Genetic tests by Inova draw warning letter from FDA, citing potential for ‘serious health consequences’

A suite of genetic tests used to predict a person’s response to specific medications is being marketed illegally by its manufacturer, Inova Genomics Laboratory, as the tests aren’t backed by scientific data, alleges the U.S. Food and Drug Administration.

The FDA sent a warning letter to Inova [April 4], advising the Virginia-based medical firm to refrain from marketing a suite of genetic tests that have yet to receive the regulator’s approval for safety and effectiveness. The tests include MediMap ADHD, MediMap Mind, MediMap Plus, MediMap Heart, and MediMap Baby—offerings collectively known as the MediMap tests. These products, called pharmacogenetic tests, use a person’s genetic variants to predict their response to certain drugs.

Gizmodo reached out to Inova for comment and will update this article when we hear back.

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In an FDA statement … the agency said no scientific data exists to show that “Inova’s tests can help patients or health care providers make appropriate treatment decisions for the listed drugs.” This could lead to “potentially serious health consequences for patients,” the FDA wrote. …

Indeed, this is some serious stuff. If people are changing or avoiding certain medications based on unproven genetic tests, that’s obviously very bad.

Read full, original post: FDA Warns Virginia Lab for Illegally Marketing Unproven Genetic Tests