accuracy of PET compared with biopsy in analysis of regional lymph nodes. They are also looking at whether PET is an accurate predictor of recurrence. The idea here is that the more lymph nodes involved, the more likely recurrence will be — permitting clinicians to maintain a closer watch on these higher risk patients.

**PET as Predictor**

Because PET can also measure the metabolic rate of a tumor by measuring glucose levels, patients whose tumors show a rapid decline in glucose metabolism after treatment may have a better prognosis than those whose tumors show a slower decline. Early results indicate that PET may be able to predict 8 days after initiation of treatment what will happen 6 months later.

Other refinements are also under development. In MRI, pictures taken at one time are compared with those taken later, but if the patient moves, the resulting images might be difficult to compare. Image alignment software — originally a defense-related application developed at Samoff with university partners and now under commercial development — can potentially assemble the many MRI scanning views into a three-dimensional model of a breast. Early clinical testing of this software is now beginning. And mammographic and sonographic techniques that analyze breast masses based on their compressibility and elasticity relative to the tissues around them are under development at several locations.

Though these projects are interesting and hold promise for improvement in breast imaging, they are still based on the old dichotomy that has characterized breast diagnosis throughout history: lump or no lump. Scientists hope that eventually, even that premise will be refined.

— Jan Ziegler

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**Health Insurance Bill Provides First Step Toward Tackling Genetic Discrimination**

Passage of the Health Insurance Portability and Accountability Act, H.R. 3103, has lulled many individuals concerned about job lock and other forms of health insurance discrimination into thinking that their worries are over. The pairing of the two sponsors, Sens. Edward M. Kennedy (D-Mass.) and Nancy L. Kassebaum (R-Kan.), has a reassuring ring: two hard-working health care reformers from opposite sides of the aisle.

But Kennedy-Kassebaum is characterized as just a first step toward real protection for all Americans, including those who fear discrimination based on genetic information.

The legislation guarantees insurance to individuals who change jobs and prohibits companies from denying coverage for pre-existing conditions. But its benefits are tenuous for the unemployed and those who leave jobs to become self-employed and are nonexistent for those who have never been insured.

Doctors and others who work with patients whose lives are shadowed by cancer say rampant discrimination pushes many patients toward decisions that are contrary to their best medical interests.

"I've seen this so much [that] I can't tell you what a horror show this is when you do DNA-based genetic counseling," said Henry Lynch, M.D., president of the Hereditary Cancer Institute of Creighton University, Omaha, Neb. Patients frequently opt for ignorance over the procurement of potentially life-saving information about their genetic profiles, said Lynch.

One well-educated man who participated in a Lynch study told Lynch that had he been aware of the level of information exchange within the insurance industry, he never would have participated in the study, for fear of the impact that an accidental breach of confidence could have on his immediate and extended families.

**Patients' Fears**

Among 279 persons from families at high risk for breast and ovarian cancers, only 43% wanted to be tested for the BRCA1 gene, according to a study published in the *Journal of the American Medical Association* this June. Concerns about insurance discrimination...
were a major reason for not pursuing BRCA1 testing," said first author Caryn Lerman, associate professor of medicine and psychiatry, Lombardi Cancer Center and Georgetown University Medical Center.

Despite patients' fears and a plethora of anecdotes to support them, no studies turned up during an exhaustive search on how often people with cancer in their personal or family history, or genetic background, experience discrimination. And only two studies surveyed genetic discrimination more generally, with no reference to cancer. In one of these studies, Lisa N. Geller, Ph.D., a member of the Division of Medical Ethics at the Harvard Medical School, and colleagues asked several disease groups to distribute 27,790 questionnaires on discrimination to their constituents.

Each group focused on one of the following disorders: hemochromatosis, Huntington's Disease, phenylketonuria, and mucopolysaccharidosis.

Of 917 total responses, the researchers followed up with phone calls to 206 individuals, all of whom lacked symptoms.

Geller emphasized that the study was not statistical, because of nonrandom sampling and other weaknesses of methodology. For example, "people who haven't experienced genetic discrimination are less likely to answer [the questionnaires] than those who do."

In another survey of people affiliated with genetic support groups, "22% of our sample of 332 families said that they had been turned down for health insurance because of their genetic condition," said E. Virginia Lapham, Ph.D., director of social work at Georgetown University Medical Center.

Perhaps the most significant thing Kennedy-Kassebaum does is to prohibit defective genes and family histories from being considered pre-existing conditions, said Karen H. Rothenberg, director of the law and health care program at the University of Maryland School of Law, Baltimore.

Nonetheless, the bill has two Achilles' heels, which act together to undermine protection. First, the legislation does nothing to protect genetic privacy, a problem that is exacerbated by provisions that would standardize and computerize medical records ostensibly for billing purposes, said an aide to Rep. Jim McDermott (D-Wash.). "We are concerned that could lead to more ways insurers might access information to use as a reason not to give you health coverage."

Vulnerable

The self-employed and the unemployed are particularly vulnerable and "may be denied individual coverage based on their genetic information . . . if a person is unemployed and has not had access to group insurance in the recent past . . . ," Rep. Louise M. Slaughter (D-N.Y.) testified at a recent congressional hearing.

The second weakness is that insurance companies are free to charge individuals any rate they want, said an aide to Kassebaum. Similarly, although all individuals in groups must be charged identically, an entire group can be charged exorbitant rates, said Joanne Hustead, deputy director of the Women's Health Program, Women's Legal Defense Fund, Washington, D.C., a nonprofit group that works on a wide range of policy issues and advocacy at the national level.

For the individually insured who are shut out of insurance, or who face exorbitant rates, "the burden falls on you to prove you were discriminated against," said Rothenberg. The same might be true for small groups of insured persons.

State Reform

Fortunately, while federal health care reform languished following the defeat of President Clinton's national plan, state governments were crafting their own reforms, many of which close some loopholes that now undermine Kennedy-Kassebaum. Forty-six states have set laws that limit premiums that can be charged to small groups, said Susan Laudicina, director of research at Blue Cross and Blue Shield's Washington, D.C., office.

About 18 of these states virtually prohibit underwriting. The rest follow the rating standard of the National Association of Insurance Commissioners, said Laudicina. The association limits per capita cost of the most expensive small-group plans to no more than twice that of the cheapest plan. Furthermore, 17 states have limited insurance companies' ability to use experience or health status to set rates for individuals, many of them following the association's standard, said Laudicina.

As for genetic privacy, laws in 10 states (Wisconsin, California, Colorado, Georgia, Minnesota, New Hampshire, Ohio, Oregon, Maryland, and Virginia) have integrated protection against insur-
ance discrimination with privacy protection in varying degrees, said Rothenberg. In California, results of genetic tests cannot be revealed without written authorization, while in Georgia and Oregon, genetic information belongs to the individual.

But in New Jersey, in September, the biotechnology industry convinced Republican Governor Christine Todd Whitman to veto legislation that the legislature had passed unanimously, which would have given patients property rights to their own DNA.

"It would have stopped clinical trials," explained Biotechnology Industry Organization President Carl B. Feldbaum. When they realized what they had done, the bill's sponsors joined in asking Whitman to veto the bill, said Feldbaum.

In fact, Feldbaum's board endorsed genetic privacy at a September meeting, and the organization is now drafting a model bill, "hopefully to be introduced in the 105th Congress," he said. "If the industry did not take a strong proactive stance, people would feel threatened by the Human Genome Project."

Ultimately, there is both irony and encouragement for those with cancer in their background, in the prospect that an industrial trade association may prod the next Congress to become more progressive on health care reform.

— David Holzman

### Gene Therapy Group Faces Uncertain Future

An "intent to propose" will emerge as a full-fledged proposal in the Federal Register this month to overhaul the structure through which the National Institutes of Health carries out gene therapy review. What that portends for the Recombinant DNA Advisory Committee — whose oversight of gene therapy spans more than 2 decades — is not yet clear.

At the Journal's press time, Lana Skirboll, Ph.D., associate director for science policy and technology transfer at NIH, said she was "loath to say anything" about whether the RAC will be replaced by a smaller multidisciplinary advisory group, some other structure will emerge, or NIH Director Harold Varmus, M.D., "will go back to ground zero" and propose a totally new plan. But whichever option Varmus chooses, she said, "there will be ample opportunity [for the public] to discuss novel protocols," such as germline corrections for a genetic disease.

### Mixed Reaction

Varmus originally published a notice in the July Federal Register, announcing his intent to dismantle the existing 25-member RAC and to replace it with a smaller advisory group of six to 10 members. In addition, the notice said, there would be scientific forums on controversial single-issue topics in gene therapy, and public participation would be encouraged.

But during the 30-day comment period, reaction has been mixed, with consumer groups and ethicists uniformly opposed to the measure, those in the biotechnology field largely enthusiastic, and scientists divided. Some 71 letters have been received by the NIH Office of Recombinant DNA Activities (ORDA), which oversees the RAC.

All of these groups will come together in what promises to be a lively meeting Dec. 9 — the first RAC meeting in a year and the first since the idea of abolishing the group surfaced. At that time, the present RAC membership may be placed in the awkward position of being asked to vote itself out of existence. But no matter what action is taken, Varmus will have the final say.

Critics of the RAC's dissolution argue that the group provides a historical perspective, as well as a unique ethical role, that will be lost if a new group is created. Also, there is concern that with the U.S. Food and Drug Administration as the sole reviewer of gene therapy experiments, the public will be cut out of the loop. FDA hearings are not open to the public, and Varmus' proposal for scientific forums addresses the need for discussion of general topics, not individual proposals.

"My overall view is that an incremental change in the size and function in the present RAC would have been sufficient to achieve the goals in the