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False Claims Act 2017 report card: $2.4 billion recovered

By Joan W. Feldman

Joan W. Feldman (jfeldman@goodwin.com) is a Partner and Health Law Group Practice Chair at Shipman & Goodwin, LLP in Hartford, CT.

On December 21, 2017, the Department of Justice (DOJ) issued its yearly report card describing its most noteworthy settlements in fiscal year 2017 with healthcare providers under the False Claims Act (FCA).[1] In addition to praising the efforts of its dedicated enforcement staff, the DOJ sent a message of both acknowledgment and encouragement to the whistleblowers who bring alleged FCA violations to its attention. It makes good sense for the DOJ to use this annual report card as a form of encouragement for those among us who believe in reporting blatant wrongdoing. Unfortunately, this message is sometimes received by bounty hunters, sometimes entirely motivated by retribution or greed, who are tempted to see wrong when there is no wrong. Nevertheless, there is plenty to learn from these significant settlements, and it never gets old reading about those in positions of power who abuse the public's trust and do the indefensible out of greed. Indeed, the cases that were featured were stunningly egregious and involved sophisticated healthcare companies.

Risks and consequences

One has to wonder why executives would risk so much. Perhaps this risk-taking behavior and the consequences are viewed by some as the cost of doing business, but for the rest of us who believe in complying with the law, the following cases are noteworthy.

Shire Pharmaceuticals LLC — $350 million

As a result of a qui tam action brought by six whistleblowers,[2] Shire Pharmaceuticals LLC and other Shire subsidiaries (Shire) paid $350 million to resolve FCA allegations that it was providing kickbacks and engaging in other unlawful methods of marketing its product Dermagraft, a bioengineered human skin substitute approved by the FDA for use in the treatment of diabetic foot ulcers. The whistleblowers alleged, among other things, that Dermagraft salespersons unlawfully induced the use of Dermagraft by incentivizing physicians with extravagant dinners, entertainment, and travel; medical equipment and supplies; unjustified payments for speaking engagements and bogus case studies; and cash gifts, rebates, and credits. Shire was also accused of marketing Dermagraft for uses not approved by the FDA. Shire sold the assets associated with Dermagraft in early 2014. Since late 2014, Shire has been operating under a Corporate Integrity Agreement with the U.S. Department of Health and Human Services that is related to the settlement of separate FCA allegations. The Office of the Inspector General (OIG) will continue to monitor Shire's compliance with federal healthcare laws through its oversight of this agreement.

Mylan Inc. — $465 million

Mylan Inc. and Mylan Specialty LP (collectively, Mylan) agreed to pay $465 million to resolve claims that they violated the FCA by knowingly misclassifying EpiPen as a generic drug to avoid paying higher rebates to Medicaid.[3] The rebate program was enacted by Congress to protect Medicaid programs from price gouging

relating to drugs available only through a single source. Brand-name drugs are subject to a higher rebate; whereas generic drugs, available from multiple manufacturers, are subject to a lower rebate. By misclassifying the drug as generic, Mylan paid only a 13% rebate to Medicaid while increasing the price of EpiPen by 400%. Sanofi-Aventis was the whistleblower and received approximately $38 million of the federal recovery. Mylan also entered into a five-year Corporate Integrity Agreement.

eClinicalWorks — $155 million

eClinicalWorks paid $155 million to resolve FCA allegations that it falsely obtained certification for its electronic health record (EHR) software when it concealed from an independent certifying entity that its software did not fully comply with all of the certification requirements.[4] Specifically, eClinicalWorks complied with coding requirements for only the drugs needed for certification testing, despite the requirement that all drugs be coded for certification. The eClinicalWorks software also failed to satisfy data portability requirements intended to permit healthcare providers to transfer patient data from its software to other vendors. This false certification resulted in false claims being submitted for Meaningful Use incentive payments by users of the software. A five-year Corporate Integrity Agreement was required with stiff requirements relating to customer usage of the software. The case was the result of a qui tam action brought by a software technician who received approximately $30 million of the federal recovery.

Life Care Centers of America, Inc. — $145 million

Life Care Centers of America, Inc. (Life Care) agreed to pay $145 million to resolve FCA allegations that it knowingly caused its more than 220 skilled nursing facilities to submit false claims for rehabilitation services that were not reasonable, necessary, or skilled.[5] Specifically, the government alleged that Life Care falsely submitted higher levels of care than its patients needed in order to receive higher reimbursement and kept patients at the facility longer than needed, so the rehabilitation services could continue to be billed. Life Care was required to enter into a five-year Corporate Integrity Agreement. The case was brought to the attention of the government by two former Life Care employees who shared $29 million of the federal government's recovery.

Freedom Health, Inc. and former COO — $32.5 million

Freedom Health, Inc., a Medicare Advantage plan, its related corporate entities, and former chief operating officer (COO) collectively paid $32.5 million to resolve FCA allegations that they submitted unsupported diagnosis codes to CMS, which resulted in a higher level of reimbursement.[6] It was also alleged that the plan made material misrepresentations regarding the scope and content of its network of physicians, specialists, and hospitals. The case was brought to the attention of the federal government by a former employee.

Pain management physician — $20 million

A pain management physician agreed to pay $20 million to resolve FCA allegations that he falsely billed federal healthcare programs by billing for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests.[7] Specifically, the federal government claimed that the physician billed for monitoring the neurological health of patients during surgery when he had a medical assistant doing the monitoring. The government further alleged that the physician billed for medically unnecessary balance tests, nerve conduction and electromyography procedures, and qualitative drug screens. The case was brought to the government's attention by three whistleblowers. In addition to the payment, the physician was sentenced to three years and two months in prison.

Medically unnecessary services — $18 million

A physician paid more than $18 million to resolve FCA allegations that he submitted claims for medically unnecessary biopsies and radiation therapy services, and radiation therapy services performed too frequently in contravention of medical standards. The government proved that more than 50% of the payments the physician received from Medicare were for services provided on days when he was not present in the clinic. The government also proved that the physician knew that a medical physicist had not performed the physicist services he had billed to Medicare. The case was brought to the attention of the government by a physician whistleblower.[8]

Cardiac monitoring companies — $13.45 million

AMI Monitoring Inc. (aka Spectocor); its owner, Joseph Bogdan Medi-Lynx Cardiac Monitoring LLC, and Medicalgorithmics, SA agreed to pay $13.45 million to resolve FCA allegations. The government alleged that the cardiac monitoring companies marketed a pocket ECG that provided three levels of cardiac monitoring services and consistently steered physicians to the more costly monitoring service, even though it was not medically necessary. The case was brought to the attention of the federal government by a former salesperson of Spectocor, who will share approximately $2.4 million of the federal government's recovery.[9]

MedStar Ambulance Inc. — $12.7 million

MedStar Ambulance Inc. agreed to pay $12.7 million to resolve FCA allegations that it routinely billed for transportation services that were not medically necessary and billed for higher levels of services than required by the patients' conditions, or services that were not actually provided. The case was brought by a former billing office employee who will share approximately $3.5 million of the federal government's recovery.[10]

Urologist practicing at Gulfstream Urology — $3.8 million

After 21st Century Oncology LLC paid $19.75 million to settle FCA claims in 2015,[11] a urologist practicing at Gulfstream Urology, which was a division of 21st Century Oncology, LLC, became the subject of FCA allegations. The urologist has agreed to pay more than $3.8 million to resolve FCA allegations that he ordered medically unnecessary tests performed on urine to detect genetic abnormalities associated with bladder cancer.[12] Medicare does not cover the test unless it is ordered after a full urologic workup or there is reason to suspect a recurrence of cancer in a patient previously diagnosed with cancer. The urologist was the number one ordering physician in the country for this test and received $2 million in bonus payments for ordering the tests. The case was brought to the attention of the federal government through a qui tam action. The physician entered into a three-year Integrity Agreement with the OIG.