English. The website is maintained with great skill and energy; it both monitors the debate in the press and the Althing in Iceland, and opens links to references in the international particularly scientific press. It is a fascinating example of a protest use of the Internet with English as the language of global mobilisation. For example, Mannvernd offered an English translation of the final December legislation well before the Ministry got round to putting a version on their website, arguably pushing the Ministry into doing so. It has also published an English translation of the Biobanks law.

The membership of Mannvernd indicates the intensity of the division among the intellectuals above all within the research and clinical communities. To give some feeling of the intensity of the conflict I can only say it reminded me of the Vietnam War, where you were either for or against the war, there was no middle space left. A manifestation of the intensity of the conflict is the widespread leaking of confidential material. Thus, I was given the same confidential material by different sources, all equally determined to get the hidden story out⁵⁵. Mannvernd includes not only concerned citizens but also people with chronic diseases who are concerned that the managerial tools deCode proposes to develop will be used within Iceland to justify cuts to health and welfare provision. It also includes some of Iceland's most distinguished scientists and clinicians together with at least one influential Icelandic entrepreneur who had initially welcomed and invested in the new company.

International criticism and support

The HSD has not only divided Iceland's scientists and clinicians but has mobilised international criticism by scientists and doctors. There has been considerable international endorsement, but typically this has come from the entrepreneurial culture rather than from that of science. Thus, in addition to the ringing endorsement given by the US magazine *Red Herring* in the start-up days of deCode, and Hoffman La Roche's early readiness to invest in the firm, deCode was similarly endorsed by the Davos economic summit in early 2000. International scientific critics included Icelandic biologists working in the USA. Both the West Coast-based physician Bogi Andersson and the molecular biologist Bernhard Palsson have intervened on a number of occasions in both the general and the scientific press⁵⁶. Palsson was sufficiently angered by the prospect of the deCode monopoly that he has established a rival biotech company in Iceland in collaboration with an Icelandic entrepreneur, Trygve Lie. Nor is

55 One for example was a letter from a US company welcoming the deCode project not least because it would be studying 'a Caucasian population'. This racialised description has entered the public record through German television, and although it is arguably only another way of discussing genetic homogeneity, the very phrase has given rise to a sense of moral scandal, which the over drive of the US media's stereotype of Icelanders as 'blond blue-eyed Vikings' has also played into.

56 Bernard Palsson and Snorri Thorgeirsson, 'Decoding developments in Iceland', *Nature Biotechnology*, 1999, 17:407.

this reaction atypical in the international genetics community. Leading US molecular biologist Leroy Hood, himself no stranger to commercial funding⁵⁷, was quoted as expressing the same doubts about a monopoly licensee. In the run up to the December legalisation, the US breast-cancer geneticist Mary-Claire King, together with Stanford-based lawyer and ethicist Henry Greely, wrote to the Prime Minister of Iceland urging him to rethink. Deeply opposed to the Icelandic development, Harvard-based population geneticist Richard Lewontin urged that, subject to the views of Icelandic geneticists, there should be a boycott of Icelandic genetics. Canadian cancer epidemiologist and World Health Organisation consultant A B Miller expressed concern about the impact on the research system. Few UK geneticists other than Steve Jones in his *Telegraph* column spelt out their views quite so publicly, although concern about the Icelandic events was routinely expressed at meetings where the ethical implications of the new genetics were under discussion. Unquestionably the most hostile and unanticipated international criticism was that made by an editorial in *Nature Biotechnology* which bluntly observed that British Biotech and deCode were the two examples of how not to do biotechnology⁵⁸.

December 1998 HSD Law

Given the size of its majority there was little surprise in the size of the vote obtained by the Government when the final bill was presented to the Althing: 37 voted for, 20 against, and six abstained. It became law on 17 December 1998. Like its precursors, it is framework legislation and in consequence much remained to be worked out between the Ministry and the successful firm. However, because such working out always includes the intentionality of the Minister, her speeches introducing the law have to be read alongside the legislation itself. The legislation offered citizens the right to opt out by mid-June 1999, well before the database was up and running, and protected their right to opt out later; however, the law does not say whether they can withdraw their data. This is a sore point in the Icelandic debate. When the Council of Europe's Steering Committee on Bioethics asked the Icelandic Government whether data could be withdrawn, the official reply was that this was 'subject to negotiation'⁵⁹. However this claim has to be set against the record of the debate in the Althing where the Minister and Government supporters had explicitly stated that data once entered could not be withdrawn⁶⁰. Further, the data on dead people, even those who had refused to be part of the database, was to be entered automatically and their families, who may themselves have opted out, have no say. Nor had the special situation of vulnerable groups such as children, learning disabled, severely mentally ill or dementing elderly people been considered. It was, for example, merely anticipated that families would consult their children before deciding. Further, it was assumed that parents would be in agreement about what was best for their children. The group of professional care staff working with learning disabled people that I met had received no guidance that this issue required professional attention and support.

In this situation, the Mannvernd critics continued to attack the opt-out concession as ethically inadequate. It offered particularly well informed citizens – such as Mannvernd members themselves – the opportunity to opt out, but it was still no-one's responsibility to discuss personally the benefits and risks to the diverse range of individuals and their families of staying in or opting out. The Director General of Public Health does carry a

57 Hood was invited to Seattle by substantial funding from Seattle based Microsoft.

For example Anderson, who teaches medicine at UC San Diego, was the lead signature to a letter to the *BMJ* making some corrections to Ruth Chadwick's article: 'The Icelandic database – do modern times need modern sagas?' *British Medical Journal*, 1999, 319:441–444. Bogi Adersen, Einar Arnason and Skuli Sigurdsson, 'Kafkaesque Ethics for Post Modern Vikings?' *British Medical Journal*, 23 August 1999.

58 *Nature Biotechnology*, 1998, 16:1017–21.

59 Reply from Iceland, Rvi 49, after the hearing to Qvi 48. Steering Committee on Bioethics, *Report of the Hearing of Icelandic Experts concerning the Law on a Health Sector Data Base*, Strasbourg: Council of Europe, 1 March 1999.

60 The Director of Public Health was hopeful that children would on maturity have the right to withdraw their data, but this hope has not been realised. Meanwhile, there is at least one legal case being taken to withdraw medical and genetic data for an individual adult patient already held by deCode.

general responsibility and this led to the production of a leaflet, which will be discussed later. However, as his department also is a main beneficiary of the data for healthcare management purposes, arguably he is not entirely disinterested⁶¹. That he was also on the scientific advisory board of deCode suggests a straightforward conflict of interests. Further an opt-out system, particularly one which is rather difficult to access, raises questions about the representativeness of the database. An informed guess suggests that those who opt out are likely to be mainly drawn from the highly educated and thence the health and illness patterns of that group. This could produce problems for the representativeness of the database. The problem was pointed out by the population geneticist Einar Arnason, member of the National Bioethics Committee and leading figure within Mannvernd, but neither deCode nor the Ministry responded⁶². Mannvernd was considering leafleting copies of the opt-out form and encouraging an action experiment in fostering take up.

The final legislation also had to meet the political and ethical challenges raised by Mannvernd and the Icelandic Medical Association (IMA) over confidentiality and privacy. The IMA consulted Ross Anderson, a Cambridge computer security expert who in Britain advises the BMA, on the database. Anderson's report was highly critical: stripping personal identifiers was not sufficient. In a country with 275 000 people, only a few pieces of data would reveal identity. He also drew blunt attention to what he saw as deCode's 'lack of competence at computer security'. While Stefansson denounced Anderson as a 'hired gun', the IMA accepted his opinion and took the problem to first the Nordic then the World Medical Association securing support for their critical stance⁶³.

The bill has also been criticised by data protection experts. Sixteen of Europe's Data Protection Commission considered the July draft in September and were of the opinion that it might violate several European treaties, not least the European Convention on Human Rights. Stefansson sought a legal opinion from members of the Reykjavik law department. This opinion was, Mannvernd pointed out, identical with the opinion given by the Iceland Government in support of its case when appearing before the Council of Europe's bioethics steering committee. Meanwhile, the legislation's opponents are preparing test cases both on patient's rights and on competition. Internationally published opinion among lawyers as to the legality of the HSD legislation is evenly divided⁶⁴.

In the furore over the legislation, Finnbogadottir was to resign. As former Icelandic President and then as recently appointed chair of UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology, she felt that it was inappropriate for her to be associated with controversy. She took the position that the deCode controversy was about bioethics, the brief of another UNESCO committee, and rejected my suggestion that the database project, as an issue of bioinformation as much as of biosamples, could arguably be seen as also falling within the terms of reference of her own committee⁶⁵.

61 This is a growing and neglected problem. Officials given responsibility for taking care of biomedical ethics in Government ministries increasingly become significant actors on the national and international bioethical policy stage.

62 Arnason withdrew from Committee items relating to deCode because of his work with Mannvernd. As a senior university geneticist he was however given deCode proposals to review and also helped draw up the informed consent guidelines.

63 'Opponents Criticise Iceland's Database', *Science*, 1998, 282:859; World Medical Association press release, 16 April 1999.

64 I am indebted to the jurist David Winickoff (op. cit) for directing me to this legal debate. Anti the HSD: Henrietta D C Roscam Abbing, 'Central Health Data Base in Iceland and Patients' Rights', *European Journal of Health Law*, 1999, 6, 4:363-71; Henry T Greeley, 'Iceland's Plan for Genomics Research: Facts and Implications', *Jurimetrics*, 2000, 40:31-67. For the HSD were O M Arnadottir, D T Bjorvinsson, and V M Matthiasson, 'The Icelandic Health Sector Data Base', *European Journal of Health Law*, 1999, 6, 4:307-62; Hrobjartur Jonatasson, 'Iceland's Health Sector Data base: A Significant Headstart in the Search for the Biological Holy Grail or an Irreversible Error?', *American Journal of Law and Medicine*, 2000, 26:31-67.

65 Telephone interview, 19 May 1999.

1999 Opting out of the HSD

Once the legislation had been passed, the Director General of Public Health issued a pamphlet to every household explaining the legislation and the citizen's right to opt out (from the legislation, it seems that the licensee would have had to pay for this exercise). The legislation recognised that it would take a little time to receive the tenders and award the contract, so gave citizens six months to opt out. The deadline was mid-June and anyone who opted out before that time would have no data entered into the HSD. After that, fresh data could be stopped from being entered but data already entered could not be withdrawn. This leaflet was a very minimal substitute for the kind of public education the critics of the legislation demanded. Of my informants not directly involved in the conflict, most said that they had never seen the modest A5 green pamphlet and expressed surprise on being shown it. Among those who followed the debate most closely, and had read the pamphlet carefully were patients with chronic and possibly genetic conditions who were conscious of the erosion of health and welfare provisions characteristic of all the old welfare states. Many who had not seen it politely speculated whether some other member of the household had thrown the pamphlet away, along with the other junk mail.

Most had picked up the issues from the debates that filled the widely read newspaper *Morgunblad* or from television or radio coverage. But this controversy, which divided the intellectual community, including the media, did not mobilise much interest among women. Even where it was evident that they had a succinct grasp of the HSD issues and the problems of predictive medicine for themselves, they did not feel sufficiently involved personally to act on them. One young woman in her late twenties, a flight attendant, said "Well I don't want to know if I am going to die of a heart attack when I'm 40 and I don't want anyone else to know either". When I asked her what she was going to do about opting out she replied that she "almost certainly wasn't going to bother, it seemed all a bit unreal". A couple of teenagers from families where the parents were involved with Mannvernd cracked up with laughter when I asked whether they had ever discussed it among themselves or at school. They saw the HSD as totally irrelevant to them although they were good-naturedly supportive of their parents' efforts.

The National Bioethics Committee, which had been set up as part of the patients' rights legislation and which had been systematically opposed to the HSD, was suddenly replaced in August 1999 by a new committee composed of civil servant professionals and one person appointed by the Director General of Public Health who, he declared, could be seen as a patients' representative. This patients' representative was in fact a nurse, leading to the curious conclusion that a nurse elected by her association to fulfil that brief could not represent patients' interests, but that one appointed by the Director would. The Director argued that the inability of the previous committee to make its mind up meant that change was necessary. However, it did not escape public comment that the new committee would be more malleable than the old.

Meanwhile, the Icelandic Government had moved towards greater control of the debate. Thus, when Dr Elaine Gadd, the British civil servant responsible for bioethics within the Department of Health, visited Iceland in August 1999 as a representative of the Council of Europe's Steering Committee on Bioethics, no time was scheduled for her to meet with the Icelandic Medical Association or Mannvernd. After sufficient pressure was put on the Ministry, a half-hour slot was provided, yet this scarcely gave her time to hear the critics' concerns⁶⁶. As the delegation had already had the advantage of hearing the Government's perspective at their earlier hearing, this meant that there was no opportunity to explore in any depth the ethical conflict which was so bitterly dividing the island's clinical and research community.

⁶⁶ Arguably this was something of a revenge move as the Icelandic Government felt they were given insufficient attention at the World Medical Association meeting. Both complaints across the divide speak of the breakdown of good working relations within the biomedical community.

So far as many clinicians and human rights lawyers were concerned, the previous year's legislation on patients' rights was now at risk from the database legislation. One of the most distinctive features of the Althing debates around the rights legislation was the question of who 'owned' the patients' records. Some politicians and patients took the view that morally patients should own their records, while the Government took the view that it did⁶⁷. Eventually the debate about ownership was side-stepped, and the old classical non-commodified concept was restored: records were a confidential record of the clinical transaction and were in the custodial care and responsibility of clinicians. This debate had raised, if ultimately side-stepped, the commodification of medical records and thus personal bioinformation. The first step in such a process of commodification is to admit the concept of ownership into the thinking about some entity or process, whether access to information or fishing, which had hitherto been seen as outside the commodity relation. This anticipatory ownership debate had culturally if not legislatively speaking let the commodity genie out of the bottle.

The position of two categories of Icelanders in the legislation, children and the dead, aroused particular concern in that their civil right to opt out was effectively erased. The dead are automatically included by the legislation, regardless of the views of their surviving children or other family members who, in the case of genetic risk, may be directly affected. The case of the dead is currently being prepared for legal challenge in the national and European courts. For a complex of reasons, the disenfranchisement of the children troubled me most (arguably social scientists and historians are less sensitive to ethical concerns about the dead because of the way we root around in the secrets of the, on the whole, long dead). As the legislation and the politicians' statements stand, the only Icelanders who have the unqualified right to opt out, that is who can prevent data about themselves from ever entering the database, are those who were over 18 in mid-June 1999. This unqualified right could be exercised only during a six-month period following the December legislation. The point being that, although after that date a citizen may cease to have data entered, no-one is allowed to withdraw data already entered. Thus, a child under 18 in June 1999 or even a child as yet to be born loses their unqualified right to opt out. Any child left in by their parents but who, on maturity, wants to opt out cannot take their data out. Therefore, only those who were adults at that moment had an effective legal right to opt out. Even to a non-lawyer this seems to be an arbitrary destruction of children's rights. I raised this in my talk for the Feminist Studies Department where it produced considerable discussion. Afterwards one of the feminist philosophers wrote a piece in the newspaper inviting the children's ombudsman to take the issue up⁶⁸.

Debating the commodification of nature

The commodification of nature, whether of green or human nature, is scarcely new. Some non-industrialised cultures have seen, and still see, nature as morally active and thus outside commodification; others have admitted restricted commodification. Land, sweet water, access to hunting and fishing have long been subject to property claims. (For that matter there is little that is innovative about slavery, prostitution, or wet-nursing.) The advent of capitalist modernity and continuous technological innovation has intensified the commodification of nature. Even though within economics commodities are treated as 'taken for granted' objects, subject to supply and demand, the social birth of a commodity is typically surrounded by intense moral debate. Today the countries of the South challenge the North with biopiracy in the North's relentless drive to commodify both indigenous nature and

67 There was a similar conflict in the UK. The initial judgement upset the joint commercial academic biomedical research appellation as they rather thought they owned the data. This was however reversed by the Court of Appeal. Tessa Robbins, 'Court Sanctions Use of Anonymised Patient Data', *British Medical Journal*, 2000, 320:77.

68 This issue of opting out is under intense and unresolved debate. Dr Sigurjonsson, Icelandic Director of Public Health, claims that not being able to withdraw unidentifiable data is normal in epidemiological research, *Eurogapp* (*op. cit.* p. 2). Tom Meade, Oxford Professor of Epidemiology and chair of the Wellcome Trust/Medical Research Council's expert working group, takes a contrary view. Asked by a sociologist who had attended a seminar where this Iceland HSD study was discussed, what was the group's view on the right to withdraw information, Meade hesitated but said he thought that it was ethically necessary. HUGO Public lectures on the Impact of the Human Genome, Oxford, May 2000.

indigenous knowledge of nature. A powerful symbol of this moral and political conflict is the patenting by Sequana of a genetic profile associated with asthma that is very strongly present among the tiny population of Tristan da Cunha. Sequana makes money from these poor island people, who gave body samples but who have received little⁶⁹. Today, medical records and tissue samples are being fought over. Endlessly squirreled away in hospitals and clinics, is it ethically appropriate for these to be mined and commodified or are privacy and confidentiality more important cultural values⁷⁰? For that matter, will the digitisation of information – as some analysts have proposed – serve to sweep away those concepts of privacy developed in a non-digital era?

For Iceland, commodification is a fresh response to the old problem of protecting access to the fishing as their commons. The new risk to the industry however is through their own over-fishing, a phenomenon associated with larger boats and more efficient scientific techniques. The Government has followed the usual regulatory mechanism of fishing quotas. These quotas can be held only by Icelanders and were originally allocated to those fishing in 1983. As time has gone on, a fisheries version of share cropping has developed, following the emergence of large firms which dominate the market and gradually come to control most of the quota, with the result that smaller firms have to rent quota. This has given rise to sharp public criticism about both fairness and market domination by a few large firms. A legal case against the arbitrary allocation of quotas to those fishing at a given moment in history with no thought to the rights of future generations has met with success in the high court. The court struck the legislation down as unconstitutional. While this re-opens fishing rights to new fishers, the victory still leaves the quota problem untouched. Because quotas are set out in quantities of haddock, cod, and so forth, problems arise if fishers catch too many of one species and cannot trade quota – then the fish must be thrown back or the fisher's quota licence is in trouble. What was seen initially as scientifically managing the commons by commodification, first perversely produced an arbitrary and somewhat feudal structure of ownership, and secondly, as fishing remains vital to Iceland, has not resolved the basic resource management task. Scientifically managing high technology fishing through commodification has proved harder, both in constitutional and conservation terms, than was originally thought.

Debates around the commodification of nature are now entrenched in Icelandic culture. The narrative of the constitutional breach of fishing quotas is mobilised by the opposition to draw parallels with the database issue and its commodification of human bodies and information. By contrast, protagonists of the database also draw on the commodification narrative – they compare exploiting Iceland's genes as the country's equivalent of Norway's successful exploitation of its oil.

Gender perspectives: Commodification or the concern for family

Those who drew on the commodification of nature, invoking either fish or oil, tended to be men. Commodification lay in the public arena to be fought over publicly. Women were less preoccupied by the commodification issue than by what the deCode project meant for solving currently intractable diseases and, most importantly, what it might mean privately for their families. In discussion groups where they had space and time to explore these issues without being drowned out with technical talk, women raised again and again their concerns for the psychic as well as the physical well-being of their family members. One with a history of breast

69 deCode is conscious of this history and has secured an agreement with Hoffman La Roche that, where therapeutics are developed as a result of the agreement, Icelanders suffering from the relevant condition will receive free drugs. Clinicians are less enthused by this deal, as the free La Roche drug may not necessarily be the most suited to the patient's medical needs. However, it does represent a growing awareness among pharmaceutical companies that they need to give something back to the communities from which they receive vital bio-information.

70 Sociologist and communitarian theorist Amitai Etzioni is intensely concerned by the trade in medical records as an invasion of privacy, saying that even the right wing Cato Institute is unhappy about this development. Letter, *Economist*, 22 May 1999. Both the AMA and President Clinton have also echoed this concern. The US debate expresses most vividly how the privacy and individualism of neo-liberalism clashes with the financial and technological imperative to mine medical records.

cancer described first how she decided to opt herself and her son out and then her struggle to persuade her father to join them. He was in favour of the HSD and erroneously saw breast cancer as a woman's disease. She explained to him that men could have breast cancer too, and reminded him that he had had a bypass. Supposing, she asked, this reflected a genetic predisposition to heart disease, did he really want to give his grandson the burden of the genetic knowledge of that risk as well as the cancer risk from her? The fact that under almost any interpretation of the HSD process, this feedback to an individual patient was an almost impossible outcome was not the point; for her it was a matter of being cautious, of protecting her son, in a newly untrustworthy context. The commercialism of the HSD erased her sense of being cared for by clinicians committed to her and her family's well being. Consent decisions that had belonged to her and her family members as patients were now going to be commercially presumed. She was not alone: women complained that their concerns, those concerns of love and responsibility for their children, were not reflected in the media debates; instead, they said, fish quotas, deCode, and sport had occupied most of *Morgunblad's* pages all year. How could they begin to decide, when there was no discussion of the issues that troubled them?

There was also a difference in terms of people's experience of disease; a difference shaped too by age and gender. Young people with a history of good health found it very hard to connect to the debate; most retreated to benign good intent for less fortunate others. They felt they had nothing to hide, no cause of health concern in the future, so for them there was no problem in participating. Others were less sure: they saw genetic information as a whole as damaging to employment possibilities, not least if the data were sold to employers. One was very concerned about the knock-on to insurance, as Stefansson had said on the radio that deCode was interested in selling data to the insurance industry. Where there was a family history with little experience of serious illness, both women and men were by and large enthusiastic about the database. For them the HSD was part of the story of biomedical progress. They saw the database as a source of hope and they were also philanthropic, for they were willing to support the database, if not to benefit themselves, then for others.

However, where people had experience of chronic disease requiring permanent medical care and medication, or with genetic disorders in their families, they were much more cautious. They saw the cumulative power of the database in a rather different way. Partly they knew much more about disease databases because they were already on the heart or the cancer base, but they saw this as associated with their clinical care and they felt directly and safely supported by the research and the researchers⁷¹. Like the woman with cancer above, they distrusted the commercialism of the deCode database and saw it as means of cutting existing levels of healthcare⁷².

Although ostensibly the database is encrypted and information can only flow upwards, several of the women were unconvinced that the information would remain as purely statistical data but felt that it would, because of Iceland's small size, be identifiable. It was not the Cambridge computer security expert who had convinced them of this, but their own knowledge of how Iceland's telephone system had worked in the past (all calls went through the local switchboard operator, who would listen in avidly) together with Stefansson's promise during the general election campaign (where he appeared alongside Government candidates) that database inputting would be put out to the regions. What Stefansson saw as a smart move to promise employment to the regions, the women saw as local node points for dangerous leaking of confidential material. Others felt confident in the guarantees given by the legislation that leaks would be severely punished. Nonetheless, women endlessly returned to the question of whether the existence of HSD information could harm their children. One woman with two severe diseases, and with a history of family predisposition for one, was tremendously concerned for the welfare of her children. Using language very similar to those mothers whose babies had been diagnosed as carrying the FHC (familial

71 There are two well curated non-profit databases in Iceland, for cardiology and for cancer.

72 Arnason expresses this hostility to the monopoly commercial interest in one of his contributions to the debate. Letter, *New England Medical Journal*, 7 December 2000, 343:23.

hypercholesterolaemia) gene defect studied by Theresa Marteau and her colleagues⁷³, she saw and resisted the determinism on behalf of her children. She, and other women like her, saw genetic knowledge as threatening and likely to make their children fatalistic.

Women who had experienced domestic violence and sexual abuse raised some very different issues. One began to recall the past when getting married meant showing your medical record to someone in authority⁷⁴. It was a minute before I recognised that this was an indirect way of raising the spectre of the eugenic past. State eugenics, controlling women's reproductive capacities on the grounds of their fitness to mother, had not entirely disappeared from the cultural memory of women. They did not raise fears of a revival of the old state eugenics, but instead used this negative experience of medical records being used against women to raise their concerns about the effect of a genetic information and surveillance system on their children⁷⁵. Few raised the concerns strongly articulated by feminists and the disability movement elsewhere of a new kind of consumer genetics.

Where women had experience of being categorised as suffering from mental disease or had experienced sexual abuse and violence, then they passionately wanted to keep themselves and their children out of the database. They wanted as few people as possible to know their painful secrets: confidentiality was immensely precious to them. One woman, however, took a totally different position. She could not come to the meeting, but sent her views through a friend. The friend explained that she wanted her own and her children's records to be in, so that the health database would have to record the abuses they and she suffered. She wanted to end the social process whereby the victims of sexual violence hide themselves, or were hidden away in the name of privacy. If men fathered babies by sexually abusing their own daughters, then it would be an act of justice for the DNA record to show just how many men had done this. There was sympathy and admiration, but no takers for her position. Some said that they had already decided to opt out even before they were invited to come to the discussion. But all said that this was the first time they had had the chance to discuss frankly and confidentially what the database meant for them, yet such discussion is the ethical heart of informed consent.

Another group of women with whom I discussed the database were those whose professional task was caring for learning disabled people. They were attending a course working with issues of sexuality and sexual abuse. This was a large group, which had come together through attendance at the course, so while they had common interests because of the topics under discussion, they did not have the deep intimacy of the other group. The discussion was initially a teach-in on what was and what was not in the law. This could have been a very uncomfortable situation for me but the course tutor carried the burden of exposition, facilitating and where necessary translating. I raised the problems of vulnerable people and opting out with regard to, for example, children, dementing elderly people, and the vulnerable group of learning disabled people they cared for. It became clear there was no policy to protect the rights of the vulnerable against ethical problems posed by the database. In addition to decisions about themselves and their children, this group of women produced a strong expression of professional anger that the group of people they were trying to empower had been so disregarded, anger matched by a will to restore rights while there was still time. Assessing the outcome properly would require following up the actions of each individual care staff person as a subsidiary research project, in consequence it can only be guessed from the intensity of their response.

73 V T Senior, T Marteau and J Weinman 'Will genetic testing for predisposition for disease result in fatalism? A qualitative study of parents' responses to neonatal screening for familial hypercholesterolaemia. Mimeo, 1998.

74 The women's group conversations were mostly in Icelandic with whisper translations to me.

75 During the years of compulsory sterilisation Iceland shared with the other Nordic countries some 700 people, mostly women, were sterilised. This collusion between state and clinicians, which denies patients rights, is precisely what, after Nuremberg and Helsinki, informed consent tries to prevent.

Because I was located in a university department, during my visit to Iceland, I also raised the HSD issue over coffee and lunch with my academic colleagues. It was clear that academic feminists were another sceptical group but their sceptical stance was shared by many of their male colleagues. Most Icelandic scholars work abroad at some point, as it is not possible to obtain postgraduate training in every field. In consequence, the academic community is strongly internationalist, typically speaking and reading fluently as additional languages English and usually German. Because they are so few, they necessarily connect almost as much to their fellow specialists in other countries as to their neighbours down the corridor. The necessary internationalism of a small and geographically isolated academic community has been hugely facilitated by the new technology of the Internet. Thus, unless they saw deCode as offering new research opportunities personally, which was certainly the case for some in biomedical research, academic conversation about the HSD was larded with hostile jokes against the combination of nationalist geneticism and populism which had so successfully attracted the general public. Most did not feel they had sufficient competence in genetics to judge deCode's performance, but they found the combination of commercialism and populist nationalism represented by the CEO deeply unattractive.

Commodification expands, from fish to genes to bioinformation

This general process of commodification within capitalist modernity is currently accelerating, powered both by the technosciences set to dominate the 21st century and also by the relentless energy of venture capital. These dual technosciences are biotechnology and informatics. Thus, while the Icelandic controversy has been conceptualised as a further extension of the commodification of nature through biotechnology by both the Icelandic anthropologist Gisli Palsson⁷⁶ and also by biologist Richard Lewontin⁷⁷, my own reading is that this is only partially the case. The most intense focus of the commodification process with the HSD is on information, albeit information about the human body. Biotechnology (using informatics) is bringing into existence an entirely new class of information – genetic information – but it is informatics itself which enables old forms of information, the medical records and the genealogies, to be brought into relation with the new, creating a historically new and marketable commodity.

Shulman, in drawing attention to the intensification of patent claims for intellectual property above all in the USA, speaks of this process as a new wealth of nations⁷⁸. He dates the acceleration from the 1980 landmark case of the successful patenting of bacteria 'designed to eat' crude oil. This Supreme Court ruling determined that 'anything under the sun made by man' was patentable. Despite the narrowness of the ruling (five votes to four), this has let loose a huge momentum for patenting indigenous knowledge and new life forms from the Neem tree to the Oncomouse. Even though academic research scientists seek to cling to the distinction between 'discovery' and 'invention', the clarity of the distinction becomes hard to maintain as the patenting enthusiasm is now extending well beyond the USA.

76 Gisli Palsson and Paul Rabinow, 'Iceland, the case of a national Human Genome Project', *Anthropology Today*, 1999, 15, 5:14–18.

77 R C Lewontin, 'People are Not Commodities', *New York Times*, 23 January 1999.

78 Seth Shulman, *Owning the Future* (Boston: Houghton Mifflin, 1999, p. 13).

79 But there is also a special problem for such publicised claims in a small society. At one press conference Stefansson spoke of the importance of a very large family with the disease, in the north of the island, in helping finding the associated polymorphisms. But this family seems likely to be already well known to the biomedical community. Crucially while the mother and her 17 children have osteoarthritis, the father is not known to have the condition. In this situation, geneticists suggest that the claim that the condition is inherited is significantly under-determined. A plausible hypothesis might lie in the culinary practices in which the mother (but not the father) was brought up and in which she has reared her children. A toxic effect might well work on the developing bodies of the young but not on the bodies of adults. For example, one risky dish is made from shark: Hakarl. Greenland shark is toxic and is rendered safe by burying the flesh so as to leach the acid out. This dish demands high risk-management skills in preparation.

DeCode has only been running for two years and, while some papers are in press or are claimed to be in preparation, to date scientific claims are being advanced through press release. Thus the *Wall Street Journal* reported in April 1999, a joint Roche–deCode claim for finding an arthritis polymorphism (earlier press claims by deCode alone have included MS and longevity genes yet, as we have seen, deCode’s MS work is invisible in one authoritative field review). The international as well as national research community is deeply hostile to publishing by press release: it wants more solid evidence, such as refereed papers and/or patentable products⁷⁹. There is a tension between deCode’s need to be seen producing deliverables because of the pressure from investors and markets, and its need to win scientific recognition. While Hoffman LaRoche is seen to be awash with money, and in consequence able to put up the huge investment money for the database, it is also, as part of the pharmaceutical industry, one of the most experienced industrial research managers. It will expect and get deliverables or it will cut its losses.

However, the climate for such high-risk new technology projects may have started to deteriorate since the inception of deCode. The joint Blair–Clinton statement cast a question over limitless patenting. In early March 2000, the Nasdaq Biotech index declined by more than 40 per cent, and by the end of the year it was down 54 per cent. Various biotech analysts from investment companies began to speak more cautiously of deCode’s prospects as it went to market in early June. “So far,” said one commentator, “on an operating basis deCode lost US\$23 million on revenues of only US\$16 million for the year ended last December 31, compared with a net loss of US\$14 million on US\$12.7 million in 1998. The purchase of some preferred stock from venture capitalists increased the 99 shortfall to US\$62 million”⁸⁰. Willoughby went on to add “the concept behind the company is exciting” but that it’s an excitement that’s “proving most hard to bottle and sell”. Because deCode works on the earliest stage of the research it is also the riskiest, not least because of the intellectual property issues that remain to be addressed. However, Stefansson’s entrepreneurial flair has not deserted him and in May, even when Nasdaq had started to slide, deCode was able to announce a new partnership with Partners Health Care, a company based on a group of Boston hospitals⁸¹.

Concluding reflections

My sharpest feeling is that the Icelandic project has been steamrollered through and that, despite any potential commercial advantage this gives or appears to give, the strategy carries too many problems for both society and science. The process has been so accelerated that it has never been possible to explore fully and calmly the fundamental question of what such a centralised database might or might not contribute to understanding the issues of health and disease⁸². This is a serious deficit for the healthy development of genetics, public health, and democracy.

I have argued that the popular support for the HSD is understood as having two main sources; first, the popular support for the charismatic figure of deCode’s CEO, who combines genetic nationalism with a narrative of science

80 Jack Willoughby, *Icy Reception? A Unique Biotech Deal Faces some Hurdles*, Barron’s p. 7, Dow Jones & Company, Inc. Downloaded from Internet, 1 June 2000.

81 Press release on the web: Partners Health Care and deCode Genetics join force against disease in Reykjavik and Boston, 25 May 2000. (No financial arrangements are included in the press release, so how far this aids deCode’s need for more investment is uncertain.)

82 Thus, in addition to Arnason’s concerns about ethical and social issues, he also sharply poses the million dollar *scientific* question of ‘can the database project work – even within its own terms?’. It is this scientific question which has never been debated rigorously. ‘With millions of juxtaposed associations, hundreds of thousands will be statistically significant by chance alone. Even if deCode possessed twice the “formidable capabilities in statistical genetics”, sifting through the rubble of false positives in a search for cures for humankind is at best an uncertain venture, but more likely a nightmare of interpretation’, *New England Journal of Medicine*, 2000, 343:33.

as technical and social progress; second, because the harsh geographical location means that Icelanders have more to fear from nature than culture; unlike most other Europeans, most Icelanders can and do still believe in the narrative of science as progress. It has been the intellectuals particularly in biomedical research, together with those sensitised to the politics of health and illness, notably patients with chronic disease and women influenced by feminism who have been most conscious of the risks as well as the potential gains posed by the HSD.

For those of us who observe rather than live with the HSD conflict, we have to be aware that legislation was necessary only because a purely market approach to genomics was adopted. In a more consensual, hybridised model of genomics, such as those currently proposed in the UK, the innovation can be simply added on to the research and health policy agenda by experts. There is no moment when the very idea of a genomics database can be debated then accepted or rejected by democratic process. This expert-driven technological innovation is a conspicuous feature of the old welfare states, particularly Britain with its highly secretive political culture, which it is so painfully trying to move beyond⁸³. I would argue that this old tradition is in need of serious challenge and overhaul. The Icelandic debate has revealed a number of moles in their governance of scientific and technological innovation, but the UK's record reveals a history of beams. Thus, it is the very fact of the Icelandic HSD legislation and the visibility of its processes which has exposed the immense innovation of genomics in that country to vigorous public debate not just nationally but internationally. This conflict has served to put the ethical issues concerning the commodification both of bioinformatics and of nature as human tissue onto the international cultural and political agenda. Careful scrutiny of Iceland's highly visible conflict over commodification could help other countries increase both the transparency and the democratic accountability of their biomedical innovations.

83 The UK Government has introduced three new institutions to meet this: the Agricultural, Environmental and Biotechnology Commission, the Food Standards Agency and the Human Genetics Commission. How the advice generated by these is to be articulated into the more conventional sources of advice into policy making remains to be seen.

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I am immensely grateful to all those Icelanders who gave me their time and shared their thoughts together with a range of both published and unpublished material. Icelandic warm hospitality was also a huge plus which I want to acknowledge: how many social researchers can regard the hotel staff where they are staying as co-members of the research project? Those who know the difficulty of maintaining privacy in a small society will understand my profound gratitude to those who trusted me with their personal narratives of pain, sickness, and disability.

Without the unstinting help of three Icelandic colleagues in science studies and in feminist studies I could never have achieved so much during my visit. I had met Dr Eiríkur Baldursson (Science Policy) in Gothenberg where I had been on his PhD examining committee while a guest professor in Science Theory and Feminist Studies; Dr Skuli Sigurdsson (History of Science and Technology) I met in Berlin where I was giving a seminar at the Max Planck Institute; and Dr Gudrun Jonsdottir (Feminist Studies and Social Work) in Bradford University where she was giving a seminar. This project was also possible in the time planned only because of the technology of e-mail, which made this European networking fast and inexpensive.

My thanks to those colleagues from both the UK and Iceland who have read and painstakingly commented on the first draft of this report together with Tom Wilkie who has edited it for publication by the Wellcome Trust. As usual, what errors remain are my own.

Lastly I am grateful to the Wellcome Trust for supporting this research and for finding a fast track to enable this study to happen while events were still unfolding.

Appendix: Methodological notes

I prepared the field study drawing on a variety of sources using *Nature Biotechnology* and *Nature* as my journals of record. Until mid-1999 Iceland and the HSD were not much discussed in the general UK press even by the science writers. There are rather practical explanations for the weak British coverage. Even though science coverage is extensive in our press, and books popularising science have huge sales (proportionately much bigger than in the USA), science writers on even our broadsheets are usually single-handed. Inevitably, covering any item in depth is difficult. By contrast, major US newspapers such as the *Washington Post* have strings of up to 12 science writers and so have much greater investigative and reflective capacity. As Iceland became a news item the coverage increased, as UK news teams command more resources and cover conflicts, including scientific conflicts, more robustly.

The websites of Mannvernd, deCode, and the Icelandic Government were extensively consulted and remain rich sources of information.

Fieldwork was carried out in Iceland over a two-week period in May and a further week in July. Splitting the visit worked out rather well. There are special features about doing fieldwork in such a small, fairly bilingual, society. First, access was extraordinarily easy, partly because the local style is informal and friendly and partly because who I needed to see was obvious to all the key actors, and they would politely check out how I was doing and make suggestions for near substitutes for anyone out of town. I had made as many contacts in advance as I could, thus both the Philosophy Department (which kindly provided me with an office) and the Women's Studies Department asked me to give seminars. I had accepted assuming they would be small departmental affairs and thus low profile, and having taught at a small university I know how precious visitors are. However both were public occasions well advertised in the newspaper to be given in a large lecture hall, with supporters and detractors of the database well in evidence. It was a distinctly challenging task but the advertising was out so I had no chance of an escape. In addition to preparing these talks, my fieldwork ran from dawn to dusk. People would visit over breakfast; during the day I usually had formal appointments, and in the evening would meet for supper or drinks and more talking late into the evening. Reykjavik does not go to bed early and weekends did not slow the pace. This was especially true during my first visit.

In addition to many casual conversations with people I met while hanging around for appointments, I interviewed some 80 people. Most came from Reykjavik, but 24 came from the far north and the far south of the island so were more rurally based. Apart from my two teenagers (I had a group of teenagers set up at a school by a social science colleague but suddenly a key civil servant was free to see me, so I lost that encounter), I mostly interviewed community people between 20 to 40-something with a handful of early 50-year-olds. I saw this younger age group as having most at stake, so potentially most interesting to interview. The intellectuals and political classes I interviewed were drawn from a rather older age band from early 40s to 60-plus. On the whole, interviews took an hour but I interviewed several people more than once. Both the detail of the chronology and the sheer complexity of the issues were so messy that I needed to spend a tremendous amount of time checking and double checking. My interviewees were extremely generous with their time and the interviews particularly with the protagonists were both technically challenging and intellectually fascinating. Thus, I spent four-and-a-half hours with Stefansson spread over two visits and I met the geneticist Einar Arnason a couple of times individually and as part of a group discussion with Mannvernd.

The other unusual feature was that most of my interviews with the civil servants and a number of the academics were arranged at least in principle ahead of my visit by an Icelandic civil service colleague on whose PhD committee on Science Policy I had served in Sweden. I also had the help of a feminist social science colleague who had studied in Yorkshire. In my proposal I explained that I particularly wanted to interview women, as there was no gendered voice within the debate let alone a feminist perspective. Yet both healthcare and health within the

family are in Iceland as elsewhere still primarily women's work so the HSD was surely a particularly relevant issue for women. My colleague, a university teacher of social work who had done her PhD in Britain on incest, introduced me to two women's groups. The first was a group of care staff working with learning disabled people who were attending a course on sexuality and sexual abuse that she was giving in Akeryi in the north of the island. The second was a group of women who had experienced sexual abuse and violence who had been meeting together with her for some time. In both cases the groups were consulted as to whether they were willing to meet me and discuss the HSD. The depth of the intimacy and trust between the women especially in the latter group, make it inappropriate to think of them as the equivalent of a focus group. It would not have been possible to meet with such groups without the generosity of my colleague. The third group of women with whom I discussed the HSD was entirely serendipitously recruited. When flying to Iceland I sat next to a young woman who worked at a women's gym. We talked about the research project and she became especially interested because I wanted to find out what women thought. She took it on herself to find me a group of young women and did. These, while a pre-existing group, were more casually linked to one another, so conversations were for the most part less intimate. It was only in the one-to-one conversations after the group had ceased that I learnt about more personal and family anxieties about the HSD. I took part in two mixed group discussions, one at the house of a leading Mannvernd member, the other was at the university; this latter included deCode and university staff interested in the ethical issues.

Other than the group discussions, the individual and family interviews were recruited in a fairly haphazard and often snowball way, with one person learning that I would like to talk to say a family of such and such a background with perhaps teenagers or young children and they would open the door for me. I travelled mainly by taxi in and around the city, and I think I can say on the basis of my extensive but non-random sample that Reykjavik taxi drivers, especially the men, are entirely behind the HSD.

Because ethnographic interviewing whether with groups, families or individuals can generate rather deep reflection, I felt that it was ethically important to interview before the six-month period ended in June. This point is further explained in the text. My hunch was right as the interviewees, and even more the women's groups, said that this had been their first opportunity to explore in a confidential setting, the implications of the HSD for themselves and their families. I would have felt uncomfortable to take part in such intimate and reflective discussions once the right to have no part in the HSD had become a qualified right.

Lastly, the kind of problems that genomics produces in Iceland, crucially that in a very small population it needs only a few identifiers and it is rather easy to guess who is being described, is also true for social research. In consequence, except when I was talking to those public figures whose opinions are also public knowledge, I have for the most part built my field data into the analysis rather than following the usual social science technique of changing a few identifiers and then quoting individuals directly. This has not been an easy choice as the interview material is very rich, however it is the ethical choice when researching in a very small, strongly networked society.