Was the FDA too quick approving test for opioid addiction risk?

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A test to gauge if it's safe to prescribe a patient an addictive opioid may have been approved too soon by the U.S. Food and Drug Administration, claims a letter sent to the agency by a group of experts.

The test, called AvertD, is meant to screen for genetic markers suggesting that a person has a higher likelihood of developing an opioid use disorder (OUD). If the test result is positive, doctors could try alternative medications.

However, the FDA approved the test in December against the advice of its own advisory panel, the experts noted in their letter. They claim that AvertD is inaccurate and could actually lead to more opioid dependencies, not less.

"This test will make the opioid crisis worse," said Dr. Andrew Kolodny, medical director of opioid policy research at Brandeis University in Massachusetts and one of the those who signed the letter.

"It will contribute to overprescribing, it will contribute to an increased incidence of opioid use disorder," he told NBC News. "In other words, more people becoming newly addicted to opioids."

He and the letter co-authors asked FDA Commissioner Robert Califf to revoke the agency's approval.

Neither the FDA nor the test's maker, California-based SOLVD Health, responded to NBC News for comment.

According to data from the Substance Abuse and Mental Health Services Administration, over 6.1 million Americans were reported to have an opioid use disorder in 2022, and opioids have contributed to over 645,000 deaths over the past 20 years.

Opioid prescriptions given after surgery or to relieve pain are a prime "gateway" to addiction for many. In theory, knowing in advance if a person had a genetic vulnerability to opioid use disorder could reduce new cases of addiction.

AdvertD promised to do just that. But the FDA's own panel of experts overwhelmingly ruled against approval, citing doubts about the test's ability to accurately spot patients at addiction risk.

That could mean that doctors are lulled into a false sense of security and prescribe an opioid to a person who is, indeed, at risk for addiction.

Or, if the person is not at high risk for opioid addiction but the test comes out positive, they may be stigmatized as a potential addict and miss out on painkillers that could help them, Kolodny and colleagues added.

In their letter, they called the test useless, saying it cannot predict the odds for addiction ""any better than chance."

When the FDA approved AvertD in December, it stressed that the test only be used and interpreted by well-trained staff, and it "should be used as part of a complete clinical evaluation and risk assessment; it should not be used alone to make treatment decisions."

AvertD is not to be used in decision-making for people suffering from chronic pain, the agency said.

"Given the totality of available evidence and the urgent need for medical devices that can make a positive impact on the overdose crisis, and specifically devices that can help assess the risk of developing OUD, the FDA determined that there is a reasonable assurance of AvertD's safety and effectiveness, taking into consideration available alternatives, patients' perspectives, the public health need and the ability to address uncertainty through the collection of post-market data," the agency said.

But Dr. Katherine Keyes, a professor of epidemiology at the Columbia University Mailman School of Public Health in New York, said any test

that relies only on a few genetic markers is bound to be flawed when it comes to predicting the likelihood of addiction.

Addiction is far too "complex" for that, she told NBC News.

"We know the risk of OUD increases with the dose and duration of an opioid prescription," Keyes said. "Receiving an opioid prescription remains one of the strongest risk factors for the development of opioid use disorder."

In its application for FDA approval, SOLVD Health said the AvertD test had a sensitivity of about 82% and a specificity of about 79%.

That means that in roughly one in every five cases, a test would produce a false-negative result (meaning it failed to spot someone at high risk) or a false-positive result (meaning it designated the person as high-risk, even though they are not).

Given those numbers, "I think the product has the potential to do harm," Dr. Adam Gordon, who was a member if the FDA's advisory panel, told NBC News. He's a professor of medicine and psychiatry at the University of Utah School of Medicine

More information: Find out more about opioid use disorder at the American Psychiatric Association.