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Department of Justice

U.S. Attorney's Office

Western District of North Carolina

FOR IMMEDIATE RELEASE

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Testing Laboratory Agrees To Pay Up To \$43 Million To Resolve Allegations Of Medically Unnecessary Tests

ASHEVILLE, N.C. – Genova Diagnostics Inc., a clinical laboratory services company based in Asheville, North Carolina, has agreed to pay up to approximately \$43 million to resolve allegations that it violated the False Claims Act, including claims that it billed for medically unnecessary lab tests, the Department of Justice and the U.S. Attorney's Office announced today.

"Government healthcare programs are designed to provide beneficiaries with care that is medically reasonable and necessary," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "Providers of taxpayer-funded federal healthcare services will be held accountable when they knowingly cause false claims to be submitted for services that do not meet this standard of care."

"The False Claims Act is an important legal tool in our rigorous fight to protect the integrity of our healthcare system from providers like Genova Diagnostics, that bill government programs for non-covered testing to boost profits at the expense of taxpayer dollars," said Andrew Murray, U.S. Attorney for the Western District of North Carolina. "This office is dedicated to ensuring that healthcare providers in the Western District make medical decisions that benefit their patients, not the providers' bottom line."

The settlement resolves allegations that Genova: (a) improperly submitted claims to Medicare, TRICARE, and the federal employee health program for its IgG allergen, NutrEval and GI Effects lab test profiles because the tests were not medically necessary, (b) engaged in improper billing techniques, and (c) paid compensation to three phlebotomy vendors that violated the physician self-referral prohibition commonly known as the Stark Law. The Stark Law is intended to ensure that physician referrals are determined by the medical needs of patients and not the financial interests of physicians.

Under the settlement, Genova has agreed to pay approximately \$17 million, through the surrender of claim funds held in suspension by Medicare and TRICARE, plus up to an additional \$26 million if certain financial contingencies occur within the next five years, for a total potential payment of up to \$43 million.

Contemporaneous with the civil settlement, Genova entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General. The CIA requires, among other things, that Genova establish and maintain a compliance program with specific requirements and that it engage an independent review organization.

“Labs are expected to bill taxpayer-supported federal health programs for medically necessary services, not pad their bottom lines as alleged by the government in this case,” said Derrick L. Jackson, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services. “We will continue working with our law enforcement partners to safeguard these vital programs.”

“The results of this investigation highlight another step forward by the Defense Criminal Investigative Service (DCIS) and its law enforcement partners to root out fraud and corruption involving medical professionals who undermine the integrity of the Department of Defense,” said Special Agent in Charge Robert E. Craig Jr., DCIS Mid-Atlantic Field Office. “DCIS will continue to target fraud, waste, and abuse to preserve and recover precious taxpayer dollars for our most vulnerable programs, such as TRICARE.”

“The OPM OIG is committed to ensuring the integrity of the Federal Employees Health Benefits Program, which depends upon fair and honest accountings by providers,” said Thomas W. South, Deputy Assistant Inspector General for Investigations, Office of Personnel Management, Office of the Inspector General.

The agreement resolves allegations brought by Darryl Landis under the *qui tam*, or whistleblower, provisions of the False Claims Act. The False Claims Act permits private citizens to bring a lawsuit on behalf of the United States for fraud and to share in any recovery. The settlement provides for a payment of up to approximately \$6 million to Dr. Landis.

This settlement was the result of a coordinated effort by the department’s Civil Division; the U.S. Attorney’s Office for the Western District of North Carolina; the Department of Health and Human Services, Office of Counsel to the Inspector General and Office of Investigations; the DCIS; the Defense Health Agency Office of General Counsel, and; the Office of Personnel Management Office of the Inspector General, with assistance from the North Carolina Department of Justice.

The lawsuit resolved by this settlement is captioned *United States ex rel. Darryl Landis, M.D. v. Genova Diagnostics, Inc., et al., No. 1:17-cv-341* (W.D.N.C.). The claims resolved by the settlement are allegations only, and there has been no determination of liability.

Topic(s):

False Claims Act

Component(s):

USAO - North Carolina, Western

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