



Department of Justice

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Medical Device Companies Alere Inc. and Alere San Diego Inc. Agree to Pay \$38.75 Million to Settle False Claims Act Allegations

Alere Entities Allegedly Sold Diagnostic Devices They Knew Had a Materially Defective Algorithm

Medical device manufacturers Alere Inc. and Alere San Diego Inc. (collectively, Alere) have agreed to pay \$38.75 million to resolve allegations that the companies violated the False Claims Act by billing, and causing others to bill, the Medicare program for defective rapid point-of-care testing devices.

The settlement announced today resolves allegations that, from 2008 to 2016, Alere knowingly sold defective INRatio blood coagulation monitors used by Medicare beneficiaries taking anticoagulant drugs, such as warfarin. For those patients, blood coagulation monitoring is essential to determining a clinically appropriate and safe dosage for their medications. Too much of an anticoagulant drug can cause major bleeding, and too little of the drug can cause blood clots and strokes.

Since at least 2008, Alere allegedly knew that the software algorithm used in each version of its INRatio monitors contained a material defect. Based on its own internal research, as well as external complaints and warnings, Alere allegedly was aware that INRatio devices had a “system limitation” that produced inaccurate and unreliable results for some patients. The United States alleged that, despite awareness that INRatio systems were linked to over a dozen deaths and hundreds of injuries, including intra-cerebral hemorrhaging and cardiovascular events following bleeding episodes, Alere concealed the defect for years and billed Medicare for the use of defective INRatio devices. Alere allegedly failed to take appropriate corrective actions until 2016, when the devices were removed from the market following a nationwide Class I product recall undertaken at the request of the U.S. Food and Drug Administration (FDA).

“Patients and health care providers rely on diagnostic devices to provide reliable health information,” said Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division. “The Department of Justice will hold accountable medical device companies that knowingly sell defective products that can harm patients and waste taxpayer dollars.”

“Health care companies have an obligation to be candid and clear in their disclosures to the FDA,” said Acting U.S. Attorney Rachael A. Honig for the District of New Jersey. “The government expects companies to be proactive in investigating issues affecting patient safety. The U.S. Attorney’s Office for the District of New Jersey will hold accountable any company that fails to meet these obligations.”

“Companies that withhold information from or provide false information to FDA put patients’ health at risk and jeopardize the integrity of the regulatory process designed to protect the public health,” said Timothy Stenzel, M.D., Ph.D., Director of the Office of In Vitro Diagnostics and Radiological Health in the FDA’s Center for Devices and Radiological Health.

“Medical device providers who cut corners or purposefully market defective tools put profit above patient health,” said Special Agent in Charge George M. Crouch Jr. of the FBI. “The FBI will not sit idly by when people’s lives are at risk. It’s an ill-advised business model that ignores the consequences of getting caught.”

This settlement was the result of a coordinated effort between the Civil Division's Commercial Litigation Branch (Fraud Section) and the U.S. Attorney's Office for the District of New Jersey, with investigative support from the FBI's Newark Division and Healthcare Fraud Unit Major Provider Response Team and the Department of Health and Human Services, Office of Inspector General.

This matter was handled by Trial Attorney Christopher Terranova of the Civil Division and Assistant U.S. Attorney Daniel W. Meyler of the District of New Jersey.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Attachment(s):

[Download Alere Settlement.pdf](#)

Topic(s):

False Claims Act

Health Care Fraud

Component(s):

[Civil Division](#)

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