

Health insurance debate stirs trouble for genetic testing

"The devil will be in the details," said Francis Collins, who heads the US National Institutes of Health's (NIH's) National Center for Human Genome Research. And it was. Collins was speaking at a meeting last month on the potential for discrimination by health-care insurers against people with a genetic predisposition to breast cancer. He pointed out that the issues raised by breast cancer extend to other genetically-determined diseases and called for a strategy for introducing legislation that would guard people against such discrimination.

Although the issues were well aired, no strategy emerged. Two women who have the *BRCA1* gene stated the central problem very clearly. To get health insurance, they must lie. Fran Visco, who heads the National Action Plan on Breast Cancer, said that she is trying, so far unsuccessfully, to get health insurance coverage for her staff. The national action plan is a highly successful lobbying group founded by Visco, who is herself a breast cancer survivor.

Judy Garber, a researcher from the Dana-Farber Cancer Center, Boston, says that she has had patients who have refused to take part in research when they learned that participation means a genetic test and that if it is positive, even if they have no symptoms, they could lose their health insurance. Garber said that she shares their anger. "We have a powerful technology," she says, "that is hard to convert to health care."

The potential for discrimination on the basis of genetic heritage goes beyond just genetic testing and could be made on the basis of family history. Said Collins, "We don't get to choose our genes . . . eventually genetic predisposition could exclude all of us [from health insurance]."

Other countries are also wrestling with the implications of genetic testing, such as privacy issues, who and when to screen, and access to life insurance. But, among the world's wealthiest nations, it is only in the United States that there is the additional problem of potentially losing your health insurance just when you are likely to need it most.

The issue of health insurance in the United States is highlighted by genetic testing, which can reveal predisposition to disease long before the person develops

symptoms. So, there is the potential to lose health insurance irrespective of whether you develop the disease.

As yet, such testing for the breast cancer susceptibility gene is not routinely used in clinical practice. Gail Geller, from the Johns Hopkins University School of Medicine, Baltimore, Maryland, estimates that it will be two years before such tests appear. In the

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Francis Collins: Keen to see legislation on genetic testing.

meantime, Geller is surveying patients and physicians to establish what information patients need to know before being given a genetic test. The intention is to develop a model informed consent form.

Last month's meeting was organized by the National Action Plan on Breast Cancer, and a joint working group of the NIH and the Department of Energy, which is responsible for examining the ethical, social and legal issues surrounding human genome research.

The intention at the beginning of the meeting was to reach consensus on a plan of action. But the questions that served as the basis for the final discussion were so detailed that the meeting became a morass of interacting and counteracting legislative proposals that seemed, at times, to be rivalled in their complexity only by the physics of chaos.

Only one position statement made during the debate — that the political impetus generated by concern about breast cancer be harnessed to push more general legislation on genetic testing and discrimination — was agreed upon.

Instead the group agreed to write a position paper on the subject. From the discussion, it seems likely that the paper will rehash what was already known before the meeting.

Collins, in closing, said (perhaps optimistically) that "it would be nice to get legislation [on these matters] not by the end of the century, but soon."

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Gene therapy: Just the tonic for sake distiller

Takara Shuzo, a Japanese sake distiller with substantial financial interests in biotechnology, claims to have developed a new twist on retroviral-based gene delivery systems for *ex vivo* gene therapy that is causing great excitement in Japan. Health ministry officials, who are trying to stimulate Japan's gene therapy effort to boost the country's international standing in this field, are keeping a close eye on developments.

The technique, known as retrovirus-mediated gene transfer by a fibronectin fragment, was developed jointly with Indiana University in the United States. It uses fibronectin fragments (snake-like molecules) to piggy-back retroviral vectors containing genes of therapeutic interest into the nucleus of haematopoietic stem cells. This approach is said to improve the efficiency of cell penetration. Moreover, there is no need to modify existing retroviral vectors, says Ikunoshin Kato, president of Takara's biomedical group.

The lack of efficient gene therapy delivery mechanisms has been one of the sticking points in the development of cost-effective treatments and is considered by many to be the key to making gene therapy commercially viable.

Takara has not yet released any results, but sources close to the company say the data from 10 months of tests on ADA- (adenosine deaminase)-deficient mice look promising. David Williams of Indiana University will announce details of the research at the International Society of Experimental Haematology, to be held later this month in Düsseldorf, Germany.

The company is also collaborating with the US National Institutes of Health in the United States, where tests on ADA-deficient primates are expected to begin next month. Takara has distilled Japanese spirits for 75 years and branched out into biotechnology only about 20 years ago.

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Who says gene therapy and sake don't mix?

Takara Shuzo's medical research facility.

Takara Shuzo