Alerts and Recalls

Generic Name (Trade Nameâ€”Company)

Uses/Notes

November 30, 2018

Genetic tests

FDA is warning about 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 adverse effects compared with 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 on the basis of these test results. 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.

According to the agency, patients and health care providers should not make changes to a patient's medication regimen on the basis of 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. 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. FDA-authorized labels for these medical products may provide general information on how DNA variations may affect the levels of a medication in a person's body, or they may describe how genetic

(No trade names—Multiple companies)

FDA warns about genetic tests with unapproved medication response claims

information can be used to determine therapeutic treatment, depending on the available 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 FDA.

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