



PRESS NOTICE

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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***

COLUMBIA, SOUTH CAROLINA – United States Attorney Bill Nettles announced today that Health Diagnostics Laboratory, Inc. (HDL), of Richmond, Virginia, has agreed to pay \$47 million, and laboratory Singulex, Inc. of Alameda, California, has agreed to pay \$1.5 million 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 government has intervened in three False Claims Act lawsuits based on similar allegations by laboratory Berkeley HeartLab, Inc.; marketing company BlueWave Healthcare Consultants, Inc., and its owners, Floyd Calhoun Dent and J.

Bradley Johnson; and former Chief Executive Officer of HDL, Latonya Mallory.

“This marks the culmination of a three year investigation into these corporations, and the individuals that benefited from this fraud can now expect to receive our full attention,” said U.S. Attorney Bill Nettles.

The United States alleged that laboratories HDL, Singulex, and Berkeley induced physicians to refer patients to them for blood tests by paying them process and handling fees of between \$10 and \$17 per referral and by routinely waiving patient co-pays and deductibles. The government also alleged that HDL and Singulex conspired with BlueWave to offer kickbacks to physicians on behalf of HDL and Singulex. As a result of those kickbacks, physicians referred patients to HDL, Singulex, and Berkeley for medically unnecessary tests. HDL, Singulex, and Berkeley then submitted claims to federal health care programs, including Medicare, for payment for the medically unnecessary tests. 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 government actions announced today stem in large part from two whistleblower complaints filed in the District of South Carolina by Dr. Michael Mayes, Scarlett Lutz, and Kayla Webster under the qui tam provisions of the False Claims Act. Under that 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 the lawsuits and take over the allegations, which were not the subject of the settlements announced today.

“The District of South Carolina has more than doubled its resources allocated to the pursuit of fraud brought to our attention by whistleblowers,” said U.S. Attorney Nettles. “Whistleblower actions are a critical tool for holding health care providers accountable for fraudulent and abusive practices not only in South Carolina but nationwide.”

As part of these 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.

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

This settlement illustrates the government’s 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 \$23.8 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 U.S. Attorney's Office for the District of South Carolina, the U.S. Attorney's Offices for the District of Columbia and the Middle District of North Carolina; the Commercial Litigation Branch of the Justice Department's Civil Division; HHS-OIG; the FBI; the U.S. Office of Personnel Management Office of Inspector General and the Department of Defense 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, et al. ex rel. Lutz, et al. v. Health Diagnostic Laboratory, Inc., et al., Case No. 9:14-CV-0230-RMG (D.S.C.); and United States ex rel. Riedel v. Health Diagnostic Laboratory, Inc., et al., Case No. 1:11-CV-02308 (D.D.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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