

*David E. Winickoff*

## Genome and Nation

### Iceland's Health Sector Database and its Legacy

Iceland is a small democratic state of nearly 300,000 inhabitants that sits in the North Atlantic between the continents of Europe, America, and the Arctic.<sup>1</sup> Although it may seem an unlikely place for innovation of global significance, the small island nation of Iceland has assumed near iconic status in one field in particular: genomics. Aided by recent advances in genetic technologies and by a bold entrepreneurial vision, Iceland's genomic innovations have helped transform medical and genealogical information into a new type of global commodity. Furthermore, these innovations—or more precisely, the controversies they have spawned—have helped precipitate the development of global norms governing the relationship between citizens, medical information, markets, and the state.

Iceland's public-private partnership has become a common reference point for other major population genomics initiatives—such as those in Sweden, the United Kingdom, Canada and the United States—but there is often an intriguing gap between what it stands for and what it has become. A November 2005 perspective piece in the *New England Journal of Medicine* is a good example of how in many accounts of Iceland, important details get lost. In this article, the authors argue that generating the next round of genetic discoveries will require a large number of “health information altruists” to supply health and DNA data and DNA. And they cite the Icelandic government's ability to construct a “national genomic databank,” in collaboration with deCODE Genetics Inc., as an example of the public's altruism.<sup>2</sup>

This sort of statement is not uncommon in articles written about Iceland, but one problem remains: the country's Health Sector Database, an international symbol of the new state-led genomics and the biotechnological frontier, was never built. Ten years ago, Kari Stefansson, an Icelandic neurologist turned biotech entrepreneur, co-founded deCODE Genetics and began operating in the suburbs of Iceland's capital. Eight years ago, Iceland passed the Health Sector Database (HSD) Act, which authorized the construction of the national database. Today, although deCODE continues to announce discoveries,<sup>3</sup> the controversial idea to allow the

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company access to the national health record data without consent of individuals (the core of the national database legislation) is dead. Did all the sound and fury swirling around the HSD Act ultimately signify nothing?

To the contrary, 10 years after the founding of deCODE, with the Health Sector Database relegated to the dustbin of history, it is more important than ever to probe a series of questions about the Iceland case. This article tracks the history of Iceland's National Health Sector Database, seeking to clarify two critical questions: how could a statute authorizing the transfer of personal medical records to a private corporation, without informed consent of individuals, pass through the Icelandic Parliament in 1998? That is, how did the HSD Act—an unprecedented achievement combining both technological, political, and normative innovation—ever come into being, and what does it tell us about the innovation–governance nexus? Second, why did the Health Sector Database itself *never* come into being?

The Health Sector Database Act ultimately came into being because it seemed to address the central political problem of Iceland as it was entering the twenty-first century. This was the problem of how such a small and remote society might remain a viable nation in the emerging global order. The national database failed to materialize because the act triggered an international controversy and could not, ultimately, satisfy an emerging consensus about the appropriate rules for governing this new type of research. Despite its failure, Iceland's Health Sector Database remains critical case study for understanding the practices of biotechnology today: in its failures as much as its successes, the Health Sector Database became an important channel through which key aspects of bioethics, individual rights, and global governance were clarified and reframed in relation to genomics and the new life sciences.

#### ICELAND'S HEALTH SECTOR DATABASE ACT

Iceland's national parliament, called the *Althing*, was established around 930 A.D., roughly 60 years after Iceland began to receive Norwegian settlers and their Celtic slaves. In these early years, the *Althing* was an annual outdoor assembly where the country's most powerful leaders met to decide on legislation and dispense justice.<sup>4</sup>

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Today, Iceland is a constitutional democracy with its 63-member *Althing* and a president, although a prime minister leads the governing coalition in Parliament and is by far the most powerful politician in Iceland. In December 1998, the *Althing* passed the Health Sector Database Act by a vote of 37 to 20, with 6 abstentions. The act set out a new regime for the control of citizen health information in a modern democracy. Such information was at once declared a “national resource” to be controlled by the state and allocated to private industry for inclusion into a commercial genomic database of national scope. The act immediately took on

international significance and has been written about widely by journalists and scholars alike.<sup>5</sup>

The core of the HSD Act was the authorization of the database’s creation and operation in Iceland by a private sector licensee, with the computerized health data to revert to the state after the license term.<sup>6</sup> The license to operate the database could be granted for a renewable term of no more than 12 years. The company deCODE Genetics secured the license to create

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and operate the database in 2000, but this was a *fait accompli* from bill’s earliest days. Notes from the bill state that the idea for the database initiated with deCODE and Kari Stefansson, and the company reportedly drafted the first version of the bill as early as the summer of 1997.<sup>7</sup> deCODE’s plans to link the health data with genetic and genealogical information were widely known, although the act itself said nothing about biological samples or DNA, and it did not mention genealogical records.

The act authorized the licensee to use the data for profit, but it provided for the protection of privacy in a number of ways. First, the licensee could not grant direct access to the database or information it contained to third parties. Second, it would have to process the information itself in ways that could not be linked to identifiable individuals. The act provided that the licensee could be civilly liable for negligent disclosure of information, and the act authorized other penalties, including fines, imprisonment, and possible revocation of the license for violations of the act, the license, or government regulations under the act.

The HSD Act’s most controversial provision authorized the transfer of all medical record data to the licensee for commercial development without the express consent of individuals, by invoking a rule of “presumed consent.” In addition, information on deceased individuals would be automatically included, despite the

potential privacy interests of relatives and individuals. According to the terms of the Act, Icelanders would have six months from the construction of the database to opt out unconditionally, a provision that had only been added to the act after an earlier draft of the legislation drew significant criticism for its lack of informed consent.<sup>8</sup> The final version of the act also specified a more rigorous encryption architecture for the health information, and it provided for lower fees for non-commercial access to the database.

A small and vocal percentage of Icelandic civil society objected to the legislation, and strenuously. The leadership of the Icelandic Medical Association publicly opposed the HSD Act for what it saw as its ethical shortcomings: the failure to protect the rights of research subjects to have informed consent, the lack of a mechanism for subjects to withdraw from the database once they were entered in, and the monopolistic aspects of the license.<sup>9</sup> Furthermore, in October 1998, a small network of physicians, scientists, human rights activists, intellectuals, and patient activists formed a group in opposition to the HSD Act, called *Mannvernd*.

*Mannvernd*'s English subtitle was the Association of Icelanders for Ethics in Science and Medicine. The Icelandic word *mannvernd* means "human protection," and this captures the organizing idea of the group, namely that the HSD Act "infringes on human rights, personal privacy, and on accepted medical, scientific and commercial standards."<sup>10</sup>

Despite the development of this loosely organized opposition, the law passed. By claiming the authority to transfer to a commercial entity the medical information of all Icelandic citizens, the government imposed a new regime of control over Icelandic medical records. One important legal effect was to sever the ability of doctors to prevent their health institutions from handing over patient medical data without their authorization. The directors of health institutions were to be empowered to negotiate all transfers of information, without review by any independent ethics committee (the normal ethical requirement for accessing medical records for research). At the same time, the government claimed the power to provide access to the medical information, and indeed to license it for commercial use. The government asserted that because the state paid for the medical care giving rise to the data, the state could control and "exploit" those data for the benefit of Iceland. Rhetorically, the act denies that medical data can be owned, but this lan-

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guage is a mere formality—access, use, and control are nothing if not the traditional components of property.<sup>11</sup> In effect, the state reduced the complex web of legal interests around the medical data by cutting off the doctors and asserting the power to license, which is a property interest.<sup>12</sup>

By December 1998, the critics had been effectively neutralized by the passage of the HSD Act. The path was paved for deCODE's exclusive commercial access to the trove of medical data on all Icelanders, and the essential conditions for construction of the Health Sector Database had been established.

#### ORIGINS OF THE HEALTH SECTOR DATABASE

The passage of the Health Sector Database Act was a watershed event, as much for the fields of genomic research, venture capital, and bioethics as it was for Icelandic society. In one unprecedented stroke, a national parliament authorized the transfer of citizen medical information to a private corporation for commercial exploitation and development, without the *a priori* permission of individual citizens. Such a coup for Kari Stefansson, CEO of deCODE, could only be achieved through the effective enrollment of Iceland's natural and social history in its business plan.<sup>13</sup> With a national heritage in tow, the business narrative would in turn have to persuade American venture capitalists and their scientific advisors, a majority of Icelandic Members of Parliament, and the public itself that their interests necessarily lay in the passage of the Health Sector Database Act. The effectiveness of Stefansson's pitch lay in its versatile ability to address the most pressing problems of these key constituencies.

#### **Enrolling Iceland's Natural and Social History**

Stefansson's genomic vision of Iceland was predicated upon a single compelling theory, namely that Iceland was likely to be a very valuable place to hunt for genetic factors of common human diseases. This hypothesis was supported by a set of foundational claims about Iceland's natural and social history. First and foremost was the idea that Icelanders were a genetically homogeneous people because of their historic isolation. In a 1995 business plan, and in language that would be echoed throughout the debates about the HSD Act, Stefansson wrote,

Iceland is a small island in the North Atlantic which was inhabited between the years 870 and 930 A.D., mostly by Norwegian entrepreneurs and Irish slaves. The year 1000 A.D. [sic], the population was around 70,000 but around the year 1410 A.D. the Plague had reduced it down to approximately 30,000. The population had again grown to about 70,000 when at 1700 A.D. Hekla, the most powerful volcano in the history of Europe, spew lava and ash all over Iceland, which led to a famine that reduced the population again down to approximately 30,000. Today, the population of Iceland is 270,000 and they are almost all derived from the original settlers or 30,000 of their descendants who lived in the country

around the year 1410 A.D. and another 30,000 who lived in the country around the year 1710 A.D. Therefore, the Icelanders are genetically a homogeneous people, and they display a strong founder effect; by following genetic markers, it is possible to trace a common origin of a large proportion of them.<sup>14</sup>

This was not a simple claim of genetic homogeneity, but one embedded in a colorful natural history of the Icelandic genome replete with plagues, volcanic eruptions, and famines. Stefansson drew a powerful connection between the founder effect that helps make Iceland attractive for gene hunting, and the founders themselves.<sup>15</sup> Although the “facts” of Icelandic homogeneity later became contested within the pages of top science journals as the Health Sector Database controversy developed,<sup>16</sup> the idea of homogeneity played powerfully both inside and outside Iceland.<sup>17</sup>

Stefansson’s second foundational claim was the existence in Iceland of intricate and detailed genealogical records. In its early business plans, Stefansson touted the existence of a lineage database for 100 percent of Icelanders back to 1910 and 85 percent of Icelanders back to 1800. He explained that this recorded lineage would make it “relatively easy to determine relationships between participants or subjects in genetics studies done in Iceland.”<sup>18</sup> A third foundational claim was the existence of high-quality medical records dating back to the 1920s, many of which were “centralized and accessible.” Hence, the business plan explained, “it is relatively easy to find a match between genotypes of Icelanders and whatever genetic traits are reflected in their diseases or health.”

As Stefansson and company representatives explained over and over again to Icelanders, foreigners, and investors alike, these factors gave Iceland an advantage for discovering new genetic factors for disease. If all three resources—Icelanders’ DNA, genealogies, and the phenotypic data—could be linked together, it would create a uniquely powerful tool for conducting genetic linkage studies as well as allelic association studies. This tripartite and integrated database was the technological bore to locate genetic diamonds in the rough. The scientific logic was simple: with fewer variations in alleles because of genetic homogeneity, it would be easier to identify candidate genetic variations that were associated with disease. And the idea of folding health data, genetic data, and genealogical information—

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compiled through generations of Icelanders—into a single resource was as culturally compelling to venture capitalists as it was to Icelanders. It was a powerful symbol of Iceland itself.

### **Enrolling Venture Capitalists**

The mid-1990s were boom years for venture capital, and biotech investors and their scientific advisors were looking for big ideas that would solve big problems. One of the big scientific and political problems facing genetics in the mid-1990s involved how to translate the massive amount of new genetic code being generated by the public human genome projects into discoveries and therapies. Gene hunting was turning out to be harder than anticipated: it proved to be difficult to identify specific genetic variants that caused common diseases, thus shifting the understanding of disease to polygenic and epigenetic models of causation. Some argued that in order to sort out more complex mechanisms, larger populations of people manifesting both health and illness would need to be sequenced, studied, and compared. Taking a “population” approach to genomics would not have been imaginable even a few years previously, as doing such studies at the desired scales required recent advances in DNA sequencing and information technology that gave birth the nascent field of “bioinformatics.”<sup>19</sup>

What was needed were promising populations of research subjects upon which these new tools could be turned. As Stefansson put it in his business plan, “it is a commonly held view that the next big steps in the genetics of human diseases will be taken by those who have access to the most suitable populations, rather than by those who ask questions or develop new technologies.” Stefansson was correct that major powerhouses of human genetics, both in academia and in industry, were searching for the appropriate populations on which to apply these new tools. He also was correct that Icelanders would be an appealing population source. In a now famous 1995 letter to Stefansson, Kevin J. Kinsella, the President and CEO of Sequana Therapeutics (which was already involved in the gene hunting business)<sup>20</sup> adopted Stefansson’s naturalized account of Iceland’s genomic potential:

As we discussed, Iceland is perhaps the ideal genetic laboratory since there has been virtually no immigration, ... it is of manageable size (200,000+ inhabitants), is an island expected to have many founder effects, has high quality national healthcare—from which we can expect excellent disease diagnosis, has formidable genealogies and the population is Caucasian—of most interest to pharmaceutical companies.<sup>21</sup>

Iceland has persistently captured the Western imagination, whether due to its literary tradition, geology and volcanoes, the Cold War, or even the World Chess Championship in 1972 between Boris Spassky vs. Bobby Fischer.<sup>22</sup> Now, the idea of the “unique” genetic endowment of its population captured investors. Stefansson allegedly raise \$12 million in U.S. venture capital in an initial round, and on this strength, another \$25 million from Icelandic institutional investors.<sup>23</sup> In 1996, the prominent U.S. technology business magazine *Red Herring* declared Stefansson

one of its “entrepreneurs of the year,”<sup>24</sup> and deCODE became a Delaware corporation. Stefansson’s ability to raise this seed money indicates that the biotech venture firms and their scientific advisors were convinced that Iceland’s population was potentially a unique resource for untangling the complex genetic factors of disease, and for addressing the translation problem.

Presenting Iceland as a promising solution to the problem of finding a population was perhaps enough to achieve a first round of major venture funding, but that raised another problem that would have to be solved before large institution investors came on board: the problem of *enclosure*.<sup>25</sup> In short, even if the Icelandic population—with its comparative homogeneity, its genealogies, and its health records—presented a promising opportunity to find disease factors when all the contributing components were thrown together, how could these common resources be packaged in such a way as to attract investment? What would give deCODE an advantage over some other highly capitalized biotech firm that might also want to engage in this gene-hunting venture?

Stefansson realized that some sort of exclusive privatization agreement with Iceland’s government authorities would be an indispensable piece of any business plan—and therein lay deCODE’s particular competitive advantage. Just

exactly what that arrangement would look like became clear when the firm reportedly faxed the first draft of the Health Sector Database Act to Iceland’s Ministry of Health in 1997:<sup>26</sup> the authorization of the Icelandic government granting an exclusive licensee the power to create and operate a database containing health record information of all Icelandic citizens for commercial biomedical research, and the now famous regime of “presumed consent.” Other companies would have had to work through individual informed consent, a much more time-consuming process likely yielding fewer participants. Stefansson’s ingenious proposal was not a direct act of enclosure, because the medical records in paper form would still be freely available to other researchers. But the Health Sector Database Act amounted to an indirect act of enclosure—a regulatory subsidy that would cost the nation nothing out of pocket, yet would confer deCODE unique terms of access to a newly imagined commons.

In the fall of 1997, the draft of the Health Sector Database legislation had not been made public, but Iceland’s Prime Minister David Oddsson, a childhood schoolmate of Stefansson’s, knew of and supported the legislation.<sup>27</sup> In February 1998, deCODE struck a deal with Hoffmann-LaRoche, then the fourth largest pharmaceutical company in existence, for rights to discoveries derived from deCODE’s existing work. David Oddsson “passed the pen” between the two com-

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panies for their meeting in Reykjavík. This deal was worth a reported \$200 million in benchmark payments over five years, giving deCODE and Stefansson national celebrity status and global recognition.<sup>28</sup> But the challenge remained to convince the Icelandic Parliament and the Icelandic public that granting access and use rights to deCODE on an exclusive and “presumed consent” basis was a good idea. Enrolling U.S. venture capital and global pharmaceutical giants went a long way towards this challenge.

### **Enrolling Politicians and the Public**

Commentaries regarding the passage of the HSD Act have espoused different theories as to why the majority coalition carried it through the *Althing*, and why the Iceland people seemed to go along with the legislation. deCODE was better able to control the public discourse through a U.S.-style publicity campaign in which critics were out-muscled and out-maneuvered, and passage reflected the confluence of strong lobbying by deCODE, a strong parliamentary majority, and party discipline.<sup>29</sup> But to read the passage of the act merely as a case of special interest politics would miss something crucial. Specifically, it would miss the important ways in which deCODE’s rhetoric addressed the central political problem of Iceland as it looked towards the twenty-first century. This was the pressing problem of survival itself: how could such a remote island society best leverage its natural and social resources to remain a viable sovereign nation in the global order?

Icelandic society has sought independence throughout its long history. Whether it has been the Norwegian or Danish monarchy, raiding Vikings, or the modern behemoths of the European Union and the United States, Iceland has struggled with foreign political determination.<sup>30</sup> The HSD Act passed because deCODE’s theory spoke boldly to the nation’s deepest aspirations and fears about survival and independence in the global economy. For some years, fishing has provided 70 percent of export earnings and employed 4 percent of the work force. The Icelandic economy remains vulnerable to declining fish stocks as well as to fluctuations in world prices for its major exports: fish and fish products, aluminum, and ferrosilicon.

Since the mid-1990s, Iceland had started a concerted campaign to develop new economic sectors such as information technology, financial services, tourism, and large-scale hydropower. Biotechnology was emblematic of the sort of new industry that Iceland’s Independence Party viewed as a solution, and deCODE was poised to launch this sector. And for its part, the Progressive Party in Iceland, which controlled the Ministry of Health and was part of the majority coalition, was more than willing to be led by this vision, perhaps convinced that this was a cheap way to computerize Iceland’s health system.

For the majority coalition, the Health Sector Database project was actually the second and smaller of two controversial policy initiatives aimed at economic growth and revitalization. The other was the Kárahnjúkar Hydropower Project, a massive system of dams, reservoirs and tunnels planned in Northeast Iceland.<sup>31</sup>

Civic protests mounted against this massive project around 1998, and continue to mount, focusing on the environmental impact of this project to tap the most powerful glacial rivers in Iceland. As a pair, both the HSD and the hydropower projects underscore the 1998 coalition government's overriding commitment to creating a viable economic future given scarce natural resources.

Politicians could also make the argument that building a strong deCODE would stem the tide of brain drain of highly-educated workers that many feared was weakening the island nation. Stefansson had created his commercial laboratory near Reykjavík by November 1997 to be operated under deCODE's Iceland subsidiary, Íslensk erfðagreining, and in a short amount of time the company had spent more on research than the Icelandic government's entire annual research budget, roughly \$65 million. The consequences of brain drain are not only economic, of course, but also social: families find themselves pulled apart. The idea of the tri-partite genomic database—weaving together individuals and families, past and present, into a single entity—presented a potent symbol of collective strength. The theme of solidarity, through the idea that deCODE could help keep families together, was invoked to outweigh abstract notions of autonomy, patient–doctor confidentiality, and erosion of scientific integrity.

The HSD Act's critics had trouble effectively countering the economic, political, and cultural strength of the deCODE–government alliance. When Minister of Health Ingibjörg Pálmadóttir introduced the first version of the bill to the *Althing*, some members of parliament highlighted concerns about citizen privacy, monopolistic private control of the database, and lack of *a priori* consent, and a number of prominent leaders of the Icelandic Medical Association agreed with these criticisms. Mannvernd argued that the Act was illegal under both Iceland's constitutional right to privacy<sup>32</sup> and international human rights norms that required informed consent in human subjects research—drawn from the Helsinki Declaration and the Nuremberg Code. Nevertheless, deCODE simply built a larger network of supporters in Parliament and Icelandic society than Mannvernd, largely because of its demonstrated ability to raise investment capital, and the power of its economic promises.

But not only so. deCODE's successful appropriation of cultural tropes and resources re-imagined Iceland, while simultaneously constructing a future for it. In political debates and interviews, Stefansson could invoke the historic struggles between the Icelandic people and a brutal physical environment, and he could give these common histories new meaning and new value. Within this narrative, these

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same hardships now made the Icelandic genome a valuable commodity in the global economy. What might seem to outsiders as a peculiar practice, the tracing of genealogical connections through countless generations, now became a lynchpin of a cutting-edge biomedical technology. A common set of Icelandic founders had passed their genetic markers down through the generations, producing a key element in a new collective history of Iceland. But just as importantly, the database's narrative of aggregation and social linkage provided a powerful cultural symbol of an integrated, independent, and modern people.

#### SHELVING THE HEALTH SECTOR DATABASE

In light of the development of our business since the Agreement was entered into, the lack of the required agreement with the [National University Hospital], and the fact that the Icelandic Data Protection Authority has not issued the required security certification, we do not expect to operate the IHD [i.e., the combined database] under the terms of the Agreement.<sup>33</sup>

—deCODE Genetics in its SEC financial disclosure statement  
for the fiscal year ending December 31, 2003

By June 2001, roughly 20,000 Icelanders or roughly 7 percent of the population had opted out of the Health Sector Database.<sup>34</sup> While this was taken as a signal of general discontent by Mannvernd, and it certainly surprised government officials, it is unlikely that this fact would have shaken deCODE. Nevertheless, little more than three years later, deCODE disclosed to its public investors that it had no expectation of ever constructing or operating either the Health Sector Database or the tri-partite “minable” database containing health, genealogical, and genetic data. Although the company publicly blamed the National University Hospital and the Data Protection Commission, the failure to reach deals with these institutions were only the proximate cause of the failed Health Sector Database. The national database failed to materialize because the act triggered an international normative controversy and could not, ultimately, satisfy an emerging consensus within and without Iceland about the norms that should govern the new population genomic research. This in turn caused crucial members of deCODE's assemblage to drop out of the network required to produce the database.

#### **The Critics' Network Expands Internationally**

While the network of critics of the Health Sector Database bill had been insufficiently strong to sway the Independence Party–Progressive Party majority or to galvanize the Icelandic public against the bill, the passage of the HSD Act helped trigger a small explosion of international scrutiny and criticism. An early salvo came in a *New York Times* op-ed by the eminent Harvard population geneticist Richard Lewontin, who provocatively declared that Iceland had just transformed “its entire population into a captive biomedical commodity.”<sup>35</sup> As major news out-

lets covered the story of the law, a volley of criticism came in the form of letters to the editor and editorials, many of them from Icelandic expatriates.<sup>36</sup> By April 1999, leadership of the Icelandic Medical Association had taken the case of the HSD Act to the World Medical Association, and at a meeting in Chile the World Medical Association declared that it stood “fully behind the position taken by the Icelandic Medical Association in opposing the Icelandic Healthcare Database legislation recently passed by the Icelandic Parliament.” The World Medical Association governing council underscored “the need to protect the integrity of patient data and to have open access to all scientific data,” and it urged “all national medical associations and governments to ensure that science is furthered by continued research that in no way breaches medical ethics and patient confidentiality.”<sup>37</sup>

By the summer of 1999, claims and counterclaims by company officials and HSD Act critics filled the opinion pages of the elite international science magazines.<sup>38</sup> The network of critics had become international, and the debate became distinctively normative: were there existing standards of informed consent that applied to this type of research? Did the act really commodify the bodies of Icelanders in an ethically problematic way, and was the ethos of sharing health data in biomedical research under attack? During this period, both sides of the debate attempted to master the intricacies both of existing international rules and of information encryption architectures. And although the debate began to play out at a high level of technicality, at stake was the very reformulation of sovereign power, individual rights in personal medical information, and the claims of patient–doctor confidentiality.

### **Normative Ambiguity and the Proliferation of Debate**

Although those on both sides of the debate tried to claim traditional bioethical norms to support their positions, a few years of hindsight have made one thing obvious: information “mining” proposed by deCODE was a new sort of research that did not fall comfortably within pre-existing bioethical norms of informed consent or pre-existing legal rules on the protection of personal data. A high profile exchange in the *New England Journal of Medicine* from the summer of 2000 between the top deCODE officers and George Annas, an internationally known professor of bioethics and law from Boston University, illustrates the terms of the emerging international debate.

On one side of the debate, Kari Stefansson and Jeffrey Gulcher, then the Chief Scientific Officer of deCODE, argued forcefully that “presumed consent” with the opt-out provision was justified and legitimate in Iceland for three main reasons. First, they argued that an exogenously imposed notion of individual consent should not trump the democratic will of a sovereign nation: the passage of the act after “vigorous debate in Icelandic society” indicated the “community consent” to the opt-out compromise. In essence, they argued from a position of cultural specificity rather than universality, stating that “norms may vary from one society to another and may change with time,” and that democratic will should rule.<sup>39</sup>

Second, they argued that “presumed consent is the standard used in research on health care data that is produced in the process of delivering medical service,” adding that “it is not certain that we would have health care as we know it today if explicit consent had been a prerequisite for the use of medical data.” Third, they argued that privacy concerns could be managed effectively through information encryption technologies rather than the use of individual rights as prophylaxis. They asserted that because the social identification numbers from the medical records would be encrypted, the information would actually be more protected than it was in non-encrypted paper form, sitting in files within health institutions.

George Annas, a strong advocate of the special sensitivity of genetic information and proponent of genetic privacy in the United States, argued against Stefansson and Gulcher to a large extent. He acknowledged that “research on data from medical records that cannot be linked to individual patients has often been considered an exception” to the general rule of informed consent for all human subjects research. In this sense, he admitted that the project did not break (at least in a flagrant way) existing bioethical norms. However, he also stated that the “commercial nature of the data bank and its for-profit agenda” militated for the requirement of explicit informed consent in this case. Thus, Annas seemed to stake out a more moderate position than Mannvernd and the Icelandic Medical Association with respect to the pre-existing requirements of informed consent for the use of health records from the medical record. His position was predicated on the assumption that the information banked in the database would be “unlinkable” back to the medical record. Because the Health Sector Database Act seemed to authorize the use only of “non personally identifiable health data” by the licensee, this was a fair assumption.

Icelandic critics of the HSD Act were operating under a different assumption, one derived from plans for data protection publicly released by the government in the legislative appendix to the act. The Icelandic Medical Association commissioned Ross Anderson, a Lecturer in the Cambridge University Computer Laboratory, to analyze the proposed design for the database in fall 1998. Anderson concluded that as a matter of logic, deCODE and the Data Protection Commission would be using a system of coded identifiers that necessarily allowed linkage: if the planned database was to be updated on an ongoing basis, the linkage had to be preserved.<sup>40</sup> This longitudinal updating of the database was one of the key features touted by the company, for in this way the database could track disease progression and differential response to pharmaceuticals over time. Furthermore, Anderson emphasized an inherent limitation of de-identified databases, namely that many patients could be identified by partial information of their circumstances, especially for a database that would contain comparatively few individuals and also would link genealogical records. If the information turned out to be linkable without an unreasonable amount of effort, then existing international informed consent standards would seem to apply.

Ross Anderson’s opinion came in the context of politicized debates over technical aspects of both the proposed encryption technology and the proper legal

standard governing the use of “non-identifiable personal information.” In a series of law articles written at the time, legal experts came to different opinions on the question of the HSD Act’s legality, in part because of ambiguity with respect to three issues. First, what was the proper standard of de-identification required under the HSD Act? Second, what was the standard of de-identification of personal data required to avoid needing a priori consent under European data protection laws? Third, did the encryption architecture proposed by deCODE meet both of these standards? Reasonable disagreement existed among knowledgeable jurists within and without Iceland on all three of these issues.<sup>41</sup> The Health Sector Database Act was based on the premise that all data would be made “non personally identifiable,” which usually means coded but linked to identifiers. But, the Notes to the Bill evince an assumption that all banked data would lack a coding “key,” and would therefore effectively be anonymous.<sup>42</sup> Furthermore, legal experts disagreed as to whether the proper criterion of non-identifiability under the European law was anonymity, which seemed to require the complete absence of any possibility of direct or indirect linkage, or merely “reasonableness”—under which data would be considered non-identifiable if identification required an “unreasonable amount of time and manpower.”<sup>43</sup> In this context, Ross Anderson’s expert assessment was important because he denied that the proposed architecture could possibly satisfy even the lesser “reasonableness” interpretation of non-identifiability.

deCODE received the operating license in January 2000. In that same year, relations began to become tense between the company and the Icelandic Data Protection Commission. The commission was responsible for overseeing rights of privacy and data protection in Iceland, and under the terms of the regulations promulgated under the HSD Act was in charge of setting the technology, security, and organizational terms under which the database would be constructed and used by deCODE.<sup>44</sup> By 2002, the company was struggling with the commission’s data protection requirements, stating in its annual Securities and Exchange Commission 10-K filing that these requirements were proving to be “expensive and time consuming and may delay the development of the Icelandic Health Sector Database and the deCODE Combined Data Processing system or make such development more expensive than anticipated.”<sup>45</sup> One important area of disagreement lay in how deCODE’s customers would access the data. deCODE’s business plans called for the marketing of access to the Health Sector Database by pharmaceutical and biotechnology firms directly over the Internet. The Data Protection Commission refused to authorize the release of data for this purpose, on the grounds that the proposed Web-based searching tool would insufficiently protect the identities of the data sources. The commission predicted that the system would allow users to deduce the identities of individuals through data linkages to genealogies and through non-coded demographic information.<sup>46</sup> This was precisely the concern raised by the Icelandic Medical Association and Ross Anderson years before, but now it was threatening to stall the implementation of the HSD Act indefinitely.

### A Shifting Business Paradigm

The company's failure to bring the Data Protection Commission and the Icelandic Medical Association leadership into line certainly was an impediment to constructing the database, but the company might have been looking for a way out of its obligations under the HSD license. In 2000, deCODE had described itself as a "genomics and health informatics company" for which the Health Sector Database would be a central selling point for investors. By 2002, deCODE was actively repackaging itself in face of real financial hardship.<sup>47</sup> Although the database and

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By the time [deCODE] filed its 10-K for 2002, it was still touting the advantages of gene hunting in Iceland, but a remarkable shift had taken place.

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bioinformational services side of its business were still discussed in its annual report, deCODE's more traditional family-linkage studies had been scientifically productive, yielding a number of potential new genetic factors involved in peripheral arterial occlusive disease, schizophrenia, and stroke. deCODE had some cash on hand, and it was looking to acquire smaller biotech companies that were selling at discount amidst the technology flop. That year, the company acquired MediChem Life Sciences, Emerald BioStructures, and Encode—companies that provided fee-for-service work in the drug discovery process,

including running clinical trials—as part of a shift in strategy to capture more of the upstream value from these research efforts. deCODE began describing itself as a diversified "biopharmaceutical company" with greater vertical integration in the drug discovery chain, and in which the future potential of operating the Health Sector Database was a smaller part.

The somewhat vague conception of how the national database itself would actually generate revenue must have seemed much less attractive to biotech investors after the dot-com bubble burst. Many biotech companies with large and speculative research investments, floated on hype and speculation, had folded or been acquired by larger pharmaceutical companies as debt accumulated and revenue failed to materialize. At some point, deCODE must have realized that its core research efforts should focus on its traditional family linkage studies that were still yielding some results, rather than on building an expensive database with only speculative value.

Furthermore, deCODE had found a way to amass large amounts of health information and samples by traditional methods—methods that did not require building the HSD architecture for Iceland. By the time the company filed its 10-K for 2002, it was still touting the advantages of gene hunting in Iceland, but a remarkable shift had taken place. Instead of speaking about the national three-part

database whose centerpiece was the Health Sector Database license, deCODE explained that in addition to assembling a computerized genealogical database, it had assembled a large set of “genotypic and detailed medical data from more than 90,000 volunteers, one of the world’s highest-throughput genotyping facilities, and statistical algorithms and software systems ... developed for storing this data and mining it for correlations between genetic variation and disease.” Rather than trying to rely on health institutions to transfer the medical data, the company explained that “all genetic and medical data being used in the company’s gene research has been obtained under the strictest standards of informed consent” and that “approximately 95 percent of all those who are asked to take part in our genetic studies agree to do so.”<sup>48</sup> This 2002 10-K filing illustrates an important reason why the company could declare its willingness to abandon hopes of building the Health Sector Database: the company was compiling a large trove of medical information, but only through the more tedious and piecemeal process of getting individual consent.

### **The Icelandic Supreme Court**

The Health Sector Database and its regime of presumed consent may have received its death knell on November 27, 2003, the day the Icelandic Supreme Court rendered judgment in the case of *Gudmundsdóttir vs. Iceland*.<sup>49</sup> The case concerned a young woman who wrote a February 2000 letter to the Icelandic Ministry of Health requesting that the information contained in her father’s medical records, and any genealogical or genetic data on him that might exist, not be transferred to the Health Sector Database. The Medical Director of Health had obtained a legal consultation by government lawyers, and based on this opinion denied her request: the HSD Act text was silent on this issue, but the Notes on the Bill had stated that it was not the legislative intent to allow children to opt-out their deceased parents.<sup>50</sup> Gudmundsdóttir initiated legal proceedings in April 2001, claiming that she had a personal interest in preventing the transfer of data from her father’s medical records to the database “as it is possible to infer, from the data, information relating her father’s hereditary characteristics which could also apply to herself.” The Icelandic District Court ruled that the medical information included in the database was not personally identifiable and that Gudmundsdóttir lacked standing to challenge the inclusion of her father’s information in the database.

The Icelandic Supreme Court reversed the lower court on the standing issue, granting that she had a personal privacy interest in her father’s medical data. But the court went much further. Noting that Icelandic medical records were required by law to contain extensive information on people’s health, their medical treatment, lifestyles, social circumstances, employment, and family, the court held that “it is unequivocal that the provisions of Paragraph 1 of Article 71 of the Constitution—the provision that ‘everyone shall enjoy freedom from interference with privacy, home, and family life’<sup>51</sup>—apply to information of this kind and ... guarantee protection of privacy in this respect.” Although the Icelandic Supreme



Court agreed with the district court's conclusion that the "one-way encryption discussed in" the HSD Act "could be carried out so securely as to render it virtually impossible to read the encrypted information," the act made no indication "as to what information from medical records must be encrypted in this manner prior to transfer." The annex to the operating license "impl[ied] that only the identity number of the patient will be encrypted in the database and that the name, both of the patient and his family, together with the precise address will be omitted." However, the "vague limits" set by the provisions of the Health Sector Database Act inadequately provided for the protection of Gudmundsdóttir's constitutional right to privacy, and therefore her right to opt-out her deceased father's health information was affirmed.

Less than four months later, deCODE filed its annual report for 2003, in which it stated it did not plan to operate the Health Sector Database under the terms of

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[T]he national database to be constructed through presumed consent and transfer of health information was a dead letter.

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the Health Sector Database Act and the license. Effectively, the national database to be constructed through presumed consent and transfer of health information was a dead letter. The demise of the database was certainly precipitated by the recalcitrance of the National University Hospital, the Icelandic Medical Association, and the failure of the company to

reach agreement with the Data Protection Commission. The company's diminishing estimation of the national database's business value was also a likely factor.

Nevertheless, the construction of the Health Sector Database under the terms of the act was ultimately undone by the emergence of consensus, in both local and external institutions, that a priori consent of patients should be indispensable for engaging in this type of research in all but the rarest exceptions. These were not simply technical disputes, but cut to the core of the relationships among individuals, clinical health institutions, markets, and the state.

#### LEGACY AND IMPLICATIONS OF THE HEALTH SECTOR DATABASE CONTROVERSY

On January 16, 2006, the *New York Times* reported on its front page that deCODE Genetics had discovered a gene variant that leads to a sizable extra risk of type 2 diabetes.<sup>52</sup> Since discoveries are being made, one could easily conclude that the story of Icelandic Health Sector Database is now moot. Furthermore, the company has built a large archive of DNA samples, with attendant health information, using traditional recruitment and *a priori* consent for use of data and DNA for research purposes.<sup>53</sup> However, deCODE's current practices were contingent on the passage of the Health Sector Database Act, and they were shaped in important

ways by the failed gestation of the Health Sector Database itself. Indeed, the history of the Health Sector Database carries important theoretical and practical implications for understanding the current practices of population genomics, for it helped produce the technological, political, and normative terrain of all large-scale genomics initiatives today, not just Iceland's. Furthermore, Iceland provides an important window on the process of innovation in the life sciences, illustrating the ways in which technological, normative, and politico-economic changes occur within a mutually dependent system.

### **Multiple Innovations of Global Significance**

Many nationally focused genomic projects have been drawn up in an explicit attempt to follow Iceland's lead.<sup>54</sup> For instance, the CARTaGENE project in Canada plans to sample one percent of all Quebec citizens between the ages of 25 and 74 to represent "the entirety of the population" for a study of "the genetic contribution to the health and illness of the entire Quebec population."<sup>55</sup> In 2002, the United Kingdom, the Medical Research Council, the Wellcome Trust (a private charitable organization), and the Department of Health funded the creation of "UK Biobank," a longitudinal prospective population genomics study to involve roughly 500,000 UK adults aged 45–69. In 2006, the Department of Veteran Affairs in the United States announced its plans to amass a genomic biobank of millions of veteran samples to be combined with its computerized medical records.<sup>56</sup>

As other countries sought to enter the population genomics game in various configurations, at least one aspect was constant: Iceland's Health Sector Database Act was invoked as a bad model for handling consent and other ethical and legal aspects of state-sponsored genomics. But this is only part of the important constructive role the HSD Act played in producing the normative conditions in which genomics operates today. As policy consultants for UK Biobank observed in 1999, "much of the recent international discussion of the issues raised by the use of biological sample collections has been stimulated by developments in Iceland ...."<sup>57</sup> Indeed, the Iceland debates became an important channel through which the stakes of individual consent and patient–doctor confidentiality were clarified and reframed in relation to issues that were new to the world of biomedical research.

The novel contexts presented by population genomics included the linkage of different forms of personal information, exclusive commercial licensing of data and databases, encryption architectures, and propriety claims by the state over medical information. There was no pre-existing answer to the question of how the traditional principle of informed consent should have been adapted to the genomics context, even though parties to the Icelandic Health Sector Database dispute claimed otherwise. Rather, they would have had to emerge through legalistic interpretation, technological specification, and active negotiation and deliberation between disparate groups at different scales of governance.

This process of norm construction and development was not linear, and interaction through social networks at national and international levels operated as a

dynamic system. Before the regime of presumed consent had been rejected within Iceland itself, it had helped precipitate an emerging global consensus that the “technological fix” of a thick encryption architectures would not replace affirmative consent from individuals prior to their enrollment in population genomics projects. As an indicator of the development spurred by the HSD Act, the World Medical Association promulgated a “Declaration on Ethical Considerations Regarding Health Databases” that attempted to codify these emergent norms in

2002.<sup>58</sup> These emergent norms of personal control of medical information fed back into the Iceland debate, and they likely helped persuade the Data Protection Commission as well as the Icelandic Supreme Court that Iceland’s presumed consent regime was incompatible with the operation of the national database as originally conceived. In the process, the Icelandic Supreme Court took up the mantle of innovation: its recognition of the collateral privacy rights of Gudmundsdóttir in the health data of her father was a bold legal innovation that has been noted in international legal circles.<sup>59</sup> For these reasons, one could be completely justified in

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Whereas one vision argued that what the nation needed was to take bold collective action to provide the optimal economic and regulatory conditions for one biotechnology company to take root, the other vision saw ethical, social, and political costs of leveraging Icelandic biotechnology in this way.

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the view that the Iceland Health Sector Database case has as much a globally important normative legacy, as a technological one.

The extent to which the Health Sector Database controversy reached distant shores, and activated international commentaries that in turn fed back into national and international bioethical debates, demonstrates how the database became an experimental site not only for genomics, but for genomic governance. In this sense, both these new genome projects and their normative maps are an important piece of the database’s legacy.

### **Society in Technology**

Within technology policy circles, there persists a view that technology exerts autonomous force on society, and that technological development occurs on a materially-determined and linear path. However, scholarship within the field of science and technology studies (STS) has for some time been demonstrating that technologies cannot be seen in isolation from the social relations that shape them,

whether they be political, economic, normative, or psychological.<sup>60</sup> The history of the Health Sector Database helps underscore this point. The precise form that technology takes in the world is contingent on the kinds of social work that go into it. The same powerful narrative that helped persuade the majority coalition in the *Althing* to support the Health Sector Database Act had already drawn venture capitalists into its fold. As Stefansson realized, establishing the exclusivity which the act seemed to allow the company to attract international attention and more investors. Without national sponsorship of the project, it is doubtful that Stefansson would have been able to raise the large amounts of speculative capital necessary to set up his genomic laboratories in the suburbs of Reykjavík.

In Iceland, we have seen how governance and technology were produced together in a system of feedback loops. Ultimately, the network of actors and technologies failed to hold together in face of various normative and political forces, but these oppositional forces nevertheless shaped genomic technology in Iceland as much as the passage of the HSD Act. Resistance to the regime of presumed consent envisioned by the Act helped give rise to new encryption technologies and a string of associated privacy commentaries. Further, the fact that many doctors refused to relinquish control of the data for ethical reasons, and that the Data Protection Commission ended up enforcing a stricter view on encryption than the company anticipated, forced the company back to more traditional familial linkage approaches, rather than the non-hypothesis driven shot-gun correlation approach associated with the tri-partite database. This strategy has become the most fruitful research path for deCODE scientifically, and the expensive construction of a national-level database with the greater degree of de-identification demanded by the act would have set the company on an alternative, and arguably less promising, trajectory.

### **Biotechnology and Nation in the Global Order**

Finally, there is a deeper story that the Iceland experience tells about the interpenetration of science, technology, and society—one that is relevant to the politics of the nation state in an era of globalization. The story of the Health Sector Database manifests the extent to which science and technology have become, or are at least widely seen to be, *constitutive* of modern nationhood itself. For the majority parliamentary coalition, the HSD Act was part of a larger strategy for nation building and for maintaining national independence in the face of a global economy and global politics that threatening to engulf Iceland. Indeed, the debates between proponents and opponents of the Health Sector Database Act were arguing not only over technicalities of encryption architectures and European Data Protection law, but also over different visions of the nation itself.

At the turn of the twenty-first century, proponents of the Health Sector Database Act were drawn to the ways in which the legislation promised to reinvent the nation by drawing together existing cultural resources (common histories, cultural practices like genealogy, traditions of science, fierce independence) and trans-

posing them into a new key. They argued that in order to underwrite future economic growth and survival, a bold new reconfiguration of state-science-market needed to be born in Iceland—only through this alchemy could Icelandic genes have been transformed into the next national resource. The act, with its regime of presumed consent, exclusivity and privatization, were a simultaneous means of creating the new resources and maximizing its extraction value to Iceland.

For its critics, the Health Sector Database Act represented a critical departure from the very codes that constituted its civilization—the codes of modern science and modern democracy. Adherence to these codes accounted for the impressive standing Iceland already enjoyed at the international level as a viable modern democracy, one capable of producing top scientific researchers and an enviable health care system. As a general matter, critics within the medical and scientific establishment in Iceland looked to an idealized ethos of science as a model for the Icelandic polity.<sup>61</sup> Traditional scientific ideals of skepticism, disinterestedness, shared property, and universalism created optimal conditions for preserving individual freedom and organizing collective action.<sup>62</sup> For the members of Mannvernd, most of whom were scientists and physicians, the Health Sector Database Act signaled the state-sanctioned departure from these ideals, because the plan dangerously embraced a naive scientific hype, commercial dominance, and the privatization of common cultural and scientific resources. Many critics saw within the attack on this scientific order a correlative erosion of Icelandic democratic order, and corruption of the state within the corruption of science. For some, science and state were being reconfigured in such a way that threatened to destabilize the very orders that underpinned Iceland's claim as a Western liberal democracy and that helped knit Iceland into the fabric of global political culture.

Whereas one vision argued that what the nation needed was to take bold collective action to provide the optimal economic and regulatory conditions for one biotechnology company to take root, the other vision saw ethical, social, and political costs of leveraging Icelandic biotechnology in this way. The fact that these two visions for Iceland clashed so starkly should not overshadow what they had in common: for both proponents and opponents, science and technology were both symbolic and practical resources for the production of the polity. This powerful insight animates political struggles in many other nations as they look to the frontiers of the life sciences, both scientific and ethical, as opportunities and vehicles for nation building.<sup>63</sup> Stem cells in South Korea and the creation of “Biopolis” in Singapore are just two other recent examples. The Icelandic Health Sector Database controversy certainly prefigures these emerging cases. It also underscores how smaller nations and their innovations, not just those of the major powers, can and do become critical sites for the formation of global order.

### **Acknowledgements**

This article is in part based on the field work conducted in Iceland in the summer of 2000 and in August 2003. The field work was supported by the Program

on Science, Technology and Society at Harvard University. Thanks to Bogi Andersen, Heather Butterfield, Jóhann Pétur Hardarsson, Einar Árnason, Pétur Hauksson, Skúli Sigurdsson, and Phil Auerswald for their helpful contributions to this article. All errors left are of course my own.

We invite reader comments. Email <editors@innovationsjournal.net>.

1. In fact, the ancient site of the Icelandic Parliament, the *Althing*, sits at a spot called Thingvellir where the fault line between the European and American tectonic plates meet.
2. Isaac S. Kohane and Russ B. Altman, "Health-information Altruists—A Potentially Critical Resource," *New England Journal of Medicine*, 353(2005): 2074–2077.
3. For example, deCODE was recently described as doing "exciting work" by Francis Collins, head of the Human Genome Research Institute in the United States, and by other prominent geneticists. Michael D. Lemonick, "The Iceland Experiment," *Time* (February 12, 2006).
4. Richard F. Tomasson, *Iceland: The First New Society* (Iceland Review, 1980), Ch. 1.
5. Dr. Skúli Sigurdsson, an Icelandic historian of science and member of the act's opposition, has been a meticulous analyst and bibliographer of the database controversy. See, e.g., Skúli Sigurdsson, "Bioethics Lite™: Two Aspects of the Health Sector Database Controversy," In Tillmann Hornschuch, Kirsten Meyer, Gerlind Rüge, and Miriam Voß, eds., *Schöne—Gesunde—Neue—Welt? Das Humangenetische Wissen und seine Anwendungen aus philosophischer, soziologischer and historischer Perspektive* (Bielefeld 2002) (IWT-Paper 28). See also Sigurdsson's highly useful bibliography of the database controversy, "Biography for Studying the HSD deCODE Controversy," <<http://www.raunvis.hi.is/~sksi/kit.html>> (accessed May 15, 2006).
6. Act on a Health Sector Database no. 139/1998 (Passed by Parliament at 123rd session, 1998–99). Article 1. <<http://ministryofhealth.is/laws-and-regulations/nr/659#allt>> (accessed May 15, 2006).
7. The Health Sector Database bill was first submitted to the *Althing* in March 1998, and it was debated at several sessions. There was immediately strong opposition to the bill from large sections of the clinical and biomedical research communities in Iceland, which led to withdrawal of the bill. A second draft of the bill was introduced in late June 1998, with a number of changes. This second version was the one that was enacted in December 1998.
8. Because official construction of the database never began, the opt-out period remained open indefinitely.
9. Tómas Zoëga, interview for the Science Channel in the Netherlands conducted by Paul Wouters, 1999. Transcript on file with the author. Zoëga was Chair of the Ethical Council of the Icelandic Medical Association (IMA) at the time. In response to the association's opposition to the bill in the summer of 1998, David Oddsson "remarked that privacy standards were so lax in Icelandic health institutions that it was hypocritical of the IMA to oppose the HSD bill on the grounds that it threatened the doctor–patient confidentiality. See Skúli Sigurdsson, "Yin-Yang Genetics, or the HSD deCODE Controversy," *New Genetics and Society* 20 (2001), 103–117, p. 106.
10. Mannvernd web page, "What is Mannvernd?" <<http://www.mannvernd.is/english/aboutmv.html>> (accessed May 15, 2006).
11. The notes to the bill state that "due to the nature of the data and their origin [Icelandic health records] cannot be subject to ownership in the usual sense. Institutions, companies or individuals cannot therefore own the data [because t]hey exist primarily due to the treatment of patients." Bill on a Health Sector Database (Submitted to Parliament at 123rd session, 1998–99). <<http://www.mannvernd.is/english/laws/HSD.bill.html>> (accessed May 15, 2006).
12. David E. Winickoff, "Governing Population Genomics: Law, Bioethics, and Biopolitics in Three

Case Studies," *Jurimetrics* 43 (Winter 2003), 187–228.

13. The tale of the passage of the Health Sector Database Act has been told many times, but seldom well. For important exceptions, see Hilary Rose, *The Commodification of Bioinformation: The Icelandic Health Sector Database* (Forward by Marilyn Strathern) (The Wellcome Trust, 2001); Skúli Sigurdsson, "Yin-Yang Genetics, or the HSD deCODE controversy," *New Genetics and Society* 20 (2001): 103–117; Skúli Sigurdsson, "Decoding Broken Promises," *openDemocracy* (March 6, 2003) <[http://www.opendemocracy.net/theme\\_9-genes/article\\_1024.jsp](http://www.opendemocracy.net/theme_9-genes/article_1024.jsp)> (accessed May 15, 2006); Michael Fortun, "Iceland Cometh to Commercial Genomics: From the Individual as Biomass to the Nation as Database," Talk presented at the American Anthropology Association annual meeting, Chicago IL, November 17–19, 1999.

14. Kari Stefansson, "deCODE Inc.," unpublished business plan, 1994. On file with the author.

15. The "founder effect" was defined by Ernst Mayr in 1963 to be the genetic effect of establishing a new population by a small number of individuals. This subset of individuals carries only a small fraction of the original population's genetic variation, and the new population may be distinctively different, both genetically and phenotypically, to the parent population from which it is derived.

16. While Stefansson used claims about Iceland's genetic homogeneity to naturalize his business narrative, some Icelandic geneticists criticized these claims as inaccurate, both in public talks and scientific studies. See Einar Árnason, et al., "Genetic Homogeneity of the Icelanders: Fact or Fiction?" *Nature Genetics* 25 (August 2000), 373–374; Einar Árnason, "Genetic Heterogeneity of Icelanders," *Annals of Human Genetics* 67 (2003), 5–16; Alison Abbott, "DNA Study Deepens Rift over Iceland's Genetic Heritage," *Nature*, 421 (February 13, 2003), 678. deCODE's scientists countered with more of their own studies. See A. Helgason, et al., "A Reassessment of Genetic Diversity of Icelanders: Strong Evidence from Multiple Loci for Relative Homogeneity Caused by Genetic Drift," *Annals of Human Genetics* 67 (2003): 281–297.

17. For more analysis deCODE's myth-making, and its uptake by an eager foreign media, see Skúli Sigurdsson, "Bioethics Lite™."

18. Stefansson, "deCODE Inc.," 8. These records already existed due to what one Icelandic anthropologist has described as an extreme Icelandic "fascination" with genealogical trees and See Gísli Pálsson, "The Life of Family Trees and the Book of Icelanders," *Medical Anthropology* 21(2002), 337–367.

19. These technologies included polymerase chain reaction (PCR) and high-through-put sequencing. See Paul Rabinow, *Making PCR: A Story of Biotechnology* (Chicago University Press, 1996); Michael Fortun, "Projecting Speed Genomics," In Michael Fortun and Everett Mendelsohn, eds., *Practices of Human Genetics: International and Interdisciplinary Perspectives*, Sociology of the Sciences Yearbook Vol. 19. (Kluwer, 1999), 25–48.

20. Sequana Therapeutics at that time was a young biotechnology company with a strong venture component. It merged with Arris in 1997 to form AXYS Pharmaceuticals, which in turn was acquired by Celera Genomics.

21. Letter from Kevin J. Kinsella, President and CEO of Sequana Therapeutics, to Kari Stefansson, May 26, 1995. On file with the author. Also quoted in, Tómas Zoëga and Bogi Andersen, "The Icelandic Health Sector Database: deCODE and the 'New' Ethics for Genetic Research," In Linda Nielsen and Claus Holm, eds., *Who Owns Our Genes?* (Nordic Council of Ministers, 2000), 33–64.

22. Skúli Sigurdsson, "Island Histories: How Science and Technology Came to Iceland," in Reinhard Siegmund-Schultze and Henrik Kragh Sørensen, eds., *Science in Scandinavia Around 1905* (Novus Forlag, 2005).

23. deCODE Genetics, public corporate summary sheet, 2000. On file with the author. The initial U.S. venture firms to commit included Advent International, Alta Partners, Atlas Venture, Arch Partners, Falcon Technologies, Medical Science Partners, and Polaris Venture Partners.

24. Rose, *Commodification of Bioinformation*, 11.

25. For a useful account of the enclosure movement in its historically land-oriented form and in its recent expansion into informational realms, see James Boyle, "The Second Enclosure Movement and the Construction of the Public Domain," *Law & Contemporary Problems* 66(2003): 33–74.

## Genome and Nation

26. The information in the faxed draft of the act is contained in Gudni Jóhannesson's treatment of the deCODE history in Icelandic. *Kári í jötunmód: Saga Kára Stefánssonar og Íslenskrar erfðagreiningar* (Reykjavík, 1999).
27. Rose, *Commodification of Bioinformation*.
28. Benchmark payments are by definition conditional upon achieving certain goals, although this \$200 million was often spoken of as if it were hard cash. The company actually received only just over one third of this amount, failing to reach expected goals. See note 5, Sigurdsson, "Bioethics Lite™" (calculating from deCODE's SEC 10-K statements that Hofmann-LaRoche ultimately transferred only \$74.3 million under the terms of the deal).
29. Anthropologists Gísli Pálsson and Paul Rabinow consider the 9-month debate leading up to the passage of the act to be a model in terms of democratic engagement and deliberation. See Gísli Pálsson and Paul Rabinow, "Iceland: The Case of a National Human Genome Project" *Anthropology Today* 15(5; 1999): 14–18. See also Gísli Pálsson and Paul Rabinow. "The Icelandic Genome Debate," *Trends in Biotechnology* 19 (2001), 166–171. Other commentators have been deeply critical of this position, especially Skúli Sigurdsson, in "Yin-Yang Genetics." See also Michael Fortune, "Open Reading Frames: The Genome and the Media" speech at Princeton University in March 2001 (stating that "the vast majority of those hundreds of media accounts that are cited as evidence of a democratic debate in Iceland were little more than dressed-up deCODE press releases issued on a regular basis, passing on messages about jobs for Icelanders, predictions of wealth in the national coffers, and pieties about how Iceland would contribute to the improvement of world health and the universal progress of biomedical research."). Reprinted in *After the Fact*, the publication of the Institute for Science and Interdisciplinary Studies (Summer 2001) and by the Council for Responsible Genetics, <<http://www.genewatch.org/genewatch/articles/14-6fortun.html>> (accessed May 16, 2006).
30. The most famous novel of Icelandic Nobel Laureate Haldór Laxness, *Independent People*, deals with this theme, linking one farmer's struggles to remain financially independent to questions of national character and collective independence. See Einar Árnason and Frank Wells, "Iceland and deCODE: A Critique," in *Encyclopedia of the Human Genome* (Macmillan, 2003), 1–5, who mention Iceland's "fear of engulfment."
31. See website of Iceland's National Power Company (Landsvirkjun), <<http://www.karahnjukur.is/en/>>. In terms of defining the future of Iceland and its economy in the late 1990s, the power economy was and is probably more important in terms of scale than biotech.
32. Icelandic Constitution, Article 71, states: "everyone has the right to respect for his private and family life and his home."
33. deCODE Genetics, Inc., *Form 10-K* (fiscal year ending December 31, 2003), 49 (annual report filed with the U.S. Securities and Exchange Commission (SEC) pursuant to the Securities Exchange Act of 1934, §§13, 15(d)).
34. After the initial rate of opt-outs dropped off, the rate of opting out rose again after deCODE received the Health Sector Database operating license in January 2000. The rate of opting out dropped again by summer 2000. See graph of "Opt outs from Icelandic Health Sector Database," <<http://www.mannvernd.is/english/>> (accessed May 24, 2006).
35. Richard C. Lewontin, "Op-ed/People Are Not Commodities," *The New York Times*, January 23, 1999, A19.
36. For example, see Bogi Andersen, "Letter/Hijacked Medical Records," *The Washington Post*, A20, February 6, 1999.
37. World Medical Association, Press Release, April 16, 1999.
38. See, for example, Bogi Andersen and Einar Árnason. "Letter/Iceland's Database Is Ethically Questionable," *British Medical Journal* 318 (June 5, 1999): 1565; Jeff Gulcher and Kari Stefansson, "Letter/Ethics of Population Research," *Nature* 400 (July 22, 1999): 307–308; Ruth Chadwick, "The Icelandic Database: Do Modern Times Need Modern Sagas?" *British Medical Journal* 319 (August 14, 1999): 441–444 (but see also Ruth Chadwick, "Correction," *British Medical Journal*, 320 [January 22, 2000]: 234). But see also one such letter published quite a bit earlier: Bogi Andersen,



David E. Winickoff

- “Letter/Icelandic Health Records,” *Science* 282 (December 11, 1998): 1993.
39. Notably, this idea of cultural context and democratic will was adopted by a pair of cultural anthropologists studying the controversy, one from the University of Iceland, the other from University of California, Berkeley. See note 29.
40. The Icelandic Medical Association had commissioned Ross Anderson in the fall of 1998, and the report he issued soon after was influential in the debates leading up to the Act’s passage. He later published his opinion in R. Anderson, “Iceland’s Medical Database Is Insecure,” *British Medical Journal* 319 (July 3, 1999): 59.
41. For an overview of the thorny legal questions and conventions involved, see Oddny Mjöll Arnardóttir, Davíð Thór Björgvinsson, and Vidar Már Matthíasson, “The Icelandic Health Sector Database,” *European Journal of Health Law* 6 (1999): 307–362; Henriette Abbing and D.C. Roscam, “Central Health Database in Iceland and Patient’s Rights,” *European Journal of Health Law* 6 (1999): 363–371.
42. The proposed encryption architecture was contained in Appendix VI of the Health Sector Database bill, and it had been prepared by an Icelandic information technology company, Stiki hf. See Arnardóttir, p. 332, fn.73.
43. This standard comes from *Recommendation R (97) 5 on the Protection of Medical Data*, pursuant to the 1981 *Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data*.
44. Icelandic Government Regulation on a Health Sector Database, Article 30.
45. deCODE Genetics, Inc., *Form 10-K* (fiscal year ending December 31, 2002), 19.
46. Personal interview with Data Protection Commission staff, Reykjavík, August 2003.
47. See Skúli Sigurdsson, “Bioethics Lite™,” for more detail on the struggles of deCODE around this time.
48. deCODE Genetics, Inc., *Form 10-K* (fiscal year ending December 31, 2002), 7.
49. *Gudmundsdóttir v. the State of Iceland*, No. 151/2003 (Nov. 27, 2003) (Ice.). <[http://www.man-nvernd.is/english/lawsuits/Icelandic\\_Supreme\\_Court\\_Verdict\\_151\\_2003.pdf](http://www.man-nvernd.is/english/lawsuits/Icelandic_Supreme_Court_Verdict_151_2003.pdf)> (Translated March 30, 2004, by court-authorized translator), accessed May 17, 2006.
50. *Gudmundsdóttir v. the State of Iceland*, §I.
51. Icelandic Constitution, Article 71. <<http://government.is/constitution>> (accessed May 18, 2006).
52. The finding of the genetic variant, which had just been published in *Nature Genetics*, made front-page American news because the variant is reportedly carried by a third of the American population. Nicholas Wade, “Gene Increases Diabetes Risk, Scientists Find,” *New York Times*, A1, (Jan. 16, 2006). deCODE first found the gene in Icelanders and subsequently in both an American and Danish population.
53. In its annual report for 2005 filed in March 2006, the company reported that it had “gathered genotypic and medical data from more than 110,000 volunteer participants in our gene research in Iceland—over half of the adult population.” deCODE Genetics, Inc., *Form 10-K* (fiscal year ending December 31, 2005), 4. The company is not clear about whether volunteers have signed broad consent for multiple research studies. The Data Protection Commission would have to approve such a departure from normal practice. *Id.* at 23.
54. J. Kaiser, “Population databases boom, from Iceland to the U.S.,” *Science* 298(2002): 1158–1161.
55. CARTaGENE, <<http://www.cartagene.qc.ca/index2.cfm?lang=1>> (accessed May 18, 2006).
56. Cory Reiss, “Agency To Seek DNA Of All U.S. Veterans,” *The Ledger* (April 23, 2006).
57. Paul Martin and Jane Kaye, *The Use of Sample Collections and Personal Medical Information in Human Genetics Research* (The Wellcome Trust, November 1999).
58. In this declaration, the World Medical Association affirmed as its first principle that “the right to privacy entitles people to exercise control over the use and disclosure of information about them as individuals,” and that “the privacy of a patient’s personal health information is secured by the physician’s duty of confidentiality.” Further, it was affirmed that as a general rule, “patients’ consent is needed if the inclusion of their information on a database involves disclosure to a third party or would permit access by people other than those involved in the patients’ care.”

## Genome and Nation

59. As an example of the ruling's international reach, the *Harvard Law Review* featured an extended case note on the case, heralding the fact that the "Gudmundsdottir Court appears to be the first to recognize that someone other than the source of genetic information—the proband—has a legally cognizable privacy interest in the proband's information." Recent Cases, *Harvard Law Review* 118(2004): 810–817.

60. See, for example, Langdon Winner, *The Whale and the Reactor: A Search for Limits in an Age of High Technology* (University of Chicago Press, 1986); Wiebe E. Bijker and John Law, eds., *Shaping Technology/Building Society: Studies in Sociotechnical Change* (MIT Press, 1992). See also work on "path dependence."

61. For the classic statement of the thesis that "science" is a model polity, see M. Polanyi, "The Republic of Science," *Minerva* 1(1962): 54–73.

62. These idealized norms were classically formulated by the sociologist Robert K. Merton in his essay, "The Normative Structure of Science" [1942], reprinted in R.K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, 1973), 267–278. For excellent modern treatments on the constitutive role of science in modern democratic order, see Yaron Ezrahi, *The Descent of Icarus: Science and the Transformation of Contemporary Democracy* (Harvard University Press, 1990).

63. See, e.g., Sheila Jasanoff, *Designs on Nature* (Princeton University Press, 2005).