

South Florida Business Journal - September 19, 2003
</southflorida/stories/2003/09/15/daily52.html>

South Florida BUSINESS JOURNAL

Friday, September 19, 2003

Off-label health care case nets U.S. \$1.5M

South Florida Business Journal

A Fort Lauderdale law firm dedicated to people and entities with evidence of fraud against federal health care programs said it has recovered \$1.5 million for the United States in a whistleblower case against a Huntersville, N.C.-based company named **Orthofix**.

The law firm of Kenneth J. Nolan said Orthofix sells electrical bone growth stimulation products under the trademark name of Physio-Stim. The products, the firm said, are approved by the Food and Drug Administration to heal fractures of long bones, such as an arm or a leg. While the company does make products specifically for the spine, the law firm said the FDA has not approved the electrical bone growth stimulation devices for use on the cervical, or neck region, part of the spine.

The firm did not mention, however, that Orthofix is **seeking FDA approval** to market a product to grow bone at the cervical area of the spine. The status of that application is not known.

"Medical devices and supplies that are prescribed for purposes other than their FDA-approved labeling are known as 'off-label' sales," said Ken Nolan, president of the firm. "I believe this may be the first completed qui tam case alleging violations of federal program requirements due to off-label sales and marketing."

A qui tam action is brought under the False Claims Act by a private plaintiff on behalf of the federal or state government. The suits are also known as whistleblower lawsuits.

In this case, the plaintiff, identified by the firm as Ms. Neel, alleged Orthofix submitted claims to Tricare - the Department of Defense health care program for active duty and retired members of the uniformed services, their families, and survivors - to pay for Physio-Stim devices that were prescribed off-label for treatment of the cervical region of the spine.

Tricare does not pay for the unapproved use of medical devices, the firm said.

The case was filed in June 2000 under the qui tam provisions of the Federal False Claims Act. The provisions provide the private citizens who bring the suit to receive between 15 percent and 30 percent of the total recovery from the defendant.

The United States' recovery of more than \$1.5 million represents about double the amount the Tricare program was allegedly overcharged, the law firm said, adding Neel, the whistleblower, received 18 percent of the judgement, or \$283,500.

All contents of this site © American City Business Journals Inc. All rights reserved.