GENETIC DATABASES

Decoding developments in Iceland

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As we write these comments, a 12-year license, which grants exclusive rights to Iceland's entire health care database, is about to be given to an American company, with a majority ownership of American venture capital funds that also hold a majority on its board of directors. This license would contain highly controversial conditions such as "presumed consent" that would allow the company to use the personal data of any individual in the database without their permission or "informed consent." Iceland's sovereignty is effectively at stake.

How did this remarkable turn of events come to pass? In August of 1996, deCODE Genetics Inc. was founded and incorporated in the state of Delaware. The company issued 20 million shares and sold 12 million to a group of seven American venture funds at a \$1 per share. A wholly owned Icelandic subsidiary was established, and with \$12 million the company started operations in Iceland. By the end of 1997 it had 45 employees, a number that has grown to 250 today. In early 1998, deCODE signed the largest deal at that time in genomics with Hoffmann-LaRoche, valued at up to \$200 million over a five-year period. This partnership was focused on linkage studies in 12 diseases. deCODE then sold an additional 2 million shares to Icelandic investors at \$5 per share. These shares trade publicly in Iceland, and have recently been trading at more than \$22 per share, bringing the market capitalization of deCODE to close to \$500 million.

By all measures deCODE was a roaring success, and it was initially well received in Iceland, bringing the benefits of high-paying jobs in a high-tech industry. Its energetic president and CEO received manifold praise and recognition for his accomplishments, including a nomination in the magazine *Red Herring* in 1998 as one of the world's top 10 entrepreneurs.

However, deCODE's troubles began in March of 1998, when it helped formulate a

bill introduced into the Icelandic Parliament, Althingi. Established in 930, Althingi is the world's oldest legislative body, and this bill is probably the most complex matter it has confronted in its more than 1,000-year history. It authorizes the establishment of a centralized health care database, which includes detailed health care records and the ability to correlate them with genealogical and genotypic information¹. One controversial part of the bill is that it includes the provision that in exchange for paying for the construction of the database-estimated to cost over \$100 million-an exclusive 12-year license would be granted for its use. The proposed law included a number of features that were unprecedented, to say the least, with regard to prior general medical, scientific, and ethical practices in the conduct of R&D of health care products.

Naturally enough, the bill attracted considerable attention and there was and is a strong opposition to it both domestically and internationally. Coverage of this issue has been extensive². In brief, a battle raged in Iceland over this legislation throughout 1998 until its eventual passage at the end of the year. Although the bill did not pass the Althingi until December of 1998, deCODE had been talking about having an exclusive license to such a database even before its original introduction in March 1998.

This database will contain genotypic data, and thus the most intimate information about the individuals who will provide tissue samples for the database. With advances in human genomics being so rapid, it is hard to tell how much will be read (correctly or not) into genotypic information obtained over the coming 12 years. Although we are promised that maximum effort to maintain privacy will be made, in a small country like Iceland, the individuals in the database can be identified with as little as three pieces of readily available information (such as gender, date of birth, parent's date of birth).

deCODE plans to go public. Thus, all the information in the centralized database and its intrinsic value will be traded as a commodity on international markets. Comprehensive hereditary and health care information for a whole nation, in a format in which every individual and his/her characteristics can most likely be identified! Nothing less than Iceland's national identity is at stake. The board of directors at deCODE holds all the cards, since it must approve and consent to all the actions that deCODE takes. Realizing this, a group of Icelandic physicians in an open letter³ made a plea to the board to reconsider its actions just before the passage of the bill, in which they cited severe criticisms of all or parts of the bill by no less than 30 Icelandic ethical and scientific associations. Their effort was predictably to no avail-perhaps understandably, as it is the venture funds that stand to gain the most, well over \$200 million if the current share price holds up. Their capital gains, if and when realized, will not even be taxed in Iceland, and it is unclear what long-term benefit if any the Icelandic nation will receive from this process.

Since Iceland is only a thousandth the size of the US, 250 high-paying jobs there are equivalent to 250,000 high-paying jobs in the US. The creation of a significant number of good jobs is every politician's dream. In this light, the actions of Althingi can be understood. Of course an exclusive license will not guarantee the existence of these jobs; only real scientific performance of the company in the highly competitive world of genomics will.

Needless to say, human genetic research can be conducted in Iceland as elsewhere without implementation of controversial issues. Interestingly, such research can be performed without the creation of such a centralized database and an infringement on the exclusive license. Many genealogical databases exist in private hands, as do patients' registries (and some are explicitly excluded in the bill) and disease-specific physician-patient groups and societies. The authors are scientists of Icelandic origin who have worked in the US for over 20 years. In response to the unacceptable, and to us embarrassing, situation that has developed in Iceland, we have chosen to participate in the founding of another Icelandic biotechnology company. We hope that this company can diversify job creation in Iceland and bring generally accepted international standards of medical research to the burgeoning industry there.

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English version of the legislation is found on http:// brunnur.stjr.is/interpro/htr/htr.nsf/pages/gagnagrensk

Hodgson, J. Nat. Biotechnol. 16, 896–897 and 16, 1017–1021 (1998); see also Nat. Genet. 20(2), 99–101 (1998), Science 280, 890–891(1998), Sci. Am. February 1998, p. 24.

See http://www.mannvernd.is/english/index.html, item 12.12.98