MarketWatch

Johnson & Johnson Whistleblower, Represented by Nolan Auerbach & White, Partners with Government in Eight-Year-Long Battle Resulting in Recovery of Over a Quarter of a Billion Dollars

By
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FORT LAUDERDALE, Fla., Nov 04, 2013 (BUSINESS WIRE) -- Today, Nolan Auerbach & White announces the conclusion of its client's 8-year-long civil False Claims Act case against Johnson & Johnson and its subsidiary Scios, Inc. The qui tam case was brought in July 2005 by Joe Strom, a former Scios Area Manager. Both Defendants will pay $184 million to resolve civil allegations that they unlawfully promoted their cardiac drug Natrecor for unapproved uses. In addition, in 2011, Scios agreed to pay an $85 million criminal fine and to plead guilty to a misdemeanor charge of introducing misbranded Natrecor into interstate commerce. This settlement was announced today by the United States as part of a $2.2 billion global settlement between the government and Johnson & Johnson.

The Food & Drug Administration (FDA) only approved Natrecor for a specific use, namely, as a treatment of patients with acutely decompensated congestive heart failure who have dyspnea at rest or with minimal activity. Mr. Strom's Complaint alleges that Johnson & Johnson and Scios broadly marketed the drug to physicians for off-label uses, including the treatment of chronic congestive heart failure patients with serial, scheduled outpatient infusions.

Sales tactics identified by Mr. Strom and the government in legal filings, included organizing third-party continuing medical education programs that were actually controlled, promoted and designed by Scios; distributing third-party articles; touting the off-label benefits of Natrecor, while not disclosing that the article was funded in part or in full by Defendants; and educating physicians on Medicare reimbursement codes for off-label uses. The legal filings further described that Defendants paid grant funds and provided other resources to health care providers to use in starting outpatient infusion clinics, provided health care professionals with their Heart Failure Clinic Marketing Resource Kit, which included, inter alia, form press releases for outpatient clinics to announce their activities, and a Clinical Resource Compendium which provided contact information for medical supplies, equipment, and reimbursement consultants.

In the years after the drug's launch, concerns about its safety emerged. In early 2005, two articles were published in prominent medical journals relating to concerns of the renal and mortality effects of the drug. In June 2006, the panel recommended that the use of Natrecor be limited strictly to patients presenting to the hospital with acutely decompensated congestive heart failure who have dyspnea at rest. The panel found that, because of the insufficiency of the evidence, Natrecor should not be used for, inter alia, intermittent outpatient infusions or scheduled repetitive use.

"When pharmaceutical manufacturers promote drugs for uses that have not cleared the FDA approval process, they are jeopardizing the safety of Americans and thwarting the federal law," explained Nolan Auerbach & White managing partner Marcella Auerbach. "Real lives are at stake when drug companies engage in off-label promotions."

Federal and State False Claims Acts allow private citizens with detailed knowledge of fraud to bring an action on behalf of the governments and to assist in the recovery of the governments' stolen dollars. These statutes allow governments to recover three times the amount they were defrauded, in addition to civil penalties of $5,500 to $11,000 per false claim. Successful whistleblowers can receive between 15 and 30 percent of the governments' recovery.

The settlement was achieved through the coordinated efforts of the U.S. Department of Justice, the FBI, the Office of Inspector General of the U.S. Department of Health and Human Services, as well as multiple state attorneys general Medicaid Fraud Control Units and other law enforcement entities. The federal government was led by an exceptional team of government attorneys, including Civil Division Chief Sara Winslow, DOJ Trial Attorneys Renee Orleans and Kimberly Friday, USAO and Assistant U.S. Attorney Thomas Green.

The case is United States et al., ex rel. Strom v. Johnson & Johnson et al., No. 3:05-cv-03004-CRB (N.D. Cal.).

The two medical journal articles cited in this press release are Sackner-Berstein JD, et al., Short-term Risk of Death After Treatment With Nesiritide for Decompensated Heart Failure: A Pooled Analysis of Randomized Controlled Trials, 293 JAMA 1900 (2005); and Sackner-Bernstein JD, et al., Risk of Worsening Renal Function With Nesiritide in Patients With Acutely Decompensated Heart Failure, 111 Circulation 1487 (2005).

The Department of Justice press release is located at: http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20131104006335/en/

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Nolan Auerbach & White
Ashley M. Padgett, 800-372-8304
