THE UNITED STATES DEPARTMENT OF JUSTICE AND THE UNITED STATES ATTORNEY FOR THE DISTRICT OF SOUTH CAROLINA SETTLE WHISTLEBLOWER LAWSUITS AGAINST HDL AND SINGULEX FOR NEARLY $50 MILLION AND INTERVENE IN ONGOING LITIGATION AGAINST ADDITIONAL DEFENDANTS

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PHILADELPHIA – April 9, 2015 – The United States Department of Justice (DOJ) and the District of South Carolina have announced that two diagnostic laboratories, Health Diagnostic Laboratory, Inc., of Richmond, Virginia, and Singulex, Inc., of Alameda, California, have agreed to pay the government a combined settlement of nearly $50 million to resolve three whistleblower (known as *qui tam*) lawsuits. The whistleblowers alleged that the companies had used bogus blood draw fees and/or sham process and handling arrangements to induce physicians to refer their patients for expensive tests, which the companies marketed as detectors of cardiovascular disease, diabetes, and other chronic conditions.

One of these successful whistleblower lawsuits was brought by the law firms of Pietragallo Gordon Alfano Bosick & Raspanti, LLP, of Philadelphia, William J. Tuck, P.A., of Florence, South Carolina, and James F. Wyatt, of Wyatt & Blake, LLP, of Charlotte, North Carolina.

The qui tam suit was brought on behalf of two South Carolina residents, Scarlett Lutz and Kayla Webster, R.N., who learned of this improper testing scheme while working for one of HDL and Singulex's highest-referring physicians nationwide. Their whistleblower lawsuit alleges that HDL and Singulex cheated the Medicare, Medicaid, and TRICARE Programs for years by illegally inducing physicians to steer patients to HDL and Singulex for laboratory testing, with both companies fraudulently billing the government for laboratory testing services that were tainted by the illegal kickbacks. The *qui tam* whistleblower lawsuit sought to recover for taxpayers millions of dollars that HDL and Singulex fraudulently collected from the United States Government and state healthcare programs.

The Lutz and Webster lawsuit was filed under seal in 2013, pursuant to the federal False Claims Act ("FCA") and a number of state false claims acts, in the United States District Court for the Western District of North Carolina – Charlotte Division. It was subsequently transferred to the District of South Carolina – Beaufort Division for investigation and resolution. At the request of the government, Federal district court Judge Richard M. Gergel unsealed the matter and issued a series of orders regarding the case on April 9, 2015.

In particular, the recently-unsealed lawsuit alleges:

- HDL AND SINGULEX USED BOGUS PROCESS AND HANDLING FEES TO INDUCE PHYSICIANS THROUGHOUT THE COUNTRY TO REFER PATIENTS TO HDL AND SINGULEX FOR LABORATORY TESTING;

- PHYSICIANS ACCEPTED KICKBACKS FROM HDL AND SINGULEX IN EXCHANGE FOR A VALUABLE REFERRAL STREAM FROM PHYSICIANS THROUGHOUT THE COUNTRY AND THE HUNDREDS OF THOUSANDS OF PATIENTS THEY CONTROLLED; AND

- HDL AND SINGULEX PAID KICKBACKS THROUGH SHAM DRAW FEE OR PROCESS AND HANDLING FEE ARRANGEMENTS.

The Whistleblower Complaint also alleges that HDL's and Singulex's sales strategy and subsequent meteoric growth was a direct result of its sham P&H arrangements with referring physicians. The qui tam lawsuit further alleges that HDL and Singulex defrauded Medicare, TRICARE and the Medicaid Programs for years.

HEALTH DIAGNOSTIC LABORATORY, INC. ("HDL")

HDL is a multi-million dollar for-profit corporation based in Richmond, Virginia which provides blood test diagnostic services to physicians, primarily a panel of lab tests that the company markets as early detectors of cardiovascular disease, diabetes, metabolic syndrome and fatty liver disease. The Whistleblowers' lawsuit also alleges that the central marketing initiative employed by HDL involved paying draw fees or process and handling ("P&H") fees up to $20 per patient to physicians who ordered HDL's tests. Founded in 2009, HDL experienced meteoric growth between 2010 and 2013, when, according to then-CEO Tonya Mallory, HDL's annual revenues reached $420 million. Approximately 41% of HDL revenues come from the Medicare program.

According to the settlement reached with HDL, the federal Government and a number of states contend that HDL, from November 25, 2008, through January 31, 2015, offered and/or paid illegal remuneration to health care providers through, among other mechanisms, "process and handling" payments related to blood collection, which was intended to induce referrals in violation of the Anti-Kickback Statute (AKS), and/or the Stark Law. The complaint also contends that HDL submitted or caused the submission of claims for payment to the Government Healthcare Programs for tests that were not medically necessary or that were not appropriately coded. As a result of this conduct, the United States alleged that HDL is liable for knowingly submitting false or fraudulent claims to Government Healthcare Programs, in violation of the federal FCA, 31 U.S.C. §§ 3729-3733.

The settlement provides for fixed payments by HDL to the government exceeding $50.4 million. There is the potential for a total settlement of $100 million, should certain contingencies occur as outlined in the settlement agreement.

SINGULEX

Singulex, also named as a defendant in the case, is a for-profit corporation based in Alameda, California that provides laboratory testing for the diagnosis and monitoring of chronic diseases, including cardiovascular disease. The Whistleblower Complaint alleges that the main sales strategy employed by Singulex involved (similar to HDL) paying draw fees or process and handling fees of approximately $10 per patient to physicians who ordered Singulex laboratory testing services.

According to the Government's settlement with Singulex, the alleged improper conduct by Singulex occurred between January 1, 2010 and October 31, 2014, and relates to the knowing submission of false claims to federal healthcare programs. The Government contends that Singulex offered and paid illegal remuneration to physician and physician practices, including alleged "process and handling" fees related to blood collection in violation of the AKS. The Government contends that Singulex submitted claims for medically unnecessary services related to over-utilization of its testing services. The complaint also contends that the sales agreement between Singulex and BlueWave, their national marketing contractor, implicates the AKS. The settlement provides for Singulex to pay the government $1.5 million in fixed payments, with a potential for a total settlement of $13.1 million, should certain contingencies occur, as outlined in the executed settlement agreement.

The Government is Moving Forward Against Additional Defendants

In addition, the government has also intervened in the whistleblowers' allegations against BlueWave Healthcare Consultants, Inc., and its founders, Floyd Calhoun Dent and J. Bradley Johnson, as well as the founder and former Chief Executive Officer of HDL, Latonya ("Tonya") Mallory. The government has advised the District Court in South Carolina that it intends to file a Complaint in Intervention, in the near future, against Mallory, BlueWave, Dent, and Johnson.

According to the United States Attorney for the District of South Carolina, Bill Nettles, the announcement of the two settlements by the government today "marks the culmination of a three year investigation into these corporations, and the individuals that benefitted from this fraud can now expect to receive our full attention."

The Federal and State Prosecutorial Team

The whistleblower lawsuits against HDL and Singulex have been investigated by the United States Department of Justice, the United States Attorney's Office for the District of South Carolina, the United States Attorney's Office for the District of North Carolina, the United States Department of Health & Human Services - Office of the Inspector General ("HHS-OIG"), the Federal Bureau of Investigation ("FBI"), Defense Criminal Investigative Services (DCIS) and a number of state Medicaid Fraud Control Units.

The claims asserted against the defendants are allegations only; there has been no determination of liability, and neither defendant has admitted any liability.

William J. Tuck, Esquire, who came to represent these two qui tam relators through his litigation practice based near Florence, S.C., recognized the courage of both relators and their decision to come forward at great personal risk: "These honest women were moved by their concern for patients, many of whom were elderly, who were repeatedly subjected to HDL and Singulex blood

tests, not because the test was the best course of treatment, but because the physician was getting paid to order them. They simply wanted the fraudulent practice and the related drain on the taxpayers to stop."

"We commend the energetic government prosecutors and investigators for their collective commitment to investigating this nationwide fraud scheme. Ms. Lutz, Ms. Webster, and their legal team are proud to have assisted in the government's efforts to halt fraud, waste and abuse," said lead counsel representing the Relators, Marc S. Raspanti, of the Philadelphia office of Pietragallo Gordon Alfano Bosick & Raspanti, LLP.

"This is a large-scale and well-orchestrated scheme aimed at influencing physicians' independent medical judgment in determining where and whether thousands of patients across the country should be subjected to expensive laboratory testing," said Michael A. Morse, a partner with the Pietragallo firm and Chair of the firm's national Qui Tam practice group.

"The executives and principals of these testing companies created and approved the promotion of HDL and Singulex testing services that was based largely on offering physicians inducements through inflated draw fees or P&H payments. The total disregard for the patients who were being subjected to unnecessary testing and treatment to justify repeat testing is shocking," said Pamela Coyle Brecht, a partner with the Pietragallo law firm, who has worked for years assisting the Government in its investigation of Ms. Lutz and Webster's allegations.

Co-counsel James F, Wyatt, III, of the Charlotte, North Carolina law firm of Wyatt & Blake, LLP, commented: "These allegations paint a pattern of inducements employed by defendants in their efforts to victimize patients and federal and state healthcare programs to feed their corporate and personal appetites for revenues."

The False Claims Act allows private persons (known as "relators") to file a lawsuit against those businesses and individuals that have directly or indirectly defrauded the federal government. The False Claims Act was enacted by Congress at the request of President Lincoln, who signed it into law on March 2, 1863. The Act was strengthened in 1986, and again with amendments enacted in 2009 and 2010. The Act is the federal government's primary tool against fraud by its contractors, as evidenced by the recovery of more than $45 billion since 1986. Under federal and state qui tam statutes, should the government decline to intervene in any part of their action, the Relators, through private counsel, may pursue those allegations on behalf of taxpayers.

Pietragallo Gordon Alfano Bosick & Raspanti, LLP, is one of the largest and most successful whistleblower law firms in the United States. Lawyers in its nationwide whistleblower practice group have served for more than 25 years as lead counsel in whistleblower cases that have recovered more than $2 billion for Federal and State taxpayers. See www.pietragallo.com and www.falseclaimsact.com for information.

The lawsuit is captioned *United States et. al. ex rel. Lutz and Webster v. HDL et.al*., No. 9:14-cv-00230-RMG (D. S.C. – Beaufort). The matter is assigned to the Honorable Richard M. Gergel.

A copy of the recently unsealed complaint and settlement agreement can be found at the South Carolina district court or on www.falseclaimsact.com.

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