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FDA warns public about genetic test claims

by from the Food and Drug Administration's Division of Pediatric and Maternal Health, Center for Drug Evaluation and Research, Center for Devices and Radiologic Health, and the Office of Pediatric Therapeutics

The Food and Drug Administration (FDA) is warning the public about genetic laboratory tests that claim to predict how a patient will respond to medications used to treat depression, acid reflux and other conditions.

The tests are offered through health care providers or marketed directly to consumers and make claims to support a medication's use, efficacy or side effect potential as compared to other medications based on a patient's genetic variations. Some software programs that interpret genetic information make similar claims.

The FDA has not reviewed most of these claims, and they may not be supported by scientific and clinical evidence. Therefore, the claims may not be accurate.

The agency's concern is that health care providers and patients are selecting or changing drug treatments based on these scientifically unsupported genetic test claims, which could result in patient harm.

The FDA supports innovation in the field of pharmacogenetics, and genetic test results can aid in the use of several FDA-approved drugs. This information can be found in FDA-approved labeling for these drugs.

The FDA offers recommendations to patients, health care providers, laboratories, genetic test manufacturers and developers about these tests in the public warning (http://bit.ly/2RkP9QP). The agency is monitoring the sale of genetic tests for unapproved uses and will take appropriate action as necessary.

Resources

- Patients and health care providers are encouraged to report problems resulting from the use of unapproved genetic tests to MedWatch, the FDA Safety Information and Adverse Event Reporting Program.
- Statement on FDA warning to consumers about genetic tests
- Additional FDA Update columns