



New Government Scrutiny of Medical Device Companies Regarding False Claim Statutes

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The government has long investigated healthcare providers and pharmaceutical companies for False Claims Act (FCA), Federal Food, Drug, and Cosmetic Act (FDCA), Anti-Kickback Statute (AKS), and other related violations of federal law. It now appears that the government has expanded its investigative focus to include medical device companies.

On July 3, 2013, Baxano Surgical, Inc. (Baxano),¹ a company that manufactures medical devices for treating degenerative conditions of the spine, announced that it had reached a settlement with the Department of Justice (DOJ) regarding an investigation which had begun in October 2011, when the government issued a subpoena for documents related to whistleblower allegations.²

The government's allegations included that Baxano had violated the FCA by advising physicians and hospitals to bill for the company's device using diagnosis or procedure codes for certain types of invasive spine fusion surgeries even though the device was developed as an alternative to these surgeries. As a result, providers received larger reimbursements for the procedures than they were entitled to receive under federal programs in violation of the FCA. Prosecutors further alleged that the company had violated the AKS by paying kickbacks to physicians for attending speaker programs and consultant meetings in order to encourage them to use the company's device. Finally, the government alleged that Baxano had promoted its device for indications not approved by the Food and Drug Administration, *e.g.*, treatment for complex spine deformity, in violation of the FDCA.

In December 2012, Baxano and the DOJ tentatively agreed to settle the federal government's investigation for \$6 million, subject to approval by the DOJ and the Department of Health and Human Services Office of Inspector General (OIG).

Although the company did not admit to any misconduct as part of the settlement, the final agreement requires Baxano to pay a \$6 million settlement and accrued interest of two percent beginning in July 2013. Also, as part of the settlement, the company entered into a Corporate Integrity Agreement (CIA) with the OIG, in which the OIG agreed to forgo the option to seek the company's exclusion from participating in federal health care programs. Under the CIA, Baxano must, among other requirements, continue and regularly update its compliance program and maintain a disciplinary procedure for compliance issues for five years. The CIA is available [here](#).³

The civil settlement also resolved a sealed qui tam lawsuit brought by a former company clinical sales manager, who will be paid \$1.02 million as a result of the case. The former employee was able to bring the suit under a whistleblower provision of the FCA, which entitles private individuals to sue on behalf of the United States for false claims and retain part of the amount the government recovers.

With the increasing number of recoveries from health care fraud enforcement actions, medical device companies should remain on alert for new OIG actions and maintain effective compliance programs.

¹ TranS1 Inc. acquired Baxano Inc., and changed its name to "Baxano Surgical, Inc." See Press Release, Baxano Surgical, Inc., (May 31, 2013), available at: <http://baxanosurgical.com/trans1-inc-announces-closing-of-acquisition-of-baxano-inc-and-financing-transaction-changes-name-to-baxano-surgical-inc/>.

² See Press Release, Baxano Surgical, Inc., (July 3, 2013), available at: <http://baxanosurgical.com/baxano-surgical-inc-announces-definitive-settlement-with-office-of-inspector-general/>; Press Release, Department of Justice, (July 3, 2013), available at: <http://www.justice.gov/opa/pr/2013/July/13-civ-755.html>; United States Securities and Exchange Commission Form 8-K, TranS1 Inc., available at: <http://www.sec.gov/Archives/edgar/data/1230355/000119312511272756/d244447d8k.htm>.

³ http://oig.hhs.gov/fraud/cia/agreements/Baxano_Surgical_Inc_06242013.pdf.

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