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Department of Justice

U.S. Attorney's Office

Northern District of Georgia

FOR IMMEDIATE RELEASE

Wednesday, December 8, 2021

Dr. Jeffrey M. Gallups and Entellus Medical agree to pay \$4.2 million to resolve False Claims Act lawsuit alleging kick-back arrangements

ATLANTA – Dr. Jeffrey M. Gallups (founder, owner, medical director and past-CEO of Milton Hall Surgical Associates (“MHSA”) a/k/a The Ear, Nose & Throat Institute) and Entellus Medical have agreed to pay approximately \$3 million and \$1.2 million, respectively, to resolve allegations that they violated the False Claims Act by entering into unlawful kickback arrangements.

“Gallups abused his position by accepting unlawful kickbacks in exchange for directing MHSA physicians – often over their objections – to order devices or administer procedures and tests that were not medically necessary,” said U.S. Attorney Kurt Erskine. “In his role, Gallups was uniquely situated to benefit his community. Instead, he chose to put his personal financial interests above the interests of his colleagues and MHSA’s patients.”

“The Anti-Kickback Statute prohibits individuals who participate in federal health care programs from knowingly and willfully offering, paying or receiving any remuneration in order to encourage recommendation of any item covered under a federal health care program,” stated Derrick L. Jackson, Special Agent in Charge with the Department of Health and Human Services Office of Inspector General. “We will continue to pursue providers who engage in kickbacks or bill for baseless procedures.”

“The False Claims Act settlement in this case will be a deterrent to those who selfishly profit from dishonest medical treatment rather than upholding their oath as a health care provider to do what is best for their patients,” said Chris Hacker, Special Agent in Charge of FBI Atlanta. “The FBI and our partners will always make it a priority to protect companies and individuals from anyone who would seek to profit

from false claims.”

“Georgia's Medicaid program relies upon the independent judgement of medical professionals to make appropriate treatment decisions for their patients. Financial relationships that undercut this independence diminish public trust and unnecessarily drive up health care costs for our citizens. We remain dedicated to working with our state and federal partners to maintain the integrity of public programs and protect taxpayers dollars,” said Georgia Attorney General Chris Carr

“Our trusted medical professionals who engage in kickback schemes to maximize profits undermine the integrity of our Department of Defense health care system,” stated Special Agent in Charge Cynthia A. Bruce, Department of Defense (DoD) Office of Inspector General, Defense Criminal Investigative Service (DCIS), Southeast Field Office. “DCIS and our investigative partners will continue to protect DoD personnel and their dependents by holding companies accountable that engage in unlawful activities.”

Between 2014 and 2018, Gallups was a non-practicing physician, and devoted his time to acting as the CEO and medical director of MHSA, which employed approximately 12-18 physicians in various locations throughout North Georgia. The government alleges that Gallups controlled these physicians in his capacity as CEO and medical director of MHSA and directed these physicians, in exchange for the kickbacks described herein, to (1) utilize sinuplasty related medical devices exclusively from Entellus; as well as to (2) order toxicology and genetic testing from NextHealth.

First, with respect to Entellus and Gallups, it is alleged that Entellus provided Gallups several forms of remuneration, including cash payments and all-expense paid trips, in return for Gallups requiring MHSA physicians to use Entellus's sinuplasty medical devices and increase the number of sinuplasty procedures conducted on MHSA patients.

Second, with respect to Gallups and a Dallas, Texas based medical laboratory called NextHealth, LLC (“NextHealth”), it is alleged that NextHealth made payments to Gallups in the form of supposed “commissions” in return for Gallups requiring MHSA physicians to order medical tests from NextHealth, regardless of medical necessity, and despite objections from MHSA physicians that such tests were not medically necessary.

Gallups/Entellus Kick-Back Scheme

Entellus is a medical device company that manufactures, inter-alia, products used to perform sinus surgery. The government alleges that Entellus provided kickbacks to Gallups to induce him to direct MHSA physicians to (1) utilize Entellus sinuplasty medical devices (as opposed to those of Entellus' competitors); and (2) increase the volume sinus surgeries performed at MHSA, thereby increasing the number of supplies ordered from Entellus. On December 7, 2017, Entellus was acquired by Stryker Corporation (“Stryker”), and Stryker's compliance personnel flagged and elected not to renew the consulting arrangement that existed between Entellus and Gallups. On September 21, 2000, Stryker agreed to pay \$1.2 million to resolve claims arising from the alleged Gallups/Entellus kickback arrangement.

Gallups/NextHealth Kick-Back Scheme

The government alleges that, in or around January 2016, Gallups entered into a kickback arrangement with a now defunct medical testing laboratory called NextHealth, pursuant to which Gallups directed MHSA physicians to order toxicology and genetic tests from NextHealth, despite physician objections that

the tests were not medically necessary. In return, NextHealth paid Gallups 50% of the revenue generated from such tests as “commissions.” The government contends the scheme ended in or around February 2017 due to increasing complaints from MHSA physicians that the tests were not medically necessary.

The civil settlement resolves claims brought under the qui tam or whistleblower provisions of the False Claims Act by Myron Jones, M.D., who is a former physician-employee of MHSA. The False Claims Act permits private parties to sue for false claims on behalf of the United States and to share in any recovery. The qui tam case is captioned *United States ex rel. Myron Jones, M.D., et al. v. Milton Hall Surgical Associates, LLC d/b/a The ENT Institute and a/k/a the Ear, Nose & Throat Institute, Jeffrey M. Gallups, M.D., et al.*, Civil Action. No. 1:17-cv-2472 (NDGA). Jones will receive approximately \$614,000.00 from the settlement.

The claims resolved by this settlement are allegations only and there has been no determination of liability. With respect to the allegations concerning NextHealth, LLC, on October 21, 2021, before the U.S. District Court for the Northern District of Georgia, Gallups pleaded guilty to health care fraud in case number 1:21-cr-00370.

This matter was investigated by the U.S. Attorney’s Office for the Northern District of Georgia, the Georgia Medicaid Fraud Control Unit, the U.S. Department of Health and Human Services – Office of Inspector General, the Federal Bureau of Investigations and the Defense Criminal Investigative Service of the U.S. Department of Defense – Office of Inspector General.

The civil settlement was reached by Assistant U.S Attorney Paris A. Wynn and Georgia Assistant Attorney General James Mooney.

For further information please contact the U.S. Attorney’s Public Affairs Office at USAGAN.PressEmails@usdoj.gov or (404) 581-6016. The Internet address for the home page for the U.S. Attorney’s Office for the Northern District of Georgia Atlanta Division is <http://www.justice.gov/usao/gan/>.

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