U.S. FOOD & DRUG ADMINISTRATION

The FDA Warns Against the use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications: FDA Safety Communication

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Audiences

- Patients receiving results from genetic tests that claim to predict response to specific medications, or patients considering taking these genetic tests offered directly to consumers or through a physician.
- Physicians considering ordering genetic tests to predict a patient's response to specific medications or receiving reports from patients that have taken these genetic tests offered directly to consumers.

Medical Specialties

All physicians and health care providers

Product

Genetic laboratory tests with claims to predict a patient's response to specific medications, that have not been reviewed by the FDA and may not be supported by clinical evidence. For example, genetic tests with claims to predict whether some medications used to treat depression may be less effective or have an increased chance of side effects.

Purpose

The FDA is alerting patients and health care providers that claims for many genetic tests to predict a patient's response to specific medications have not been reviewed by the FDA, and may not have the scientific or clinical evidence to support this use for most medications. Changing drug treatment based on the results from such a genetic test could lead to inappropriate treatment decisions and potentially serious health consequences for the patient.

Summary of Problem and Scope

The FDA has become aware of genetic tests with claims to predict how a person will respond to specific medications in cases where the relationship between genetic (DNA) variations and the medication's effects has not been determined. These genetic tests might be offered through health care providers or advertised directly to consumers and claim to provide information on how a patient will respond to medications used to treat

conditions such as, depression, heart conditions, acid reflux, and others. They might claim to predict which medication should be used or that a specific medication may be less effective or have an increased chance of side effects compared to other medications due to genetic variations. Results from these tests may also indicate that the health care provider can or should change a patient's medication based on results from these tests. The FDA is also aware of software programs that interpret genetic information from a separate source that claim to provide this same type of information. However, sufficient clinical evidence is not currently available for these genetic tests or software programs and, therefore, these claims are not supported for most medications. For example, the FDA is aware of genetic tests that claim results can be used to help physicians 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 medication has never been established. The FDA is aware that health care providers may have made inappropriate changes to a patient's medication based on the results from genetic tests that claim to provide information on the personalized dosage or treatment regimens for some antidepressants. Patients and health care providers should not make changes to a patient's medication regimen based on the results from genetic tests that claim to predict a patient's response to specific medications, but are not supported by sufficient scientific or clinical evidence to support this use, because doing so may put the patient at risk for potentially serious health consequences.

There are a limited number of cases for which at least some evidence does exist to support a correlation between a genetic variant and drug levels within the body, and this is described in the labeling of FDA cleared or approved genetic tests and FDA approved medications. The FDA authorized labels for these medical products may provide general information on how DNA variations may impact the levels of a medication in a person's body, or they may describe how genetic information can be used in determining therapeutic treatment, depending on the available evidence.

Descriptions for how to use genetic information to manage therapeutic treatment can be found in the following sections of the FDA approved drug labeling: warnings (Boxed Warning, or Warnings and Precautions sections), Indications and Usage, Dosage and Administration, or Use in Specific Populations, as appropriate.

Recommendations for Patients

- Do not change or stop taking any medicine based on a report from a genetic test you took on your own. Discuss the results of the genetic test with your health care provider, including whether the medication label includes information on how to use genetic information to determine dosage, and whether your health care provider recommends changes to your treatment. Medicine should always be taken as prescribed by your health care provider.
- Be aware that most genetic tests that make claims about the effects of a specific medicine are not supported by enough scientific information or clinical evidence.

Recommendations for Health Care Providers and Laboratories

- If you are using, or considering using, a genetic test to predict a patient's response to specific medications, be aware that for most medications, the relationship between DNA variations and the medication's effects has not been established. Check the FDA-approved drug label, or the label of the FDA-cleared

or approved genetic test for information regarding whether genetic information should be used for determining therapeutic treatment.
- If a patient brings you a test report from a genetic test offered directly to consumers that claims to predict a person's response to a specific medication, seek information in the FDA-approved drug label regarding whether genetic information should be used for determining therapeutic treatment.
- Be aware that there are some FDA-approved drug and genetic test labels, and labels of FDA-cleared genetic tests that provide general information about the impact of DNA variations on drug levels, but do not describe how that genetic information can be used for determining therapeutic treatment. These labels are intended to be informational, but do not indicate that there is sufficient evidence to support making treatment decisions based on the information provided by the genetic test.
- Know that information regarding therapeutic treatment recommendations for patients with certain genetic variations can be found in the warnings (Boxed Warning, or Warnings and Precautions), Indications and usage, Dosage and Administration, or Use in Specific Populations sections of the FDA approved drug labeling, as appropriate.
- Be aware that most genetic tests that make claims regarding effects of a specific medication have not been evaluated by the FDA.

Recommendations for Genetic Test Manufacturers and Developers

- If your test claims to predict a patient's response to specific medications, confirm that the FDA-approved drug labels for medications included in your test labeling describe how genetic information can be used in determining therapeutic treatment. Know that information regarding therapeutic treatment recommendations for patients with certain genetic variations can be found in the warnings (Boxed Warning, or Warnings and Precautions), Indications and usage, Dosage and Administration, or Use in Specific Populations sections of the FDA approved drug labeling, as appropriate.
- Assure your test report and any labeling support an intended use that is consistent with the FDA-approved use of the medication.
- Contact the FDA if you have any questions about genetic tests that are intended to be used to direct use of specific medications.

FDA Actions

The FDA is looking into certain developers that may be inappropriately selling genetic tests for the unapproved uses noted above, and will take compliance actions when appropriate. We will continue to monitor reports of adverse events associated with this issue and will keep the public informed if significant new information becomes available.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products. If you suspect or experience a problem with a laboratory test, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Additional Resources

- List of cleared or approved companion diagnostic devices
- Direct-to-Consumer (DTC) Tests

Contact Information

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041, or 301-796-7100.

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