



BUSINESS AND REGULATORY NEWS

Collapse of Framingham data deal highlights lack of cooperative model

An agreement between US federal officials and Boston University to allow private firm Framingham Genomic Medicine (FGM; Cambridge, MA) to analyze and sell data from the Framingham Heart Study collapsed in late December, raising questions about the commercial use of publicly funded data.

University officials had announced a deal in June 2000 allowing FGM to capitalize on data from the Framingham heart study. This has tracked 6,000 living residents of Framingham, MA since 1948 and provided medical researchers with valuable long-term epidemiological data, including patient histories and tissue samples, about the causes of such diseases as stroke, arthritis, and heart disease (*Nat. Biotechnol.*, 18, 818, 2000). The Framingham study was initially funded and overseen by the US National Institutes of Health (NIH; Bethesda, MD) until Boston University became its administrator in 1971; today, both institutions share joint control over the data, which BU licenses to private firms (but freely to academics) for use in drug development.

With \$21 million raised in venture capital, the idea was that FGM would create a new digitized database of information from the original Framingham Heart Study, combined with information from 160 other health studies using Framingham Heart Study participants. While the original heart study data would remain under the control of BU, FGM would sell access to the amalgamated database to pharmaceutical companies, while allowing free access to university/academic researchers. FGM also planned to sell bioinformatics tools to search for disease-related genes, and conduct linkage studies similar to those being done by Gemini Genomics (Cambridge, UK) and deCODE Genetics (Reykjavik, Iceland).

But in late December, discussions broke down over access to the data. Although neither side will disclose specific details, Susan Paris, vice president for university relations at BU, says the issue wasn't public support—BU received less than 10 complaints about a private firm having data originally designed for public health studies. She says the issue was that BU, which has a 20% stake in FGM, would not have had control over the new, improved dataset. "BU was minority holder

and we could not control the company. . . that's where we had some concern."

In addition, NIH officials insisted that all data—even value-added data created by the company through linkage studies—would have to be freely available to everyone, including potential competitors, thus precluding the firm from any intellectual capital. Claude Lenfant, director of the NIH's Heart, Blood

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and Lung Institute says the firm would have been using data without contributing to the advancement of knowledge. "Clearly the company was receiving data supported by public funds and we wanted it to return to public database. That is where the dispute was."

As a result, FGM will be disbanded, and Paris says the university will seek government grants or other sources of money to compile the medical information onto a single database, but doesn't plan another commercial venture.

The rocky relationship between government agencies and private firms that want to mine data from taxpayer-funded studies still has a long way to go before becoming a happy marriage, according to Steve Holtzman, chief business officer at Millennium Pharmaceuticals (Cambridge, MA), a genomics firm that is using data from the human genome project to develop potential drugs. He points out that FGM would have added value to the original data by putting together information generated since the study's inception onto one database and should be compensated for it. "The distinction between for-profit and non-profit research is ridiculous," says Holtzman. "The [NIH] left no room for Framingham to provide something back to research community that was an improvement and yet leave something of value for themselves."

Fred Ledley, president and CEO of Framingham Genomics, points out the diffi-

culty in resolving this fundamental difference: "A lot of hard work went into this, but there's no general consensus on relationships between companies and universities and governments."

Indeed, one bioethicist says the Framingham agreement was itself a potential model for joint industry-academic-government projects using public health studies. Bartha Maria Knoppers, professor of law at Montreal University, says the cooperative BU-Framingham approach was a better alternative than the competitive model adopted by Celera (Rockville, MD) in its race against federal officials to sequence the human genome last year. "It's too bad [the BU-FGM agreement] stopped," says Knoppers, "It was a prototype, and the fact that it failed is going to put all other agreements on hold." Knoppers agrees that private companies have to return something of value to the public if they are going to capitalize on publicly funded studies, but acknowledges that government agencies also have to allow firms to have some profit motive in order to drive drug discovery. "No one seems to have come up with a model," says Knoppers.

Meanwhile, efforts elsewhere in the world to conduct genetic research based on the public's medical records face similar issues. In Iceland, for example, the government passed legislation in 1999 granting public firm deCODE Genetics a 12-year exclusive license to collect patient information from hospitals and clinics for large-scale gene linkage studies. However, the company is facing opposition from residents and doctors opposed to a private firm controlling access to information gathered by public health agencies (*Nat. Biotechnol.*, 17, 620, 1999). Petur Hauksson, a Reykjavik psychiatrist and chairman of Mannvernd, a group that has filed a lawsuit against deCODE, says the plan to assemble a retrospective database of health records from Icelandic citizens violates their right to privacy.

Mindful of these ethical difficulties, officials in Estonia have tried to avoid this type of conflict by setting up a joint venture between the government and the non-profit Estonian Genome Centre Foundation to create a database of health and genetic data from 70% of Estonia's 1.4 million population, as part of the Estonian Genome Project (*Nat. Biotechnol.*, 18, 1135, 2000). However, the real test may come when the project sets up a for-profit subsidiary to sell access to the database, an agreement that has yet to be completed.

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