

# It's All In The Genes: The Business Of Predicting Diseases

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When scientists cracked the human genetic code early last decade, it opened up several new possibilities to use molecular markers to guide the treatment of cancer and other diseases.

One of the venture firms to spearhead the movement to turn this promise into reality is [TPG Biotech](#), which has funded [Genomic Health](#) Inc. and several other diagnostics pioneers.

Along the way, the partners of the San Francisco firm have learned a good deal about what works and what doesn't in the field of molecular diagnostics, which involves correlating the activity of specific genes or proteins with a disease state.

The firm searches for opportunity to use molecular tests to guide medical decisions in ways that could save the health-care system money.

“Historically, it has been possible to get products in the market and make them successful even if they didn't lower overall health costs,” said TPG Biotech Partner and Managing Director Fred Cohen. Today, “if you can't come up with a pharmacoeconomic rationale for the tests you're going to introduce, the road to adoption will be very choppy.”

The rationale for Genomic Health, which the firm first backed in 2002, was to use genomics to help oncologists determine how best to treat individual cancer patients. Its first test analyzes the expression level of 21 genes to predict the likelihood of chemotherapy benefit and disease recurrence in certain breast-cancer patients. The company, which has also developed a predictive colon-cancer diagnostic, went public in 2005.

While Genomic Health tests aid decisions about cancer treatment, another TPG company, CardioDx Inc., makes a gene test that seeks to answer another important question: Which patients with chest pain need to be evaluated for obstructive coronary-artery disease? Many people with chest pain who undergo a catheterization do not actually have the condition, some studies indicate.

Yet investors have to consider more than medical benefit when evaluating a new diagnostic. How the test fits into a doctor's daily workflow is also important, according to Cohen. TPG, for example, often sees interesting screening test ideas that would be used by general internists. But internists are busy and often don't readily adopt screening tests until they're incorporated into clinical guidelines, according to Cohen.

Firms also have to take into account how a diagnostic would affect a physician's practice. A test that is inconvenient for the doctor, or forces the physician to refer the patient to another medical practice, is not one destined to gain much traction, but a diagnostic that helps a doctor treat patients and maintain them in their own practice is a better bet, Cohen said.

“We want to align interests with our customers, who are both the patients and the doctors,” he said.

Molecular diagnostics are only as good as the particular genes or proteins they employ. One of the toughest decisions for investors is know when these markers are sufficiently effective. About a year ago, TPG and other backers of ProteoGenix Inc., a developer of maternal-fetal health diagnostics, decided to close the company down after deciding that its noninvasive alternative to amniocentesis wasn't predictive enough. In amniocentesis, a needle is used to gather amniotic fluid. The procedure can identify infection, birth defects or chromosomal problems, but it carries risks for the mother and fetus.

ProteoGenix's originally sought to develop eight proteins that could help identify mothers who will need to deliver a child preterm because of intra-amniotic infection. After further research, however, it found that only two or three of them were truly effective, which was not enough to justify the test, according to Cohen.

In addition to tests that guide treatment decisions, TPG sees several new avenues that could open up. One possibility is to use molecular tests to help drug companies get their products approved in new indications by pinpointing molecularly defined populations in which the therapy is likely to work. By better defining the target audience through a gene- or protein-based test, a company also might improve the performance of a therapy that's lagging others in the marketplace.

TPG has yet to make investments of these particular types, but they are among the options the firm would consider. "We are always looking for opportunities to redefine disease in molecular terms," Cohen said.