

Health News

Consumer Gene Tests: Help or Harm?

Experts, Test Makers Battle Over Selling Genetic Tests to Patients

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April 3, 2008 -- Firms use misleading claims to sell genetic tests to patients, and federal authorities should crack down, Johns Hopkins researchers say.

Several companies market genetic tests directly to consumers over the Internet. For a price, they'll send you a kit, you swab your cheek or spit in a sample jar and send it back, and they'll test your DNA. Test makers offer all kinds of information about what your genes say about things like your ancestry, paternity, and [nutrition](#).

They also offer to tell how well a large number of [prescription drugs](#) will work -- or not work -- for you. That's a misleading claim, suggests a *Science* editorial from Johns Hopkins' Genetic and Public Policy Center.

"We think consumers ought to be able to have confidence in the tests that are out there -- that they are performed accurately and provide information that promotes health," editorial co-author Gail Javitt, JD, MPH, law and policy director the center, tells WebMD. "Right now we have genetic tests that impede that goal."

If that's true, why don't the FDA and the Federal Trade Commission (FTC) take action against the companies?

"Consumers should be aware of the lack of oversight of these tests," Javitt says. "From our public-opinion research, consumers expect and believe these tests are regulated by government agencies. But these expectations and beliefs are not supported by the facts."

Javitt and colleagues call for FDA regulation -- and for FTC enforcement action if marketers are deemed to have made false claims.

One of the firms the editorial singles out for criticism is the Seattle firm Genelex, which offers directly to consumers a wide variety of genetic tests on its web site.

"I don't believe we have any unsupported claims on the web site," Genelex CEO Howard Coleman tells WebMD. "There is all this talk about personalized medicine, but some of this genetic testing is very underutilized. We have been doing this since 2000, clearly ahead of the marketplace."

Genetic Tests for Antidepressant Sensitivity

Javitt and colleagues point to a specific example of why they feel genetic testing must be regulated. Genelex, they note, offers to test patients for specific genetic mutations that affect liver enzymes. These CYP enzymes determine how quickly the body processes a number of drugs -- including the SSRI class of [antidepressants](#).

Genelex offers not only to test for enzymes that affect SSRI processing, but also to interpret the test results. Although the web site clearly states that these interpretations are intended as an aid to patients' doctors, the results are provided directly to the patient who pays for them.

The Genelex site makes specific claims about the types of information genetic testing CYP will provide -- such as proper dosage and [drug interactions](#).

Yet a January 2007 review of CYP tests for SSRI sensitivity -- by the CDC's EGAPP (Evaluation of Genomic Applications in Practice and Prevention) working group -- found the test wasn't ready for prime time. Alfred O. Berg, MD, MPH, professor and chairman of the family medicine at the University of Washington, chairs the EGAPP working group.

Genetic Tests for Antidepressant Sensitivity continued...

"We don't say the test can't be helpful. We just say you can't tell, and until you can tell, don't use it," Berg tells WebMD. "We are not saying the manufacturers are making false claims. ... We were a little disappointed that the evidence wasn't stronger than it was."

Coleman says the EGAPP standard is too high.

"That is the very most rigorous, very most conservative standard of proof," he says. "It is certainly appropriate for new drugs, but not for new genetic tests. These demands for clinical trials are over the top in terms of the level of proof we need to use this testing. There is an asymmetry between the level of benefit [from genetic testing] and this level of proof."

Berg says EGAPP is skeptical of this "genetic exceptionalism" suggesting that genetic tests are somehow different than other medical tests.

"One of the things these companies don't emphasize is that you can develop a plausible argument for how these genetic tests might work, but we are also interested in the harmful effects," he says. "With all tests, there are potential benefits and potential harms. We did not find evidence for either one of those in CYP tests for SSRI sensitivity."

How Should Genetic Tests Be Used?

Javitt and colleagues worry that patients armed with genetic test results will stop taking their medicines or change their doses without first consulting their doctors.

Is it really so hard to understand the results of genetic tests? Yes, says Jeffery M. Vance, MD, PhD, chairman of human genetics and genomic medicine at the University of Miami.

"Direct-to-consumer testing is never something that should be condoned and probably something that needs to be monitored," Vance tells WebMD. "With genetic tests, like other medical tests, you really need someone who can put it into context. That requires a physician. So it is the direct-to-consumer testing that is really a big problem."

But Vance thinks people should get genetic tests and have that information kept with their medical records.

"You could, for instance, get a CYP test and have your genotype known early in life," he says. "So say you're a slow responder to some drugs. Well, through your life there may be different drugs that come up where this is important or not important. The information is very important, but only in certain situations: It has value only in terms of the context in which it is used."

Vance predicts genetic testing will one day be routine and that doctors certainly will use the information to individualize drug treatments.

Coleman, however, argues that patients themselves should control this information.

"There is concern about the privacy of this information -- and if you don't trust the medical system to maintain the confidentiality of genetic testing, you may not get it or get the benefit from it," he says. "It is a bedrock right of patients to control this information about themselves."

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