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TranS1, Inc. Agrees to \$6M Settlement ***Lawsuit Claimed It Caused Providers To Improperly Bill Government***

Baltimore, Maryland, July 3, 2013 – Medical device manufacturer TranS1, Inc., now known as Baxano Surgical, Inc., has agreed to pay the federal government \$6 million to settle a whistleblower lawsuit that alleged off-label marketing and promotion of a medical device.

The lawsuit centered on a device known as AxiaLIF which is used for minimally invasive spinal fusion surgeries. Until January 1, 2013, TranS1’s AxiaLIF device was assigned a Category III, or “T-code.” A T-code denotes an experimental or emerging technology, one that must be used in all billings, but is not reimbursed by Medicare, Medicaid or other government payers.

TranS1 was accused of intentionally hiding its T-code in marketing and promotions, and actively encouraging physicians and hospitals to improperly seek reimbursement from the government.

“A medical device company cannot encourage physicians and hospitals to use improper billing codes to get reimbursement that is not owed,” said Jay Holland, one of the attorneys from Joseph, Greenwald & Laake, P.A. representing the whistleblower.

Brought under the False Claims Act, the whistleblower lawsuit alleged that as a result of this marketing, physicians and hospitals were misled into wrongly billing Medicare and other health care programs, resulting in millions of dollars improperly paid by the federal government.

“Medical device companies must be truthful and not misleading in all aspects of marketing and promotion,” said Veronica Nannis, one of the attorneys for the whistleblower. “If they are not, the False Claims Act is a crucial tool used by private individuals working in partnership with the government to stop wrongdoing and recover lost funds for the federal treasury.”

The company’s actions came to light when a sales representative reported them and filed suit under the False Claims Act in federal court in Maryland. The lawsuit alleged that TranS1 began off-label promotion related to AxiaLIF from the time it first received the T-code (January 1, 2009) and that this was a national, company-wide practice. The lawsuit also contained allegations of unlawful kickbacks paid by TranS1.

“The government was a focused and dedicated partner in this effort,” said Nannis. “Led by United States Attorney for the District of Maryland Rod J. Rosenstein and his team, including Assistant U.S. Attorneys Thomas Barnard and Thomas Corcoran and Trial Attorney Colin Huntley of the Justice Department Civil Division,” Holland added, “the government understood

all angles of this medical device case, assembled an experienced and dedicated team from a number of agencies, and brought it to an early resolution,” he said.

Suit was filed in the United States District Court for the District of Maryland in Baltimore in April, 2011 under the federal and North Carolina False Claims Acts. The whistleblower was represented by experienced whistleblower counsel, Jay Holland and Veronica Nannis, from Joseph, Greenwald & Laake, P.A. in Greenbelt, Maryland. In addition to the monetary recovery, the lawsuit resulted in the company entering into a corporate integrity agreement under which it will be monitored by HHS. This is the latest example of a successful civil off-label lawsuit after the 2nd Circuit’s *Caronia*¹ decision, which, when it came down in December of last year, led some to question the continued strength or viability of these cases.

The False Claims Act incentivizes whistleblowers to file lawsuits against companies that are defrauding the government by offering a reward for their efforts if funds are recovered.

Jay Holland is a partner, Executive Committee member, and Chair of the Labor, Employment, and Qui Tam practice at the firm. He was counsel to a Relator in the “Botox” off-label marketing case in which the maker of Botox, Allergan, Inc., settled civil and criminal claims with the government for \$600 Million. His recent articles on protecting whistleblowers have appeared in Trial Magazine and D.C. Trial Lawyer. He can be reached at jholland@jgllaw.com.

Veronica Nannis is a partner and the Chair of the firm’s Civil Litigation department. She can be reached at vnannis@jgllaw.com. Her article about the Caronia decision and its effect on off-label cases like this one was published in April by the ABA Health e-Source and is available at: http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1304_nannis.html

Joseph, Greenwald & Laake, P.A. is a full-service law firm that has been serving Maryland and D.C. for over 40 years. www.jgllaw.com

¹ *United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012).