JULY 2014

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An eye on whistleblowers, false claims and compliance

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Move over Big Pharma: Health care is not the only industry susceptible to False Claims Act scrutiny

By Andrea P. Brockway and Gina M. Russoniello

IN BRIEF

• In contrast to the recent, public and record-breaking False Claims Act settlements with Big Pharma, the government's intervention in a relator's suit against a computer software company, alleging that the contractor overcharged agencies by at least \$100 million since 2006, should be a warning to other industries – the classic FCA suit is still as effective as ever in recovering against fraudulent billing based on a contract for services.

The Contract

The company (formerly known as Computer Associates International, Inc. or CA, Inc.) ("CA") had contracted with the U.S. General Services Administration ("GSA") to provide software licenses, software maintenance, and consulting services to executive agencies including the Department of Defense; Department of Energy; Department of Health and Human Services; Department of Treasury; Department of Labor; and Department of Veterans Affairs. The GSA negotiated the contract terms, which included maximum prices and price monitoring mechanisms to ensure that the government receives prices and discounts at the same rate as commercial customers. The GSA signed an agreement with CA (the "2002 Multiple Award Contract") in which CA promised to provide the government with prices and discounts that were the same as, or lower than, those given to commercial customers. Pursuant to the 2002 Multiple Award Contract, discounts and pricing were to be disclosed so that GSA could negotiate the best prices for its customer agencies. In a "Price Reductions Clause," GSA promised to provide quarterly updates and adjustments if necessary.

The Allegations

Dani Shemesh, the "relator" who filed the lawsuit and former head of sales at CA Software Israel, a wholly owned subdivision of CA, alleged that while CA gave the government discounts ranging from 35 percent

to 55 percent off CA's list prices for software licenses and 10 percent to 15 percent off of prices for maintenance, the company offered commercial customers discounts that exceeded 90 percent off of list prices.

The U.S. government recently joined and assumed primary responsibility for the lawsuit, which has the practical effect of bolstering Shemesh's case. The government's complaint alleges that CA violated the FCA and harmed the government with its "defective pricing" through making false statements during negotiations for contract extensions in 2007 and 2009; making false statements during the contract's performance; failing to comply with the contract's Price Reductions Clause; and overcharging the government generally by at least \$100 million since 2006.

According to the complaint, the government, in deciding to extend the contract, relied on false statements that CA knowingly made. The complaint alleges that "[b]ecause CA fraudulently induced the United States to enter into the [c]ontract extensions, each claim for payment made by CA under those extensions was a false claim," and "[b]ecause CA overcharged the United States, its claims were also false each time the ordering agency received a discount that was less

than it would have received had CA made accurate, complete, and current disclosures regarding its commercial pricing." (emphasis added). The complaint seeks three times the amount of damages from CA, along with penalties of up to \$11,000 for each violation.

Takeaways

Since its first iteration, signed into law by President Abraham Lincoln, the FCA has been an effective tool in combating against, and recovering for, fraud on the government. By intervening in this case, the Department of Justice is going back to these roots. The allegations raised by the government demonstrate the classic contract for services and fraudulent billing formula. The most famous and largest cases during the last decade have all been in health care. This case reminds us that all government vendors have exposure. No company or government vendor, regardless of market sector, should consider itself immune to the civil and criminal penalties of the FCA. Companies should understand that defrauding the government can occur based on active missteps as well as failures to provide pricing or discounts that match the discounts given to non-governmental customers. Importantly, no specific intent is required for a company to be found liable for fraud.

Third Circuit affirms dismissal of False Claims Act suit, citing contract ambiguity

By Jennifer A. DeRose

Ambiguous contract terms are ordinarily a liability for government contractors, opening the possibility of misunderstandings, expensive disputes, and, potentially, unpaid additional work. However, contract ambiguity recently came to the aid of a federal contractor accused of False Claims Act ("FCA") violations. The U.S. Court of Appeals for the Third Circuit upheld dismissal of a suit alleging FCA violations by a contractor for the Pennsylvania Department of Transportation, holding that internally contradictory and vague contract language defeated the possibility of a jury finding of requisite intent for an FCA violation.

The qui tam plaintiff, August W. Arnold, alleged in his complaint that CMC Engineering Inc. overcharged PennDOT for the services of inspectors who worked on federally-funded highway projects. Arnold, a former PennDOT assistant construction engineer, helped oversee selection of private engineering firms for PennDOT. In his complaint, Arnold contended that CMC knowingly misrepresented the qualifications of its inspectors to trigger higher pay rates than were appropriate given the inspectors' actual qualifications.

Having reviewed the language of PennDOT's contracts with CMC, the court concluded that the contracts contained several mutually contradictory pay-rate schedules. The court noted that the contracts were also ambiguous in allowing "any equivalent combination of experience or training" as a substitute for at least some qualifications. PennDOT employees testified

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that this created "a big gray area" and that the contracts' terms were "open to interpretation." To violate the FCA, a defendant must have "knowingly" made a false claim or false certification. In this instance, the court held, a reasonable jury could not find CMC to have knowingly misrepresented the

inspectors' qualifications, given the uncertainty about what qualifications were really required for various pay rates. In short, where a defendant and a relator reasonably disagree about how to interpret ambiguous contract language, there may be ground for dismissal of an FCA claim.

False claims by any other name: Medtronic and Omnicare cases illustrate the interplay between the False Claims Act and other federal laws regulating commerce with Medicare and Medicaid

By Brian P. Simons

IN BRIEF

- Government allegations of Medtronic's alleged incentives to physicians for prescribing its medical devices lead company, while denying wrongdoing, to settle False Claims Act suit predicated on Anti-Kickback Statute.
- Omnicare, meanwhile, faces a potential appeal to the Supreme Court in a False Claims Act suit premised on the Food, Drug, and Cosmetic Act.

Medtronic, Inc. has agreed to pay \$9.9 million to the U.S. government to bring a False Claims Act ("FCA") suit focused on eight years' worth of alleged illegal kickbacks to a close, and Omnicare, Inc. awaits the Supreme Court's decision on a petition for *certiorari* in a whistleblower case with the potential to render goods or services that violate regulations "false or misleading" under the FCA when paid for by the federal government.

Medtronic

In its civil suit against Medtronic, *United States ex rel. Schroeder v. Medtronic, Inc.*, No. 2:09-cv-0279 WBS EJB (E.D. Cal.), the government alleged that Medtronic influenced physicians to prescribe its brand of pacemakers and implantable defibrillators by paying physicians to speak at events in exchange for their referral business, by providing implanting physicians with free marketing plans and gifts including wine and alcohol, trips to strip clubs, and sporting event tickets. These pacemakers and defibrillators were then billed to Medicare and Medicaid. The suit describes a plan to instruct sales representatives to "review patient charts in friendly doctor's offices" and to suggest which patients should receive an implant. The lawsuit further alleged that physicians

were influenced to implant devices into patients whose mild heart conditions did not warrant such procedures under applicable Food and Drug Administration ("FDA") criteria.

The Department of Justice press release quotes Assistant Attorney General Stuart F. Delery of the Justice Department's Civil Division, saying, "This case demonstrates the Department of Justice's commitment to pursue medical device manufacturers that use improper financial relationships to influence physician decision-making."

While paying out a hefty sum under the terms of the settlement agreement, Medtronic expressly denies any wrongdoing. The lawsuit itself originated with a complaint filed under the *qui tam* provisions of the FCA by whistleblower Adolfo Schroeder, a former Medtronic employee. Approximately \$1.73 million will flow to Schroeder as a result of the settlement. The Department of Justice Civil Division, the U.S. Attorney's Office for the Eastern District of California, and the Office of Inspector General of the U.S. Department of Health and Human Services all collaborated on the settlement.

This case highlights the civil ramifications of the Anti-Kickback Statute ("AKS"), which itself is a criminal statute. In 2010,

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the FCA, 31 U.S.C. §§ 3729-33, was amended to make clear that claims submitted to the government in violation of the Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b), automatically constitute violations of the FCA. The AKS makes criminal the offer (and receipt) of remuneration in exchange for referring patients to receive certain government-funded services. Thus, any allegation of kickbacks may lead to criminal and civil action.

In Schroeder, the allegation of kickbacks was sufficient to permit the government to proceed under the FCA without the need to plead a false or misleading statement regarding goods or services provided. Non-kickback cases with no showing of fraud do not fare as well - though one case pending before the Supreme Court seeks to challenge that.

Omnicare

In February 2014, we brought you the story of a whistleblower who appealed the dismissal of his suit to the U.S. Circuit Court of Appeals for the Fourth Circuit, which affirmed the

dismissal, in U.S. ex rel Rostholder v. Omnicare, Inc., 745 F.3d 694 (4th Cir. 2014). There, qui tam relator Barry Rostholder had alleged that products sold by Omnicare and reimbursed by Medicare and Medicaid violated the FCA because they were "adulterated" within the meaning of the Food, Drug, and Cosmetic Act. The appellate court reasoned that "the submission of a reimbursement request for lan approved drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations." The court had rejected the reasoning that inferior quality in and of itself can be "misleading" under the FCA.

Rostholder seeks to challenge that determination, and filed a petition for certiorari on May 22, 2014. If the Court overturns the decision below, the result could have wide-reaching ramifications. Not only will it open the door nationwide to civil liability under the FCA for sale of goods and services to the government that violate any applicable regulation, but it may incite a wave of qui tam litigation that seeks to test the boundaries of a newly-interpreted FCA.

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