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Western District of Wisconsin

FOR IMMEDIATE RELEASE

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Nutritional Supplement Provider and CEO Plead Guilty To False Claims Act Violations

MADISON, WIS. - John W. Vaudreuil, United States Attorney for the Western District of Wisconsin, announced that the United States has reached a global settlement with NeuroScience, Inc., Pharmasan Labs, Inc., and Gottfried Kellermann, 75, the founder of both companies, to resolve criminal and civil liability arising from violating laboratory testing requirements and manipulating testing data.

Osceola-based Pharmasan is an independent laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) that provides various types of laboratory tests. The CLIA program is administered by the Centers for Medicare and Medicaid Services (CMS), which is part of the U.S. Department for Health and Human Services. Through the CLIA program, CMS regulates laboratory testing performed on human specimens for the purposes of medical diagnosis, treatment, and prevention.

NeuroScience, which is also located in Osceola, provides assessments and reports results for tests conducted by Pharmasan and, based on the results, recommends nutritional supplements for products sold by NeuroScience.

Kellermann is the founder of both NeuroScience and Pharmasan and is the former laboratory director of Pharmasan and CEO of NeuroScience. One type of test that Pharmasan performs is a urinary "neurotransmitter" test designed to identify the levels of various amino acids and other compounds that act as chemical messengers between the brain and other systems.

As part of the global settlement, NeuroScience pleaded guilty today in U.S. District Court in Madison to conspiring to obstruct CMS's administration of the CLIA program. Additionally, as part of the global settlement, Gottfried Kellermann pleaded guilty to intentionally violating CLIA requirements.

NeuroScience faces a maximum fine of \$500,000; Kellermann faces a maximum penalty of one year in prison and a fine of \$100,000. Judge James D. Peterson scheduled sentencing for January 19, 2017. NeuroScience, Kellermann, and Pharmasan also agreed to pay \$6,138,134 to resolve allegations that they violated the False Claims Act by submitting false claims to Medicare and TRICARE, which provides health insurance coverage for military forces personnel and retirees, and their dependents.

One important aspect of CLIA regulation is that each test performed by a laboratory must be subjected to a process commonly known as “method validation” to ensure that the test is reliably and accurately reporting results. In his guilty plea, Kellermann admitted that he intentionally subjected neurotransmitter testing to a “multiplication factor” that altered the results of the testing, without performing method validation on the multiplication factor.

Additionally, in its guilty plea, NeuroScience admitted that it conspired to obstruct the administration of the CLIA program. NeuroScience intentionally reported neurotransmitter test results as high or low based not on a properly validated reference range, but based on a narrowed range that had not been subjected to method validation. NeuroScience then recommended products to patients that fell outside of this narrowed and unvalidated range. These practices were not disclosed to CMS.

As part of a separate statement of facts accompanying the False Claims Act settlement, Pharmasan, NeuroScience, and Kellermann agreed that the United States could demonstrate that their violation of CLIA regulations resulted in the submission and payment of false claims under the Medicare and TRICARE programs.

“Patients and their medical practitioners make critical health care decisions based on the test results reported by independent laboratories and it is crucial that laboratories report their results accurately and reliably,” said U.S. Attorney Vaudreuil. “Intentionally subjecting test results to alterations and narrowed reference ranges that have not been properly validated violates a laboratory’s responsibility not only to the United States but, more importantly, to the public, and will not be tolerated.”

The United States’ joint civil and criminal investigation stems from a whistleblower action filed by a former NeuroScience employee under the *qui tam* provisions of the False Claims Act. In November 2015, Pharmasan and NeuroScience previously paid over \$8.5 million to resolve separate allegations, brought by a different whistleblower, that they violated the False Claims Act with respect to Medicare billing on other types of testing conducted by Pharmasan. The whistleblower action that resulted in the resolution reported today is captioned *U.S. ex rel. Ailts Campeau v. NeuroScience, et al.*, 13-811 (W.D. Wis.). The whistleblower will receive \$1,258,240 as part of this resolution.

“The American public has a right to trust that the companies they are doing business with are acting in a lawful way. IRS Criminal Investigation is committed to working with our law enforcement partners to provide financial investigative expertise to stop those individuals and companies who violate that trust,” said Shea Jones, Special Agent in Charge of IRS Criminal Investigation’s St. Paul Field Office.

"The Defense Criminal Investigative Service is committed to working with our partner agencies to combat fraud impacting the Department of Defense's vital programs and operations and maintaining the integrity of the Governments healthcare systems." said Brian J. Reihms, Special Agent in Charge, Defense Criminal Investigative Service.

"CLIA was enacted to establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results", said Lamont Pugh III, Special Agent in Charge - Chicago Region, U.S. Department of Health & Human Services, Office of Inspector General. "Intentionally deviating from these standards can ultimately corrupt the medical decision making process and adversely affect a patient's health and well-being. The OIG is committed to ensuring that those who violate health care laws are identified and held accountable."

This resolution was the result of an investigation conducted by Department of Health and Human Services' Office of Inspector General; IRS Criminal Investigation; Federal Bureau of Investigation; and Department of Defense, Office of the Inspector General – Defense Criminal Investigative Service. The prosecution of this case was handled by Assistant U.S. Attorneys Antonio M. Trillo, Daniel Hugo Fruchter, and Peter M. Jarosz.

USAO - Wisconsin, Western

Topic:

Healthcare Fraud

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