FDA NEWS RELEASE

FDA issues warning letter to genomics lab for illegally marketing genetic test that claims to predict patients' responses to specific medications

For Immediate Release:

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Today, the U.S. Food and Drug Administration issued a warning letter (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/inova-genomics-laboratory-577422-04042019) to Inova Genomics Laboratory (Inova) of Falls Church, Virginia, for illegally marketing certain genetic tests that have not been reviewed by the FDA for safety and effectiveness. The tests claim to predict patients' responses to specific medications based on genetic variants. Selecting or changing drug treatment in response to the test results could lead to potentially serious health consequences for patients. The FDA is unaware of any data establishing that Inova's tests can help patients or health care providers make appropriate treatment decisions for the listed drugs. The action today reflects the agency's commitment to monitor the pharmacogenetic test landscape and take action when appropriate to address a significant public health risk.

"Consumers are increasingly embracing genetic testing to better understand their individual risk for developing diseases. With this rise in popularity and availability, we're also 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 particular drugs. Without appropriate evaluation to determine whether these tests work, patients are being put at risk—potentially impacting treatment decisions by providing false promise that they will respond well to a certain medicine or keeping them from using therapies that may benefit them," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "We are issuing this warning letter as part of our ongoing efforts to protect the public from the significant risk these tests pose. We are particularly concerned about pharmacogenetic tests that claim to predict patients' responses to specific medications where such claims have not been established and are not described in the drug labeling and continue to warn patients and health care professionals that they should not rely on these tests for treatment decisions."

"To be able to detect genetic variants and use them in determining an appropriate course of care is one way in which we encourage research and innovation. 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," said Janet Woodcock, M.D., director of the

FDA's Center for Drug Evaluation and Research. "While we are committed to supporting innovation in this area, we will also be vigilant in protecting against the potential risks and are therefore issuing this warning letter to help protect patients and providers from acting on data that has not been demonstrated to promote the safe and effective use of drugs."

The use of some drugs can be informed by pharmacogenetic testing. When the agency has reviewed scientific evidence demonstrating a relationship between the drug's effects and genetic variants and determined the information is sufficient to be included in the drug labeling, information about how to use the genetic test results to manage medication treatment is described in the labeling for the specific drug to assure safe use of the drug.

The FDA issued a warning letter to Inova for marketing pharmacogenetic tests that have not been reviewed by the FDA and that claim to predict patients' clinical responses to specific named drugs, including antidepressants, opioids, cancer treatments, anesthesia and diabetes medications. The FDA has not reviewed and is unaware of any data establishing that Inova's tests can help patients or health care providers use the listed drugs more safely or effectively. The warning letter requests that Inova respond, within 15 working days from the date the warning letter was received, with details of how the violations noted in the warning letter will be corrected. Any violations not corrected could lead to enforcement action such as seizure, injunction or civil money penalties.

Tests that make claims that have not been evaluated by the FDA may influence health care providers and patients to inappropriately select or change drug treatment based on the results from genetic tests. Acting on these results could lead to potentially serious health consequences for patients. For example, patients may change the dose of their medication for a particular condition or disease based on the results of such a genetic test, which may lead to an incorrect treatment or worsening illness.

Last year, the agency issued (/news-events/press-announcements/jeffrey-shuren-md-jd-director-fdas-center-devices-and-radiological-health-and-janet-woodcock-md) a safety communication warning consumers and health care professionals about pharmacogenetic tests being marketed directly to consumers or offered through health care providers that claim to predict how a patient will respond to specific medications.

Following issuance of the safety communication, the FDA reached out to several firms marketing pharmacogenetic 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 established. Most firms addressed the FDA's concerns by removing specific medication names from their labeling, including promotional material and patient test reports.

These actions, including the warning letter issued today, reflect the agency's commitment to advancing policies that enhance the FDA's oversight of device safety. As part of the Medical Device Safety Action Plan (/media/112497/download), the FDA has warned the public when safety issues are identified, such as with thermography devices (/news-events/press-announcements/fda-issues-warning-letter-clinic-illegally-marketing-unapproved-thermography-device-warns-consumers).

Health care professionals and consumers should report any adverse events related to these and other genetic tests to the FDA's MedWatch (/about-fda/page-not-found) Adverse Event Reporting program. To file a report, use the MedWatch Online Voluntary Reporting Form (/about-fda/forms/medwatch-information-and-adverse-event-reporting-program-voluntary-html). The completed form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) can be submitted online or via fax to 1-800-FDA-0178. The FDA monitors these reports and takes appropriate action necessary to ensure the safety of medical products in the marketplace.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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