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Alere's $33.2m Settlement May Reflect Growing US Fed Focus On Dx

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Executive Summary

Abbott subsidiary Alere is paying $33.2m to settle allegations the company knowingly allowed hospitals to bill for tests performed using unreliable diagnostics marketed by the company. It's one of the first times that US DoJ has held a company responsible for false claims filed due to faulty test results.

US DEPARTMENT OF JUSTICE

Device manufacturer Alere Inc. has agreed to pay $33.2m to the US government to settle allegations the company violated the False Claims Act by knowingly selling unreliable diagnostic testing devices that were then billed to federal health-care programs. The US Department of Justice announced the settlement on March 23.

"What the allegations suggest is that Alere was put on notice well before FDA issued a mandatory nationwide recall, and that makes this case somewhat

qualitatively different from other recall cases," says Jason Mehta, a former US federal prosecutor.

The charges, which arose from a whistleblower complaint, are tied to Alere's distribution of *Triage* point-of-care testing devices between January 2006 and March 2012. The assays are intended to help diagnose heart failure, drug overdose and acute coronary syndrome, and were often used in emergency settings where fast, accurate results were needed, DoJ said.

According to the government case, Alere's customers began to complain about faulty test results after the firm made modifications to the device without alerting FDA. However, Alere is said to have taken no action on the complaints until FDA learned of the issues and ordered a nationwide recall in 2012. (Also see "Alere recalls 800,000 Triage tests on quality control issues" - Medtech Insight, 24 May, 2012.)

The $33.2m settlement will include $28.3m to the federal government and $4.9m to individual states, DoJ said. Whistleblower Amanda Wu, who formerly worked for Alere as a senior quality control analyst, will receive approximately $5.6 million.

Abbott Laboratories Inc. purchased Alere in 2017. (Also see "Despite Legal Dispute, Abbott Set To Buy Alere for $5.3bn" - Medtech Insight, 18 Apr, 2017.) Alere did not immediately respond to a request for comment.

Settlement Reflects Growing Focus On Dx Firms

The settlement helps to highlight the US government's growing enforcement focus on diagnostics companies, said Jason Mehta, a former assistant US Attorney who is now a partner with law firm Bradley Arant Boult Cummings LLP.

Mehta said he saw a few diagnostics settlements as a prosecutor, but the Alere settlement is "somewhat novel" because it's one of the first times DoJ has held a company responsible for false claims filed due to faulty test results. He believes this is tied to an increased DoJ focus on clinical diagnostics in general.

"A lot of that is driven in large part by the increasingly large share of federal money that is spent on clinical diagnostic testing," he said.

Mehta also made special note of the fact the whistleblower's complaint and resulting DoJ action followed an FDA-led recall of Triage units. Typically, he said, DoJ doesn't move against companies that have already recalled the product in question. But he suspects the penalty may have been driven by slow or lacking corrective actions on Alere's part. "What the allegations suggest is that Alere was put on notice well before FDA issued a mandatory nationwide recall, and that makes this case somewhat qualitatively different from other recall cases."

The key lesson for other manufacturers, Mehta said, is to pay attention to and perform root cause analyses on customer complaints, especially if they're aggregated in large numbers and focused on a specific device feature. "This settlement really illustrates that an ounce of prevention is worth a pound of cure," he said. Similarly, he encourages companies to limit their risk of FCA allegations by voluntarily self-disclosing known device issues to the government.

From the editors of The Gray Sheet