

# Doubt Hangs Over Personal Gene Scans

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SAN FRANCISCO (AP) \* For the price of a good men's suit, a batch of new services will scan your genes and spot potential health risks, from cancer to lower back pain.

It's the business world's answer to a deluge of new genetic discoveries pouring forth from scientists' labs. Key investors in two of the companies, 23andMe Inc. and Navigenics Inc., are among the biggest names in new technology.

But some analysts and investors wonder if consumers are ready to trust these startups when their own fine print warns against using their information to make serious medical decisions.

"I am a bit skeptical that many people are going to pay \$1,000 for information that's not very useful just for entertainment value," said Douglas M. Fambrough, a biotech venture capitalist with Oxford Bioscience Partners in Boston.

"I would say that getting your whole genome sequenced is really at this point just a vanity exercise."

Most of these direct-to-consumer services don't actually scan all 3 billion letters of an individual's DNA \* although Knome of Cambridge, Mass., will for \$350,000. Many more will search for specific genes or clues to your family history for a few hundred dollars.

But some serious money has been invested in three companies that charge about \$1,000 to \$2,000 for an analysis of 500,000 to 2 million points where research suggests connections to specific health conditions.

To take the test, customers get simple kits for taking saliva samples that the companies then analyze. After a few weeks, customers can log into secure Web sites to view possible health risks embedded in their genes.

With that information in hand, patients have a powerful tool for homing in on potential medical problems before they show up, said Mari Baker, president and chief executive of Redwood Shores-based Navigenics.

"Our goal as a company is to improve health outcomes," said Baker. "This isn't about genetic curiosity."

When it launches in April, Navigenics will offer clients a scan of 2 million genetic markers, along with counseling from experts on how to interpret the results.

The Navigenics service costs \$2,500 for the initial scan along with a year's worth of counseling and updates on the latest research. After the first year, customers can pay a \$250 annual subscription fee for updates on new discoveries related to their own genes.

A disclaimer on Navigenics' Web site emphasizes that the company doesn't give medical advice. It warns customers not to make any health care decisions based on their genetic information without consulting a doctor.

In recent months, debate has swirled over whether patients will heed that caution. Even if they do, most physicians lack training in how to interpret unverified results from these almost wholly unregulated businesses.

A recent editorial published in the New England Journal of Medicine urged doctors to advise skepticism about the companies' tests.

Research into genetic risk is still in its earliest stages, wrote the editorial's three authors \* a prominent Harvard cancer prevention researcher, the head of genomic public health at the Centers for Disease Control and Prevention and the journal's editor-in-chief.

"For the patient asking whether these services provide information that is useful for disease avoidance," the authors wrote, "the prudent answer is 'Not now \* ask again in a few years.'"

Nevertheless, the biggest names in Silicon Valley are betting serious money on these startups. They're expecting these businesses to give them a jump on the consumer side of the personalized medicine revolution widely predicted by genetics researchers.

Last year, Google Inc. invested \$3.9 million in 23andMe, co-founded by Anne Wojcicki, wife of Google co-founder Sergey Brin. Biotech pioneer Genentech Inc. is another major backer.

Along with health-risk information, the Mountain View-based 23andMe offers gene-based ancestry tools. Users can share and compare DNA with friends and family in an online genetic social network.

The company also provides ample just-for-fun data, such as whether a person is genetically likely to avoid Brussels sprouts or turn red when drinking alcohol.

But 23andMe's more serious long-term ambition is to gather enough DNA so that researchers can conduct new genetic research using the company's own data.

"People feeling empowered that they can really be a part of active research is a compelling reason that they want to sign up," Wojcicki said.

Meanwhile, Navigenics has secured more than \$25 million from several funders, including marquee Silicon Valley venture capital firm Kleiner Perkins Caufield & Byers \* Genentech's founding investor in the 1970s.

To earn returns for their investors, the companies are counting on health-conscious consumers with the disposable income to cover the cost of tests, since insurers are not likely reimburse them.

Josh Umbehr, 26, was awaiting the results of his Navigenics test after taking it for free in March as a reviewer for a medical technology blog. The first-year resident at a Wichita, Kan., medical center said if he'd had to pay, he wouldn't have taken the test until he was out of medical school.

The cost is an issue for him, he said, as is the uncertainty surrounding the new technology.

"Since it's a tool I've never had, it's hard to say how useful it would be," he said.

At the same time, Umbehr is no stranger to the effects of genetics on health. His grandmother, mother and three aunts all had aggressive forms of breast cancer at relatively young ages. His oldest daughter, now almost 2, was born with Down syndrome.

In 10 years, Umbehr said, he could see family doctors like him recommending more sophisticated genetic tests as they become available. For now, he said, he would stick to proven methods.

"I know without a genome test now that half of all people get hypertension. I don't need an expensive test for that," Umbehr said. "And I can treat people for that in traditional ways."

Despite the unproven usefulness of whole genome evaluations, one other company's leader believes more widespread acceptance of tests by consumers and doctors is near.

Reykjavik, Iceland-based deCode Genetics Inc. is publicly traded and has a market capitalization of about \$100 million. It recently began offering its own personal genomic scanning service, deCodeme, which analyzes about 1 million genetic variations for just under \$1,000.

"I am convinced that within five years every college-educated person in America is going to have a profile like this," said deCode chief executive Kari Stefansson. "You cannot afford not having this."

In contrast to its U.S. rivals, deCode also develops drugs and researches genetic links with various diseases, publishing findings in several scientific journals.

Yet in March, the company laid off 60 of its 450 workers, according to a spokeswoman. The global credit crunch forced the cuts, which did not affect its genetic testing division, Stefansson said.

Still, the downsizing set tongues wagging among biotech bloggers who asked if the market for at-home genetic testing had already become saturated.

Some analysts believe that the success of consumer companies doing whole genome scans remains in doubt until doctors recommend the tests and insurers cover them.

"This is not the genetic community saying here's something important that you should pay attention to," said Fambrough, the venture capitalist. "This is the Web 2.0 community looking for a market."

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