Expert Analysis

Current Trends in False Claims Act Enforcement in Health Care

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Combating health care fraud has been a top priority of the Obama administration since announcing formation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) in May 2009 — and the False Claims Act has served as the federal government’s most powerful civil enforcement tool.

In the three years since the HEAT initiative began, the Department of Justice has used the FCA to recover more than $6.6 billion in federal health care dollars, which is “more recovered under the act than in any other three-year period” and amounts to a $7 recovery for every dollar spent on enforcement activities.

In 2011 alone, the DOJ recovered $2.8 billion in settlements and judgments under the FCA’s qui tam provisions, which permit whistle-blowers to file suits on behalf of the government and to share in the recovery. The bulk of those recoveries ($2.4 billion) came from cases alleging health care fraud, the most common cases involving allegations of off-label marketing, illegal kickbacks and fraudulent billing practices.

Over the same period, the DOJ and U.S. attorneys’ offices “opened more than 1,100 new criminal health care fraud investigations,” “had more than 1,800 health care fraud criminal investigations pending” and “reached an ‘all-time high’ in the number of health care fraud defendants charged — more than 1,400 in nearly 500 cases.”

Reports from the first four months of 2012 demonstrate that the trends of 2011 — historically high settlements, increased civil and criminal enforcement activity, and expanding areas of FCA liability — show no signs of abating. Indeed, almost $3 billion in health-care-related FCA judgments and settlements have already been reported as of May, with at least one FCA commentator predicting that an additional $6 billion in FCA settlements will be announced later this year, due in large part to several anticipated health care industry settlements that are expected to tally in at $1 billion or more each.
FEDERAL STATUTORY FRAMEWORK

FCA overview and background

The False Claims Act, 31 U.S.C. § 3729, also known as the “Lincoln Law,” was adopted during the Civil War to combat fraud against the government related to procurements by the Union Army. The FCA imposes treble damages and civil penalties on any person or corporation that “knowingly presents, or causes to be presented, a false or fraudulent claim for payment” to the federal government. The FCA’s scope is remarkably broad — especially in recent years — and any company that does business with the government, even indirectly, could face FCA liability.

Companies violate the FCA when they knowingly misrepresent the nature of goods or services that they provide to the government, and that misrepresentation causes the government to make payment. “Reverse” false-claims liability occurs when a company improperly conceals, avoids or decreases an obligation to pay the government. Companies can also be liable for conspiring to present false claims to the government or causing third parties to submit false claims.

Much of the FCA’s power comes from its qui tam provisions, which permit private “whistle-blowers” (called relators) to bring claims under the FCA on behalf of the government and to recover between 15 percent and 30 percent of any judgment or settlement in the government’s favor for doing so successfully. The qui tam provisions are particularly helpful to the government because they enable the case to remain under seal while the DOJ investigates the claim.

Since the qui tam provisions were strengthened in 1986 to provide relators with a greater share of recoveries, the U.S. government has reportedly recovered $30.3 billion under the FCA, with $3.03 billion recovered in 2011 alone, just less than the $3.09 recovered in 2010. In addition, the DOJ has reported that of the 762 new FCA cases initiated in 2011, the number of whistle-blower-initiated lawsuits increased significantly, rising from between 300 and 400 cases per year to 638. This number constitutes 84 percent of the total FCA cases filed last year and is more than in any other prior year on record.

PPACA amendments

In 2010, the Patient Protection and Affordable Care Act amended the FCA to provide additional incentives for whistle-blowers to report health care fraud and strengthened the provisions of the federal Anti-Kickback Statute. In particular, the Affordable Care Act amended the FCA to specifically provide that a violation of the Anti-Kickback Statute causes all “claims” for payment to the government related thereto to be false under the FCA.

Although this amendment is not expressly retroactive, the 1st U.S. Circuit Court of Appeals held in 2011 that compliance with the Anti-Kickback Statute is a precondition of payment of Medicare claims. The court also said a violation of the kickback law can cause factually true claims to be false and form the basis for liability under the FCA — regardless of whether the providers expressly certified compliance with the Anti-Kickback Statute.

The FCA’s public disclosure bar prevents relators from profiting from disclosures of fraud that have already been exposed and have reached the public domain.
But the Affordable Care Act amended the FCA’s public disclosure bar to make it easier for relators to argue that they are the “original source” for false-claims allegations against companies.

The Affordable Care Act also amended the FCA to make it clear that Medicare and Medicaid overpayments must be reported and returned within 60 days after discovery or the date a corresponding hospital report is due. A health care provider’s failure to timely report and return an overpayment exposes the provider to liability under the FCA.

**SIGNIFICANT DEVELOPMENTS IN FCA ENFORCEMENT**

*Continued push toward ‘implied certification’ theory of liability*

Federal courts have struggled with the scope of FCA liability where the actual claim submitted to the government is not “factually false.” Some courts have adopted a theory of liability in which facially accurate claims are considered “legally false” where the submitter failed to comply with an applicable statutory, regulatory or contractual obligation. Liability attaches even if the submitter never expressly certified that it did comply with these obligations. This so-called “implied certification” theory of liability is particularly hazardous for heavily regulated industries like health care and financial services. Companies in these industries face the prospect of any regulatory infraction — even where no express certification accompanied the particular claim — potentially giving rise to FCA liability.

Various circuit courts have discussed implied-certification liability in the health care context. In an early case, the 2nd Circuit addressed implied certification in the context of alleged violations of the FCA by defendant physicians who submitted claims to Medicare for reimbursement of spirometry procedures that purportedly did not comply with the standard of care. The 2nd Circuit held that “implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.” *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001).

*Qui tam* relators and the DOJ continue to push implied-certification liability in cases against health care industry defendants, even when compliance is not an express prerequisite for payment, arguing that all claims for payment submitted to the government carry an “implied certification” of regulatory compliance. Supporters of this broader application got a boost from the 1st Circuit in 2011 in two health care cases.

In *United States ex rel. Hutcheson v. Blackstone Medical*, 647 F.3d 377 (1st Cir. June 1, 2011), the appeals court reversed the dismissal of an FCA case premised on the defendant manufacturer’s violations of the Anti-Kickback Statute. The relator, a former regional sales manager for medical device manufacturer Blackstone Medical, alleged that the company had caused hospitals and physicians to submit false claims to Medicare in violation of the FCA because it had engaged in a nationwide kickback scheme to induce physicians to use its medical devices in spinal surgeries, which constituted a violation of the Anti-Kickback Statute. *Blackstone*, 647 F.3d at 378-379. Since there had been no showing that compliance with kickback law was an express condition of payment, a Massachusetts federal
judge dismissed the relator’s claims on the grounds that the complaint failed to identify any materially false claims for payment. Id. at 379.

On appeal, the 1st Circuit rejected the “judicially created categories” of express or implied certification, positing that such categories “sometimes can help carry out a statute’s requirements, but they can also create artificial barriers that obscure and distort those requirements.” Blackstone, 647 F.3d at 385. “The text of the FCA does not refer to ‘factually false’ or ‘legally false’ claims, nor does it refer to ‘express certification’ or ‘implied certification.’ Indeed, it does not refer to ‘certification’ at all.” Id.

Instead, “in enacting the FCA, ‘Congress wrote expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the government.’” Id. at 392. According to the 1st Circuit, compliance with the Anti-Kickback Statute is an “implied condition of payment,” and the submission of a claim is a representation that such condition has been met; and, where there has been a violation of the Anti-Kickback Statute, the representation of compliance with the statute — through the submission of a claim for reimbursement — is false. Id. at 392-395.

The 1st Circuit came to a similar conclusion in New York ex rel. Westmoreland v. Amgen Inc. et al., 652 F.3d 103 (1st Cir. July 22, 2011), where it again reversed the dismissal of FCA claims premised upon violations of the Anti-Kickback Statute. Similar to the allegations in Blackstone, the relator alleged that pharmaceutical manufacturer Amgen and two other corporate defendants violated the state false-claims laws of California, Georgia, Illinois, Indiana, Massachusetts, New Mexico and New York by engaging in a kickback scheme to induce Medicaid providers to prescribe the anemia drug Aranesp. The relator argued that the alleged kickbacks violated the Anti-Kickback Statute prohibitions, thereby rendering all of the related Medicaid reimbursement claims false under the state false-claims laws. Id.

Applying similar reasoning as the lower court in Blackstone, the district court in Amgen dismissed the action on the grounds that the relator had failed to allege any materially false claims for payment. Id. at 105-108. On appeal, the 1st Circuit again reversed that finding. The court held that although it is “fact-intensive and context-specific inquiry;” to be false, the claims need only misrepresent “compliance with a material precondition of Medicaid payment such that they were false or fraudulent.” Id. at 110-111.

In December 2011, the U.S. Supreme Court declined to grant certiorari in the Amgen case in order to resolve what Amgen argued in its petition has become “a dizzying array of different tests [applied by the circuits] in deciding whether claims like this qualify as ‘false or fraudulent’ within the meaning of the FCA.”

**Drug maker challenges ‘off-label’ marketing prohibitions**

In light of the widespread FCA prosecution of alleged “off-label” marketing by drug companies, last year one drug manufacturer decided to take the government head-on.

On Oct. 14 Par Pharmaceutical filed suit in the U.S. District Court for the District of Columbia against the United States, the Food and Drug Administration, the FDA commissioner, and the secretary of the Department of Health and Human Services,
seeking a declaratory judgment that the application of FDA off-label marketing regulations to Par’s marketing of Megace ES violates its First Amendment rights to free speech. Off-label refers to uses that have not been approved by the FDA.

The case, *Par Pharmaceuticals v. United States et al.*, No. 11-cv-01820, complaint filed (D.D.C. Oct. 14, 2011), is being closely watched by both the legal profession and the health care industry, due in large part to the DOJ’s aggressive FCA actions in recent years against drug makers for violating the off-label restrictions.

Par alleges that the FDA’s “intended use” regulations of 21 C.F.R. §§ 201.100 and 201.128 unlawfully prevent it from engaging in truthful speech regarding approved uses of Megace ES, which is approved for treating loss of appetite, malnutrition and weight loss in patients with AIDS, called “AIDS-related wasting.”

Par argues that, while the drug is prescribed for AIDS-related wasting, the majority of the prescriptions are for off-label uses, frequently for geriatric and cancer patients, uses that physicians are legally allowed to prescribe the drug for. Par alleges that the FDA regulations essentially create a Catch-22 for drugmakers, which are ostensibly not allowed to “market” drugs in settings where they know that physicians may prescribe it for off-label uses.

In such settings, the manufacturer would be required to provide “adequate directions” on the labeling for the off-label use, which is not allowed since only information regarding FDA-approved uses may be on the labeling. “Changing the drug’s labeling to add directions for the off-label use violates the act’s criminal ‘new drug’ rule, but based on the government’s view of the FDA’s ‘intended use’ regulations, not changing the labeling to add those directions violates the act’s ‘misbranding’ rule.”

Par contends this Catch-22 prevents it from marketing Megace ES for on-label uses in long-term-care and oncology settings where Par knows that physicians may prescribe it for off-label uses and that: “The ongoing threat of prosecution for alleged ‘off-label promotion’ based on Par’s truthful and non-misleading speech to health care professionals concerning the FDA-approved use of Par’s FDA-approved prescription drug currently chills Par’s speech.”

On May 1 the parties jointly requested a 60-day stay of the litigation in order to engage in settlement discussions. In the motion for stay, the parties acknowledged that that the government has been investigating Par since 2008 “relating to the drug product Megace ES to determine, among other things, whether Par committed any violations of the Federal Food, Drug, and Cosmetic Act ... and/or caused false claims to be submitted to federal health care programs in violation of the False Claims Act.” The motion said the parties have been engaged in “global discussions to resolve all pending litigation and investigations” since December 2010. The stay will expire July 1 if a global resolution is not reached.

**RECENT SETTLEMENTS AND JUDGMENTS**

Of the more than $3 billion in FCA settlements in 2011, $2.4 billion (80 percent) was from the health care industry. 2011 saw big settlements in the pharmaceutical industry, and this trend has continued in 2012.
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<tr>
<th>Company/Date</th>
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<td>Abbott Laboratories (May 7)</td>
<td>$1.5 billion</td>
<td>Agreed to pay $1.5 billion to the U.S. government and several states to resolve unlawful promotion of the prescription anti-seizure drug Depakote for uses not approved as safe and effective by the FDA. The $1.5 billion—the second largest payment by a drug company ever—consists of a criminal fine and forfeiture totaling $700 million and civil FCA settlements with the federal government and various states totaling $800 million.</td>
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<td>Johnson &amp; Johnson, Janssen Pharmaceutica (April 11)</td>
<td>$1.2 billion</td>
<td>Ordered by an Arkansas court to pay $1.2 billion after a jury found that Johnson &amp; Johnson and its subsidiary Janssen Pharmaceutica minimized the dangers associated with the antipsychotic drug Risperdal. The company has also reportedly agreed to pay $1 billion to the U.S. government and various states to resolve related civil and criminal claims, although no final settlement has yet been announced.</td>
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<td>Actavis Group (Jan. 6)</td>
<td>$202 million</td>
<td>Agreed to pay $202 million to resolve claims that it had falsely reported inflated prices of drugs, causing the U.S. and five state governments to overpay for drugs. The settlement came after Actavis lost at trial last year and was ordered by a Texas jury to pay $170 million for inflating billings to the Texas Medicaid program.</td>
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<td>McKesson Corp. (April 26)</td>
<td>$190 million</td>
<td>Agreed to pay more than $190 million to the U.S. government to resolve claims that it knowingly reported inflated pricing information for a large number of prescription drugs, causing Medicaid to overpay for those drugs.</td>
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<td>Odyssey HealthCare (March 1)</td>
<td>$25 million</td>
<td>Agreed to pay $25 million to resolve claims arising from its billing of claims for hospice services. The settlement resolved several <em>qui tam</em> cases filed by former employees, one of whom was the former executive director of an Odyssey hospice. The whistle-blowers will receive payments totaling more than $4.6 million as a result of the settlement.</td>
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<td>AmMed Direct (April 13)</td>
<td>$18 million</td>
<td>Agreed to pay $18 million to the U.S. government and Tennessee in order to resolve claims that it had engaged in unlawful marketing and solicitation efforts concerning sales of its diabetes testing supplies, vacuum erection devices and heating pads to Medicare and Tennessee Medicaid beneficiaries from 2008 until 2010 and had wrongly failed to refund money to Medicare and Tennessee Medicaid from 2006 until 2010.</td>
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<td>Walgreens (April 20)</td>
<td>$7.9 million</td>
<td>Agreed to pay $7.9 million to the U.S. government and participating states to resolve claims that it offered illegal inducements to beneficiaries of government health care programs, including Medicare, Medicaid, TRICARE and the Federal Employees Health Benefits Program, in the form of gift cards, gift checks and other similar promotions that are prohibited by law, to transfer their prescriptions to Walgreens pharmacies.</td>
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<td>Health Medical Center (Jan. 5)</td>
<td>$6.3 million</td>
<td>Agreed to pay $6.3 million to the U.S. government and the state of Colorado to settle allegations that it had overbilled Medicare and Medicaid by misclassifying patients for hospital admissions. Its former auditor was the whistle-blower.</td>
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In January a Johnson & Johnson subsidiary paid $158 million to settle claims that it defrauded Texas’ Medicaid program by promoting the anti-psychotic Risperdal for off-label uses.

In May the DOJ announced that global health care company Abbott Laboratories agreed to pay $1.5 billion to the U.S. government and several states to resolve criminal and civil liability arising from the company’s promotion of the prescription anti-seizure drug Depakote for off-label uses.

While the bulk of 2011 and 2012 settlements were recovered from pharmaceutical companies, other types of health-care-related defendants included medical device manufacturers, medical product manufacturers, distributors and suppliers, home health care providers, medical centers and insurers.

NOTES


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