

Marketing of unproven genetic tests a threat to public health

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No mechanism currently exists to ensure that genetic tests are supported by adequate evidence before they go to market, or that marketing claims are truthful and not misleading, according to a policy analysis to be published April 4 in *Science*. Misleading claims about genetic tests may lead health-care providers and patients to make inappropriate decisions about which tests to take and how to use genetic tests that have potential for profound medical consequences, the authors argue.

Authors Sara Katsanis, Gail Javitt, and Kathy Hudson of the Genetics and Public Policy Center at Johns Hopkins University recommend rapid action to bolster the role of the Food and Drug Administration (FDA) in overseeing certain genetic tests developed in-house by diagnostic laboratories; creation of a mandatory, publicly accessible registry of information about each available genetic test, including data that support the intended uses of the test; and enhanced enforcement by the Federal Trade Commission (FTC) to impede false or misleading advertising claims about the benefits of genetic testing. The Center is supported by The Pew Charitable Trusts.

The success of personalized medicine depends upon public confidence in accurate, reliable genetic tests, the authors write. Tests for more than 1,500 diseases and conditions are available, yet the efficacy of many of these tests has not been evaluated. With the increasing availability of genetic testing services, and the promise of pharmacogenetics, “it is essential to be certain that the regulatory infrastructure is tailored in a manner beneficial to public health,” they note. While most genetic tests

must be ordered through a doctor, a growing number also are available directly to the consumer (DTC) over the Internet. These DTC tests are especially troubling, the paper explains, “because there is no health-care provider to serve as a ‘gatekeeper’ to prevent inappropriate test ordering or misinterpretation of test results.”

The authors reviewed claims made by testing businesses about the value of genetic testing for variability in cytochrome P-450 (CYP450) enzymes in predicting how individuals will metabolize antidepressants called selective serotonin reuptake inhibitors (SSRIs). At least 15 businesses currently offer CYP450 genotyping services, and four of those companies make specific claims that a CYP450 test can be used to recommend treatment, drug choice, and dosage. However, an independent working group initiated by the Centers for Disease Control and Prevention released a report last year that “discourages the use of CYP450 testing for patients beginning SSRI treatment until further clinical trials are completed,” the authors point out.

As a consequence, they warn, “a patient informed of his or her CYP450 profile might independently change the dose of antidepressant medication with adverse health outcomes,” more so because some companies involved offer the test DTC. Moreover, they say, “the current situation also could lead both providers and patients to lose trust in the value of genetic testing to improve drug-prescribing decisions,” the cornerstone of personalized medicine.

Two federal agencies with key roles in genetic testing oversight need to step up regulation, they say. Currently, FDA oversight is limited to tests that are sold as complete kits or selected test components. Furthermore, FDA review covers only the uses specified by the manufacturer of the kit, and not the broader potential uses for such tests. The authors urge that FDA oversight be expanded in scope, and to encompass laboratory-developed tests used in drug selection and dosage. This expansion of

FDA review would “better protect the public against tests that lack adequate evidence of clinical benefit and whose use could lead to selection of ineffective medications, adverse drug reactions, or failure to take a drug that would be effective.”

The situation is somewhat different at FTC, which has the authority to prohibit false or misleading advertising claims but has so far declined to exercise it against genetic testing businesses. The agency should use evidence available from the CDC-sponsored reviews and elsewhere to “take decisive action against companies making false or misleading claims about the benefits of genetic testing,” the authors recommend.

Lastly, they advocate that those offering genetic tests – traditionally or DTC – first be required to submit information about the test and data supporting its intended use to a registry that would be accessible to the public. “The availability of this information would aid doctors and patients in test selection and interpretation, and would afford a degree of transparency that is absent from the genetic testing marketplace,” they write.

“Genetic tests offer doctors and patients an unprecedented opportunity for improving health care,” says Center Director Kathy Hudson. “Marketing unproven tests to an unsuspecting public could undermine the very future of personalized medicine.”

Source: Johns Hopkins University

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