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Lessons Learned From FCA Settlements With Pharmaceutical and Medical Device Manufacturers



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Although the term ''government contractor'' typically conjures up thoughts of defense, security, or technology firms, pharmaceutical and medical device companies are often solicited by the federal government to supply government agencies, such as the Department of Veterans Affairs (''VA'') and the Centers for Disease Control and Prevention (''CDC''), with medical equipment, supplies, and pharmaceuticals.

In such a role, pharmaceutical and medical device company contractors, like their defense contracting counterparts, are susceptible to liability under the False Claims Act (''FCA''). The FCA prohibits the knowing submission of false claims to the federal government for payment.[1] Uniquely, the FCA, under its qui tam provisions, permits private citizens to bring FCA actions on behalf of the federal government and receive a portion of any recovery.[2]

Although not as active in the pharmaceutical and medical device industries as other industries, the Justice Department and whistleblowers have pursued a number of FCA enforcement actions against such companies over the past year, signaling that no industry is safe from procurement based FCA liability. With the government becoming increasingly focused on FCA enforcement, a review of pharmaceutical and medical device settlements can help other entities avoid a similar fate.

[1] The False Claims Act is codified at 31 U.S.C. § 3729, et seq.

[2] *Id.*

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Ansun Biopharma, Inc. (f/k/a NexBio, Inc.)

- Case involved alleged overbilling to maximize reimbursement under federal grants and contracts.
- $2 million settlement.

On January 7, 2015, Ansun Biopharma, Inc. (''Ansun''), formerly known as NexBio, Inc., agreed to pay $2 million to resolve criminal and civil FCA investigations based on allegations that Ansun overbilled the government by submitting fraudulent bills under several National Institutes of Health (''NIH'') grants and contracts. As part of settlements, the Company admitted that, among other things, the company's Vice President of Finance, at the direction of the Chief Executive Officer, ''fabricate[d] timesheets'' to ''maximize billing'' under various NIH grants and contracts. To resolve the criminal matter, the Company agreed to pay the NIH $1,654,600. Ansun also agreed to pay $495,000 under a separate settlement agreement to resolve civil FCA allegations.[3]

[3] See http://www.fbi.gov/sandiego/press-releases/2015/ansun-biopharma-to-pay-more-than-2-million-for-overbilling-the-u.s.

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Smith & Nephew, Inc.

- First TAA based FCA action against a medical device manufacturer.
- $8.3 million settlement.

On September 4, 2014, Smith & Nephew, Inc., a U.K. based medical device manufacturer, agreed to pay over $8 million to settle a first-of-its-kind whistleblower action based on allegations that the company falsely certified compliance with the Trade Agreements Act (''TAA'').[4] The TAA demands that government contractors with contracts valued over $204,000 comply with various TAA requirements. One such requirement is a certification that only products from specifically ''designated countries,'' those that have entered into Trade Agreements with the United States, are sold to the U.S. government.

In December 2008, Smith & Nephew disclosed to the Office of Inspector General and the VA National Acquisition Center that it sold items to the government from Malaysia, a non-designated country, in a possible violation of the TAA. Subsequently, a former Company employee brought a whistleblower action against the company for intentionally violating the TAA. The court denied the Company's motion to dismiss based on the public disclosure bar, which ultimately pushed the Company to settle. Notably, the whistleblower received $2.8 million of the total settlement.[5]

McKesson Corporation

- Non-compliance with the contract terms led to FCA whistleblower action.
- $18 million settlement.

On August 8, 2014, McKesson Corporation (''McKesson'') agreed to an $18 million settlement to resolve allegations that the company violated the False Claims Act when it failed to adhere to the provisions of a CDC contract. Under a vaccine distribution contract with the CDC, McKesson was required to set electronic temperature monitors to detect whether shipping container temperatures drifted beyond a specified narrow temperature range. According to the whistleblower, McKesson set the monitors to a wider range than permitted under the contract and submitted false claims to the CDC that it satisfied its contractual obligations. McKesson agreed to the settlement despite acknowledgement from the CDC that the company instituted ''redundant measures'' that ensured that the vaccines were transported within the appropriate temperature range even though the monitors were noncompliant.[6]

Stryker Corporation and Alliant Enterprises

- Alleged withholding of pricing information to inflate cost to government.
- $1.05 million settlement.

On March 24, 2014, it was announced that Stryker Corporation (''Stryker'') and Alliant Enterprises (''Alliant'') had entered into a $1.05 million settlement to resolve a qui tam lawsuit alleging that the entities withheld complete pricing information and projected government sales in order to ''avoid heightened scrutiny of a government contract.'' The whistleblower alleged that Stryker and Alliant did not provide to the government complete pricing information during contract negotiations. As a result, the VA, and any other government agencies buying medical supplies under Alliant's Federal Supply Schedule contract, paid elevated prices. Under the settlement, Stryker paid $911,219 and Alliant paid $151,215.[7]

Lessons Learned

The above settlements show the variety of misconduct that can give rise to FCA liability for government contracts in the pharmaceutical and medical device industries. From TAA compliance to contract adherence, it is imperative that all government contractors devote the appropriate resources necessary to ensure effective compliance programs that can limit unwelcome exposure to FCA liability.

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[4] The Trade Agreements Act is 19 U.S.C. §§ 2501, et. seq.

[5] See *United States ex rel. Cox v. Smith & Nephew Inc.*, No. 2:08-cv-02832 (W.D. Tenn., order of dismissal, Sept. 4, 2014).

[6] See http://www.justice.gov/opa/pr/mckesson-corp-pay-18-million-resolve-false-claims-allegations-related-shipping-services.

[7] *See* DOJ release at http://www.justice.gov/usao/cac/Pressroom/2014/032a.html.

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