

HEALTH CARE FRAUD

Expert Analysis

2010 Year-End False Claims Act Update: Part 1

*By Robert C. Blume, Andrew S. Tulumello and Jessica H. Sanderson
Gibson, Dunn & Crutcher LLP*

False Claims Act litigation and enforcement exploded in 2010 with unprecedented intensity. Indeed, the government secured more than \$3 billion in civil settlements and judgments for its fiscal year ending Sept. 30, 2010 — a 25 percent increase over the previous year, and the second-largest yearly recovery amount ever. The Justice Department's total recoveries in False Claims Act cases from January 2009 through January 2011 have exceeded \$6.8 billion, which is far greater than any other previous two-year period. With these new numbers on the books, the total amount recovered under the False Claims Act since Congress amended the statute in 1986 has climbed to the staggering amount of more than \$27 billion.¹

The Department of Justice boasts of an “aggressive, coordinated and sustained effort at the federal level to hold perpetrators of fraud accountable, be they large companies or individuals.” For its part, DOJ's Civil Division has focused its fraud-fighting efforts on “increased use of the False Claims Act.”²

Further, in 2010, the False Claims Act remained the focus of congressional interest. After amending the act in May 2009 (for the first time in more than 20 years), Congress amended the FCA *twice* in 2010, each time closing perceived loopholes in the statute and removing judicially created limitations on FCA litigation. And while the plaintiffs' bar continues to pursue aggressive theories of liability and damages, federal courts continue to grapple with the contours of the recently revised statute.

WHY THE FCA IS SUCH A POWERFUL WEAPON

The False Claims Act, 31 U.S.C. §§ 3729-33, is one of the federal government's primary weapons to redress fraud against government programs. In simple terms, the FCA imposes liability upon anyone who (a) knowingly submits, or causes another to submit, a false claim for payment to the United States government, or (b) knowingly avoids or decreases an obligation to pay the United States government, which may include the knowing retention of an overpayment.

The FCA is a potent weapon for three primary reasons:

First, potential damages available under the FCA can be staggering: A violator is subject to *three times* the amount of actual damages plus civil penalties of up to \$11,000 *per false claim*. The FCA does not itself provide a framework for calculating

The DOJ boasts of an “aggressive, coordinated and sustained effort at the federal level to hold perpetrators of fraud accountable, be they large companies or individuals.”

actual damages or for calculating the number of claims. Under aggressive theories of liability and damages accepted by a handful of courts, damages may equal up to *three times the amount of all money the government paid out*, regardless of the value of goods or services received in exchange.

The method for calculating penalties under the FCA is equally vague. For example, in a typical contract situation, “claims” may be calculated as the number of contracts (which in most instances will be a small number). They may also be the number of invoices submitted pursuant to a contract (which likely are submitted monthly for up to 6-10 years depending on the statute of limitations period) or the number of line items on all claims or invoices (which may be an immense number of “claims”). The uncertainty regarding the appropriate measure of damages and penalties has contributed to massive settlements and no doubt motivates the *qui tam* plaintiffs’ bar.

In addition, a violator may be liable for *causing* another person or entity to submit false claims. An FCA defendant accordingly may face hundreds of millions of dollars in damages and penalties when that defendant, itself, neither directly submitted a claim to nor received any money from the federal government. Consider for example the pharmaceutical company settlements announced in 2010 for alleged off-label drug promotion (discussed below).

Although the pharmaceutical companies themselves did not directly submit any claims to the United States government for payment for the costs of those drugs, they allegedly “caused” others to seek reimbursement from government-funded health plans for uncovered medications and/or inflated costs, thereby potentially creating liability and facing substantial damages and penalties under the act.

Second, *qui tam* provisions authorize private individual whistle-blowers, known as “relators,” to sue on behalf of the United States and share in up to 30 percent of any recovery. Relators’ counsel also may be entitled to attorney fee awards. Although a May 13, 2010, study released by the New England Journal of Medicine suggested that most whistle-blowers in health care FCA cases were not motivated by financial gain, it is difficult to accept that conclusion.

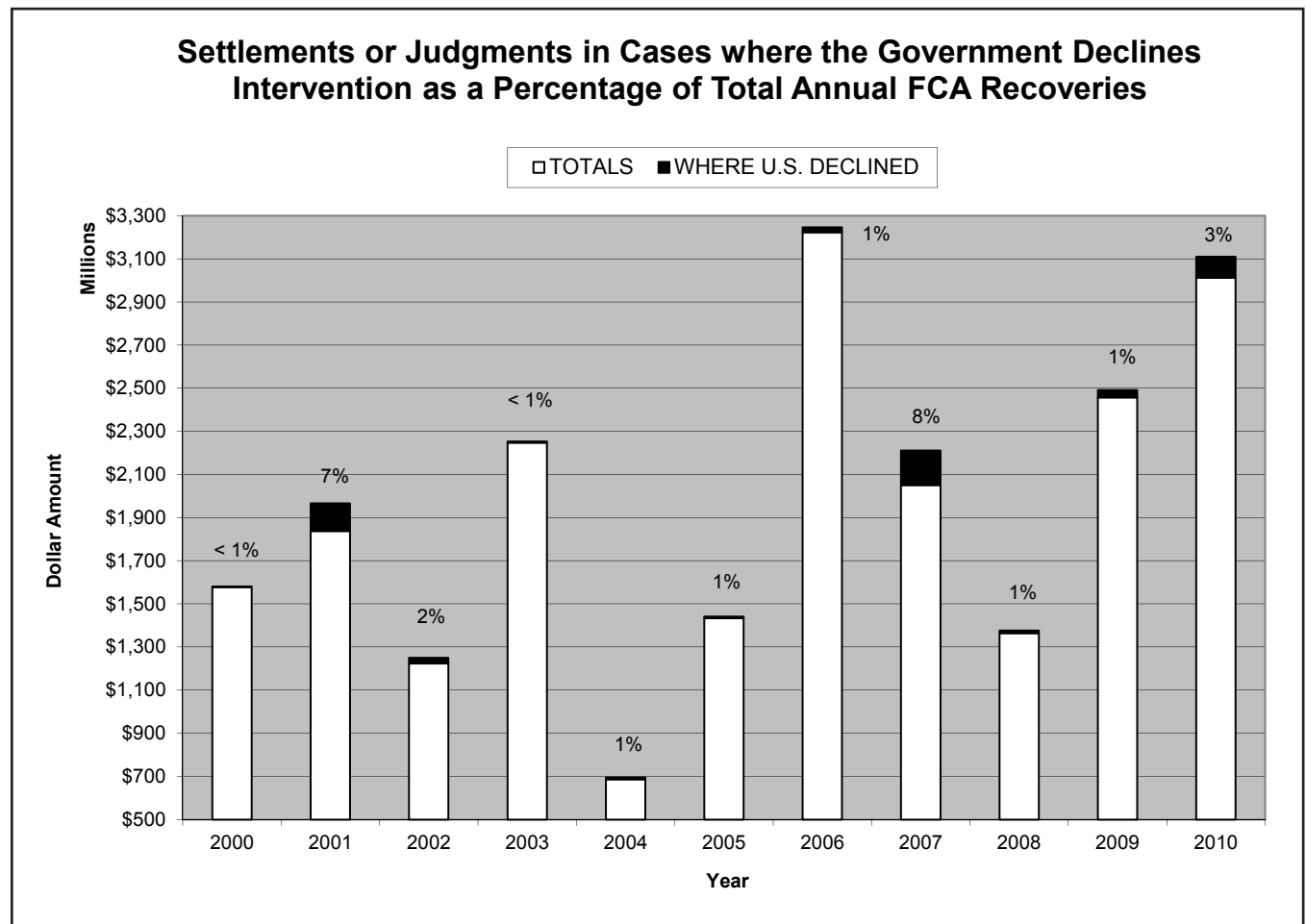
Consider, for example, Ven-a-Care, a small Florida company that “blew the whistle” on several drug companies. In December 2010, FCA settlements with certain pharmaceutical manufacturers resulted in relator share awards to Ven-a-Care in the amount of \$155.6 million.³ Although providing incentives to private individuals may increase fraud detection and enforcement, it also may lead to abusive litigation. This point is evidenced by the fact that, as discussed further below, private individuals have initiated the majority of FCA actions over the past several years, but cases where the government declines intervention typically account for less than 3 percent of all FCA recoveries.

Third, despite U.S. Supreme Court warnings, the FCA continues to develop into an “all-purpose anti-fraud statute.” *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008). DOJ and relators continue to pursue theories of express or implied certification, and courts continue to accept such theories. Under these theories, plaintiffs argue that a defendant’s claims for payment are “false” if the defendant falsely certified compliance with a statute or regulatory scheme and the government would not have paid the claims had it known the defendant was not complying.

In this way, plaintiffs seek to use the FCA to enforce compliance with a myriad of government regulations, many of which provide alternative, less drastic remedies for noncompliance, and virtually none of which contemplate private enforcement mechanisms such as *qui tam* actions.

Similarly, anyone who does business with the government or receives government funds, *directly or indirectly*, is subject to potential liability under the act. In the “typical” FCA case, the statute clearly applies where a party contracts to provide goods or services to the federal government and falsely bills for such goods or services. The FCA has given rise to increasingly creative theories of liability, so that FCA cases frequently arise in unexpected contexts.

In September 2010, for example, the Wall Street Journal and the New York Daily News reported that Floyd Landis, the 2006 Tour de France winner whose title was revoked due to alleged drug use, filed a *qui tam* action against his former teammate and seven-time Tour de France winner, Lance Armstrong. Presumably, Landis argues that Armstrong defrauded the U.S. Postal Service out of team sponsorship funds by failing to disclose his alleged use of illegal performance-enhancing drugs. (Because Landis’ complaint, if any, is under seal, the authors cannot verify the statements in the press or the actual theory of any FCA claims).



FCA ENFORCEMENT ACTIVITY IN 2010

Total recovery amounts — another record year

As stated above, for the fiscal year ending Sept. 30, 2010, the federal government secured more than \$3 billion in civil settlements and judgments, a 25 percent increase over the previous year and the second-largest yearly recovery amount ever. From January 2009 through January 2011, the government secured more than \$6.8 billion in recoveries. The total amount recovered under the FCA since 1986 has risen to more than \$27 billion. And for the first quarter of fiscal year 2011 (October through December 2010), DOJ already has announced approximately \$1 billion in FCA recoveries.

Whistle-blowers continue to drive the massive recoveries under the FCA, and the government continues to rely heavily upon private plaintiffs to detect and expose fraud. Of the 709 new FCA matters opened during the last fiscal year, 573 — more than 80 percent — were matters initiated pursuant to the act's *qui tam* provisions, and more than \$380 million in recoveries were awarded to private plaintiffs under the FCA.⁴

The government's decision to intervene, however, is still a key indicator of success. Of the approximately \$3 billion recovered in fiscal year 2010, only 3.2 percent was obtained from actions in which the government elected *not to intervene*, a percentage that is consistent with historical data. As a result, companies facing whistleblower suits are well-advised to hire qualified counsel early to minimize the chance of government intervention and maximize the chances for a successful defense.

Industry breakdown

In December 2010 Assistant Attorney General Tony West noted the cases that make up that record-breaking amount (of FCA recoveries) cover the full spectrum of Justice Department Civil Division fraud cases. These range from the financial fraud cases, like mortgage fraud that victimizes homeowners who are already struggling to hold on to their homes, to procurement fraud cases involving substandard provisions supplied to our troops in Iraq and Afghanistan, to the investor fraud scams involving fake business opportunities that cheat honest small businesspeople out of their hard-earned investments.⁵

The overwhelming majority of FCA recoveries in the past decade, however, have come from the health care sector, and 2010 was no exception. The new Patient Protection and Affordable Care Act, passed by Congress in 2010, brought an even greater emphasis on detecting and preventing health care fraud, resulting in a record year for FCA recoveries in this sector. The following chart tracks total recoveries as well as recoveries in the health care and defense sectors over the last 10 years.

Health care

In the words of Attorney General Eric Holder, DOJ has "taken [the government's] fight against health care fraud to a new level." 2010 was a record-breaking year for FCA cases in the health care sector, with the total amount recovered exceeding a staggering \$2.5 billion. In addition, each of the 10 largest FCA recoveries in FY 2010 involved health care, including several massive recoveries against pharmaceutical companies such as AstraZeneca and Ortho-McNeil.⁶

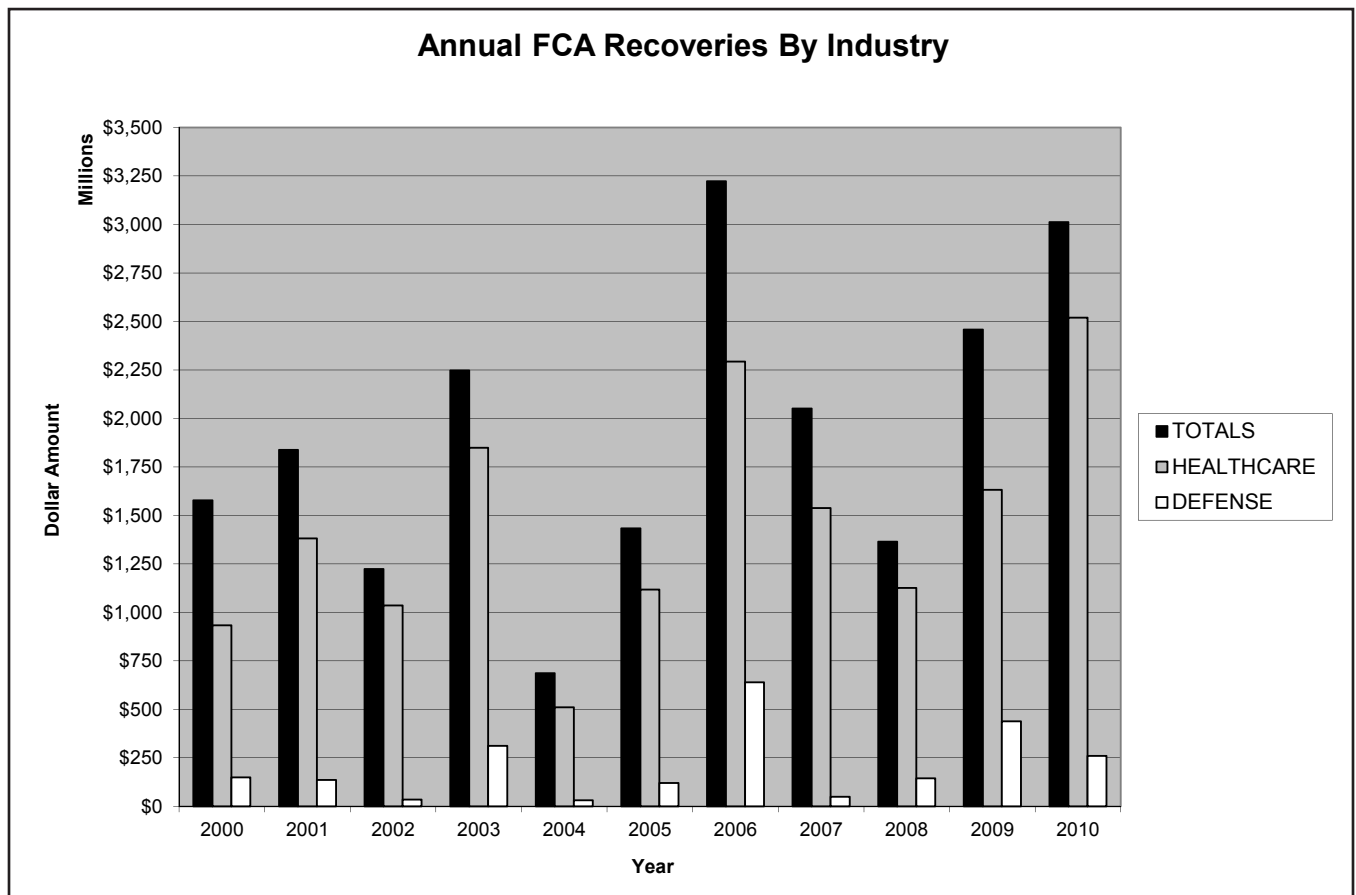
The passage of major health care reform legislation in 2010 — which included several provisions strengthening and broadening the FCA — suggests health care fraud will continue to be a top priority for DOJ.

“From day one, President Obama and Attorney General Eric Holder have been focused like a laser beam on tacking health care fraud in all of its many forms,” West said in October 2010. This “laser” focus is reflected in the government’s Health Care Fraud Prevention and Enforcement Action Team, or “HEAT,” a collaboration between DOJ and the Department of Health and Human Services that began in 2009.

Legislative changes in 2010 further ensured programs like HEAT would strengthen in the coming years. For example, the PPACA allocates \$350 million over the next decade to health care fraud enforcement. And with private advocacy groups suggesting that the FCA generates more than \$15 in recoveries for every \$1 spent on health care fraud enforcement — a view the government appears to share — the government will continue to fund the effort.⁷

In the second half of 2010, DOJ announced settlements in numerous high-profile cases against pharmaceutical companies, including the following:

- Abbott, Roxane, B. Braun Medical, and Dey Inc.: In December 2010 (the government’s fiscal year 2011), DOJ resolved allegations against Abbott Laboratories Inc., Roxane Laboratories Inc., B. Braun Medical Inc., Dey Inc. and related entities.



The settlements addressed allegations that the companies illegally inflated the reported “average wholesale price” of various drugs, thereby increasing the reimbursement amount the government paid for the drugs under programs such as Medicare. Collectively, the companies paid \$701.2 million as part of the settlements.

As mentioned above, Ven-A-Care, a small Florida company, initiated the cases against Abbot, Roxane, B. Braun and Dey under the *qui tam* provisions of the FCA. In connection with the settlements of the cases announced in December 2010 against Abbott, Roxane, B. Braun and Dey, Ven-A-Care received approximately \$155.6 million.

Notably, Dec. 24, 2010, four days after DOJ announced the \$280 million settlement with Dey, Mylan Inc. — Dey’s parent company — announced that it settled lawsuits brought against it on behalf of the federal government and the state of Texas for \$65 million. And, just one year ago, in October 2009, DOJ announced that Mylan Pharmaceuticals and UDL Laboratories agreed to pay \$118 million to resolve claims that they violated the FCA by failing to pay proper rebates to state Medicaid programs for drugs paid for by those programs. Whistle-blower Ven-a-Care received approximately \$10.8 million as its share of that settlement.⁸

- Elan Corp.: DOJ announced a settlement Dec. 15, 2010, with Elan Corp. PLC and its U.S. subsidiary Elan Pharmaceuticals Inc. to resolve civil and criminal allegations stemming from the alleged illegal promotion of an epilepsy drug.⁹ Elan agreed to pay about \$100 million in criminal fines and forfeitures and nearly \$102.9 million to resolve FCA claims. It also entered into a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. In a separate, related civil settlement, a Japanese drug marketer, which purchased the epilepsy drug from Elan, agreed to pay \$11 million to resolve FCA claims premised on off-label marketing. The civil settlements also resolved a *qui tam* action. The whistle-blower in that action will receive more than \$11 million from the federal share of the two settlements.
- GlaxoSmithKline: DOJ announced Oct. 26, 2010, that SB Pharmco Puerto Rico Inc., a subsidiary of GlaxoSmithKline PLC, had agreed to plead guilty to criminal charges relating to the manufacture and distribution of adulterated drugs.¹⁰ The company agreed to pay a criminal fine and forfeiture of \$150 million and civil penalties of \$600 million to resolve allegations that it caused false claims to be submitted to government health care programs for adulterated drugs. The federal share of the civil settlement amount is approximately \$436.4 million. The civil settlement also resolved a *qui tam* action; the whistle-blower in that case will receive approximately \$96 million from the federal share of the settlement.
- Novartis: DOJ announced Sept. 30, 2010, that Novartis Pharmaceuticals Corp. agreed to pay \$422.5 million to resolve criminal and civil liability arising from the alleged illegal marketing of certain drugs. The federal share of the FCA settlement was \$149.2 million. The FCA settlement resolved four *qui tam* actions. The relators in those actions, all former Novartis employees, reportedly were awarded more than \$25 million from the federal government’s share of the civil recovery.¹¹
- Forest Laboratories: DOJ announced Sept. 15, 2010, that Forest Pharmaceuticals Inc., a subsidiary of Forest Laboratories Inc., agreed to a \$313 million settlement to resolve allegations that the company illegally distributed an unapproved drug product, Levothroid and promoted “off-label” uses for the drug Celexa.

It also allegedly caused false claims to be submitted to federal health care programs for Levothroid, Celexa, and another drug, Lexapro, and paid kickbacks to induce physicians to prescribe Celexa and Lexapro. In addition to criminal penalties, Forest paid \$149 million in civil penalties to resolve allegations under the FCA, including \$14 million paid to the private whistle-blowers who initiated the case.¹²

- Allergan: DOJ announced a \$600 million settlement Sept. 1, 2010, with pharmaceutical manufacturer Allergan Inc., to resolve allegations that the company marketed its drug Botox for “off-label” uses. The Food and Drug Administration had not approved the drug to treat certain conditions and, as a result, the company’s marketing efforts allegedly violated the Food, Drug, and Cosmetics Act. As part of the total settlement, which included criminal and civil charges, the company paid \$225 million to resolve allegations under the FCA with \$37.8 million awarded to the *qui tam* relators who initiated the action. Furthermore, in addition to these monetary penalties, the settlement required the company to execute a five-year corporate integrity agreement, which mandates that the company implement a comprehensive compliance program. This agreement and the company’s compliance efforts will be overseen by the Department of Health and Human Services.¹³

The foregoing pharmaceutical settlements announced during the second half of 2010 followed on the heels of several other massive pharmaceutical settlements earlier in 2010. In a one-week period, from April 27, 2010, to May 4, 2010, DOJ announced four separate settlements of FCA claims by pharmaceutical manufacturers totaling more than \$695 million. One of those settlements, with AstraZeneca Pharmaceuticals LP, resulted in “the largest amount ever paid by a company in a civil only settlement of off-label marketing claims.”

The Public Citizen’s Health Research Group released a study Dec. 16, 2010, that focused specifically on civil and criminal settlements within the pharmaceutical industry. In that study, the authors reported, “Of the 165 settlements comprising \$19.8 billion in penalties during [the last] 20-year interval, 73 percent of the settlements (121) and 75 percent of the penalties (\$14.8 billion) have occurred in just the past five years (2006-2010). Four companies (GlaxoSmithKline, Pfizer, Eli Lilly and Schering-Plough) accounted for more than half (53 percent or \$10.5 billion) of all financial penalties imposed over the past two decades.”¹⁴

Government contracting and procurement

As military operations and reconstruction efforts continue in Iraq and Afghanistan, and the government continues to pump huge sums of money into the national economy through various recovery efforts, DOJ’s attention remained focused on combating procurement fraud.

In November 2010 Assistant Attorney General Lanny Breuer remarked, “[G]iven the size and number of the contracts, grants, and loans awarded under the [American Reinvestment and Recovery] Act, we must be prepared for financial criminals to work hard at devising fraudulent schemes aimed at stealing the moneys disbursed under the act.”

He continued, “[P]rotecting the integrity of Recovery Act funds is a priority for the administration and for the Justice Department, and we are 100 percent committed to following through on any case that merits it.”¹⁵

Whistle-blowers continue to drive the massive recoveries under the FCA, and the government continues to rely heavily upon private plaintiffs to detect and expose fraud.

The overwhelming majority of FCA recoveries in the past decade have come from the health care sector, and 2010 was no exception.

As a result, the government initiated various programs to police the expenditure of government funds in the past year, including the National Procurement Fraud Initiative and the Financial Fraud Enforcement Task Force. And a primary weapon of these government initiatives is the FCA.

Significant settlements obtained during the second half of 2010 as a result of these efforts include:

- **Louis Berger Group:** In November 2010 New Jersey-based engineering company Louis Berger Group Inc., settled criminal and civil claims against it regarding its handling of reconstruction contracts in Iraq and Afghanistan. According to the government, the company allegedly overbilled for overhead costs relating to work performed overseas. As part of the settlement, the company agreed to pay a criminal penalty of \$18.7 million and entered into a civil settlement requiring payment to the government of \$46.3 million, in addition to credits provided to the government totaling an additional \$4.3 million. A former employee of the company's accounting department initiated the case under the FCA's *qui tam* provisions. According to the whistle-blower's attorney, the \$69 million total settlement against the Louis Berger Group was "the largest recovery in a case involving war-zone contractors in Afghanistan and Iraq."
- **Cisco:** DOJ announced Sept. 7, 2010, that Cisco Systems and Westcon Group North America agreed to pay \$48 million to settle FCA claims that the companies made misrepresentations to General Services Administration ("GSA") contracting officers, which allegedly resulted in defective pricing of Cisco products and the submission of false claims.
- **U.S. Foodservice:** Also in September 2010, U.S. Foodservice Inc., a major food supplier for the Departments of Defense and Veterans Affairs, paid \$30 million to settle allegations under the FCA. DOJ alleged that the company overcharged for food products supplied under various contracts, including contracts involving military bases in the United States. The case was brought by DOJ's Civil Frauds Unit, in coordination with the Financial Fraud Enforcement Task Force.¹⁶

Other sectors

In the second half of 2010, the government also used the FCA to combat fraud against companies in other industries, including the following:

- **Student aid lenders:** In November 2010 DOJ announced a settlement with four student aid lenders for a total recovery amount of \$57.75 million. The lenders allegedly created billing systems that allowed them to receive improperly inflated interest rate subsidies from the U.S. Department of Education. A former employee of the department initiated these actions under the *qui tam* provisions of the FCA and will receive a total of \$16.65 million from the settlements. Notably, DOJ did not intervene in this action.
- **Mortgage fraud:** In his testimony before the Financial Crisis Inquiry Commission at the outset of 2010, Breuer announced, "Since Fiscal Year (FY) 2006, the Department (of Justice) has used the False Claims Act to recover \$116 million in matters involving mortgage fraud and has enforced the False Claims Act against a variety of fraudulent mortgage practices."

In March 2010, the U.S. attorney's office for the Southern District of New York announced the formation of a special Civil Frauds Unit to combat "large-scale and

sophisticated financial frauds” through the FCA and other civil enforcement mechanisms. Working in coordination with President Obama’s Financial Fraud Enforcement Task Force, the special unit has already obtained results. For example, the U.S. attorney for the Southern District of New York announced Dec. 13, 2010, that the government filed a civil fraud lawsuit, which includes FCA claims, against 14 defendants, including sellers, lenders and appraisers, alleged to have engaged in a conspiracy to commit mortgage fraud in New York City.¹⁷

CONCLUSION

The massive FCA settlements announced in the second half of 2010 suggest DOJ will continue its “unparalleled focus” on anti-fraud efforts and its “aggressive use” of the act, and we expect 2011 to be another big year for FCA enforcement. In part two of this article, which will appear in the upcoming issue of *Westlaw Journal Health Care Fraud*, the authors explore legislative and judicial developments in the FCA realm in the last half of 2010.

NOTES

- ¹ See Press Release, Dep’t of Justice, Department of Justice Recovers \$3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010); Press Release, Dep’t of Justice, Seven Hospitals in Six States to Pay U.S. More Than \$6.3 Million to Resolve False Claims Act Allegations Related to Kyphoplasty (Jan. 4, 2011); see generally Dep’t of Justice, Briefing Room, <http://www.justice.gov/opa/pr/2010/December/index.html> (last visited Feb. 23, 2010) (featuring DOJ press releases regarding recent recoveries under the FCA).
- ² Dep’t of Justice, Briefing Room, Department of Justice Assistant Attorney General Tony West Speaks at Press Conference Announcing Major Settlements with Pharmaceutical Manufacturers (Dec. 7, 2010); Department of Justice Assistant Attorney General Tony West, Remarks at the American Bar Association National Institute on the Civil False Claims Act and Qui tam Enforcement, at 1 (June 3, 2010).
- ³ See Aaron S. Kesselheim, David M. Studdert & Michelle M. Mello, Special Report, *Whistle-Blowers’ Experiences in Fraud Litigation against Pharmaceutical Companies*, 362 N. ENGL. J. MED. 1832, 1834-35 (2010); Press Release, Dep’t of Justice, Pharmaceutical Manufacturer to Pay \$280 Million to Settle False Claims Act Case (Dec. 20, 2010); Press Release, Dep’t of Justice, Pharmaceutical Manufacturers to Pay \$421.2 Million to Settle False Claims Act Cases (Dec. 7, 2010).
- ⁴ See U.S. Dep’t of Justice, Civil Div., *Fraud Statistics*, at 2 (Nov. 23, 2010).
- ⁵ Dep’t of Justice, Briefing Room, Department of Justice Assistant Attorney General Tony West Speaks at Press Conference Announcing Major Settlements with Pharmaceutical Manufacturers (Dec. 7, 2010).
- ⁶ See Press Release, Dep’t of Justice, Departments of Justice and Health and Human Services Team Up to Crack Down on Health Care Fraud (Nov. 5, 2010); Press Release, Dep’t of Justice, Department of Justice Recovers \$3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010); Patrick Burn, *Over \$3 Billion in Fraud Recoveries Under the False Claims Act in FY 2010, Taxpayers Against Fraud Education Fund* (Oct. 25, 2010).
- ⁷ Department of Justice Assistant Attorney General Tony West, Remarks at the GlaxoSmithKline Press Conference (Oct. 26, 2010); Jack A. Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck, Taxpayers Against Fraud Education Fund*, at 4 (July 2006); see Press Release, Dep’t of Justice, Departments of Justice and Health and Human Services Team Up to Crack Down on Health Care Fraud (Nov. 5, 2010) (“Investments in fraud detection and enforcement pay for themselves many times over, and the administration’s tough stance against fraud is already yielding results.”).
- ⁸ See Press Release, Dep’t of Justice, Pharmaceutical Manufacturer to Pay \$280 Million to Settle False Claims Act Case (Dec. 20, 2010); Press Release, Dep’t of Justice, Pharmaceutical Manufacturers to Pay \$421.2 Million to Settle False Claims Act Cases (Dec. 7, 2010); Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, *Four Pharmaceutical Companies Pay \$124 Million for Submission of False Claims to Medicaid* (Oct. 19, 2009). Ven-A-Care, founded in 1987 as a small pharmacy providing in-home services, has evolved into a professional whistle-blower over the past 20 years, netting hundreds of millions in relator’s share awards and prompting settlements from some of the largest pharmaceutical companies in the world, including Bayer AG, GlaxoSmithKline, Mylan and Teva Pharmaceuticals. See David S. Cloud & Laurie McGinley, *Medicare Monitor: How a Whistle-Blower Spurred Pricing Case Involving Drug Makers’ High U.S.*

Reimbursement Caught Eye of Newcomer to Home-Care Business, WALL ST. J., May 12, 2000, at A1; Joni James, *State Files Drug Price Lawsuit*, ST. PETERSBURG T., July 21, 2005, at 1B.

- ⁹ See Press Release, Dep't of Justice, Pharmaceutical Companies to Pay \$214.5 Million to Resolve Allegations of Off-label Promotion of Zonegran (Dec. 15, 2010).
- ¹⁰ See Press Release, Dep't of Justice, GlaxoSmithKline to Plead Guilty & Pay \$750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010).
- ¹¹ See Press Release, Dep't of Justice, Novartis Pharmaceuticals Corp. to Pay More Than \$420 Million to Resolve Off-label Promotion and Kickback Allegations (Sept. 30, 2010).
- ¹² See Press Release, Dep't of Justice, Drug Maker Forest Pleads Guilty; To Pay More Than \$313 Million to Resolve Criminal Charges and False Claims Act Allegations (Sept. 15, 2010).
- ¹³ See Press Release, Dep't of Justice, Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox (Sept. 1, 2010).
- ¹⁴ Department of Justice Attorney General Eric Holder, Remarks at the AstraZeneca Settlement Announcement (Apr. 27, 2010); Sammy Almashat, Charles Preston, Timothy Waterman & Sidney Wolfe, *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991-2010*, PUBLICCITIZEN, Dec. 16, 2010.
- ¹⁵ Department of Justice, Criminal Division, Attorney General Lanny A. Breuer, Remarks at the "Focus on Recovery" Biennial National Procurement and Grant Fraud Conference (Nov. 17, 2010).
- ¹⁶ See Press Release, U.S. Attorney's Office for the District of Maryland, Scheme to Defraud Government on Reconstruction Contracts Leads to Criminal Charges and Civil Penalties for Louis Berger Group Inc. (Nov. 5, 2010); PR Newswire, *Whistle-blower Exposed Fraud By The Louis Berger Group; \$69.3 Million Settlement Sets Record for Afghanistan and Iraq Contractor Fraud Case*, PR NEWswire, Nov. 5, 2010; Press Release, Dep't of Justice, Cisco Systems and Westcon Group North America Pay \$48 Million to Settle False Claims Act Allegations (Sept. 7, 2010); Press Release, U.S. Attorney's Office for the S.D.N.Y., U.S. Foodservice to Pay United States \$30 Million to Resolve Civil Fraud Allegations (Sept. 13, 2010).
- ¹⁷ See Press Release, Dep't of Justice, Four Student Aid Lenders Settle False Claims Act Suit for Total of \$57.75 Million (Nov. 17, 2010) (despite not intervening, the government did provide assistance in this case, including during the settlement process); Department of Justice, Criminal Division, Attorney General Lanny A. Breuer, Testimony to the Financial Crisis Inquiry Commission (Jan. 14, 2010); Jonathan Stempel, *U.S. attorney in Manhattan creates civil fraud unit*, REUTERS, Mar. 24, 2010 (quoting U.S. Attorney for the Southern District of New York Preet Bharara); Press Release, U.S. Attorney's Office for the S.D.N.Y., Manhattan U.S. Attorney Sues Sellers, Lenders and Appraisers Alleging Broad Consumer Mortgage Fraud Conspiracy (Dec. 13, 2010).



Robert C. Blume (left) is a partner in the Washington and Denver offices of **Gibson, Dunn & Crutcher LLP**. **Andrew S. Tulumello** (center) is a partner in the Washington office. **Jessica H. Sanderson** (right) is of counsel in the firm's Denver office. All three are members of Gibson Dunn's white collar defense and investigations practice group. The authors would like to thank Gibson Dunn associates Laura Sturges, Fred Yarger, Brian Baak and Allison Kostecka for their extraordinary contributions to this article.

©2011 Thomson Reuters. This publication was created to provide you with accurate and authoritative information concerning the subject matter covered, however it may not necessarily have been prepared by persons licensed to practice law in a particular jurisdiction. The publisher is not engaged in rendering legal or other professional advice, and this publication is not a substitute for the advice of an attorney. If you require legal or other expert advice, you should seek the services of a competent attorney or other professional. For subscription information, please visit www.West.Thomson.com.