WILMERHALE

False Claims Act Alert

January 6, 2012

LITIGATION/CONTROVERSY

The False Claims Act: 2011 Year-In-Review

TABLE OF CONTENTS

Introduction 2

Overview of the False Claims Act 2

Congressional and Regulatory Update: Efforts to Strengthen the False Claims Act 3

Latest Developments in Settlements & Judgments: Aggressive Enforcement of the False Claims Act by the Obama Administration 5

Case Law Developments 8

- **Supreme Court - Public Disclosure Bar** 8
- **First Circuit - Indirect Liability; Implied Certification; What Makes a Claim "False"** 9
- **Third Circuit - Implied Certification** 10
- **Fourth Circuit - (1) FCA Seal Provisions Are Constitutional; (2) Government-Knowledge Defense** 11
- **Fifth Circuit - Indirect Liability; Reverse False Claims** 12
- **Sixth Circuit - Pleading Fraud with Particularity under Fed. R. Civ. P. 9(b)** 13
- **Seventh Circuit - Public Disclosure Bar** 14
- **DC Circuit - First-to-File Rule** 14

Trends from 2011 and Tips for 2012 15

Conclusion 17

About WilmerHale's False Claims Act Practice 17

INTRODUCTION

The last few years have ushered in an unprecedented wave of activity by Congress, the Obama Administration, and the courts in the False Claims Act (FCA) arena. This renewed focus by all three branches means that companies doing business with the federal government must remain vigilant to avoid liability. The 2009 and 2010 amendments to the FCA are giving rise to new and expanded legal theories. The growing number of FCA cases means that courts will continue to have numerous opportunities to redraw the boundaries of the Act. And the Obama Administration has shown no signs of backing off from its aggressive enforcement of the Act, including its efforts to increase the number and size of blockbuster settlements. Since January 2009, the Department of Justice (DOJ) has recovered $8.7 billion through FCA cases—the largest three-year recovery total in the Department of Justice's history and more than one-fourth of the total FCA recoveries over the last 25 years.[1]

Companies should pay attention to these developments and strengthen their internal compliance programs to resolve potential problems early and internally—before they lead to protracted litigation and potentially hefty fines and other penalties. To help our clients stay ahead of the curve, WilmerHale provides updates about significant changes in FCA law, analyzing what these developments mean as a practical matter, and suggesting compliance tips to avoid potential liability. At the end of each year, we will look back and identify major developments and translate these into compliance tips.

Here is our False Claims Act 2011 Year-In-Review. First, we summarize the FCA and the key provisions that every company working with the government should know. Next, we explain Congress's watershed FCA amendments during the last few years. Then, we discuss the Obama Administration's stepped-up enforcement activities. From there, we analyze the important decisions rendered by the US Supreme Court and other federal courts that are reshaping the contours of FCA law. Finally, we synthesize all of this information to identify some key trends in the FCA arena and suggest some tips for 2012.

OVERVIEW OF THE FALSE CLAIMS ACT

The False Claims Act was passed during the Civil War to combat fraud against the government. The Act imposes liability on any person or corporation who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government.[2] The FCA's scope is remarkably broad. Any company that does business with the government—even indirectly—may face FCA damages and penalties.

Traditionally, a company violates the FCA when it knowingly and materially misrepresents the nature of a good or service that it provides to the government, and that misrepresentation—either in contractual language or other communications—leads to a government payment. A company also can be liable for conspiring to present a false claim to the government or causing a third party to submit a false claim.[3] In addition, companies can incur "reverse" false claims liability if they improperly conceal, avoid or decrease an obligation to pay the government.[4]

An FCA case can originate in two ways. First, the United States itself can bring a case. Second, a private litigant (called a "relator") can bring an action on behalf of the United States under the FCA's *qui tam* provision.[5] Relators can receive between 15 and 30 percent of any judgment or settlement in the government's favor.[6] When a relator files a *qui tam* case, the case remains under seal while the DOJ investigates the claim. Following the investigation, the DOJ can move to dismiss the case, settle with the defendant, intervene as a plaintiff, or decline to intervene but allow the relator to pursue the case.

FCA damages and penalties can be enormous. Standard damages are treble the loss suffered by the government. However, if the company voluntarily discloses a violation as described in the Act, damages are reduced from treble to double.[7] Not only do companies face treble damages, but they also face a civil penalty of $5,500 to $11,000 per "false claim"—which can become numerous if, for example, companies submit regular invoices to the government for ongoing services.[8] Due to the damages and penalties at stake, FCA claims are most commonly filed against companies that receive substantial and regular government payments, such as health care and defense companies.

CONGRESSIONAL AND REGULATORY UPDATE: EFFORTS TO STRENGTHEN THE FALSE CLAIMS ACT

False Claims Act Amendments That Remained Important in 2011

Congressional interest in the False Claims Act has increased significantly during the last few years, as evidenced by the passage of monumental FCA amendments in 2009 and 2010 after more than two decades of Congressional inaction. These recent laws continue to have important repercussions for companies doing business with the federal government because they expanded the types of cases that may be brought. The boundaries of these amendments will continue to be tested in litigation.

The uptick in legislative activity began in 2009 when Congress passed the Fraud Enforcement and Recovery Act (FERA), which amended several FCA provisions.[9] In particular, FERA:

- expanded liability for "reverse" false claims by imposing liability for knowingly or recklessly retaining overpayments from the government, even in the absence of any false statement;[10]
- enabled liability for claims presented not only to the government but also to entities administering government funds;[11]
- allowed the Department of Justice to conduct longer investigations by permitting the government's complaint to relate back to the filing of the relator's complaint; and[12]
- expanded the prohibition on retaliation against relators to cover contractors and agents in addition to employees.[13]

The March 2010 health care reform legislation, the Patient Protection and Affordable Care Act (PPACA), also made important changes to the FCA, primarily by significantly narrowing the public disclosure bar against *qui tam* actions by relators.[14] Because of PPACA, defendants can no longer use information in certain types of public sources (such as state and local administrative reports) to demonstrate that a relator's claim was publicly disclosed prior to the complaint.[15] PPACA also changed public disclosure from a jurisdictional bar to an affirmative defense and forbade dismissal under this defense if the government opposes dismissal.[16] PPACA also expanded the definition of an "original source" (allowing the relator to have "independent knowledge that materially adds to the publicly disclosed allegations" instead of "direct knowledge").[17] Additionally, under PPACA, a company must report and return a Medicare or Medicaid overpayment within 60 days of discovery to avoid FCA liability.[18]

Also in 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act strengthened the FCA provisions prohibiting retaliation against whistleblowers.[19] The Dodd-Frank Act expanded the definition of protected conduct to include employees' lawful efforts to investigate or stop FCA violations.[20]

Relators have taken advantage of the FERA, PPACA, and Dodd-Frank amendments by filing an increasing number of *qui tam* cases in recent years. While the annual number of *qui tam* cases averaged in the double digits in the late 1980s, it reached 573 in 2010 and more than 630 in 2011.[21] Relators and the federal government have collected billions of dollars in damages and penalties in settlements and judgments, and many of these settlements and judgments dwarfed the actual damages suffered by the government.

Congressional Activity in 2011

Although no bills were enacted in 2011, there was False Claims Act and whistleblower-related activity in both the House and Senate, including congressional inquiries questioning whether the recent amendments have succeeded in striking the appropriate balance between facilitating internal corporate resolution and prevention of unlawful behavior on the one hand, and promoting whistleblower activity on the other hand.

- The Senate passed S. 633, the "Small Business Contracting Fraud Prevention Act." The bill focuses on penalizing businesses that misrepresent themselves as small businesses or as owned

and controlled by, for example, service-disabled veterans. The bill expands remedies for such a misrepresentation to include civil remedies available under the False Claims Act, such as treble damages. The bill also allows for recovery of the full amount received from the federal government, even if work was performed in return for the payments made, or losses sustained. Although a companion bill was introduced in the House (H.R. 2131), no action has been taken.

- The Senate Judiciary Committee reported out S. 890, the "Fighting Fraud to Protect Taxpayers Act," co-sponsored by Chairman Patrick Leahy and Ranking Member Charles Grassley. The bill would require the Attorney General to report annually to the House and Senate Judiciary Committees on DOJ settlements and compromises of claims or actions that alleged FCA violations or major frauds against the United States and sought damages of more than $100,000.

- One other area attracting attention in the Senate is the protection of government contractors who serve as whistleblowers. The Senate Homeland Security and Governmental Affairs Committee held a hearing on December 6, 2011 focusing on S. 241, the "Non-Federal Employee Whistleblower Protection Act." This proposed piece of legislation would bolster whistleblower protections for government contractors and other non-federal employees.

- The House activity reflected a slightly different approach to whistleblowers this year, although it is not focused on the False Claims Act. The House Financial Services Subcommittee on Capital Markets reported out H.R. 2483, the "Whistleblower Improvement Act," on a 19(R)-14(D) party line vote. The bill, which addressed Dodd-Frank, would require whistleblowers to report misconduct to their employers before notifying the SEC in order to be eligible for a monetary award, unless the employers do not have either an anti-retaliation policy or an anonymous reporting system in place. Supporters said this provision would allow correction of small-scale misconduct to be corrected internally more quickly than through SEC involvement. The bill also would make a whistleblower award discretionary instead of mandatory, and would repeal the minimum award requirement. H.R. 2483 was a primary focus of a May 11 subcommittee hearing on "Legislative Proposals to Address the Negative Consequences of the Dodd-Frank Whistleblower Provision." Although the bill would not impact the False Claims Act itself, it represents a different direction from the significant expansion of whistleblower mechanisms over the past few years.

Primary Regulatory Activity in 2011

On March 21, the Office of Inspector General of the Department of Health and Human Services (OIG) completed a review of state false claims act equivalents to determine whether those state laws were sufficient to qualify the states for an increased share of monetary recovery from certain lawsuits.[22] To qualify for the financial incentive, a state's false claims act must:

- establish liability to the state for false or fraudulent claims, as described in the federal FCA, with respect to Medicaid spending;

- contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in the FCA;

- contain a requirement for filing an action under seal for 60 days with review by the State Attorney General; and

- contain a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.[23]

The OIG concluded that, due to recent amendments to the federal FCA in 2009 and 2010, numerous state laws were no longer in compliance. For these states, which included California, Illinois, Massachusetts, New York, and Texas, the OIG granted a two-year grace period ending on March 31, 2013, during which time the states can update and resubmit their amended state false claims acts to the OIG for approval and continue to receive the 10 percent incentive.

In addition, the US Department of Agriculture (USDA) in December 2011 issued a "direct final rule," effective February 29, 2012, adding a new clause to the Agriculture Acquisition Regulation entitled "Labor Law Violations." This new clause requires every USDA contractor to certify that they are "in compliance with all applicable labor laws" and that, to the best of their knowledge, all of their subcontractors (at any tier) and suppliers are also in compliance with all applicable labor laws. The rule explicitly states that the USDA "considers certification under this clause to be a certification for purposes of the False Claims Act."

LATEST DEVELOPMENTS IN SETTLEMENTS & JUDGMENTS: AGGRESSIVE ENFORCEMENT OF THE FALSE CLAIMS ACT BY THE OBAMA ADMINISTRATION

Since the False Claims Act was amended in 1986, the federal government has recovered more than $30 billion in settlements and judgments.[24] Helped in recent years by increasingly aggressive relators, the Department of Justice has accelerated its efforts and shown dramatic results. Indeed, since January 2009, the government has recovered $8.7 billion[25]—more than triple the annual rate of recovery of the 1986–2008 time period. The acceleration in enforcement activity has been intentional. Tony West, Assistant Attorney General for the Civil Division, explained:

> Twenty-eight percent of the recoveries in the last 25 years were obtained since President Obama took office. These record-setting results reflect the extraordinary determination and effort that this administration, and Attorney General Eric Holder in particular, have put into rooting out fraud, recovering taxpayer money and protecting the integrity of government programs.[26]

In 2011, the federal government continued its aggressive enforcement efforts. For the second year in a row, the government recovered more than $3 billion in civil settlements and judgments under the False Claims Act.[27] The overwhelming majority, $2.8 billion, was recovered under the *qui tam* provisions.[28] That is not surprising given that the number of *qui tam* lawsuits filed in 2011 easily broke the annual record.[29] Relators filed 638 *qui tam* lawsuits in 2011—roughly a 10% increase over the 573 such lawsuits filed in 2010 (which was the previous record), and almost a 50% increase over 2009, when 433 *qui tam* lawsuits were filed.[30]

The following chart details the DOJ's overall increased FCA enforcement, along with the upward trend in *qui tam* lawsuits over the last 25 years:[31]

Fiscal Year	New Matters (non-*qui tam*)	New Matters (*qui tam*)	Settlements and Judgments (non-*qui tam*)	Settlements and Judgments (*qui tam*) – United States intervened	Settlements and Judgments (*qui tam*) – United States declined to intervene	Settlements and Judgments (*qui tam*)	Settlements and Judgments (total)
1987	343	30	$86,479,949	$0	$0	$0	$86,479,949
1988	210	43	$173,287,663	$2,309,354	$33,750	$2,343,104	$175,630,767
1989	224	87	$197,202,180	$15,111,719	$1,681	$15,113,400	$212,315,580
1990	243	72	$189,564,467	$40,483,367	$75,000	$40,558,367	$230,122,734
1991	234	84	$270,530,467	$70,384,431	$69,500	$70,453,931	$340,984,398
1992	285	114	$137,958,206	$133,949,447	$994,456	$134,943,903	$272,902,109
1993	304	138	$181,945,576	$183,643,787	$6,603,000	$190,246,787	$372,192,363
1994	280	218	$706,022,897	$379,018,205	$2,822,323	$381,840,528	$1,087,863,425
1995	233	269	$269,989,642	$239,204,292	$1,635,000	$240,659,292	$510,648,934
1996	185	341	$247,357,271	$124,361,203	$13,522,433	$137,883,636	$385,240,908
1997	184	547	$465,568,061	$621,919,274	$6,021,200	$627,940,474	$1,093,508,535

1998	120	468	$151,435,794	$438,834,846	$30,248,075	$469,082,921	$620,518,715
1999	140	493	$195,390,485	$492,924,785	$5,067,503	$497,992,288	$693,382,773
2000	94	363	$367,887,197	$1,208,370,688	$1,688,957	$1,210,059,645	$1,577,946,841
2001	85	311	$494,496,974	$1,215,525,916	$128,587,151	$1,343,525,095	$1,838,022,070
2002	61	318	$119,598,292	$1,078,174,023	$25,786,140	$1,103,960,162	$1,223,558,454
2003	92	334	$703,003,368	$1,539,357,284	$5,185,911	$1,544,543,195	$2,247,546,563
2004	106	432	$115,656,023	$561,717,502	$9,261,879	$570,239,382	$685,895,404
2005	105	406	$276,914,983	$1,149,047,524	$7,481,593	$1,156,529,117	$1,433,444,099
2006	71	384	$1,710,529,257	$1,489,706,466	$22,661,363	$1,512,367,829	$3,222,897,086
2007	129	365	$563,626,844	$1,336,729,091	$160,246,894	$1,486,895,913	$2,050,522,757
2008	161	379	$318,419,711	$1,032,920,939	$12,678,936	$1,045,599,875	$1,364,019,587
2009	132	433	$466,654,681	$1,957,410,366	$33,776,480	$1,990,963,967	$2,460,521,527
2010	136	573	$620,354,025	$2,323,508,953	$122,653,500	$2,391,953,584	$3,085,640,238
2011	124	638	$241,225,995	$2,639,570,971	$148,453,147	$2,788,023,938	$3,029,249,933
TOTAL	**4,289**	**7,843**	**$9,296,033,668**	**$20,274,004,251**	**$745,555,872**	**$21,019,560,124**	**$30,315,593,792**

Noteworthy Settlements

As has been the case for the past decade, the vast majority of the DOJ's recoveries occurred in the health care sector. In 2011, approximately $2.4 billion of the $3 billion in FCA settlements and judgments was obtained from companies operating in the health care industry.[32] However, the health care industry was not the only focus of the DOJ in 2011. Significant settlements occurred in other industries that conduct business with the federal government, including more general government procurement contractors, which accounted for more than $350 million of the 2011 recovery.[33]

The following were some of the most significant settlement announcements in the past year.

Health care

- **Elan Pharmaceuticals, Inc.**: In a February press release, the DOJ announced that Elan Pharmaceuticals, Inc. agreed to pay $103 million in FCA civil damages, along with $100.5 million in criminal penalties for misdemeanor misbranding, to resolve allegations that the company promoted the sale of Zonegran for off-label uses. The federal share of the FCA civil settlement was $59 million. Elan also agreed to enter into a corporate integrity agreement with the OIG. The agreement required Elan to implement procedures and reviews to avoid and detect conduct similar to that alleged in the *qui tam* lawsuit.[34]

- **Medline Industries, Inc.**: Medline Industries, Inc. paid $85 million to settle allegations that it violated the FCA by giving kickbacks to health care providers that purchase medical products under Medicare and Medicaid. Notably, the government declined to intervene in the suit. This settlement is one of the largest FCA settlements in which the government did not intervene.[35]

- **Average Wholesale Price Litigation Brought By Ven-A-Care**: In 2011, a number of pharmaceutical companies agreed to settle state and federal FCA claims brought by Ven-A-Care of the Florida Keys Inc. The *qui tam* lawsuits claimed that the companies caused Medicaid to overpay for drugs by inflating the reported "Average Wholesale Price." The settlements amounts from 2011 ranged from $29.8 million to $150 million. Ven-A-Care has settled more than 20

lawsuits since 2000, recovering about $3 billion for state and federal governments, of which Ven-A-Care received more than $400 million. The consolidated litigation is still ongoing.[36]

- **Maxim Healthcare Services, Inc.**: Maxim Healthcare Services, Inc. agreed to pay approximately $130 million in FCA civil damages to the Medicaid and Veterans Affairs programs, along with a $20 million criminal penalty for health care-fraud conspiracy, to resolve allegations that Maxim billed for services not rendered, services that were not documented properly, and services performed by unlicensed offices. The federal government's share was $70 million. Maxim also agreed to a corporate integrity agreement with the OIG, which required certain actions and monitoring under the OIG's supervision. Finally, Maxim agreed to retain and pay an independent monitor to review its business operations and regularly report upon the company's compliance with federal and state health care laws, regulations, and programs.[37]

- **LHC Group Inc.**: LHC Group Inc. agreed to pay $65 million plus interest to resolve an FCA *qui tam* suit alleging that it improperly billed Medicare, TRICARE, and the Federal Employees Health Benefits program for home health care services that were not medically necessary and for services rendered to patients who were not homebound. LHC also agreed to a Corporate Integrity Agreement with the OIG, under which the OIG will oversee a review of LHC's fraud prevention efforts.[38]

- In addition, several health care companies have issued press releases announcing settlements they have reached in principle. These include GlaxoSmithKline, settling civil and criminal liabilities related to its sales and marketing practices, its use of a Medicaid exception, and its development and marketing of Avandia, in the amount of $3 billion,[39] and Amgen, setting aside $780 million to settle federal civil and criminal investigations, state Medicaid claims, and 10 *qui tam* suits related to its sales and marketing practices.[40] Similarly, Abbott Laboratories announced that it had set aside $1.5 billion of litigation reserves related to settlement discussions with the DOJ regarding Depakote.[41]

Procurement

- **DynCorp International LLC and The Sandi Group**: DynCorp International LLC and The Sandi Group (TSG) agreed to pay more than $8.7 million to settle FCA allegations related to DynCorp's contract with the Department of State to provide civilian police training in Iraq. More specifically, DynCorp agreed to pay $7.7 million to resolve allegations that it submitted inflated claims for construction of container camps. DynCorp's subcontractor, TSG, agreed to pay $1.01 million to resolve claims for reimbursement of danger pay that, according to allegations, it falsely claimed to have paid.[42]

- **Accenture LLP**: Accenture LLP agreed to pay $63.675 million to settle allegations that it received kickbacks, inflated prices and rigged bids in connection with federal information technology contracts.[43]

- **Major Information Technology Settlement**: A set of major information technology government contractors agreed to pay $199.5 million plus interest to resolve allegations that the companies failed to disclose their best prices for products and services offered through the GSA's Multiple Award Schedule program. According to DoJ, this is the largest FCA settlement ever obtained by GSA.[44]

  Earlier in the year, one of these companies also agreed to pay $46 million to settle allegations that (1) a company that it acquired in 2010 paid kickbacks for recommendations that federal agencies purchase its products and (2) the acquired company's GSA Schedule contracts were incorrectly priced. Two whistleblowers—who have filed similar suits against other IT companies—originally filed the qui tam suit alleging the improper kickbacks. The United States intervened and, based on an audit conducted by the GSA Office of Inspector General, added the pricing claims.[45]

Other

- **General Communication Inc.**: General Communication Inc. (GCI) paid $1.5 million to settle FCA claims. The settlement resolved allegations that Alaska DigiTel LLC, now owned by GCI, submitted claims for ineligible subscribers under the Low Income Support Program of the Universal Service Fund, which offers free or discounted telephone service to eligible individuals.[46]

- **BP Amoco**: BP Amoco agreed to pay $20.5 million to resolve FCA allegations that BP underpaid royalties owed on natural gas produced from federal and Indian land leases. The United States had initially declined to intervene in the suit, but intervened for the purpose of completing the settlement.[47]

CASE LAW DEVELOPMENTS

The following analyzes the important decisions issued by the US Supreme Court and federal courts of appeals in 2011 and explains how these cases affect potential exposure under the FCA. As explained in greater detail below, the Supreme Court and Seventh Circuit addressed the public disclosure bar, while the First and Third Circuits resolved issues regarding implied certification. Both the First and Fifth Circuits grappled with questions regarding indirect liability, and the First Circuit also addressed the fundamental question of what makes a claim "false." In addition, the Fourth Circuit held that the FCA seal provisions are facially constitutional, and it considered questions pertaining to the government-knowledge defense. Finally, the Fifth Circuit addressed reverse false claims, the Sixth Circuit addressed the requirements for pleading fraud with particularity under Federal Rule of Civil Procedure 9(b), and the DC Circuit grappled with the first-to-file rule.

Supreme Court – Public Disclosure Bar

***Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885 (2011)**

The Supreme Court held that a federal agency's written responses to Freedom of Information Act (FOIA) requests are "reports" within the meaning of the public disclosure bar of the FCA. The decision provides support for defendants seeking to dismiss *qui tam* suits on this frequently litigated ground.

About the Case

In 2005, Daniel Kirk, a former employee of Schindler Elevator, filed an FCA action against Schindler Elevator, alleging that the company had submitted false claims for payment under federal contracts. To support his allegations, Kirk relied on information that his wife received from the Department of Labor in response to FOIA requests.

The company moved to dismiss on multiple grounds, including the FCA's pre-PPACA public disclosure bar (as previously codified at 31 U.S.C. § 3730(e)(4)). The district court ruled that the relevant claims were based on either an administrative "report" or "investigation" under the FCA and were therefore barred. The Second Circuit reversed, concluding that a federal agency's response to a FOIA request was neither a "report" nor an "investigation" under the FCA.[48]

The Supreme Court reversed, holding that a federal agency's written response to a FOIA request constitutes a "report" as that term is used in the FCA's public disclosure bar—and that "[a]ny records the agency produces along with its written FOIA response are part of that response." 131 S. Ct. at 1893. The Court left open whether agency records that are released under FOIA but not attached to a written response fall within the public disclosure bar. *Id*. at 1894-95. In reaching this conclusion, the Court explained that the case "seems to us a classic example of the 'opportunistic' litigation that the public disclosure bar is designed to discourage," because "anyone could have filed the same FOIA requests and then filed the same suit" or simply could "submit FOIA requests until he discovers a federal contractor who is out of compliance, and potentially reap a windfall." *Id*. at 1894. The Court did not reach the broader question of whether the public disclosure bar precluded Kirk's suit, leaving for remand whether other statutory requirements of the bar were met.

Implications for Future False Claims Act Cases

This is the second time in two years that the Supreme Court has construed the public disclosure bar expansively to foreclose potential sources of information available to prospective *qui tam* relators. In *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 130 S. Ct. 1396 (2010), the Court held that the bar encompassed reports and investigations from state or local agencies in addition to those at the federal level. Together, *Graham County* and *Schindler Elevator* reflect the Court's understanding of a broad public disclosure bar. In *Graham County*, the Court explained that the bar is intended to have "a broad[ ] sweep," *id*. at 1404, and that the statutory "touchstone" is whether the allegations have, in fact, been "public[ly] disclose[d]." *Id*. at 1410. In *Schindler Elevator*, the Court further explained that the statute reflected "a wide-reaching public disclosure bar" and an "intent to avoid underinclusiveness." 131 S. Ct at 1891.

Shortly after the Court decided *Graham County*, however, Congress abrogated that decision through PPACA's FCA amendment clarifying that the public disclosure bar was limited to reports and investigations at the federal level. *See* 31 U.S.C. § 3730(e)(4)(A)(i)-(ii); *see also* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The dissenting justices in *Schindler Elevator* called on Congress to do so again, noting that the Court's decision "severely limits whistleblowers' ability to substantiate their allegations" and that the matter was "worthy of Congress' attention." Unless and until that occurs, *Schindler Elevator* provides strong support for defendants seeking dismissal of *qui tam* suits under the public disclosure bar.

First Circuit – Indirect Liability; Implied Certification; What Makes a Claim "False"

***United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011), *cert. denied,* No. 11-269, 2011 WL 3841712 (U.S. Dec. 5, 2011)**

The First Circuit held that third parties that do not themselves submit claims to the government may be liable under the FCA if they knowingly cause submitting entities to make false claims through their submissions. In so holding, the court of appeals rejected framework other circuits employ to analyze falsity under the FCA; in its view, the requisite falsity exists where an entity "represent[s] compliance with a material condition of payment that was in fact not met," 647 F.3d at 379, and no distinction need be drawn between claims that are factually false and legally false, or between claims based on implied and express certifications of compliance.

About the Case

The relator alleged that Blackstone Medical, a device manufacturer, engaged in a nationwide kickback scheme to induce doctors to use its products—and that Blackstone knew that receipt of the kickbacks would cause doctors and hospitals (unwittingly) to make material misrepresentations to the federal health care programs when seeking payment. The physicians and hospitals were not named as defendants. To establish the requisite falsity, the relator cited language in provider agreements (signed by doctors and hospitals to establish eligibility for Medicare reimbursements) and cost reports (submitted by hospitals with their reimbursement claims). The former expressly certified compliance with the federal Anti-Kickback Statute; the latter certified compliance with "the laws and regulations regarding the provisions of health care services" and prohibited the procurement of services through kickbacks.

The district court dismissed the claims and the First Circuit reversed, making two important rulings. First, it held that claims can be false or fraudulent under the FCA where they "represent[ ] compliance with a material condition of payment that was in fact not met." 647 F.3d at 379. The First Circuit rejected the contention that such conditions must be expressly set forth in a statute or regulation; rather, the provider agreements and cost reports were sufficient. Second, the court held that even third parties that do not themselves submit claims to the government may be liable if they knowingly cause submitting entities to make false claims through their submissions. *See id*. at 390 ("The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent."). Moreover, the First Circuit took the view that third-party liability is "not conditioned . . . on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct." *Id.*

The First Circuit analyzed a number of decisions from other circuits—which supported the district court's dismissal—and rejected what it described as those decisions' "artificial barriers that obscure and distort" the FCA's statutory language. *Id*. at 385. In particular, the First Circuit rejected the conventional distinction between claims that are factually false and those that are legally false, as well as the distinction between implied and express certifications of compliance. Instead, the First Circuit held that the fundamental standard for fraud or falsity is whether the claims "represented compliance with a material condition of payment that was in fact not met." *Id*. at 379.

The United States did not intervene in the action but supported the relator as *amicus curiae* in both the district court and on appeal. The Supreme Court denied Blackstone's petition for certiorari on December 5, 2011.

Implications for Future False Claims Act Cases

As with the Fifth Circuit's decision in *United States v. Caremark, Inc.*, 634 F.3d 808 (5th Cir. 2011) (described below), the First Circuit's decision in *Hutcheson* adds to the potential theories of False Claims Act liability for entities that may not have any direct dealings with the federal government. Further, the Supreme Court's denial of *certiorari* in *Hutcheson* means that the bounds of implied certification liability will continue to vary from circuit to circuit.

Third Circuit – Implied Certification

***United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011)**

The Third Circuit joined other circuits in adopting the implied false certification theory of liability under the FCA.

About the Case

The relators, former employees of UnitedHealth Group and AmeriChoice, filed a *qui tam* action alleging that sales representatives from their former companies violated the FCA by offering illegal kickbacks to physicians in violation of the Medicare Anti-Kickback Statute (AKS) and by failing to comply with Medicare marketing rules. The relators did not identify any specific false or fraudulent claims for payment that the companies made to the federal government. Instead, they alleged that the companies certified each month to "continue[ ] compliance with all [Medicare] Guidelines and based on such certification [continued] to receive the monthly capitation payment," and that defendants were liable under the FCA on that basis alone.

The district court granted the defendants' motion to dismiss on Rule 12(b)(6) grounds because the complaint did not identify "even a single claim for payment to the Government." *United States ex rel. Wilkins v. United Health Group, Inc.*, No. 08-3425, 2010 WL 1931134, at *4 (D.N.J. May 13, 2010). The court rejected the relators' AKS-based claims because the relators failed to allege that the companies specifically certified compliance with the AKS, or that the Government made payments based on such a certification. *Id*.

Affirming in part and reversing in part, the Third Circuit held that FCA liability may exist even though the complaint does not identify a particular false claim, as long as the defendant knew at the time it submitted a claim for payment that it was not complying with a statute or regulation to which it had certified compliance. 659 F.3d at 313. The court was careful to explain that a defendant would not be liable for an implied false certification if compliance with the provision at issue is simply a condition for *participation* in the government program. Liability may exist only if compliance with the particular statute or regulation is a condition for government payment. *Id*. at 309. Thus, even though defendants never expressly certified compliance with AKS, the court reversed the dismissal of the relators' AKS-based claims because (1) defendants were required monthly to certify continued compliance with Medicare guidelines as a prerequisite to eligibility under the Medicare program; (2) AKS was part of those guidelines; and (3) compliance therewith was an express condition of payment. On the other hand, the panel affirmed the dismissal of the relators' allegations based on Medicare marketing regulations because compliance with

those regulations was only a requirement for Medicare participation—not a condition for government payment. *Id*. at 308.

Implications for Future False Claims Act Cases

Now adopted in one form or another by a majority of circuits (First, Second, Third, Sixth, Ninth, Tenth, Eleventh and District of Columbia), the implied false certification theory has expanded the scope of FCA liability. These courts have held that an FCA violation may occur without a factually false claim or a false certification submitted with a claim for payment. Instead, the government or a relator typically must allege: (1) a general certification of compliance with the statutes or regulations regarding the government program at issue; and (2) a later submission of a claim for payment at a time the contractor was out of compliance with the statutes or regulations. Relators have argued that defendants should be liable for violating any statute or regulation that was a condition of participation in the government program; courts that have adopted the theory, however, have been careful to cabin it by requiring that the provision at issue set forth an express condition of payment.

Fourth Circuit – (1) FCA Seal Provisions are Constitutional; (2) Government-Knowledge Defense

***United States ex rel. Ubl v. IIF Data Solutions*, 650 F.3d 445 (4th Cir. 2011)**

The Fourth Circuit held that a government-knowledge defense can be supported by evidence that the government customer was satisfied with the contractor's work, even if that customer was not the contracting entity or the entity that paid the invoices.

About the Case

The relator alleged: (1) IIF fraudulently induced the award of three GSA Schedule contracts, and (2) after receiving orders to perform services for the National Guard Bureau, IIF submitted fraudulent invoices misclassifying the educational level of some of its employees and billing them at rates higher than warranted. Under the GSA Schedule contract orders, GSA was responsible for billing and payment, but the National Guard Bureau was IIF's actual customer.

In the district court, the relator challenged the admission of evidence that (1) the National Guard Bureau could alter the terms of the GSA Schedule contracts and (2) the Bureau approved of the IIF personnel assigned to its contracts and was satisfied with their work. The relator argued that, under a GSA Schedule contract, the contract is with the GSA, and any knowledge the Bureau had was irrelevant to the fraud case.

Affirming in part and reversing in part, the Fourth Circuit ruled that the Bureau employees' "knowledge of IIF's performance under the contracts was relevant to the question of whether IIF acted with the requisite intent" and was admissible evidence. 650 F.3d at 453.

First, the court found that government satisfaction with the contractors work can be relevant to the intent elements of the FCA and a government-knowledge defense: "Evidence that the government knew about the facts underlying an allegedly false claim can serve to distinguish between the knowing submission of a false claim, which is generally actionable under the FCA, and the submission of a claim that turned out to be incorrect, which generally is not actionable under the FCA." *See id*. at 452-53. Second, the court held that government knowledge is not limited to employees of the contracting agency and knowledge held by the agency for whom the work is performed under a GSA schedule contract is relevant to the government-knowledge defense. *See id*. at 453.

Implications for Future False Claims Act Cases

The Fourth Circuit's decision strengthens the ability of defendants advancing a government-knowledge defense to counter arguments that knowledge must be held by a narrow subgroup of government employees.

***American Civil Liberties Union v. Holder*, No. 09-2086, 2011 WL 1108252 (4th Cir. March 28, 2011)**

The Fourth Circuit held that the FCA's seal provisions are facially constitutional. These provisions do not violate the First Amendment or the constitutional separation of powers.

About the Case

The ACLU and other organizations filed a complaint against the Attorney General of the United States, alleging that the mandatory seal provisions of the FCA violate the First Amendment and the constitutional separation of powers by infringing on a court's inherent authority to decide on a case-by-case basis whether a particular *qui tam* complaint should be sealed. A divided panel of the Fourth Circuit rejected the organizations' challenge.

With respect to the First Amendment, the court reasoned that the government has a "compelling interest in protecting the integrity of ongoing fraud investigations" and that the seal provisions are narrowly tailored to serve that interest. 2011 WL 1108252, at *7.

The court also held that the seal provisions do not violate the Constitution's separations of powers. The court determined that the power to seal a complaint falls within the least significant category of inherent power held by lower federal courts: "those reasonably useful to achieve justice." *Id*. at *10. While the seal provisions place mandatory requirements upon the judiciary, the seal provisions "are a proper subject of congressional legislation and do not intrude on 'the zone of judicial self-administration to such a degree as to prevent the judiciary from accomplishing its constitutionally assigned functions.'" *Id*.

Implications for Future False Claims Act Cases

The organizations declined seek further review in the Supreme Court, so the Fourth Circuit's decision stands. However, the court of appeals left open the possibility of a challenge to these provisions by a relator who wishes to speak out about their *qui tam* complaint. For now, the seal provisions—which both benefit and challenge defendants—remain unaffected, and the current pattern of long-term sealing can be expected to continue.

Fifth Circuit – Indirect Liability; Reverse False Claims

***United States v. Caremark, Inc.*, 634 F.3d 808 (5th Cir. 2011)**

The Fifth Circuit held that a defendant that has no direct obligations to the federal government may be liable for indirect reverse false claims submitted by another entity under 31 U.S.C. § 3729(a)(7) (recodified as amended at 31 U.S.C. § 3729(a)(1)(g)).

About the Case

This suit targeted Caremark in its role as plan administrator for pharmacy benefits plans enrolling "dual-eligible" individuals—i.e., individuals covered by both third-party insurance and state Medicaid programs. In cases of dual eligibility, federal law requires state Medicaid agencies to seek reimbursement from third-party insurers and to return a portion of any third-party recovery to the federal government. The suit alleged that Caremark made false statements to the state agencies that allowed Caremark to avoid reimbursing the state programs, which in turn had the effect of concealing, avoiding or decreasing the states' own reimbursement obligations to the federal government.

The United States sought to impose liability on Caremark under two theories. First, the federal government provides direct funding to state Medicaid agencies, and because defrauding a state agency has a direct impact on the federal government, it is the same as defrauding the federal government itself. Second, even if Caremark did not itself owe an obligation to the federal government, its false statements caused the state agencies to make false statements to the federal government with respect to their own obligations, which violated 31 U.S.C. § 3729(a)(7) (recodified as amended at 31 U.S.C. § 3729(a)(1)(g)).

The Fifth Circuit adopted the second theory and declined to rule on the first. 634 F.3d at 815. The court explained: "The statute does not require that [a false] statement impair the *defendant's* obligation; instead, it requires that the statement impair 'an obligation to pay or transmit money or property to the Government.'" *Id*. at 817.

Implications for Future False Claims Act Cases

Along with the First Circuit's decision in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011), *Caremark* is another in a series of recent cases highlighting the prospect of liability even for entities that may have no direct dealings with the federal government. The general availability of such liability as a matter of law can be expected to lead to greater reliance on case-specific defenses based on the FCA's materiality, knowledge and causation requirements.

Sixth Circuit – Pleading Fraud with Particularity under Fed. R. Civ. P. 9(b)

***United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461 (6th Cir. 2011)**

The Sixth Circuit strictly applied Federal Rule of Civil Procedure 9(b) to hold that a relator must, at a minimum, allege a representative false claim that was actually submitted to the government; the relator is not entitled to a relaxed application of Rule 9(b) on the ground that the requisite facts are solely within the control of the defendant.

About the Case

The relators alleged that VPA, an in-home medical services provider, submitted false claims for radiological exams to Medicaid and Medicare. According to the complaint, the exams were either completely nondiagnostic (i.e., worthless) or defective in that they failed to meet testing standards established by the American College of Radiology and the Society for Vascular Ultrasound.

The Sixth Circuit affirmed the district court's dismissal of the complaint on two grounds. First, it concluded that the relators could not prevail on an implied certification theory of liability because they could not identify any Medicare or Medicaid regulations that mentioned the industry standards upon which they relied. The court explained: "[N]oncompliance constitutes actionable fraud only when compliance is a prerequisite to obtaining payment. Thus, a relator cannot merely allege that a defendant violated a standard—he or she must allege that compliance with the standard was a required to obtain payment." 655 F.3d at 468. Accordingly, the Sixth Circuit affirmed the dismissal of the complaint insofar as it was based on defective tests. As to the allegedly worthless (or nondiagnostic) tests, the court held that such claims could be actionable as a matter of law on the ground that they were equivalent to billing the government for services that were not actually performed. *Id*. The Sixth Circuit, however, held that these claims failed to satisfy Rule 9(b) and dismissed them on this second ground.

In affirming the dismissal on Rule 9(b) grounds, the court cited prior Sixth Circuit decisions requiring the relator to identify, at a minimum, "a representative false claim that was actually submitted to the government." *Id*. at 470. The court declined to "relax" the requirements of Rule 9(b) merely because the relators, as independent contractors, had no access to the defendant's billing records. *Id*. at 471. The court left open the possibility that a relaxed standard might apply where the relator pleads facts that support a "strong inference" that a false claim was submitted—circumstances that were not present where, as here, the relators had no personal knowledge of the defendant's billing practices. *Id*. at 471-72.

Implications for Future False Claims Act Cases

The Sixth Circuit's decision in *Chesbrough* provides strong support for defendants seeking to dismiss claims on the ground that relators have failed to allege at least a representative false claim that was actually submitted to the government as a result of the challenged practices.

Seventh Circuit – Public Disclosure Bar

***United States ex rel. Baltazar v. Warden*, 635 F.3d 866 (7th Cir. 2011)**

The Seventh Circuit held that governmental reports of industry-wide practices are insufficient to require dismissal of a *qui tam* suit under the FCA's public disclosure bar where the relator adds "vital" "defendant-specific facts" that were not in the public domain.

About the Case

The relator, a chiropractor, alleged that her former employer submitted false claims to Medicare and Medicaid by: (1) billing for services that had not been rendered; and (2) "upcoding" other services to increase reimbursements for covered services. These allegations were supposedly based on her personal knowledge as an employee and her own investigation into her former employer's practices. The district court, however, dismissed her complaint under the FCA's public disclosure bar on the ground that several governmental reports had already disclosed similar false claims submitted from across the industry—including a 2005 report by the OIG that concluded that 57 percent of sampled chiropractors' claims were for uncovered services and that another 16 percent were for services that had been miscoded.

The Seventh Circuit reversed and, in doing so, explained its view of the proper application of the FCA's pre-amendment public disclosure bar in the context of industry-wide disclosures of potentially fraudulent practices. The court said that the critical question is whether the relator "supplied vital facts that were not in the public domain." 635 F.3d at 869. In so holding, the Seventh Circuit distinguished its earlier decision in *United States ex rel. Gear v. Emergency Medical Associates of Illinois, Inc.*, 436 F.3d 726 (7th Cir. 2006). In that case, the Government Accountability Office (GAO) had concluded that the nation's 125 teaching hospitals regularly billed Medicare for services performed by residents that were still in training; the relator, the court explained, "did not add one jot to the agency's fund of information." 635 F.3d at 869. In contrast, the relator in *Baltazar* supplied "defendant-specific facts" about the defendant's scienter that were based on her personal knowledge of the defendants' billing practices. *Id*.

Implications for Future False Claims Act Cases

Relators can be expected to rely on *Baltazar* in seeking to avoid application of the False Claims Act's public disclosure bar in cases where the practices at issue have already been investigated and disclosed at an industry level by either the government or the media. To do so successfully, however, they will need to establish that they have added "vital" facts that are specific to the defendant and that go beyond the existing base of publicly available information.

DC Circuit – First-to-File Rule

***United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204 (D.C. Cir. 2011)**

The DC Circuit held that the FCA's first-to-file rule bars subsequent actions even where the first complaint does not satisfy the pleading requirements of Rule 9(b). Subsequent suits are barred where they allege the "same material elements of fraud," such that a governmental investigation of the first complaint would uncover the fraud alleged in the second.

About the Case

Batiste was the second of two *qui tam* suits filed against SLM Corporation (Sallie Mae) alleging that Sallie Mae encouraged student loan forbearances that violated Department of Education (DOE) regulations. Although the complaints both alleged nationwide schemes beginning in late 2004, they focused on distinct facts available to the relators as employees in different offices (New Jersey and Nevada) and different Sallie Mae subsidiaries. The first suit was dismissed because the relator failed to obtain counsel by the required deadline; the second suit was dismissed on the basis of the first-to-file rule, 31 U.S.C. § 3730(b)(5).

The DC Circuit affirmed the dismissal of the second suit. It found that the complaints alleged the same material elements of a fraudulent scheme, reasoning that, if the government had investigated the allegations in the first complaint on a nationwide basis, it would have discovered the fraud alleged in the second complaint. More generally, the court held that the first-filed complaint need not satisfy Rule 9(b) to bar later complaints; rather, it "must provide only sufficient notice for the government to initiate an investigation into the allegedly fraudulent practices, should it choose to do so." 659 F.3d at 1210. In so holding, the court rejected the contrary views of the government, which argued that the rule should apply only where the earlier compliant meets Rule 9(b).

Implications for Future False Claims Act Cases

The DC Circuit's holding conflicts with the Sixth's Circuit's decision in *Walburn v. Lockheed Martin Corp.*, 431 F. 3d 966, 972 (6th Cir. 2005), which held that the first-to-file rule applies only where the earlier complaint satisfies Rule 9(b). *Batiste* provides strong support to defendants seeking to dismiss *qui tam* suits where a closely similar case has been previously filed.

TRENDS FROM 2011 AND TIPS FOR 2012

Vigorous activity by Congress, the Obama Administration and the federal courts in the FCA arena produced some important trends for companies doing business with the federal government. Below are a few key themes identified from the events of 2011 and a discussion about what these developments could mean for clients. Following that is some advice for how companies can navigate the ever-shifting FCA landscape to avoid potential liability in the future.

Key Developments and Trends in 2011

Increased Use of Civil Investigative Demands. One of the less remarked upon, but increasingly important, changes to the FCA was Congress's decision in 2009 to make it significantly easier for DOJ investigators to obtain discovery prior to initiating a lawsuit through the issuance of Civil Investigative Demands (CIDs). CIDs can be issued to any person who may have "information relevant to a false claims law investigation," and can be used to obtain documents as well as interrogatory responses and oral testimony.[49] Prior to a new rule implementing that legislation that took effect in March 2010, only the Attorney General could authorize issuance of CIDs; today, they can be approved by any US Attorney or the Assistant Attorney General for the Civil Division. The effect of the new rule has been a noticeable increase in the use of CIDs in 2011, which makes it easier for the government to build its case before ever filing a complaint—thereby subjecting targets to more government "fishing expeditions" and increasing the odds that a future complaint will meet the FCA's rigorous pleading standards and survive a motion to dismiss.

Continued Push Toward "Implied Certification" Theories of FCA Liability. In 2011, *qui tam* relators and the DOJ continued the push to expand FCA liability by arguing that claims can become false if the company submitting the claim violated a regulatory requirement connected with the goods or services that are being reimbursed by the government, since the claims carried a false "implied certification" of regulatory compliance. "Implied certification" liability is particularly hazardous for densely regulated industries like health care or financial services, where any regulatory infraction—even those subject to a separate enforcement scheme by the primary regulator, and even where no express certification accompanied the particular claim—can potentially give rise to FCA liability. In 2011, the First and Third Circuit joined six other circuits that had previously embraced the "implied certification" theory,[50] and the government and relators continued to pursue such theories aggressively in newly filed lawsuits.

Qui Tam Suits Against Entire Industries. Although the Supreme Court has held that the FCA does not permit "claim smuggling" and thus relators must establish jurisdiction over each claim,[51] relators nonetheless are increasingly bringing FCA lawsuits against entire industries that are believed to share common practices, even where the relators may know detailed facts regarding, at most, only one of the players. Recent examples include an FCA case against multiple lenders in the student loan industry, which resulted in a nearly $60 million settlement in 2010.[52] In 2011, multiple *qui tam* suits were unsealed that each brought claims against nearly every major mortgage servicer for alleged abuses connected with home loan servicing and foreclosure.[53] These suits typically do not feature traditional "insider" or

whistleblower allegations against particular companies, but rather represent efforts to identify problems or patterns within entire industries—typically, a pattern of alleged regulatory non-compliance—that can subject large numbers of defendants to FCA liability.

Increasing Use of "Reverse False Claims" Theory. In 2009, FERA amended the FCA to expand liability for those who allegedly improperly avoid returning or withhold overpayments owed to the government.[54] Although so-called "reverse false claims" had been possible prior to FERA, the FERA amendments created new risk that mere retention of overpayments, even absent any other affirmative act to withhold or conceal them, could itself give rise to FCA liability. PPACA, which was enacted in 2010, further expanded exposure for health care providers by defining "overpayments" to include "any [Medicare or Medicaid] funds that a person receives or retains . . . to which the person, after applicable reconciliation, is not entitled."[55] All companies, particularly those in the health care industry, therefore need to be especially alert to having systems in place to detect and return overpayments.

Tips for 2012

Incorporate FCA Analysis into Assessments of Risk Exposure. Particularly with the rise of "implied certification" theories of FCA liability, any regulatory violation that is connected to a claim for payment from the government may become a future source of FCA liability. Therefore, when a company is considering alternative courses of action with regard to regulatory compliance, it is no longer enough simply to determine whether the supervising agency would agree that a proposed action complies with the terms of the contract or regulations, or to assess the likelihood and costs of regulatory enforcement. Instead, companies must also consider how the DOJ might evaluate the proposed action when deciding whether to intervene in a *qui tam* suit and how a jury might view the action if the lawsuit were to proceed to trial. Further, a release or settlement of liability for regulatory violations by the supervising agency may not bind the DOJ.

Utilize the FOIA Process. In light of the Supreme Court's decision in *Schindler Elevator* that *qui tam* relators cannot bring FCA suits based on information learned through responses to Freedom of Information Act requests (see page 8), companies faced with *qui tam* suits should immediately file FOIA requests with all relevant agencies to determine whether the plaintiffs or their attorneys may have obtained the information underlying the complaint via FOIA. Because FOIA requests can take months or even years to process, such FOIA requests should be filed early in the lawsuit and drawn as narrowly as possible to elicit a response that can aid in a motion to dismiss.

Review Post-Employment Releases. Many *qui tam* suits are brought by disgruntled former employees who utilize information learned on the job. However, in 2010, the Fourth Circuit held that a post-employment release and waiver of claims against the employer can also be construed to include release of *qui tam* claims.[56] The argument that pre-filing releases can act as a bar to subsequent *qui tam* suits was accepted by more courts in 2011, including the District of Massachusetts.[57] Accordingly, companies seeking to limit their FCA exposure should review any releases for departing employees to ensure that the release encompasses future FCA claims.

Ensure Preservation of Documents by Opposing Parties. One of the pitfalls of the sealing provisions of the FCA is that a case may be filed and pending for months or years before the defendant becomes aware of the lawsuit. This limits the defendant's ability to remind the other side of its duty to preserve all relevant documents, possibly limiting discovery opportunities when the suit is ultimately unsealed. Although preservation obligations would exist regardless, they may not be scrupulously adhered to without the specter of active litigation. Accordingly, companies that become aware that an FCA lawsuit is pending or possible—for example, companies subjected to pre-filing discovery via Civil Investigative Demands or that receive a partially unsealed copy of a complaint—should move quickly to send a letter to the government or relator reminding them of their duty to preserve relevant documents.

CONCLUSION

Congress, the Obama Administration and federal courts show no signs of letting up their attention to the False Claims Act, as evidenced by all three branches' growing activity in this arena during the last few years. Looking ahead, 2012 promises to bring another year of significant changes to the law. We will continue to track and alert you of important developments as they occur.

ABOUT WILMERHALE'S FALSE CLAIMS ACT PRACTICE

With a team of veteran litigators and former Justice and Defense Department lawyers, WilmerHale brings unparalleled knowledge and experience to defending against allegations of fraud, and in particular FCA matters. We regularly represent clients in sectors of the economy facing the greatest FCA activity, including pharmaceutical and health care, defense, information technology and financial services. Our team includes lawyers who were directly responsible for the litigation, management and settlement of major FCA investigations and cases during periods of government service and who now defend against them. We approach each matter with a deep understanding of the government's objectives, and we have obtained favorable resolutions of numerous matters without a formal action being filed.

We have been able to obtain early dismissal or resolution of suits brought by *qui tam* plaintiffs and the government by focusing on precedent-setting legal defenses, including innovative uses of the public-disclosure bar. By conducting credible internal investigations and negotiating with the DOJ, we have also helped clients avoid criminal prosecution and accomplish appropriate civil resolutions of parallel criminal, civil and administrative proceedings. If a case goes to trial, we have experienced courtroom advocates who have tried and won FCA cases before juries.

Our FCA Practice includes:

- A former Deputy Attorney General of the United States, who in that capacity had ultimate oversight over the DOJ's Civil Frauds Unit and considered major interventions and settlements. She also had served as General Counsel of the Department of Defense, responsible for overseeing all litigation, including FCA litigation.

- A former Deputy Attorney General in the Obama Administration, who as the second ranking official in DOJ supervised all of its litigating and law enforcement components and co-led (with the Deputy Secretary of HHS) the Administration's "HEAT" initiative against health care fraud; previously supervised civil frauds and False Claims Act enforcement for the United States while serving as Assistant Attorney General for the Civil Division; and supervised all litigation—including False Claims Act and government contracts litigation—for the Department of Defense while serving as Deputy General Counsel.

- A former First Assistant US Attorney and Deputy Chief of the Civil Division of the Boston US Attorney's Office, one of the most active offices in the country, where she litigated and supervised major FCA actions.

- A former Deputy General Counsel of the Department of Defense, who in that capacity managed major civil fraud and government contract matters.

- A former Deputy Assistant Attorney General and Principal Deputy Associate Attorney General of the DOJ, who in those capacities worked closely with the Civil Frauds Unit on several high-profile matters, and who in the latter capacity considered major interventions and settlements proposed by that unit.

- A former Assistant Attorney General for Legal Policy, who worked extensively on behalf of the Department of Justice negotiating amendments proposed by Congress to the FCA.

- Numerous lawyers with FCA trial experience, as well as litigators who specialize in handling government contracts litigation, including bid protests, disputes concerning performance or payment, and suspension and debarment proceedings.

For questions about any information discussed in this alert or regarding the False Claims Act, please contact any members of our practice group who would be happy to assist you.

FOR MORE INFORMATION ON THIS OR OTHER FALSE CLAIMS ACT MATTERS, CONTACT:

Washington DC

David W. Ogden +1 202 663 6440 david.ogden@wilmerhale.com
Jonathan E. Paikin +1 202 663 6703 jonathan.paikin@wilmerhale.com
Jennifer M. O'Connor +1 202 663 6110 jennifer.oconnor@wilmerhale.com
Todd R. Steggerda +1 202 663 6472 todd.steggerda@wilmerhale.com
Jonathan G. Cedarbaum +1 202 663 6315 jonathan.cedarbaum@wilmerhale.com
Carl J. Nichols +1 202 663 6226 carl.nichols@wilmerhale.com
Christopher E. Babbitt +1 202 663 6681 christopher.babbitt@wilmerhale.com

New York

Boyd M. Johnson III +1 212 230 8862 boyd.johnson@wilmerhale.com
Robin L. Baker +1 212 937 7261 robin.baker@wilmerhale.com

Boston

Karen F. Green +1 617 526 6207 karen.green@wilmerhale.com
Stephen A. Jonas +1 617 526 6144 stephen.jonas@wilmerhale.com

Contributions to this alert were provided by Jennifer O'Connor, Jonathan Cedarbaum, Christopher Babbitt, Elisebeth Cook, Gregory Petkoff, Robin Baker, Brent Bickley, Laura Hussain, Madhu Chugh, Emily Murphy, Jimmy Doan, Matthew Haws, Carla Weiss, Natalie Hirt Adams, and Edgar Zoz.

---

[1] Press Release, Office of Pub. Affairs, U.S. 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.

[2] 31 U.S.C. § 3729(a)(1)(A).

[3] *Id*.

[4] 31 U.S.C. § 3729(a)(1)(G).

[5] 31 U.S.C. § 3730(b), (e)(4). The latter provision attempts to encourage whistleblowers to disclose non-public violations while also preventing opportunistic individuals from filing cases based on information available to the public.

[6] 31 U.S.C. § 3730(d).

[7] 31 U.S.C. § 3729(a)(1)-(2).

[8] 31 U.S.C. § 3729(a)(1).

[9] Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617.

[10] 31 U.S.C. § 3729(a)(1)(G).

[11] 31 U.S.C. § 3729(b)(2)(A)(ii).

[12] 31 U.S.C. § 3731(c).

[13] 31 U.S.C. § 3730(h).

[14] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

[15] 31 U.S.C. § 3730(e)(4).

[16] *Id*.

[17] *Id*.

[18] 42 U.S.C. § 1320a-7j(d).

[19] Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).

[20] 31 U.S.C. § 3730(h)(1).

[21] *See Latest Developments in Settlements & Judgments*, *infra* (pp. 5-6) for a chart of annual data on *qui tam* cases.

[22] 42 U.S.C § 1396H.

[23] *Id*. at § 1396H(b).

[24] *See* Press Release, Office of Pub. Affairs, U.S. 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.

[25] *Id*.; *see also supra* text accompanying note 1.

[26] *Id*.

[27] *Id*.

[28] *Id*.

[29] *See* Civil Div., U.S. Dep't of Justice, *Fraud Statistics – Overview*, *available at* http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

[30] *Id*.

[31] *Id*.; "New Matters" represent newly received referrals, investigations, and *qui tam* actions. Non-*qui tam* settlements and judgments do not include matters delegated to United States Attorneys' offices.

[32] *See* Press Release, *supra* note 4.

[33] *See* Press Release, *supra* note 4.

[34] *See* Press Release, U.S. Atty's Office, Dist. of Mass., *Elan Pharmaceuticals Pleads Guilty, Sentenced for Off-Label Marketing of Zonegran* (Feb. 28, 2011), *available at* http://www.justice.gov/usao/ma/news/2011/February/ElanSentencingPR.html.

[35] *See* The Health Law Side Bar, *Medline Settles False Claims Act Allegations for $85 Million in Spite of Government's Failure to Intervene* (Mar. 17, 2011), http://healthlawsidebar.com/?p=178; *see also* Press Release, United States Attorney's Office, Northern District of Illinois, *Chicago U.S. Attorney's Office Collected $142.6 Million in Civil and Criminal Actions in Fiscal Year 2011* (Nov. 16, 2011), *available at* http://www.justice.gov/usao/iln/pr/chicago/2011/pr1116_02.pdf.

[36] *See* Voreacos & Fisk, Bloomberg Businessweek, *Actavis Will Pay $118.6 Million to End Drug-Pricing Claims* (Jan. 5, 2012), *available at* http://www.businessweek.com/news/2012-01-05/actavis-will-pay-118-6-million-to-end-drug-pricing-claims.html; Rosen, Bloomberg, *FDIC Nominee, Investor Fraud, MF Global, Sandoz, Facebook: Compliance* (Nov. 18, 2011), *available at* http://www.bloomberg.com/news/2011-11-18/fdic-nominee-investor-fraud-mf-global-sandoz-compliance.html; Palmer, Law360, *Baxter To Exit Drug Price Inflation MDL For $30M* (Oct. 7, 2011), *available at* http://www.law360.com/articles/276845; Voreacos & Rosenblatt, Bloomberg Businessweek, *Watson, Sandoz Pay $145 Million to Settle Drug-Price Case* (Sept. 15, 2011), *available at* http://www.businessweek.com/news/2011-09-15/watson-sandoz-pay-145-million-to-settle-drug-price-case.html.

[37] *See* Press Release, U.S. Atty's Office, Dist. of New Jersey, *Maxim Healthcare Services Charged with Fraud, Agrees to Pay Approximately $150 million, Enact Reforms After False Billings Revealed as Common Practice* (Sept. 12, 2011), *available at* http://www.justice.gov/usao/nj/Press/files/Maxim%20News%20Release.html.

[38] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Louisiana-Based LHC Group Inc. Agrees to Pay U.S. $65 Million to Resolve False Claims Act Allegations* (Sept. 30, 2011), *available at* http://www.justice.gov/opa/pr/2011/September/11-civ-1299.html.

[39] *See* Press Release, GlaxoSmithKline, *GlaxoSmithKline Reaches Agreement in Principle to Resolve Multiple Investigations with U.S. Government* (Nov. 3, 2011), *available at* http://www.gsk.com/media/pressreleases/2011/2011-pressrelease-710182.htm.

[40] *See* Press Release, Amgen, *Amgen's Third Quarter 2011 Revenue and Adjusted Earnings Per Share (EPS) Each Increased 3 Percent to $3.9 Billion and $1.40* (Oct. 24, 2011), *available at* http://www.amgen.com/media/media_pr_detail.jsp?year =2011&releaseID=1620695.

[41] *See* Press Release, Abbott, *Abbott Reports Strong Ongoing Third Quarter Results; Confirms Double-Digit Ongoing Earnings Growth Outlook for 2011* (Oct. 19, 2011), *available at* http://www.abbott.com/news-media/press-releases/2011-oct19.htm.

[42] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Dyncorp International LLC and the Sandi Group Pay U.S. More Than $8.7 Million to Resolve False Claims Allegations* (Apr. 22, 2011), *available at* http://www.justice.gov/opa/pr/2011/April/11-civ-513.html.

[43] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Accenture Pays U.S. $63.675 Million to Settle False Claims Act Allegations* (Sept. 12, 2011), *available at* http://www.justice.gov/opa/pr/2011/September/11-civ-1167.html.

[44] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Oracle Agrees to Pay U.S. $199.5 Million to Resolve False Claims Act Lawsuit* (Oct. 6, 2011), *available at* http://www.justice.gov/opa/pr/2011/October/11-civ-1329.html.

[45] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Oracle America to Pay United States $46 Million to Resolve False Claims Act Allegations Against Sun Microsystems* (Jan. 31, 2011), *available at* http://www.justice.gov/opa/pr/2011/January/11-civ-128.html.

[46] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Alaska-Based Company Pays U.S. More Than $1.5 Million to Settle False Claims Allegations* (Feb. 22, 2011), *available at* http://www.justice.gov/opa/pr/2011/February/11-civ-218.html.

[47] *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *BP Amoco to Pay U.S. $20.5 Million to Resolve Allegations of Royalty Underpayments from Indian and Federal Lands* (Sept. 16, 2011), *available at* http://www.justice.gov/opa/pr/2011/ September/11-civ-1201.html.

[48] That holding was consistent with the Ninth Circuit's decision in *United States ex rel. Haight v. Catholic Healthcare West*, 445 F.3d 1147 (9th Cir. 2006), but conflicted with the Third Circuit's decision in *United States ex rel. Mistick PBT v. Housing Authority of Pittsburgh*, 186 F.3d 376 (3d Cir. 1999).

[49] 31 U.S.C. § 3733(a)(1).

[50] *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (6th Cir. 2011).

[51] *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007).

[52] *See* Department of Justice Press Release, *Four Student Aid Lenders Settle False Claim Act Suit for Total of $57.75 Million*, (Nov. 17, 2010), *available at* http://www.justice.gov/opa/pr/2010/November/10-civ-1307.html.

[53] *See, e.g.*, *Suit Alleges Banks and Mortgage Companies Cheated Veterans and U.S. Taxpayers*," Wash. Post, Oct. 4, 2011, *available at* http://www.washingtonpost.com/politics/suit-alleges-banks-and-mortgage-companies-cheated-veterans-and-us-taxpayers/2011/10/04/gIQATp4RLL_print.html.

[54] *See* 31 U.S.C. § 3729(a)(1)(G) (liability attaches for "knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government").

[55] *See* PPACA § 6402(a), 124 stat. 755.

[56] *See United States ex rel. Radcliffe v. Purdue Pharma LP*, 600 F.3d 319 (4th Cir. 2010).

[57] *United States ex rel. Nowack v. Medtronic, Inc.*, Nos. 08-cv-10368, 1:09-cv-11625 (July 27, 2011).