FDA Warns Consumers About Tests That Predict Response to Specific Medications

Changing drug treatment based on results from insufficiently substantiated genetic tests could lead to serious health consequences.

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Jeffrey Shuren, MD, J.D., director of the FDA's Center for Devices and Radiological Health and Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research on agency's warning to consumers about genetic tests that claim to predict patients' responses to specific medications

As a public health agency, one of our key roles is to promote and advance safe and effective medical product innovations. One rapidly advancing, and very promising, area of science and medicine is the field of genetic tests. Genetic testing can provide helpful information about how an individual's genes may predispose them to certain diseases and conditions, which may prompt consumers to be more engaged in pursuing the benefits of healthy lifestyle choices and more aware of their health risks.

Consumers are increasingly embracing direct-to-consumer genetic testing to better understand their ancestry or individual risk for developing diseases. Health care providers are using genetic testing to help inform decisions about their patients' health, health risks and more. Further, we are seeing significant activity in the field of pharmacogenetics, which is the process of understanding what, if any, role genetics plays in a patient's reaction to drugs. The use of some drugs can be aided by pharmacogenetic testing; there is sufficient scientific evidence demonstrating a relationship between certain drugs and genetic variants. For example, the blood thinner clopidogrel (Plavix) has a boxed warning that indicates health care providers should consider an alternative therapy for patients with specific genetic variants.

Today, we are warning the public about the FDA's concerns with pharmacogenetic tests whose claims have not been reviewed by the FDA. Specifically, we are warning consumers about many such genetic tests being marketed directly to consumers or offered through health care providers that claim to predict how a patient will respond to specific medications. Tests that make such claims that have not been evaluated by the FDA and are not supported by prescribing recommendations in the FDA-approved drug label, may not be supported by scientific and clinical

evidence, and may not be accurate.

In our safety communication, a collaboration between the FDA's Center for Devices and Radiological Health and Center for Drug Evaluation and Research, we note our concern about health care providers and patients inappropriately selecting or changing drug treatment based on the results from insufficiently substantiated genetic tests, which could lead to potentially serious health consequences for patients. For example, a patient may change the dose of their medication for a particular condition or disease based on the results of an unproven genetic test, which may result in inadequate care or worsening illness.

We are aware that these types of genetic tests are promoted to predict how a person will respond to specific medications used to treat conditions such as depression, heart conditions, acid reflux and others. They may claim that a specific medication may be less effective or have an increased chance of side effects due to a patient's genetic variations or indicate that the health care provider can or should change a patient's medication based on results from these tests.

For example, the FDA is aware of genetic tests that claim results can be used by physicians to identify which antidepressant medication would have increased effectiveness or side effects compared to other antidepressant medications. However, the relationship between DNA variations and the effectiveness of antidepressant medications has never been established. Moreover, the FDA is aware that health care providers have made changes to patients' medication based on genetic test results that claim to provide information on the personalized dosage or treatment regimens for some antidepressant medications, which could potentially lead to patient harm.

It is important to note that there are some drugs whose use can be aided by the results of pharmacogenetic information. In those cases, there is scientific evidence to support relationships between the genetic variant and how a patient responds to a drug, which has been reviewed by the FDA. The FDA-approved labeling for such a drug and genetic test provide health care providers with adequate information on how to use genetic information reported by the genetic test to manage medication treatment using the drug.

For example, the FDA has evaluated and authorized for marketing, tests that alert patients to drug metabolizing enzymes, such as for warfarin sensitivity. Another example is the direct-to-consumer genetic variant test authorized for marketing yesterday, which is intended to provide information regarding genetic variants that may play a role in the metabolism of some medicines. However, we have required that the test label make clear that it is not intended to provide information on a patient's ability to respond to any specific medication. Furthermore, health care providers should not use the test to make any treatment decisions, without additional testing. This application was granted with limited indications and is subject to special controls.

We believe, with more scientific study, there is great potential for pharmacogenetics. We have so much more to learn about the use of these tests for specific medications, what the results mean, and how we can apply the information to improve a patient's health. While we are committed to supporting innovation in this area, we will also be vigilant in protecting against the potential risks.

We will continue to closely monitor this area and take appropriate enforcement action as necessary. Additionally, the agency reminds patients and providers that they may file adverse event reports, including adverse events stemming from unapproved genetic health tests, to MedWatch, the FDA Safety Information and Adverse Event Reporting program.

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