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**THE NATION**

## Firms Sell Gene Tests Directly to Public

■ Health: Marketing has experts worried. They fear that consumers will be tempted to buy tests that are unneeded or of doubtful value.

By AARON ZITNER, TIMES STAFF WRITER

WASHINGTON -- When a slew of medical problems hit at once, Peter Dyck found himself taking an array of drugs: three for a heart condition, one for a digestive disorder and two for other ailments. It left him wondering how his body was handling all the medications.

So Dyck, an electrician in Portland, Ore., swabbed some cells from inside his cheek and sent them to a Seattle company for genetic analysis. Two weeks later came the report: Dyck's body was programmed to break down one of his drugs unusually slowly, a warning that the drug might be building to harmful levels in his bloodstream.

"The information was pretty amazing," said Dyck, who took the report to his doctor. "We ended up downgrading the dosage."

Scientists have long promised that the gene revolution would open an era of "personalized medicine," with health care and nutrition tailored to each person's unique genetic makeup.

But understanding how genes work has proved difficult. Although more than 100 diseases can be diagnosed by searching for particular genes, those diseases are generally uncommon and testing has been limited to the small world of genetic disease specialists.

Now, a handful of companies is bypassing the specialists and marketing directly to consumers. The firms are offering tests not only to diagnose disease, but also that claim to help people pick the medications, vitamins and even skin creams that work best with their genes. The costs range from hundreds to thousands of dollars.

The marketing efforts have many experts worried that consumers, driven

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by the fear of disease and the allure of gene research, will be prompted to buy tests that are unneeded or of doubtful value. Some say the tests available so far can produce confusing results that can mislead patients.

The push into the U.S. consumer market also comes as federal health officials consider whether to retreat from regulating genetic tests, most of which may be sold without a review of their usefulness or marketing claims by the U.S. Food and Drug Administration.

Bewildered by the array of nutritional supplements? GeneLink Inc. of New Jersey says its test, available as of Aug. 2, tells clients which mix of vitamins is best for them. Sciona Ltd. of England offers customized nutritional advice based on DNA and a health questionnaire. Personalized skin creams and anti-aging formulas are also in the works.

Other companies help diagnose diseases. HealthcheckUSA of San Antonio sells a mail-order test for hereditary hemochromatosis, a disorder that causes iron build-up in the blood. Customers do not need to show the company a physician's approval, and results are reported directly to them. A spokesman says tests for cystic fibrosis and factor V Leiden, a blood-clotting disorder, will be available within weeks.

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### Small Numbers

It's too early to know how consumers will respond to these tests. Genetic tests for metabolism and general health have not been widely available in the U.S. even from doctors. Although a growing number of people have used genetic tests obtained from doctors to diagnose diseases or help with reproductive decisions, their numbers are small because the diseases diagnosed by these tests are not common.

Still, various health experts have been urging the FDA to review tests before they are sold, much as the agency reviews drugs and medical devices. "If there are claims about products that might not pan out and might hurt people, wouldn't you want the government looking at it?" asked Dr. Richard Roberts, chairman of the American Academy of Family Physicians.

Others say that before testing becomes widespread, laws are needed to prevent employers and insurers from using the results to penalize people.

The FDA has spent two years developing an oversight plan, but the agency now says it may not have legal authority to regulate the tests. Agency lawyers are reviewing the question. "This was a surprise, because the FDA had said in the past that they had statutory authority," said Kate Beardsley, a Washington lawyer who specializes in FDA law.

Separately, the U.S. Department of Health and Human Services is considering whether to disband an advisory panel of experts who called on the FDA to tighten regulations two years ago. The committee's August meeting has been postponed until officials complete a review not only of this panel but also of the other 257 groups that advise the department on policy matters.

A department official said it was only to be expected that the Bush administration would revisit actions started under President Clinton. "You have to give every administration the right to review key issues," he said.

Despite the questions, many people are enthusiastic about home DNA tests.

"I was really glad it was there," said Brooke Shiotani, a 25-year-old pharmacy student in Seattle. Shiotani tried the drug metabolism test, offered by Genelex Corp. of Redmond, Wash., after she had adverse reactions to several antidepressants. She worried that her body was slow in breaking down the drugs and that the medication was lingering in her body.

The \$250 test showed that Shiotani processed the drugs at normal rates. "But that gave me peace of mind that my doctors weren't overdosing me," she said.

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#### Another Tool

The tests are just one new tool for patients who want to monitor their own health. Bypassing the family doctor, clinics offer full-body radiological scans that look for signs of disease. Viagra and other prescription drugs are available on the Internet. Some commercial laboratories allow clients to roll up a sleeve and order their own blood test, checking everything from cholesterol levels to signs of ovarian cancer.

"There's a need and a strong desire to take charge of your health, and we're giving people the ability to do this," said Holt Vaughan, an official at HealthcheckUSA.

Some doctors bristle at the trend. Unless people have a good reason to be tested, they say, tests can create more problems than benefits. Full-body scans, for example, sometimes produce images of tiny tumors that turn out not to exist, said Dr. Benjamin Wilfond, a bioethics researcher at the National Institutes of Health. He said this provokes needless anxiety.

Genetic tests in particular pose tricky questions about who should be tested and what the results mean.

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The tests look for mutations or subtle variations that make one person's genes different from another's. Sometimes, these mutations are associated with disease or other health conditions, but only remotely, and experts say patients should review test results with doctors or genetic counselors.

Other genetic mutations are strongly associated with disease. Women with certain forms of the BRCA 1 and BRCA 2 genes, for example, are thought to face an 85% chance of getting breast cancer by age 70.

But that does not mean every woman should be tested. Because BRCA genes account for no more than 10% of breast cancer cases, many experts say the tests are best used by women who have a reason to think they carry the genes. These include women whose relatives have been diagnosed with breast or ovarian cancer.

Utah-based Myriad Genetics Inc. plans a trial run of television and radio advertisements in the fall for its breast and ovarian cancer tests. The tests are available only through doctors, but the campaign marks the first effort to mass-market them.

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#### Some Coverage

The cost will range from \$295 for someone with a known genetic defect in the family--and therefore only one gene to test--to \$2,800 for someone with no such defect. Myriad says insurance generally covers the cost for people with a family history of breast or ovarian cancer. Critics already have complained that Myriad's limited print ads have targeted women who are not good candidates for testing. "Almost every woman overestimates her risk of breast cancer, and these ads are encouraging people to take that overestimation to their primary care physician, who is not trained in genetics, and to ask for this very expensive test," said Barbara Brenner of Breast Cancer Action, a San Francisco-based advocacy group.

"This will be worse with TV ads," she said, "because there's a lot less information than in print ads, and the impression people will get will be all positive about the benefits of the test."

The radio and TV ads will run for five months in Atlanta and Denver. Myriad will also start promoting the tests to 200,000 primary care physicians nationwide.

A Myriad spokesman, Bill Hockett, said the company's ads "are intended to be clear that breast cancer genetic screening is not for everyone." He said the company had previously focused on telling cancer doctors about its tests. But that effort "could not reach the majority of women who could be helped, because they haven't been diagnosed with cancer."

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### Evidence Lacking

Critics of consumer marketing are less worried about DNA testing that aims to give people nutritional advice or information about their overall health. But some specialists say there is not yet enough evidence that people should change their diet or medication based on their DNA.

Sciona, for example, studies nine genes as part of its \$200 assessment of a person's general health, including one gene named MTHFR.

Some people have a form of MTHFR that reduces their ability to process folic acid, an important vitamin. When the company finds clients with this form of the gene, it recommends that they eat more foods rich in folic acid, such as asparagus, broccoli and yeast.

Chris Martin, chief executive of Sciona, said he fell into this group. He said the gene test, which showed that folic acid was important for him in particular, inspired him to start eating Marmite, the yeasty sandwich spread popular in Britain. "There's no way I would do that based just on a newspaper article that said folic acid is important." He said the company's claims for its test were supported by more than 300 peer-reviewed scientific papers.

Several specialists said there could be little harm in recommending that people eat a diet rich in folic acid, which is thought to help anyone avoid cardiovascular disease and other ailments. But they said it is premature to claim that some people needed more folate than others because of their MTHFR gene.

"We have some suggestive data, but we do not have the clinical data we need to be confident that certain genetic profiles should lead to specific diets," said Dr. Wylie Burke, who leads the department of medical history and ethics at the University of Washington. "There is no one we've identified who would be a candidate for these tests. Their predictive value is unknown."

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### Link to Health Woes

Wilfond, of the NIH, raised another question: Different versions of MTHFR have been associated with heart disease, colon cancer and blood clotting, though the link is not always clear. "At what point is it necessary," he asked, "for it to be explained to people that there are all these possible meanings" to the result of an MTHFR test?

Sciona has sold about 600 of its tests since last summer, some through the

mail to customers in the United States and elsewhere. It also sold them through British pharmacies and retail stores. But many stores dropped the kit this summer when a consumer watchdog group said the tests were potentially misleading.

The company now sells the tests only through doctors and dietitians. It plans a push into the U.S. market in September. GeneLink sells its DNA tests to other companies, which in turn sell nutritional and skin care products they say are personalized for each customer. The company does not reveal which genes it tests.

"People are taking handfuls of vitamins, and it may be doing them some harm," said John DePhillipo, GeneLink's chief executive. "We can say that you may not need these vitamins; you may need less. So, we're specifically targeting a regimen just for you."

Under current law, laboratories must make sure their equipment, chemicals and practices meet federal standards.

The FDA is deciding whether to go further. One question is whether genetic tests are medical devices, which the FDA regulates, or doctors' services, which it doesn't. Because the tests are sometimes customized for individual patients and the results often require so much interpretation, some argue that they are more like a service.

Another question is whether all genetic tests should be regulated, or only those that diagnose disease.

If it decides to act, the FDA could ask test providers to show that their claims are truthful. The agency could also bar tests from the market until providers show that test results actually help physicians and patients make decisions.

Some worry that proving this could require long experience with a large number of clients and that many tests could not meet a high standard for usefulness.

"If you applied full FDA review, we wouldn't have very many genetic tests in the world today," said Elliott Hillback Jr., senior vice president at Genzyme Corp. in Cambridge, Mass., and a member of the Department of Health panel on genetic testing. Beardsley and Burke are also members of that committee.

Some say that would be a mistake, because the tests have proved helpful.

Dyck, 49, said the drug metabolism test seemed useful. It not only guided him to a better dosage for his heart medication but also helped explain a problem he had several years ago.

Dyck was hospitalized in 1993 with a blood clot in his leg, and doctors were giving him a blood thinner to prevent the clot from breaking off and causing damage. But it took a week before they could figure out the right dosage, which kept Dyck in the hospital.

Sure enough, Dyck said, the genetic test he took recently shows that his body is unusually slow to metabolize the blood thinner.

"If they had had this information, maybe they would have been able to narrow down the field of doses to give me," he said, "and I would have gotten out sooner."

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