showing that over 60 percent of patients thought they should have access to a genetic test "despite a physician's recommendation to the contrary."

Another big issue, says Caulfield: "With the exception of tests for single-gene disorders, most of the genetic information generated by testing will be probabilistic risk information," notoriously difficult for most people to understand.

And the risks for physicians who fail to clarify the meaning of risk for their patients could be substantial, he points out. For example, "there seems little doubt that wrongful birth actions can succeed," he says. "In these cases the plaintiff(s) allege(s) that 'but for' the negligence of a physician, a child with a given genetic condition...would not have been born."

Another issue: Who pays for genetic counseling?" According to some estimates, counselors are likely to spend three to four hours with a single patient. In the past, neither public nor private insurers have worked out very satisfactory schemes to reimburse for consultative visits.

If the health care market continues to evolve as it has recently, counseling will be paid for, but not very well, argues futurist Ian Morrison in the April 2000 *GeneLetter* published by the Internet-based health company GeneSage. Loosely managed health plans such as PPOs run by a handful of large insurers per region are becoming the dominant insurance model in the United States, he notes. Since PPOs and similar plans don't like "saying 'No' too much" to patients, fee-for-service genetic testing and counseling will gain a foothold, he predicts. However, the power of the few large plans and the tough price negotiations engaged in by loosely managed health plans "will tend to drive any excess profit margin out....If the biotechnology sector is expecting their high price tags to be picked up by any payer aside from the well-to-do consumer, they may be disappointed. Certainly, they will have to demonstrate their value in the language of population health outcomes and cost-effectiveness."

Whether that will happen is anybody's guess. Some industry scientists, however, do say cost-effectiveness is demonstrable even today.

> *"I have yet to see a doctor who really doesn't want evidence-based tools that can help make decisions about what to target with prevention."*

The cost of analyzing genetic material for the single nucleotide polymorphisms (SNPs) associated with disease is "dropping almost daily," wrote Charles Cantor in *GeneLetter*. "Until recently, the cost of measuring a single SNP in a large scale project was about $1, so a full genome scan of, say, 100,000 SNPs in a 2,000-person case control study, would have been $200 million. Now through sample pooling and assay multiplexing these costs are reduced to $1 million or less, " wrote Cantor, Chief Scientific Officer of Sequenom, a company developing data on SNPs that predispose people to major disorders. Once tests are developed, the cost savings will lie in identifying people who don't have any high-risk SNPs, he explains. They won't need periodic testing for diseases like cardiovascular conditions, diabetes, and various cancers.

Most analysis of whether genetic testing will improve health and save costs focuses on whether the health care system can shift from a therapeutic model to a preventive one. Many genome boosters are pinning their hopes on prevention; others aren't so sure.

"The entire biomedical complex is spending millions and millions of dollars to get ready for genetic advances," but the advances they're thinking of are technological quick fixes, says Jessie Gruman, executive director of the Center for Advancement of Health. "But in the behavioral and social sciences, what is happening" to get ready for the genome revolution? Basically nothing in the way of funding, she says. Yet these "are the people that try to understand questions like, How do you talk about risk in a way that is helpful, get people to follow clinical regimens? The federal government isn't really putting money in these areas."

Even those who believe — or hope — that the paradigm can change aren't sure who'll put up dollars to change it. "Notoriously, we've been bad at doing this [prevention]," says Smith. Nevertheless, he argues evidence-based numerical risk assessment tools have value that should be obvious, since 70 percent of health care spending relates to preventable conditions.

One likely market, says BioSignia: self-insuring employers trying to hold down costs and maintain a healthy workforce. BioSignia's setup would report aggregate data on workers' health to employers so they could tailor prevention programs to get the most bang for the buck, says Smith. A "triple fire wall" of encryption and multiple individual passwords would protect physician-patient confidentiality. Another potential buyer, Smith says: HMOs looking for better ways to manage care.

Who pays for risk assessments "remains to be worked out," says Rienhoff. Payers, employers, and "in some cases the at-risk person themselves" all are possibilities. In the future, workers "may be given a voucher by the employer to purchase health care. That's the trend," he says. "That should motivate people to take more control of their health."

Genome science's long-term promise to reveal individuals' lifetime risk for major illnesses also raises questions about the future viability of pooling risk for insurance purposes. In the large-group market, some analysts argue that insurers will inevitably use genetic tests to, for example, eliminate future diabetics from their rolls. Others, however, contend that genetic advances would show disease predisposition in so many people that trying to skim off risks wouldn't be worth it. A likely response by insurers will be to essentially ignore risk profiling in the large-group market but use it heavily in the individual market and some small-group markets where medical rating is relied on much more often, Wertz suggests in *GeneLetter*. That would worsen an already bad situation for the approximately one in 10 people covered in the individual market, who already have a fairly signifi-