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Alere To Pay U.S. $33.2 Million To Settle False Claims Act Allegations Relating To Unreliable Diagnostic Testing Devices

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Baltimore, Maryland – Massachusetts-based medical device manufacturer Alere Inc. and its subsidiary Alere San Diego (Alere) have agreed to pay the United States $33.2 million to resolve allegations that Alere caused hospitals to submit false claims to Medicare and other federal healthcare programs relating to the use of materially unreliable point-of-care diagnostic testing devices.

The settlement agreement was announced today by Acting United States Attorney for the District of Maryland Stephen M. Schenning, Maureen Dixon, Special Agent in Charge for the Office of Inspector General for the Department of Health and Human Services, Robert Craig, Special Agent in Charge for the Defense Criminal Investigative Services, Mid-Atlantic Division and Mark McCormack, Special Agent in Charge for the Office of Criminal Investigations, Food and Drug Administration, Washington Field Division.

"Physicians who work to treat patients with suspected myocardial infarctions rely upon devices such as Alere's Triage Cardiac products for quick and accurate readings," said Stephen M. Schenning, Acting United States Attorney for the District of Maryland. "When manufacturers such as Alere make changes to the specifications that affect the product's reliability without informing physicians or the FDA, patient care is put at substantial risk."

The United States alleged that between January 2006 and March 2012, Alere knowingly sold materially unreliable rapid point-of-care testing devices marketed under the trade name Triage®. The Triage® devices aid in the diagnosis of acute coronary syndromes, heart failure, drug overdose, and other serious conditions, and the devices are frequently used in emergency departments where timely decisions are critical to ensuring proper patient care. According to the government's allegations, Alere knew that certain devices it sold produced unreliable results that had the potential to create false positives and false negatives that adversely affected clinical decision-making. The United States alleged that Alere personnel were aware of customer complaints regarding erroneous test results and that the decreased precision of its testing devices put the company at considerable regulatory and financial risk, yet the company failed to take appropriate corrective actions until FDA inspections prompted a nationwide product recall in 2012.

The civil settlement resolves a lawsuit filed under the whistleblower provision of the False Claims Act, which permits private parties to file suit on behalf of the United States for false claims and obtain a portion of the government's recovery. The civil lawsuit was filed in the District of Maryland and is captioned United States ex rel. Wu v. Alere, Inc., et al., GLR 11-1808. As part of today's resolution, Ms. Wu will receive approximately $5,675,778 from the settlement.

The federal share of the civil settlement is $28,378,893, and the state Medicaid share of the civil settlement is $4,860,779. The claims resolved by this settlement are allegations only, and there has been no determination of liability.

Acting U.S. Attorney Stephen M. Schenning commended the HHS Office of Inspector General, Food and Drug Administration's Office of Criminal Investigations and the Department of Defense's Criminal Investigative Services for their work in the investigation. Assistance also was provided by the National Association of Medicaid Fraud Control Units and offices of various state Attorneys General. The case was handled by Assistant United States Attorney Thomas Corcoran and Assistant Director Colin Huntley of the Department of Justice Civil Fraud Section.

Component(s):
USAO - Maryland

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