The False Claims Act: The Impact in 2012
Part II in a Continuing Series on Health Care Enforcement

BY HOPE S. FOSTER, TRACY A. MINER, AND BRIAN P. DUNPHY

This second part in our ongoing series reviewing health care fraud enforcement activities in 2011,[i/] and monitoring enforcement in 2012, expands upon our prior discussion in part one (Part One Report) of the federal False Claims Act (FCA)—the government's primary and most powerful civil health care fraud enforcement tool. The FCA has been used with substantial success in past years to recover funds paid by the government allegedly for (1) services billed but not provided; (2) services provided but not billed in accordance with statutory or regulatory requirements, or administrative guidelines; and (3) services provided and accurately billed but not provided in compliance with an underlying statutory, regulatory, or contractual obligation. In 2011, this trend continued and accelerated.

Much of the FCA's power comes from its *qui tam* provisions, which permit private relators (often called "whistleblowers") to bring claims under the FCA on behalf of the government and which reward them financially for doing so successfully. The Department of Justice (DOJ) reported recovering $2.8 billion in settlements and judgments under the FCA's *qui tam* provisions last year. By far the largest portion of the 2011 settlement amounts—$2.4 billion—related to federal health care programs. In addition, the DOJ reported that the number of *qui tam* lawsuits in 2011 increased significantly—rising from between 300 and 400 cases per year to 638.[ii/]

Emphasizing the strength of the FCA as a fraud-fighting tool, on January 31, 2012, the DOJ held an event commemorating the twenty-fifth anniversary of the 1986 amendments to the FCA, which, among other things, strengthened the law's *qui tam* provisions.[iii/] Attorney General Eric Holder used the occasion to publicize the government's staggering FCA recoveries and the role of relators in obtaining such recoveries: "Over the last quarter century, the Department of Justice has recovered more than $30 billion under the False Claims Act. Whistleblowers have filed nearly 8,000 actions—including a record high of 638 in the past year alone."[iv/] Tony West, Assistant Attorney General for DOJ's Civil Division, also commented on both the increasing recoveries under the FCA and the government's growing focus on health care: "nearly 30% of that staggering amount—$8.8 billion—has been recovered since January 2009, with $6.6 billion of that accounting for health care fraud recoveries."[v/]

While the statistics are indeed staggering, behind the numbers, several trends emerged in 2011. We anticipate that these trends will continue into 2012.

Whistleblowers Continue to Bring the Vast Majority of FCA Cases

Most FCA cases are brought by *qui tam* whistleblowers. Available estimates suggest that more than 80% of FCA cases are filed by whistleblowers.[vi/] Whistleblowers share in a portion of the recovery, which can be lucrative. During FY 2011, according to the Health Care Fraud and Abuse Control Program's Annual Report, relators received payments in an amount exceeding $419 million.[vii/] Given these rewards, there are powerful incentives to bring these cases. Thus, the number of FCA cases filed by whistleblowers will likely continue to increase. In a recent example announced on March 1, 2012, the DOJ disclosed that Odyssey HealthCare had agreed to pay $25 million to resolve FCA claims arising from its billing of claims for hospice services.[viii/] The settlement resolved several *qui tam* cases filed by former employees, one of whom was the former executive director of an Odyssey hospice. The whistleblowers will receive payments totaling more than $4.6 million as a result of the settlement.

In addition to large recoveries, there has been a notable trend in the identity of whistleblowers filing FCA suits. Both insiders with oversight responsibilities, such as compliance officers and auditors, and even competitors, have filed *qui tam* whistleblower cases. For example, in a recent case in the Massachusetts Federal District Court, the whistleblower was Robert Cunningham, a compliance officer of the defendant's competitor.[ix/] In January 2012, Denver Health Medical Center paid $6.3 million to settle allegations that it had overbilled Medicare and Medicaid by misclassifying patients for hospital admissions. Its former auditor was the whistleblower.[x/]

Increased Cooperation Between Federal and State Agencies

Combating health care fraud is a federal "cabinet-level priority," and collaboration among federal agencies and between federal and state agencies has increased as a result.[xi/] Although focused mainly on criminal enforcement, through both the Health Care Fraud Prevention and Enforcement Action Team (HEAT) and the Medicare Fraud Strike Force (Strike Force), divisions of DOJ, Health and Human Services (HHS), U.S. Attorneys' Offices, and state law enforcement agencies, including state Medicaid Fraud Control Units, have worked together to open numerous health care fraud investigations. As a result of these collaborations, as well as recent partnerships on large, multi-year/multi-state pharmaceutical cases, the foundation has been laid for future federal-state coordinated enforcement actions.

Through these partnerships, and new state FCAs (which are often similar to the federal FCA), federal and state enforcement authorities are increasingly working together and are using the same cooperative models that have been utilized in federal investigations to bring FCA claims at the state level for alleged fraud against Medicaid. "The fact that federal and state attorneys and investigators working in individual states now know and trust each other as a result of their cooperative efforts in national cases has translated into collaboration on joint in-state investigations and has significantly increased the number of Medicare and Medicaid fraud cases pursued at both the state and federal level" said Ellyn Sternfield, the former Director of the Oregon Medicaid Fraud Control Unit and co-chair of the National Association of Medicaid Fraud Control Units' Global Case Committee. Ms. Sternfield is now working as Of Counsel to Mintz Levin's Health Care Practice Group and is a member of the firm's Health Care Enforcement Defense Group.

An example of this emerging federal/state collaboration can be seen in a state Medicaid *qui tam* case in Georgia involving Innovative Resources Group, LLC, doing business as APS Healthcare Midwest (APS). APS recently agreed to a $13 million settlement with the State of Georgia and the United States to resolve FCA allegations which arose from a contract that APS had entered into with the Georgia Medicaid Program to provide case management and disease management services to Medicaid recipients. APS allegedly submitted monthly invoices, which were paid by Medicaid, when the range of services represented on the claims was not always provided to the Medicaid recipients.[xii/] The Georgia Attorney General's Office led the investigation, which was conducted jointly with the United States Attorney's Office, the Federal Bureau of Investigation, and the Office of Inspector General of HHS (HHS-OIG). A similar collaboration resulted in a $26 million settlement in which Medicaid managed care contractor CareSource (including CareSource Management Group Co. and CareSource USA Holding Co.) agreed to pay the United States and Ohio $26 million to resolve allegations that CareSource had caused Medicaid to pay for assessments and case management services that had not been provided.[xiii/]

In another Medicaid case, the State of Illinois and the United States Attorney's Office for the Northern District of Illinois announced a $25 million Medicaid settlement with Blue Cross Blue Shield of Illinois to resolve allegations that it had denied nursing care coverage for sick children and fraudulently shifted the cost of this care to Medicaid.[xiv/] The case was brought jointly under the FCA, the Illinois State False Claims Act, and the Illinois Consumer Protection Statute, and there was no *qui tam* relator. Of the $25 million settlement, $23.75 million was allocated to Medicaid damages and penalties under the state and federal FCA.

On February 8, 2012, the DOJ announced that Dava Pharmaceuticals, Inc. paid $11 million to resolve allegations that it had violated the FCA in connection with the state Medicaid Drug Rebate Program.[xv/] This settlement followed an investigation that included collaboration among the Justice Department's Civil Division, the United States Attorney's Office for the District of Maryland, HHS-OIG, and the National Association of Medicaid Fraud Control Units. The government alleged that Dava violated the FCA by inappropriately reducing its obligations to pay rebates to the Medicaid Drug Rebate Program. To do so, Dava allegedly treated its version of certain drugs as generic drugs rather than branded products and incorrectly calculated average manufacturer prices of the drugs, both of which had the effect of reducing the rebates it owed to Medicaid.

Large FCA Settlements Were Obtained Across Many Industries

Not only did the government strengthen coordination between state and federal enforcement agencies, but, in 2011, it directed enforcement activities toward a broad spectrum of the health care industry. Large settlements in the pharmaceutical industry drew much attention in 2011 (See Table 2 in the Part One Report listing some of these settlements). That trend has continued in 2012. In January 2012, a Johnson & Johnson subsidiary paid $158 million to settle claims that it defrauded Texas's Medicaid program by promoting Risperdal for uses not approved by the FDA (known as "off-label" uses). In that case, Texas had sought $579 million in damages and as much as $500 million more in penalties. The case settled during the trial, which was notable for its timing, given that most FCA cases settle before trial.[xvi/]

Beyond the headline-grabbing recoveries in the pharmaceutical industry, FCA claims have been brought against other types of providers and manufacturers. In 2011, there were many other substantial settlements covering categories of defendants such as medical device manufacturers; product manufacturers, distributors,

and suppliers; renal disease providers; home health providers; hospice providers; medical centers; and insurers. Demonstrating the breadth of the FCA, the allegations of misconduct varied widely, but included Anti-Kickback Statute (AKS) violations; Stark Law violations; fraudulent billings; misrepresentation of drug dosages; denial of coverage for care; and the provision of medically unnecessary services. For example, a national supplier of durable medical equipment, Hill-Rom Company, Inc., settled allegations under the FCA for $41.8 million. The government alleged that Hill-Rom knowingly submitted false claims to the Medicare program for certain specialized medical equipment (such as bed support surfaces for treatment of pressure ulcers) for patients who did not qualify for this equipment, including patients for whom the equipment was not medically necessary and patients who had died or were no longer using the equipment.[xvii/]

In the medical device industry—particularly cardiac devices—there were several notable settlements in 2011. Guidant, LLC paid $9.25 million to settle allegations that it inflated the cost to federal health care programs of replacement pacemakers and defibrillators.[xviii/] The Guidant case also serves as a good example of the breadth of the underlying violations that can give rise to alleged FCA liability; Guidant allegedly promoted the longevity and reliability of its pacemakers and defibrillators by touting warranties and rebates should a device need to be replaced during a warranty period and then failed to grant these warranty credits and rebates to hospitals for pacemakers and defibrillators that required replacement. In a December 2011 settlement of another medical device case, Medtronic, Inc. agreed to pay the United States $23.5 million to resolve allegations that the company had violated the FCA by using physician payments related to post-market studies and device registries as kickbacks to induce doctors to implant Medtronic pacemakers and defibrillators.[xix/]

Legal Developments in FCA Jurisprudence

There were also several important developments in FCA jurisprudence during 2011. In particular, federal circuit courts addressed an important and still-unresolved question under the FCA about how far, using a legal theory known as "implied certification," the FCA should be used to police violations of the myriad other laws and regulations that apply to providers and pharmaceutical and medical device manufacturers. The First and Sixth Circuit Courts of Appeals issued opinions on the implied certification theory, adding to a pre-existing split in the circuits. Although the parties in the affected cases decided by the First Circuit petitioned the Supreme Court to resolve the circuit split, the Court decided not to weigh in and provide clarity.

Implied certification is a legal doctrine under which factually accurate claims submitted to the government for payment can nevertheless be "false or fraudulent" because of an underlying violation of law. Several circuit courts have addressed the viability and legal standards applicable to implied certification. In a seminal certification case, the Second Circuit addressed this question in the context of alleged violations of the FCA where defendant physicians submitted claims to Medicare for reimbursement of spirometry procedures that did not comply with the standard of care. The Second Circuit took a narrow view of implied certification and 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."[xx/] In 2011, the Sixth Circuit followed the Second Circuit's reasoning and rejected a claim based upon violations of a standard of care and another federal statute, holding that "noncompliance [with a regulation] constitutes actionable fraud only when compliance is a ***prerequisite to obtaining payment***."[xxi/]

The First Circuit, however, in *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, adopted another approach. The court reversed the dismissal of an FCA case against a medical device manufacturer premised on the manufacturer's violations of the AKS. The court rejected the "judicially created categories" of express or implied certification. Instead, it held that compliance with the AKS is an "implied condition of payment" and the submission of a claim is a representation that such condition has been met. If there has been a violation of the AKS, the representation of compliance with the AKS—through the submission of a claim for reimbursement—is false, because the Provider Agreement and Hospital Cost Report made compliance with the AKS a precondition of payment.[xxii/]

In *State of New York et al. ex rel. Westmoreland v. Amgen Inc. et al.*, the First Circuit again reversed the dismissal of FCA claims premised upon violations of the AKS. The court held that to be false, claims must misrepresent "compliance with a material precondition of Medicaid payment such that they were false or fraudulent." [xxiii/]

While the new health care reform law explicitly makes violations of the AKS actionable under the FCA, the courts' views on the implied certification theory will have a significant impact on the use of the FCA as a vehicle for enforcement of alleged regulatory and statutory violations.

Conclusion

The first three months of 2012 suggest that the trends of 2011 will continue. It appears that relators are still a primary driver of FCA enforcement and they will continue to earn substantial rewards for bringing such cases. Relators are filing *qui tam* cases against a wide range of provider and manufacturer types, and the categories of individuals who decide to become *qui tam* relators is expanding. The government is taking the information provided by relators and is employing increasingly sophisticated investigative techniques, in a coordinated and integrated fashion, to investigate and then prosecute many of these whistleblower allegations. Because health care providers, insurers, and pharmaceutical and medical device manufacturers operate in a highly-regulated environment, the FCA has been, and likely will continue to be, used successfully to recoup huge sums of money to federal and state health care programs, oftentimes by bootstrapping regulatory violations into alleged FCA violations. We predict that 2012 will look a lot like 2011—only more so.

[i/] Part one, entitled "2011—The Year In Review: Trends in Health Care Enforcement," is available at: http://www.mintz.com/newsletter/2012/Advisories/1618-0112-NAT-HCED/1618-0112-NAT-HCED_index.pdf.

[ii/] Press release, Dep't of Justice, Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011 (Dec. 19, 2011), available at: http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html; *see also* press release, Dep't of Justice, Health Care Fraud Prevention and Enforcement Efforts Result in Record-breaking Recoveries Totaling Nearly $4.1 Billion (Feb. 14, 2012), available at: http://www.justice.gov/opa/pr/2012/February/12-ag-213.html.

[iii/] Press release, Dep't of Justice, Assistant Attorney General Tony West Speaks at the 25th Anniversary of the False Claims Act Amendments of 1986 (Jan. 31, 2012), available at: http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-120131.html.

[iv/] Press release, Dep't of Justice, Attorney General Eric Holder Speaks at the 25th Anniversary of the False Claims Act Amendments of 1986 (Jan. 31, 2012), available at: http://www.justice.gov/iso/opa/ag/speeches/2012/ag-speech-120131.html.

[v/] Press release, Dep't of Justice, Assistant Attorney General Tony West Speaks at the 25th Anniversary of the False Claims Act Amendments of 1986 (Jan. 31, 2012), available at: http://www.justice.gov/iso/opa/civil/speeches/2012/civ-speech-120131.html.

[vi/] Taxpayers Against Fraud, False Claims Act Update & Alert (Oct. 25, 2010), available at: http://www.taf.org/whistle295.htm.

[vii/] The Dep't of Health and Human Services and Department of Justice, Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 2011, at p. 5 (Feb. 2012), available at: http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf.

[viii] Press release, Dep't of Justice, Hospice Provider Odyssey Healthcare Agrees to Pay $25 Million to Resolve False Claims Act Allegations (Mar. 1, 2012), available at: http://www.justice.gov/opa/pr/2012/March/12-civ-272.html.

[ix] *See United States ex rel. Estate of Cunningham v. Millennium Laboratories of California*, No. 09-12209-JLT, Memorandum at 3 (D. Mass. Jan. 30, 2012).

[x] Press release, Colorado Attorney General, Denver Health Medical Center to pay $6.3 million to settle allegations relating to overbilling Medicare and Medicaid (Jan. 5, 2012), available at: http://www.coloradoattorneygeneral.gov/press/news/2012/01/05/denver_health_medical_center_pay_63_million_settle_allegations_relating_overbi.

[xi] Press Release, Dep't of Justice, Assistant Attorney General Tony West Speaks at the 12th Annual Pharmaceutical Regulatory and Compliance Congress (Nov. 2, 2011), available at: http://www.justice.gov/iso/opa/civil/speeches/2011/civ-speech-111102.html.

[xii] Press Advisory, Attorney General of Georgia, APS Healthcare Pays $13 Million to Settle Investigation into False Medicaid Claims (Feb. 22, 2011), available at: http://law.ga.gov/00/press/detail/0,2668,87670814_87670929_168474870,00.html.

[xiii] Press Release, Dep't of Justice, Ohio-Based Managed Care Plan Contractor CareSource & Entities to Pay $26 Million to Resolve False Claims Allegations (Feb. 1, 2012), available at: http://www.justice.gov/opa/pr/2011/February/11-civ-138.html.

[xiv] Press Release, Dep't of Justice, United States Attorney's Office, Northern District of Illinois, BlueCross BlueShield of Illinois to Pay $25 Million to Settle Civil Medicaid Fraud Claims (Feb. 24, 2011), available at: http://www.justice.gov/usao/iln/pr/chicago/2011/pr0224_01.pdf.

[xv] Press Release, Dep't of Justice, Dava Pharmaceuticals to Pay U.S. $11 Million to Settle False Claims Act Allegations (Feb. 8, 2012), http://www.justice.gov/opa/pr/2012/February/12-civ-182.html.

[xvi] Jeff Feeley, Margaret Cronin Fisk and David Voreacos, *J&J to Pay $158M to Settle Texas Drug Case*, BLOOMBERG, Jan. 19, 2012, http://www.bloomberg.com/news/2012-01-19/johnson-johnson-to-pay-158-million-to-settle-texas-risperdal-drug-case.html.

[xvii] Press Release, Dep't of Justice, United States Attorney William C. Killian, Eastern District of Tennessee, Hill-Rom Company, Inc. Will Pay $41.8 Million to Resolve Federal Health Care Fraud Investigation (Sept. 27, 2011), available at: http://www.justice.gov/usao/tne/news/2011/September/092711A%20Hill-Rom%20Settlement.html.

[xviii] Press Release, Dep't of Justice, Boston Scientific Subsidiary Guidant Pays U.S. $9.25 Million to Settle False Claims Act Allegations (Sept. 26, 2011), available at: http://www.justice.gov/opa/pr/2011/September/11-civ-1256.html.

[xix] Press Release, Dep't of Justice, Minnesota-Based Medtronic Inc. Pays US $23.5 Million to Settle Claims That Company Paid Kickbacks to Physicians (Dec. 12, 2011), available at: http://www.justice.gov/opa/pr/2011/December/11-civ-1623.html.

[xx] *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (emphasis added).

[xxi] *United States ex rel. Chesbrough v. VPA, P.C. dba Visiting Physicians Ass'n*, 655 F.3d 461, 468 (6th Cir. 2011) (emphasis added).

[xxii] *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011), *cert. denied*, 132 S. Ct. 815 (U.S. 2011).

[xxiii] *State of New York et al. ex rel. Westmoreland v. Amgen Inc. et al.*, 652 F.3d 103, 110 (1st Cir. 2011), *cert. dismissed*, 132 S. Ct. 993 (U.S. 2011).