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## Policy Paper Calls for More Pharmacogenetic Oversight

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NEW YORK (GenomeWeb News) – A new policy paper is raising concerns about the clinical validity, oversight, and marketing of pharmacogenetic tests.

In the paper, which appeared online today in *Science*, researchers from the Genetics and Public Policy Center at Johns Hopkins University argue that there is insufficient oversight of genetic tests that are currently being marketed as personalized medicine tools. As a result, the authors suggest, some companies are using misleading claims to push tests that have limited clinical validation — something they say may ultimately hurt the pharmacogenetics field.

Some of those offering pharmacogenetic tests have already refuted the claim. They argue that — where scientific data is available to support pharmacogenetic tests — individuals should be free to learn their genotype and how it might affect their response to drugs and other treatments.

The field of genetic testing has grown rapidly in the past few years. In particular, there has been increased interest in pharmacogenetics — using genetic information to predict an individual's response to therapeutics and tailor their treatment accordingly. Consequently, several companies are marketing pharmacogenetic tests looking for variants in genes that may have a role in drug response.

“Certainly there is a lot of interest in pharmacogenetics because it does have the potential to improve patient care,” author Gail Javitt, law and policy director at Johns Hopkins University's Genetics and Public Policy Center, told *GenomeWeb Daily News*.

But there is limited oversight of these tests. That has the authors of the policy paper calling for more regulation of the pharmacogenetic testing industry. For example, they noted, the US Food and Drug Administration doesn't regulate most laboratory-developed tests, though clinical laboratories are certified under the Clinical Laboratory Improvement Amendment, established in 1988.

“There are several entities that could and should be involved here,” Javitt said.

For instance, she said, the Federal Trade Commission oversees other consumer products and should demand that genetic tests meet the same standards as other products. “Like any consumer or healthcare product on the market,” Javitt said, “claims need to be truthful and not misleading.”

And while there certainly has been a lot of research to identify variants of potential interest in disease risk or treatment, “finding the variants is only part of the story,” Javitt added.

“There is no mechanism to ensure that genetic tests are supported by adequate evidence before they are marketed or the marketing claims for such tests are truthful and

not misleading,” the authors wrote.

In particular, they focused on tests for genetic variants in CYP450 genes. These genes code for enzymes involved in the metabolism of many drugs, including selective serotonin reuptake inhibitors. Because of this relationship, there has been a great deal of interest in using CYP450 variants to predict drug treatment responses, especially for SSRIs.

But, the authors noted, in 2007 the Evaluation of Genomic Applications in Practice and Prevention working group, commissioned by the Centers for Disease Control and Prevention, recommended against CYP450 testing for those starting SSRI treatment.

Still, companies are offering the test and some are “making specific claims about the benefit of such testing for SSRI prescribing or dosing.” Among the companies mentioned by name was the Seattle-based DNA testing company Genelex, which offers CYP450 genotype testing and interpretation directly to consumers.

In response to the paper, Genelex CEO Howard Coleman issued a statement today maintaining that the company’s web site was quoted out of context and reaffirming the company’s belief that individuals should have the right to learn and control information about their genotype.

“I think individuals have the right to learn their genotype,” Kristine Ashcraft, director of operations at Genelex, told *GenomeWeb Daily News* today.

In an earlier e-mail message, Ashcraft noted that although no randomized trials are completed yet, there are several other studies that support the use of pharmacogenetic testing for SSRIs. And she emphasized that waiting on the results of these clinical trials could deny some individuals potentially helpful information, particularly for those who have had adverse drug reactions in the past.

Ashcraft also defended Genelex’s direct-to-consumer marketing of CYP450 genetic tests, arguing that individuals may not get tested otherwise due to confidentiality concerns — something that could impede the adoption of such DNA testing.

In contrast, Javitt and her colleagues argued that premature marketing and use of tests without clinical validity may ultimately hurt the field, if doctors or patients lose faith in the accuracy of tests or have doubts about the motivation behind them. “Doctors and patients both have to trust that this will improve health,” Javitt said.

Among their recommendations in the paper, the authors called for enhanced enforcement of genetic test marketing by the Federal Trade Commission, FDA oversight, and mandatory registration of tests, which would lead to information that’s easily accessible to doctors and patients.

For her part, Ashcraft agreed that the pharmacogenetic field would benefit from better access to information and peer-reviewed literature related to the genetic tests being marketed. But, she said, that could be accomplished using a peer-reviewed rating system for tests rather than increased government oversight.