# SSRI-Sensitivity Gene Tests for Consumers Called 'Misleading'

By Michael Smith, North American Correspondent, MedPage Today
Published: April 03, 2008
Reviewed by Dori F. Zaleznik, MD; Associate Clinical Professor of Medicine, Harvard Medical School, Boston.


NEW YORK, April 3 -- Much like investing on Wall Street, buying personalized genetic information can represent ownership of an expensive piece of paper with little or no value, researchers here warned.

At least four companies make claims that understanding the variability of cytochrome P450 (CYP450) enzymes will aid treatment with selective serotonin reuptake inhibitors (SSRIs), according to researchers led by Kathy Hudson, Ph.D., of the Johns Hopkins University Genetics and Public Policy Center here.

And two of those companies market personalized data directly to the public, Dr. Hudson and colleagues said in a Policy Forum in the April 4 issue of *Science*.

Action Points

- Explain to interested patients that many genetic tests are available, most only through a doctor, who provides counseling and information about the meaning of results.
- Note that this report suggests that direct-to-consumer marketing of such tests has risks and should be under stricter federal regulation.

The problem is there's no evidence to support such claims, the researchers said, arguing that the federal government should take a more active role in regulating genetic tests marketed directly to consumers.

"Doctors as well as consumers need to be aware of the lack of oversight (by federal regulators) of genetic tests in general, as highlighted by the CYP450 tests," said Sara Katsanis, M.S., a co-author.

While most genetic tests on the market are only ordered by physicians, those sold directly to consumers are "particularly troubling," especially if marketing claims are misleading, the researchers said.

In such cases, "there is no healthcare provider to serve as a 'gatekeeper' to prevent inappropriate test ordering or misinterpretation of test results," the researchers said.

Dr. Hudson and colleagues cited the case of cytochrome P450 -- enzymes that are involved in metabolizing drugs -- because a CDC-commissioned review said last year there is little good evidence that such tests "are useful in medical, personal, or public health decision-making."

The review of 37 published papers, by the Evaluation of Genomic Applications in Practice and Prevention working group, found that tests exist for the detection of some of the common polymorphisms of CYP450 and that the tests are both sensitive and specific.

What the review didn't find was any evidence that:

- Testing for CYP450 polymorphisms in adults entering SSRI treatment for non-psychotic depression leads to improvement in outcomes, compared with not testing.
- CYP450 testing influences treatment management decisions by patients and providers in ways that could alter outcomes.

On the other hand, the review also found no evidence of "direct or indirect harm associated with testing for CYP450 polymorphisms or with subsequent management options."

But the bottom line, the researchers noted, was that the working group urged that CYP450 testing not be used until clinical trials are completed. That recommendation is being ignored, they said.

In a case study, they found that at least 15 companies are offering CYP450 testing, using either an FDA-approved test kit or home-grown methods.

Most are circumspect about the value of the tests, but four firms -- Seryx, DNA Direct, LabCorp, and Genelex -- "make explicit claims about the utility of CYP450 testing for particular drugs," the researchers said.

Two of them -- DNA Direct and Genelex -- aim their marketing at the public, the researchers said.

The danger of such claims is that patients may change the dose of their medication with the possibility of adverse outcomes, the researchers said.

Dr. Hudson and colleagues called for three policy changes:

- Enhanced enforcement by the Federal Trade Commission against misleading claims. The agency has that authority, the researchers said, but it has "has not been a priority."
- Development of a mandatory registry for those offering genetic tests. They would be required to submit data supporting the intended use of the tests to a publicly accessible database.
- FDA oversight of laboratory-developed tests, as opposed to those sold as a kit, which are already regulated by the agency.

"When a test is being used to inform treatment decisions or other high-impact interventions, there needs to be an assessment of whether that test provides clinically relevant information," said Gail Javitt, J.D., the paper's other author.

Dr. Hudson and Dr. Javitt were co-authors of a statement by the American Society for Human Genetics on the issue, published last year (See: Gene-Test Marketing Raises Public Health Fears). The statement also called on the federal government to take a stronger role.

The Center is supported by the Pew Charitable Trusts. The researchers did not report any conflicts.

**Primary source:** Science
Source reference:
Katsanis SH, et al "A case study of personalized medicine" *Science* 2008; 320: 53-54.

**Additional source:** Agency for Healthcare Research and Quality
Source reference:
"Testing for cytochrome p450 polymorphisms in adults with non-psychotic depression treated with selective serotonin reuptake inhibitors (SSRIs)."*Agency for Healthcare Research and Quality* 2007.

**Related Article(s):**

- Gene-Test Marketing Raises Public Health fears

**Additional Genetic Testing Coverage**

**Find this article at:**
http://www.medpagetoday.com/Genetics/GeneticTesting/tb/8998

☐ Check the box to include the list of links referenced in the article.