

Personal genetic tests: genius or bogus?

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When Kathy Dyck's weight ballooned to a lifetime high of 250 pounds, she ditched her usual weight-loss tricks: Atkins and other commercial diets.

Instead, Ms. Dyck, who lives on Vancouver Island, turned to the Internet and discovered a new and rapidly growing genre of personalized health products -- diets tailored to genetic makeup.

Ms. Dyck swabbed her inner cheek and mailed a DNA sample, along with a \$550 (U.S.) fee, to a Seattle laboratory run by Genelex Corp. Soon, a 45-page report came back with nutritional advice that it said matched her genetic profile. Ms. Dyck's body needed more calcium, the report said, and was programmed to metabolize certain fats slowly.

"Some of it was Greek to me," admits Ms. Dyck, 56, a retired university administrator with two grown children. But she overhauled her diet according to the company's advice, adding more salmon, fruit and a daily multivitamin - and lost 42 pounds in six weeks. "It wasn't just everybody's diet," she says. "It was for me."

Canadians are increasingly tapping into a rapidly growing and largely unregulated world of direct-to-consumer genetic testing. With a quick Internet search, consumers can order tests that promise to reveal their risk for specific diseases, determine the best medicines for their genetic make-up, or personalize their diet and exercise program. The tests can cost up to \$1,000 each and involve obtaining a DNA sample and mailing it to a laboratory, in most cases in the United States, for analysis.

But the alliance between genetics, the Internet and big business may not deliver on its promises.

Critics, including leading geneticists and health-policy advisers, say that many of the tests are unproven and unnecessary, and promise more than science can currently deliver. For most diseases, they say, genes are only one component of a complicated puzzle that determines who is at risk.

"Whatever information they're giving, it's not the whole story," says Kathy Siminovitch, a doctor who runs a genetic counselling service at Toronto's Mount Sinai Hospital.

Even more problematic, she and others say, is that people receive information but are not offered the resources to understand their results. Those who learn they carry risk genes for diseases such as breast cancer or cystic fibrosis get that news without having a doctor or genetic counsellor to advise them.

Dozens of companies, most of them U.S.-based, now offer direct-to-consumer genetic tests. Some predict a customer's risk for such ailments as heart disease, osteoporosis and cystic fibrosis. Pharmacogenetic tests are used to recommend medicines and dosages. Nutrigenetic tests, such as the one used by Ms. Dyck, use genetic information to tailor diet and exercise programs.

Right now, Canadian regulators have little authority over these tests. Only a small part of the service - the collection kits containing the inner-cheek swab materials - falls under Health Canada legislation. Once the cheek is swabbed and the sample is mailed back to the United States, testing falls under U.S. guidelines. And even if the lab and the tests are up to par, it's still up to the consumer to discern whether genetic testing companies are making legitimate claims.

A year ago, one of the industry's major players set up shop in Canada. Quixtar Inc. of Grand Rapids, Mich., has sold 10,000 of its two genetic tests to Canadians since opening up a distributor in London, Ont., says Lise Beland, the company's senior health-product marketer.

Its heart health genetic test, which predicts risk of cardiovascular disease, accounts for 60 per cent of sales and costs about \$245 per test. A general nutrition genetic test costs about \$135 and recommends vitamins and supplements, which are also sold by Quixtar.

"We're not trying to treat disease," Ms. Beland says. "We're giving risk factors and showing you how you're predisposed to different things."

Canadians are also buying genetic tests and services from U.S. companies through the Internet.

"We certainly like serving the Canadian market," says Howard Coleman, who in 1987 founded Genelex, one of the oldest companies in the industry. Mr. Coleman estimates 10 per cent of the privately owned Seattle-based company's sales are to Canadians.

Genelex is one of several companies to report sales are growing, boosted by media coverage and excitement over the promise of the Human Genome Project, an international effort to sequence the entire human genome. Genelex saw \$2.2-million in revenues last year, Mr. Coleman says.

Paternity tests are top sellers, but rapidly gaining ground are pharmacogenetic and nutrigenetic tests, he said. Sales of those tests, which range in cost from \$395 to \$1,000 (U.S.), are doubling every year, Mr. Coleman says.

Three years ago, Ms. Dyck's husband, Peter, tried a Genelex pharmacogenetic test to see how his body was handling the six drugs he was taking for a heart problem and other ailments. Mr. Dyck's 6-foot-tall, 250-pound body was programmed to metabolize one of his medicines very slowly, the test results said, and it could be building to dangerous levels in his blood.

"I adjusted my drugs a little bit," Mr. Dyck said. The tweaks, made with his doctor's permission, have helped to boost his energy levels, he says.

Some experts say that tests such as these should be considered health products by Health Canada - a designation that would enable regulators to take a tougher watchdog role.

"One of the tough decisions that policy makers are going to have to make - and actually should be making right now - is what kind of product is this?" says Timothy Caulfield, a research chairman in health law and policy at the University of Alberta.

Americans are beginning to take a harder look at direct-to-consumer genetic testing.

Nutrigenetic tests recently came under fire in a presentation to the U.S. Senate after four products being sold online were analyzed by the Government Accountability Office, which plays a similar role to Canada's auditor-general.

According to the GAO's July, 2006 report, those products "misled the consumer" by making "medically unproven" and "ambiguous" health-related predictions that were virtually meaningless.

Two of the companies also recommended personalized nutritional supplements, claiming they were tailor-made for the customer's DNA. But the GAO found the supplements to be extremely expensive, potentially dangerous and "not unique in any way."

But how much can the human genome really tell us about our risk of diseases? Not enough, says Roderick McInnes, scientific director of the Institute of Genetics, which is part of the Canadian Institutes of Health Research, the country's main funding agency for health research.

Dr. McInnes is among those who say it's too early to be making the kinds of predictions being made by direct-to-consumer genetic tests. "The vision is terrific," Dr. McInnes says. "It's wonderful and exciting. It's just not yet ready for prime time."

There are a number of problems with the vast majority of direct-to-consumer genetic tests, Dr. McInnes says. First, many people carry risk genes for certain disorders, but there is a big leap between carrying the gene and actually getting the disorder. Thus, many tests create unnecessary worry.

Second, very few diseases are known as "single-gene" diseases, he says. For those rare diseases, such as Huntington's disease or cystic fibrosis, predictive genetic tests are important. But more common conditions such as heart disease involve multiple risk factors, such as environment and lifestyle, that play a huge role in

determining whether a person gets the disease.

Third, medicine already has plenty of ways to test for conditions such as cardiovascular disease, such as getting your blood pressure monitored, or checking up on your family history.

"You don't need the direct-to-consumer test to do this," Dr. McInnes says. "It's playing on the fears of the public who want to stay healthy."

Ms. Dyck and her husband now spend their winters in Phoenix and their summers on Vancouver Island, eating salmon and halibut they have pulled from the Pacific.

As far as Mr. Dyck is concerned, scientists should be trying to harness the predictive potential of genetic technology "as hard as they chase it down."

What Canadians think about genetic testing

ACCURACY

The majority of Canadians - 83 per cent - believe that genetic testing is accurate, according to a poll conducted by the Strategic Counsel for The Globe and Mail. And most Canadians say they are open to using tests to screen for disease risk.

CANCER TESTING

Almost one in five would spend more than \$1,000 to test for susceptibility to a treatable form of cancer, while one in 10 would pay that much to test for an incurable form of the disease or for an incurable neurological disorder.

CHILDREN

One in five Canadians would spend the \$1,000 to test for their child's susceptibility to a curable cancer, while just over one in 10 would test for incurable cancers at that price. The same number of Canadians would spend the same amount to determine their child's risk of developing heart disease.

WHAT FOR?

Few Canadians want to see testing used for purposes other than disease screening. Checking for a child's sexual orientation through testing was supported by only 11 per cent, while only 9 per cent support using such tests to determine a couple's romantic compatibility.

Elena Cherney

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