



Department of Justice

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THURSDAY, APRIL 9, 2015
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TWO CARDIOVASCULAR DISEASE TESTING LABORATORIES TO PAY \$48.5 MILLION TO SETTLE CLAIMS OF PAYING KICKBACKS AND CONDUCTING UNNECESSARY TESTING

United States Sues Two Other Companies and Three Individuals for Similar Violations

WASHINGTON – Cardiovascular testing disease laboratories Health Diagnostics Laboratory Inc. (HDL), of Richmond, Virginia, and Singulex Inc., of Alameda, California, have agreed to resolve allegations that they violated the False Claims Act by paying remuneration to physicians in exchange for patient referrals and billing federal health care programs for medically unnecessary testing, the Department of Justice announced today. Under the settlements, which stem from three related whistleblower actions filed under the federal False Claims Act, HDL will pay \$47 million and Singulex will pay \$1.5 million. The government also intervened in the lawsuits as to similar allegations against another laboratory, Berkeley HeartLab Inc.; a marketing company, BlueWave Healthcare Consultants Inc., and its owners, Floyd Calhoun Dent and J. Bradley Johnson; and former CEO Latonya Mallory of HDL.

“Health care providers that attempt to profit by providing illegal inducements will be held accountable,” said Acting Assistant Attorney General Benjamin C. Mizer for the Justice Department’s Civil Division. “We will continue to advocate for the appropriate use of Medicare funds and the proper care of our senior citizens.”

As alleged in the lawsuits, HDL, Singulex and Berkeley induced physicians to refer patients to them for blood tests by paying them processing and handling fees of between \$10 and \$17 per referral and by routinely waiving patient co-pays and deductibles. In addition, HDL and Singulex allegedly conspired with BlueWave to offer these inducements on behalf of HDL and Singulex. As a result, physicians allegedly referred patients to HDL, Singulex and Berkeley for medically unnecessary tests, which were then billed to federal health care programs, including Medicare.

The Anti-Kickback Statute prohibits offering, paying, soliciting or receiving remuneration to induce referrals of items or services covered by federally funded programs. The Anti-Kickback Statute is intended to ensure that a physician’s medical judgment is not compromised by improper financial incentives and is instead based on the best interests of the patient.

“The District of South Carolina has more than doubled its resources allocated to the pursuit of fraud, including matters brought to our attention by whistleblowers,” said U.S.

Attorney Bill Nettles of the District of South Carolina. “Whistleblower actions are a critical tool for holding health care providers accountable for fraudulent and abusive practices not only in South Carolina but nationwide.”

“When health care companies pursue profits by paying kickbacks to doctors, they undermine a patient’s ability to trust that medical decisions are being made for scientific reasons, not financial ones,” said Acting U.S. Attorney Vincent H. Cohen Jr. of the District of Columbia. “Those kickbacks also harm the taxpayer because they drive up the cost of federal health care programs with medically unnecessary tests. This significant settlement shows our determination to work with whistleblowers and our federal partners to defend the integrity of the health care system from illegal agreements that hurt patients and taxpayers.”

As part of the settlements, HDL and Singulex have agreed to enter into separate corporate integrity agreements with the Department of Health and Human Services’ Office of Inspector General (HHS-OIG). Those agreements provide for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to these settlements.

“Today’s announcement that DOJ has settled in part and intervened in part in these whistleblower actions reflects the commitment by DOJ, our agency and our other law enforcement partners to ferret out alleged improper Medicare billings by health care companies that are looking to increase their profits at the expense of taxpayers,” said Special Agent in Charge Derrick L. Jackson of the HHS-OIG Atlanta Regional Office.

The lawsuits were filed by Dr. Michael Mayes, Scarlett Lutz, Kayla Webster and Chris Reidel under the *qui tam*, or whistleblower, provisions of the False Claims Act. Under the act, private citizens can bring suit on behalf of the government for false claims and share in any recovery. The whistleblowers’ share of the settlements has yet to be determined. The act also permits the United States to intervene in and take over a whistleblower suit, as it has done in part in the three actions. The United States advised the court that it would be filing its own complaint against the corporate and individual defendants against whom it has intervened within 120 days.

Two of the lawsuits separately allege that the former CEO Phillippe Goix of Singulex and Quest Diagnostics Inc., parent of Berkeley, are liable for the scheme; the government declined to intervene in the allegations against Goix and Quest.

The government’s actions illustrate its emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$23.9 billion through False Claims Act cases, with more than \$15.2 billion of that amount recovered in cases involving fraud against federal health care programs.

These matters were investigated by the Civil Division's Commercial Litigation Branch, the U.S. Attorney's Offices of the District of South Carolina, the District of Columbia and the Middle District of North Carolina, HHS-OIG, the FBI, the U.S. Office of Personnel Management's Office of Inspector General, and the Department of Defense's Office of Inspector General Defense Criminal Investigative Service.

The cases are captioned *United States ex rel. Mayes v. Berkeley HeartLab Inc., et al.*, Case No. 9:11-CV-01593-RMG (D.S.C.); *United States ex rel. Riedel v. Health Diagnostic Laboratory, Inc., et al.*, Case No. 1:11-CV-02308 (D.D.C.); and *United States, et al. ex rel. Lutz, et al. v. Health Diagnostic Laboratory, Inc., et al.*, Case No. 9:14-CV-0230-RMG (D.S.C.). The claims settled by these agreements and asserted against these companies and individuals are allegations only, and there has been no determination of liability.

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