

Fraud and Abuse

Device Company Settles Allegations Of Causing Spinal Surgery False Claims

By [Brian Broderick](#)

Medical device company Baxano Surgical Inc. has [agreed](#) to pay \$6 million to settle allegations the company caused submission of false claims to Medicare and other programs for spinal surgeries, according to a July 3 announcement from federal prosecutors (*United States ex rel. Ryan v. TranS1 Inc.*, D. Md., Civ. No. MJG 11-1041, *settlement* 7/3/13).

Raleigh, N.C.-based Baxano, formerly known as TranS1 Inc., allegedly caused health care providers to submit claims with incorrect diagnosis or procedure codes for minimally invasive spine fusion surgeries using TranS1's AxiaLIF System, the Department of Justice said. This medical device, DOJ said, was developed as an alternative to invasive spine fusion surgeries.

The government alleged that the company improperly counseled physicians and hospitals to bill for the AxiaLIF System by “using incorrect and inaccurate codes intended for more invasive spine fusion surgeries. The United States alleged that, as a result, health care providers received greater reimbursement than they were entitled to for performing the minimally-invasive AxiaLIF procedures.”

In addition, the government claimed that Baxano/TranS1 “knowingly paid illegal remuneration to certain physicians for participating in speaker programs and consultant meetings intended to induce them to use TranS1 products, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and thereby caused false claims to be submitted to federal health care programs.”

DOJ also said the device company allegedly promoted the sale and use of its AxiaLIF System for uses that were not approved or cleared by the Food and Drug Administration--including use in certain procedures to treat complex spine deformity--and thus were not covered by federal health care programs.

As part of the settlement, Baxano will enter into a corporate integrity agreement with the Health and Human Services Office of Inspector General.

Whistleblower.

The False Claims Act whistleblower in the case filed in federal district court in Maryland, Kevin Ryan, will receive \$1 million as part of the case.

A statement released by the law firm representing the whistleblower said that until Jan. 1, 2013, TranS1's AxiaLIF device was assigned what is known as a "T-code." This 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, the firm of Joseph, Greenwald & Laake PA said. The law firm said 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.

The law firm also said that this "is the latest example of a successful civil off-label lawsuit after the 2nd Circuit's *Caronia* decision, which, when it came down in December of last year, led some to question the continued strength or viability of these cases."

In *United States v. Caronia*, the U.S. Court of Appeals for the Second Circuit found in late 2012 that the criminalization of truthful, nonmisleading promotion of Food and Drug Administration-approved pharmaceuticals violates the First Amendment (232 HCDR, 12/4/12).

"A medical device manufacturer violates the law when it advises physicians and hospitals to report the wrong codes to federal health insurance programs in order to increase reimbursement rates," Rod J. Rosenstein, U.S. attorney for the District of Maryland, said in the government's statement. "Health care providers are required to bill federal health care programs truthfully for the work they perform."

In May, publicly traded TranS1 Inc. announced that it had completed its acquisition of Baxano, a privately held medical device company, but kept the Baxano name.

Representatives of the company did not respond to a request for comment.

According to the settlement, Baxano is represented by Peter S. Spivack, of Hogan Lovells, in Washington.

Ryan is represented by Jay Holland and Veronica Nannis, of Joseph, Greenwald & Laake PA, in Greenbelt, Md.

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