

# Medicine & Health Perspectives

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## Will Genome Science Shift Clinical, Insurance Paradigms?

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Difficult as it will be to tease out the multiple gene pathways that predispose us to common diseases, that information will be available one giant step earlier than new therapeutics, since developing therapies requires the difficult extra work of finding or synthesizing molecules to affect cellular operations the faulty genes set in motion.

Today, genome science is in its earliest stages. And in this heavily statistical science, before there is knowledge there must be data. Lots of it. Tissue and medical histories from many thousands of people will be needed for pure research that, in its early forms at least, will heal no one. And therein lies the rub. Privacy concerns and questions of who ultimately will benefit plague some efforts to gather those resources.

Consider the case of Iceland. Nearly all of the country's 275,000 people descend from ninth century Norse and Celtic settlers. Iceland's homogeneous environment, extensive genealogical records, and a public health system with clinical records beginning in 1915 make it prime territory for gathering data. In December 1998, Iceland's parliament approved a plan to pool the nation's public and private medical records in one database, with individuals having the freedom to keep their data out. Key to vocal criticism of the plan that has arisen at home and abroad is that in January of this year the country also

inked a deal to receive \$12 million from a startup genome science firm, deCode Genetics Inc., to operate the database exclusively for 12 years. The company plans to study the genetics of between 25 and 35 common diseases, including multiple sclerosis, alcoholism, colon cancer, diabetes, heart disease, and schizophrenia. Any commercial diagnostic test or drug developed through the research will be provided free to all Icelanders during its patent life.

In public opinion polls a solid majority supports the initiative, and earlier this year the journal *Science* reported that only about 5 percent of Icelanders had asked to have their data excluded.

But the medical community is largely opposed. On some accounts, fully one-third of the country's doctors have said they won't turn over patient records. The plan is objectionable because it "allows only for people to opt out of the database but not to give any other form of consent," says the Iceland Psychiatric Human Rights Group. Those who don't opt out are considered to have consented, which could include deceased people, newborns, and the mentally ill. Furthermore, giving a single company monopoly over the data "endangers freedom of scientific research as well as freedom to engage in commerce," the group argues.

Inclusion of ancestral data creates most of the privacy concerns. Data are encrypted and name identifiers removed. However, "there are obvious problems in obscuring the recognition of families as many can easily be recognized by the pattern of their rela-

tionship," according to Oxford University biochemist J.H. Edwards.

Ironically, the long-term ancestral data may not be much help in deciphering major diseases, which are multifactorial, resulting from interactions among several — perhaps many — genes and the environment, say Edwards and others. DeCode researchers say that data from closely related people will make it easier to find genetic associations for all diseases by eliminating the "background noise" of other genetic differences. But other scientists argue that, since multiple-gene diseases don't have simple inheritance patterns and data from one family isn't likely to yield a significant number of extra cases of one condition, the advantage gained may not be enough to warrant the privacy issues created.

The Internet-based genomics company Mountain View CA-based DNA Sciences, Inc., is pursuing "the same end game" as the Iceland database: greater understanding of disease, says CEO Hugh Rienhoff, MD. But the company is taking a much different approach to assembling its database — 5,000 patients in each of six disease categories, including asthma, diabetes, and breast cancer. Dubbing its DNA Sciences Gene Trust Project "the first-ever large-scale consumer research initiative designed to discover the links between genetics and common diseases," the company uses its web site, DNA.com, to seek consumers willing to donate blood samples and medical histories on a voluntary, opt-in basis.

While Rienhoff says he does "worry about so-called patient advocates taking up arms against" the effort, he argues that the program's voluntary nature puts it "out of their domain." Consumers who ask to do