Healthcare Fraud and Abuse Review
2014

BASS BERRY SIMS PLC

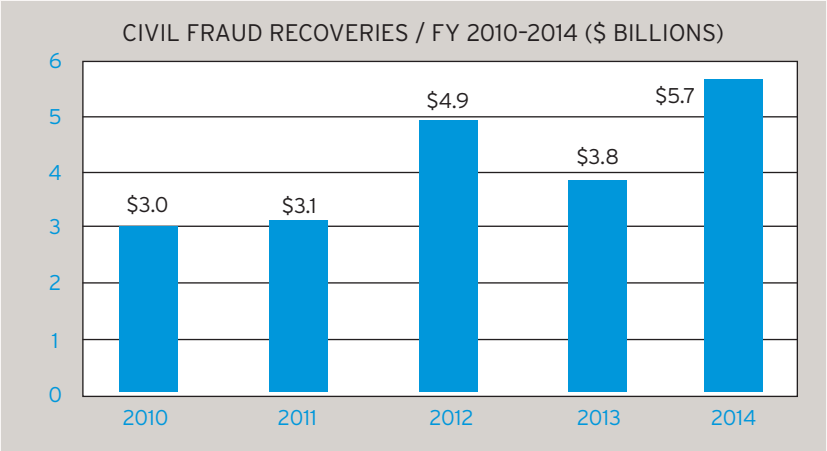
A LOOK BACK...A LOOK AHEAD

The previous year saw federal and state regulators continue the trend of increased enforcement concerning healthcare fraud and abuse.

During the fiscal year ending September 30, 2014, the federal government recovered nearly $5.7 billion – a $1.9 billion increase in recoveries from the previous fiscal year.[1]

Matters arising under the False Claims Act ("FCA") accounted for more than $5 billion of the government's recoveries, bringing the total to more than $20 billion recovered during the last five years. And, nearly $2.3 billion of last year's recoveries related to matters involving false claims against the federal healthcare programs. This is the fifth straight year where recoveries by the federal government under the FCA related to the federal healthcare programs have exceeded $2 billion.

With the benefit of several years' worth of civil enforcement efforts since the passage of legislation that strengthened the FCA, the government racked up significant settlements and judgment against providers in virtually every sector of the healthcare industry. DOJ notched several large settlements against hospitals and health systems, physicians, pharmaceutical manufacturers, skilled nursing facilities, home health companies, among other providers.



In FY 2014, the United States recovered $5.7 billion in fraud-related civil settlements and judgments.

The number of new *qui tam* lawsuits filed by whistleblowers likewise has continued to increase at an alarming pace. For the second straight year, *qui tam* whistleblowers filed more than 700 new lawsuits.[2] And, whistleblowers recovered more than $435 million as their share of proceeds in *qui tam* judgments and settlements, which amounted to nearly a $100 million increase from the previous year.

On September 17, 2014, DOJ's Criminal Division made news by announcing its increased "commitment to criminal investigations and prosecutions that stem from allegations in False Claims Act lawsuits."[3] Along with the announced increased commitment, DOJ explained that the Criminal Division had "implemented a new procedure so that all new *qui tam* complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed." Given the fact that a significant number of criminal prosecutions already result each year from the filing of civil *qui tam* lawsuits, healthcare providers and counsel must pay close attention to the possibility of parallel civil and criminal investigations.

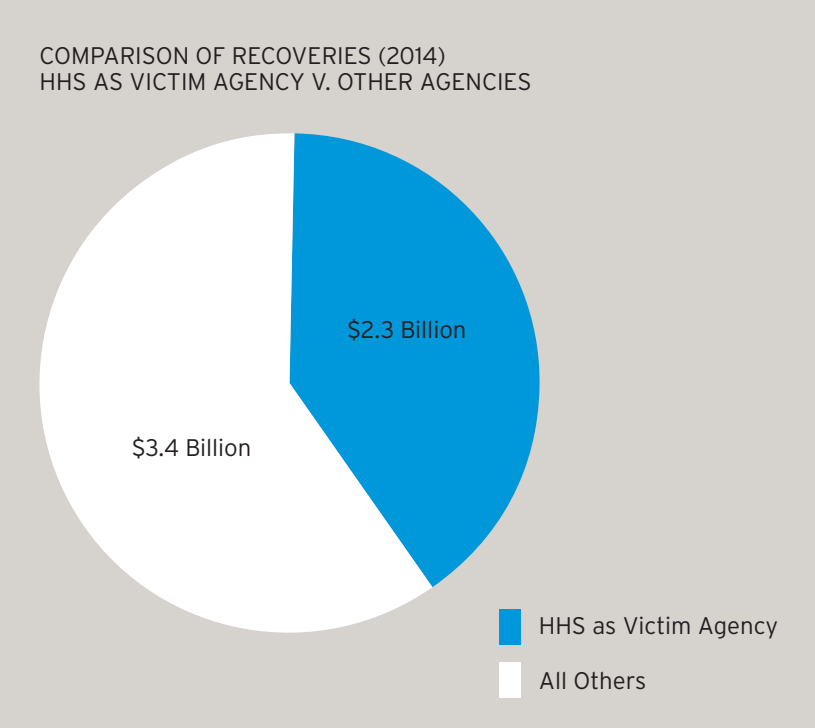
1. *See* http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.
2. There were 713 new *qui tam* lawsuits filed in 2014, compared with 754 new *qui tam* lawsuits filed in 2013. *See* http://www.justice.gov/civil/pages/attachments/2014/11/21/fcastats.pdf.
3. *See* Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at TAF Education Fund Conference (Sept. 17, 2014), at http://www.justice.gov/criminal/pr/speeches/2014/crm.

As in years past, DOJ again secured a number of high-profile criminal convictions and pleas in healthcare fraud matters against providers. Led by the Medicare Fraud Strike Force as part of the Health Care Fraud Prevention & Enforcement Action Team ("HEAT"), DOJ and Health and Human Services ("HHS-OIG") announced numerous enforcement results throughout the year. In May 2014, the Strike Force announced a nationwide takedown in six cities resulting in charges against 90 individuals, including 27 doctors and other professionals, for their alleged participation in Medicare fraud schemes involving an estimated $260 million in false billings.[4] And, in December 2014, the organizer of a $56 million healthcare fraud scheme and his accomplice physician pleaded guilty to conspiracy to commit healthcare fraud and conspiracy to falsify records in a federal investigation regarding home health services and durable medical equipment.[5]

For its part, HHS-OIG reported expected recoveries of more than $4.9 billion consisting of nearly $834.7 million in audit receivables and $4.1 billion in investigative receivables.[6] HHS-OIG reported 971 criminal actions against individuals or entities that had engaged in crimes against federal healthcare programs and 533 civil actions, including lawsuits alleging false claims and unjust-enrichment, seeking civil monetary penalties and administrative recoveries related to provider self-disclosures. HHS-OIG also excluded more than 4,000 individuals and entities from participation in federal healthcare programs.

HHS-OIG also delivered its report concerning its Fraud Prevention System, which is its state-of-the-art analytics technology in which predictive algorithms are run against all Medicare fee-for-service claims prior to payment. HHS-OIG announced that Centers for Medicare & Medicaid Services ("CMS") had made significant progress using the Fraud Prevention System to identify bad actors and take administrative action to protect the federal healthcare programs against unscrupulous providers.[7]

As the government, relators and defendants signify an increased willingness to litigate healthcare fraud matters, courts have continued to tackle key legal questions. More than ever before, it is critically important for providers to pay close attention to legal developments concerning the FCA and related healthcare fraud and abuse statutes. Not surprisingly, the government and relators are continuing to push the bounds of liability under these statutes and are pursuing damages theories that will have profound impacts on healthcare fraud and abuse matters for years to come.



We hope our firm's annual Healthcare Fraud and Abuse Review will assist healthcare providers in staying abreast of legal developments relevant to their business and will offer insight as to what providers might see during the coming year. Without question, the government will continue its emphasis on enforcement and courts will consider an increasing number of complex issues arising under the FCA in the coming year.

4. *See* http://www.hhs.gov/news/press/2014pres/05/20140513b.html.
5. *See* http://www.justice.gov/opa/pr/mastermind-56-million-medicare-fraud-scheme-and-doctor-plead-guilty.
6. *See* https://oig.hhs.gov/reports-and-publications/semiannual/index.asp.
7. *See* https://oig.hhs.gov/reports-and-publications/semiannual/index.asp.

NOTEWORTHY SETTLEMENTS

The past year was the first year that total recoveries from settlements and judgments in civil cases brought by the United States under the FCA exceeded $5 billion.

Although recoveries from financial services companies in cases arising out of the housing and mortgage crisis accounted for more than half of this amount, recoveries from healthcare fraud cases still exceeded $2.3 billion, which marked the fifth year in a row that recoveries surpassed $2 billion. Further, this number reflects only federal recoveries and does not take into account additional amounts recovered by state enforcement agencies for Medicaid losses.[8] The vast majority of FCA investigations arise as a result of filing of *qui tam* lawsuits by whistleblowers. After more than 500 *qui tam* cases involving healthcare fraud matters were filed in fiscal year 2013, that number declined slightly to 469 in fiscal year 2014, but is still substantially higher than the number of cases filed per year prior to the 2009/10 amendments to the FCA.[9] The bulk of recoveries in FCA lawsuits comes from cases in which the United States intervenes, and that trend continued in 2014 with more than 95% of recoveries attributable to intervened cases.[10] However, many relators' counsel continue to demonstrate willingness to litigate non-intervened cases, and 2014 witnessed some of the largest recoveries in history for non-intervened cases.[11]

Appendix A to our Healthcare Fraud and Abuse Review contains a detailed breakdown of noteworthy settlements from the past year, many of which are referenced in the section below. Appendix B summarizes important FCA actions from the past year in which the federal government has intervened.

HOSPITALS AND HEALTH SYSTEMS

Settlements of FCA claims against hospitals totaled more than $300 million during fiscal year 2014. This included settlement of cases involving patient status issues where the government alleged that hospitals submitted claims for inpatient services that should have been billed as outpatient claims, cases involving lack of adequate supervision of residents, and cases involving billing for medically unreasonable or unnecessary procedures, in particular coronary procedures.[12]

The government and relators continue to bring significant numbers of cases alleging that remuneration arrangements between providers and physicians violate the Anti-Kickback Statute ("AKS") and/or the Stark Law. The past year saw multiple settlements of AKS and Stark claims, including arrangements involving physician employment, the use of physician consultants or advisors, and lease agreements.[13]

COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (2010-2014)

Year	Intervened Cases	Declined Cases
2010	$2.26 billion	$121.3 million
2011	$2.64 billion	$183.5 million
2012	$3.28 billion	$45.28 million
2013	$2.85 billion	$153.9 million
2014	$2.93 billion	$51.95 million

8. United States Department of Justice, "Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014" (Nov. 20, 2014), available at http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.
9. http://www.justice.gov/civil/pages/attachments/2014/11/21/fcastats.pdf.
10. *Id.*
11. *See, e.g.,* United States Department of Justice, "Nation's Largest Nursing Home Pharmacy Company to Pay $124 Million to Settle Allegations Involving False Billing to Federal Health Care Programs" (Jun. 25, 2014) (discussing settlement of Omnicare case in which United States originally declined intervention).
12. See Appendix A.
13. *Id.*

PHYSICIANS

Physician groups and individual physicians continue to be the targets of increased enforcement efforts, a trend that is expected to continue following CMS's release of Open Payments data in September 2014, which provides Medicare reimbursement data for physicians. Settlements over the past year involved a variety of allegations, including the upcoding of evaluation and management ("E/M") codes, billing for services provided by extenders without proper supervision from the physician, improper bundling of services and billing for medically unnecessary services. Additionally, as the government increasingly pursues not only the payer of kickbacks, last year saw physicians settle claims that they had received or been offered improper inducements such as sham consulting and medical director agreements to induce patient referrals.[14] Physicians also continue to resolve civil and criminal actions arising under the Food, Drug and Cosmetic Act stemming from the use of foreign-sourced drugs and devices.

HEALTH PLANS

Although we continue to see an increase in the number of investigations involving health plans, few of those cases to date have resulted in settlements, which could change in upcoming years as additional cases move forward. The past year did include settlement of claims for providing services to individuals who were ineligible to receive care or where care was provided in contravention of plan terms.[15]

LONG-TERM CARE

The past year saw numerous large settlements involving long-term care providers, including skilled nursing facilities ("SNFs"), home health companies, and hospice providers. Settlements involving SNFs included claims for allegedly providing medically unreasonable and unnecessary therapy services, placing patients in the highest Resource Utilization Group ("RUG") level unless it was shown that patients could not tolerate that amount of therapy, arbitrarily shifting therapy minutes between therapy disciplines to meet RUG targets, and recording rounded or estimated minutes instead of the actual amount of therapy provided.[16]

The government settled multiple *qui tam* cases with one of the nation's largest providers of home health services involving allegations that it billed Medicare for medically unnecessary services and for providing services to patients who were not homebound. The government also settled claims that a home health provider overstated the severity of patients' conditions in order to increase reimbursement.[17]

Hospice settlements included cases involving allegations that providers had billed Medicare for hospice services for patients who were not eligible for hospice care.[18]

PHARMACEUTICALS AND MEDICAL DEVICE COMPANIES

The pharmaceutical sector accounted for a substantial part of the United States' total healthcare fraud recoveries over the past year. As in previous years, this was fueled by a handful of settlements involving off-label promotion of drugs, including one settlement that exceeded $2 billion. The government also settled cases with pharmaceutical companies over allegations that they entered into kickback arrangements with providers to induce the providers to select their products for patients. The alleged kickbacks took a variety of forms including consulting agreements, entertainment/trips, discount/rebate arrangements, and "swapping" arrangements where discounts on certain items or services were offered in exchange for the referral of federal program referrals.[19]

The past year also witnessed settlements of claims involving allegations that pharmacy companies had improperly inflated usual and customary pricing information. We are also seeing an increasing number of cases and settlements involving the selling of products that do not comply with country-of-origin regulations.[20]

14. See Appendix A.
15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.*
20. *Id.*

FALSE CLAIMS ACT UPDATE

The FCA continues to be the federal government's primary civil enforcement tool for investigating allegations that healthcare providers defrauded the federal healthcare programs.

With recent legislation designed to lower the bar for bringing such actions and an ever-increasing number of FCA actions filed by whistleblowers, healthcare providers should pay close attention to legal developments concerning the FCA.

THE FCA'S PUBLIC DISCLOSURE BAR

The FCA's public disclosure bar prevents a relator from filing a *qui tam* complaint based on information previously disclosed to the public, thereby discouraging parasitic lawsuits based on publicly available information. Although case law, including decisions by the U.S. Supreme Court, generally has pushed a broad interpretation of the public disclosure bar, Congress narrowed its scope as a result of amendments to the FCA set forth in the Patient Protection and Affordable Care Act ("PPACA"). Since PPACA, courts have continued to define the contours of the public disclosure bar, including whether to apply the bar as amended by PPACA or in its previous form. Because PPACA narrowed the language of the provision in some respects, whether the public disclosure bar applies and effectively precludes the allegations at issue in an FCA lawsuit sometimes depends on which version of the statute is applied.

Whether to Apply the Public Disclosure Bar as Amended by PPACA

Signed into law on March 23, 2010, PPACA amended the FCA's public disclosure bar in numerous ways. Courts are split on a number of issues relating to those amendments, such as whether the amended, post-PPACA bar remains jurisdictional in nature.[21] There is even a split of authority regarding the day on which the PPACA amendments to the FCA took effect.[22] Determining which version of the statute applies in any given case can have a substantial impact on the success of a defendant's reliance on the public disclosure bar to defeat a relator's FCA allegations.

Although some courts in the past have determined which version of the statute to apply based on the date of the filing of the original complaint, the strong trend last year was to apply the version of the statute in place when the underlying conduct occurred. The allegations in ***U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC,*** however, involved conduct that occurred both before and after the enactment of the PPACA amendments. Citing U.S. Supreme Court precedent, the district court applied the pre-PPACA version to conduct that occurred before PPACA's enactment and applied the amended version to conduct after its enactment.[23] The district court applied both versions of the statute to the alleged conduct even though the original complaint in the case was filed after the PPACA amendments took effect.

Applying the version of the statute in effect when the relevant conduct occurred now appears to be the majority approach, but courts varied slightly in determining what constitutes the "relevant, underlying conduct." In both ***Majestic Blue Fisheries*** and ***U.S. ex rel. Saunders v. Unisys Corp.,*** the district courts considered the alleged public disclosures to be the relevant conduct that occurred.[24] As a result, the pre-amendment version applied to the disclosures that occurred before PPACA's enactment, and the amended version applied to the disclosures that occurred after its enactment.[25]

21. *Compare Chen v. EMSL Analytical, Inc.,* 966 F. Supp. 2d 282 (S.D.N.Y. 2013) (holding that the amended, post-2010 public disclosure provision is no longer jurisdictional in nature) *with U.S. ex rel Beauchamp v. Academi Training Ctr., Inc.,* 933 F. Supp. 2d 825, 839 (E.D. Va. 2013) ("[C]ontext makes clear that the public disclosure bar remains jurisdictional, as the public disclosure bar has long been interpreted as jurisdictional and is contained in a subsection entitled 'certain actions barred.'").
22. *Compare U.S. ex rel. Cervantes v. Deere & Co.*, 2011 U.S. Dist. LEXIS 127575, 2011 WL 5325466 at 11 n.3 (E.D. Wash. Nov. 3, 2011) ("The public disclosure provisions were amended effective July 22, 2010") *with U.S. ex rel. Gohil v. Aventis Pharm., Inc.,* 387 F. App'x 143, 145 (3d Cir. 2010) (treating the FCA amendments as effective March 23, 2010).
23. 2014 U.S. Dist. LEXIS 133036, *13-14 (D. Del. Sept. 23, 2014) (citing *Hughes Aircraft Co. v. U.S. ex rel. Schumer,* 520 U.S. 939 (1997)).
24. *Id.*; 2014 U.S. Dist. LEXIS 37830 (E.D. Va. Mar. 21, 2014).
25. 2014 U.S. Dist. LEXIS 133036, at *15-30; 2014 U.S. Dist. LEXIS 37830, at *11.

In ***U.S. ex rel. Ellis v. City of Minneapolis,*** on the other hand, the district court considered the defendant's conduct and the alleged submission of false claims to be the conduct that would determine which version of the public disclosure bar would apply.[26] The district court applied the pre-PPACA version of the statute to claims based on allegedly false certifications submitted to the government from April 2005 to April 2010, and it applied the post-PPACA version to claims based on an allegedly false certification submitted in February 2011.[27]

The effects of PPACA's amendments to the public disclosure bar were evident in two cases this year where district courts applied both versions of the statute in the same case. In ***Ellis,*** the district court's application of the two different versions of the statute was outcome-determinative with respect to the public disclosure bar analysis. Applying the pre-PPACA version of the statute to claims based on false certifications from 2005 to 2010, the district court found that such claims had been previously disclosed in other lawsuits and, therefore, were barred in the instant case.[28] The district court reached a different conclusion, however, with respect to claims based on a certification submitted in 2011, holding that one of the previous lawsuits was not a "public disclosure" under the FCA's amended public disclosure provision because PPACA narrowed the definition of "public disclosure" to include only hearings in which the federal government or its agent is a party. Because the federal government was not a party to the case in question, that litigation could not serve as a public disclosure of subsequent FCA allegations, and the court did have jurisdiction over the relator's claim with respect to the 2011 certification.

In ***U.S. ex rel. Judd v. Quest Diagnostics, Inc.,*** the defendant argued that the relator's allegations were based on three separate prior FCA cases.[29] The district court distinguished the third case, which was filed in a California state court, from the first two cases, which were filed in federal courts. The district court noted that the third case could have no effect on conduct alleged to have occurred after PPACA's enactment because proceedings in a state court do not constitute "public disclosures" under the amended public disclosure provision.

When Are Disclosures Sufficient to Bar FCA Allegations?

Where previous years resulted in a number of public disclosure bar decisions favorable to providers in fending off FCA claims, last year produced more mixed results. Though courts continue to refuse to require complete identity between public disclosures and FCA allegations for the public disclosure bar to apply, developments about how or to whom information must be disseminated in order to constitute a "public disclosure" under the FCA are worth watching.

In ***U.S. ex rel. Guardiola v. Renown Health,*** the district court held that information reported in recovery audit contractor ("RAC") audits had not been publicly disclosed.[30] The district court rejected a bid to dismiss the FCA action of a former director of compliance, even though the RAC audit results giving rise to the former director's claim were disclosed to multiple sources outside the government. The district court held that the RAC audit results were not "publicly" disclosed because the 585 non-employee doctors who had access to those results were "economically linked" to the defendants and, therefore, were not true "outsiders." Rather, the disclosures made to those affiliated individuals were tantamount to disclosures made in private.

In ***U.S. ex rel. Acad. Health Ctr., Inc. v. Hyperion Found., Inc.,*** a relator cited certain state surveys, news stories and litigation in other states in its complaint to support its allegations that the defendants submitted claims for worthless nursing services nationwide.[31] The defendants moved to dismiss the complaint on the grounds that the claims at issue were based on documented public disclosures. The district court granted the defendants' motion to dismiss the allegations on public disclosure grounds, finding that "personal injury lawsuits and other information on file with the courts," which formed the basis for many of the relator's allegations, constituted public disclosures. The district court reaffirmed that the relator's allegations

26. 2014 U.S. Dist. LEXIS 111406, *11-12 (D. Minn. July 24, 2014).
27. *Id.; see also U.S. v. SouthernCare, Inc.,* 2014 U.S. Dist. LEXIS 137457, *12-25 (S.D. Ga. Sept. 29, 2014) (applying the pre-PPACA version of the statute to allegations that the defendant fraudulently admitted 18 ineligible patients to hospice care before PPACA was passed and applying the amended statute to allegations that the defendant fraudulently admitted nine ineligible patients after the passage of PPACA).
28. 2014 U.S. Dist. LEXIS 111406, at *16-27.
29. 2014 U.S. Dist. LEXIS 73760, *19-20 (D.N.J. May 30, 2014).
30. 2014 U.S. Dist. LEXIS 148227 (D. Nev. Oct. 13, 2014).
31. 2014 U.S. Dist. LEXIS 93185, *93 (S.D. Miss. July 9, 2014).

that were even partially based on these public disclosures were precluded by the public disclosure bar.

The Seventh Circuit's opinion in ***U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc.,*** involved allegations of sub-standard care that had originally surfaced in government reports.[32] Though ultimately vacating the district court's judgment and remanding the case for judgment to be entered for the defendants (see below), the Seventh Circuit held that the relator's lawsuit was not barred by the public disclosure bar, as the government reports in question did not disclose that the defendant had the scienter required by the FCA.

In ***U.S. ex rel. White v. Gentiva Health Servs.,****** the district court dismissed much of a lawsuit where a relator had alleged that the defendant had engaged in a number of different schemes against the government to submit false claims.[33] The district court dismissed the allegations relating to two of the alleged schemes, which concerned alleged fraudulent billing for unnecessary home health services and improper marketing of those services under the public disclosure bar because there was "no doubt" that the relator's allegations mirrored those disclosed in "tightly focused" news articles and press releases from both Congress and the defendant.[34]

In ***U.S. ex rel. Boise v. Cephalon, Inc.,*** the relator's FCA claims were premised on alleged off-label promotion of various medications, particularly the potent pain reliever Fentora.[35] In amending his initial complaint, the relator buttressed his Fentora claims by parroting allegations made in a later-filed and related proceeding. Because the relator's amended complaint borrowed more substantive allegations made in another proceeding, the district court dismissed the relator's claims under the public disclosure bar and, as detailed below, the first-to-file bar.

In ***U.S. ex rel. Oliver v. Philip Morris USA Inc.,*** the D.C. Circuit reversed a district court's public disclosure bar dismissal and revived a relator's lawsuit claiming that government-run military exchanges paid above most-favored-customer pricing for nearly two million cartons of cigarettes.[36] Because Philip Morris' cigarette deal with the government was not disclosed outside the government, the court took a narrow view of the public disclosure bar and held that both the plain language and history of the FCA demonstrate that the government's general awareness of a transaction and its details does not amount to that transaction's public disclosure for purposes of the FCA's bar.

And, in ***U.S. ex rel. Doe v. Staples, Inc.,*** the D.C. Circuit subsequently affirmed dismissal of FCA claims where the relator had alleged facts collected from an online database and administrative reports—that is, facts the anonymous relator had collected from public-sphere sources. Since the suit was "based upon" those publicly disclosed "allegations or transactions," and since those allegations or transactions were sufficient to "set government investigators on the trail of fraud," the court held that the public disclosure bar applied.

When Is a Relator an Original Source?

Last year, courts continued to clarify when information obtained by the relator is sufficiently "independent" and "materially adds to" public disclosures such that the relator's claims may proceed, particularly where allegations were related to the relator's "independent" investigations and prior civil lawsuits.[37] Continuing a trend from previous years, some courts also continued to straddle pre-PPACA and post-PPACA original source definitions in determining whether a relator qualified as an original source by noting that the version of the statute that applied would not be outcome-determinative.[38]

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32. 764 F.3d 699 (7th Cir. 2014).

*Denotes matter handled by Bass, Berry & Sims attorneys.

33. 2014 U.S. Dist. LEXIS 86156 (E.D. Tenn. June 25, 2014).
34. Another marketing-based FCA lawsuit, *U.S. ex rel. Paulos v. Stryker Corp.,* involved allegations that the defendants violated the FCA by marketing pain pumps to encourage their placement directly—and improperly—into patients' joint spaces after orthopedic procedures. The district court dismissed the relator's claims, concluding that the relator's allegations had been publicly disclosed, and the Eighth Circuit affirmed. "[B]ecause numerous media reports, FDA reports, and federal regulatory disclosures essentially revealed the allegations of fraudulent marketing forming the basis for [the relator's] claims," the court found no meaningful distinction between the public disclosures and the relator's claims. 762 F.3d 688, 692-93 (8th Cir. 2014).
35. 2014 U.S. Dist. LEXIS 143742 (E.D. Pa. Oct. 9, 2014).
36. 763 F.3d 36 (D.C. Cir. 2014).
37. In *U.S. ex rel. White v. Gentiva Health Servs.,* the district court held that while the relator did allege some independent knowledge of the defendant's alleged schemes, that she had not alleged anything materially adding to the publicly disclosed allegations relating to therapy thresholds and improper marketing, detailed in the section above. 2014 U.S. Dist. LEXIS 86156, at *32-35. The details given by the relator provided only "illustrative examples of specific behavior that the public disclosures already described with specificity." *Id.* at 33.
38. In *Moore & Co., P.A.,* the district court found that the relator did not qualify as an original source under either the pre-PPACA or post-PPACA definitions. *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC,* 2014 U.S. Dist. LEXIS 133036 (D. Del. Sept. 23, 2014). The relator was a law firm that opposed the defendant in a wrongful-death suit and discovered the fraudulent activities through FOIA request in the course of discovery. The court found that the "independent" information relied upon by relator was duplicative of information discovered in the course of litigation and did not "materially add" to the public disclosures. Id. at 29-30.

Although it determined that information reported during a RAC audit was not "publically disclosed" for purposes of the FCA, the district court in ***Guardiola*** (discussed above), nevertheless stated that the relator qualified as an original source.[39] Where the relator was the director of compliance for the defendant, learned of the fraudulent actions from her own review of patient charts, and reported that information to her superiors and executives on multiple occasions, the district court found that she sufficiently alleged "independent knowledge of the information on which the allegations are based."[40]

In ***Acad. Health,*** the district court held that the relator had not brought "sufficiently new information" to the table and, therefore, did not qualify as an original source.[41] The relator had entered into a lease agreement with the defendant to run a skilled nursing facility and became concerned when the defendant breached the lease by failing to pay rent. The relator "conduct[ed] an investigation" and concluded that the defendant was providing and billing for worthless services. Notwithstanding the investigation conducted by the relator, the district court concluded that the information discovered was not "independent," as it was based on publicly disclosed reports (such as Life Safety Code violations and citations). The district court noted that "collateral research and investigations" do not establish direct and independent knowledge where there are no additional compelling facts or new and undisclosed relationships between disclosed facts.

In contrast, in ***U.S. ex rel. Fryberger v. Kiewit Pac. Co.,*** the district court found that an independent investigation into construction defects and false certifications of compliance by defendant contractors materially added to the publicly disclosed allegations relating to the failures of certain walls during freeway construction in California.[42] The independent investigation of relators involved independent observations and records of the defendants' actions and deviations from contract requirements, analysis of reports and interviews of former employees, independent testing of materials, and video and photographic evidence of the drainage system at issue. In finding the relator to be an original source, the district court held that the relator's detailed allegations went "far beyond" the information disclosed in news reports and government investigations.

DEVELOPMENTS IN FCA PLEADING STANDARDS

Courts continue to grapple with the pleading requirements necessary to establish a violation of the FCA. Whether considering how to apply Rule 9(b) of the Federal Rules of Civil Procedure, or what facts should be required to plead falsity, materiality or knowledge, courts are continuing to issue rulings in FCA cases that are of considerable importance to healthcare providers facing FCA allegations.

Pleading with Particularity under Rule 9(b)

In numerous cases, federal courts examined the particularity of pleading required by Rule 9(b) in the context of FCA claims. Although courts generally agree that a relator must plead the "who, what, when, where, and how" of the alleged fraud, the manner in which courts applied this standard and the types of allegations considered sufficient to satisfy Rule 9(b) varied greatly.

Pleading Actual Claims

The question of whether relators must plead particular facts regarding actual false claims continues to divide courts. Some courts, including the Sixth Circuit, have taken the view that a relator must identify and plead the details of actual false claims.[43] The Third, Fifth, Seventh and Ninth Circuits, by contrast, have held that a relator's complaint may satisfy the requirements of Rule 9(b), if the complaint alleges a fraudulent scheme to submit false claims, so long as the allegations contain "reliable indicia" to support a "strong inference" that false claims were submitted as part of that scheme.[44] The First, Eighth, Tenth and Eleventh Circuits have decided cases within these jurisdictions that seemingly have reached different conclusions on this question.[45]

39. *U.S. ex rel. Guardiola v. Renown Health,* 2014 U.S. Dist. LEXIS 148227, *16 (D. Nev. Oct. 13, 2014).
40. *Id.* at 19-20.
41. *U.S. ex rel. Acad. Health Ctr., Inc. v. Hyperion Found., Inc.,* 2014 U.S. Dist. LEXIS 93185 (S.D. Miss. July 9, 2014).
42. *U.S. ex rel. Fryberger v. Kiewit Pac. Co.,* 2014 U.S. Dist. LEXIS 67165, 21-32 (N.D. Cal. May 14, 2014).
43. *See, e.g., U.S. ex rel. Bledsoe v. Community Health Sys., Inc.,* 501 F.3d 493, 504 (6th Cir. 2007).
44. *See Forglia v. Renal Ventures Mgmt., LLC,* 754 F.3d 153, 155-57 (3d Cir. 2014); *U.S. ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 190 (5th Cir. 2009); *U.S. ex rel. Lusby v. Rolls-Royce Corp.,* 570 F.3d 849, 854 (7th Cir. 2009); *Ebeid v. Lungwitz,* 616 F.3d 993, 998-99 (9th Cir. 2010).
45. *Compare U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.,* 360 F.3d 220, 232 (1st Cir. 2004) (applying strict standard) *abrogated on other grounds, Allison Engine Co. v. U.S. ex rel. Sanders,* 553 U.S. 662 (2008), *and U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.,* 441 F.3d 552, 560 (8th Cir. 2008) (same), *and U.S. ex rel. Sikkenga v. Regence BlueCross BlueShield,* 472 F.3d 702, 727-28 (10th Cir. 2006) (same), *and Hopper v. Solvay Pharm., Inc.,* 588 F.3d 1318, 1326 (11th Cir. 2009) (same), *with U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.,* 579 F.3d 13, 29 (1st Cir. 2009) (applying flexible standard), *and U.S. ex rel. Thayer v. Planned Parenthood of the Heartland,* 765 F.3d 914, 916-19 (8th Cir. 2014) (same), *and U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.,* 614 F.3d 1163, 1172 (10th Cir. 2010) (same), *and U.S. ex rel. Mastej v. Health Mgmt. Assocs.,* 2014 U.S. App. LEXIS 20921, *25-29 (11th Circuit Oct. 30, 2014) (same).

In ***U.S. ex rel. Nathan v. Takeda Pharm. N. Am. Inc.,*** the Fourth Circuit affirmed the dismissal of a *qui tam* complaint under Rule 9(b), holding that "when a defendant's actions, as alleged and as reasonably inferred from the allegations *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment."[46] That said, the Fourth Circuit acknowledged that, in certain situations, "the requirements of Rule 9(b) can be satisfied in the absence of particularized allegations of specific false claims."

Following the Fourth Circuit's ruling, the relator petitioned for a writ of certiorari to the U.S. Supreme Court, which was denied on March 31, 2014.[47] The Solicitor General, on behalf of the U.S. as *amicus curiae,* argued against a *per se* rule requiring dismissal of all *qui tam* complaints that failed to identify specific requests for payment.[48] Nonetheless, the Solicitor General argued against certiorari on the grounds that courts appear to be moving toward a more nuanced approach to the Rule 9(b) standard, and in any event, the relator's allegations in that case failed under any pleading standard.

During the previous year, courts reached conclusions on either side of the holding by the Fourth Circuit in ***Takeda,*** with some courts adopting a stricter standard requiring the "identification" of actual false claims, and others courts adopting a more lenient standard, which would only require a "reliable indicia" that false claims had been submitted for payment.

Cases Requiring the Identification of Actual False Claims. Although the Second Circuit has yet to rule on the pleading of actual claims issue, district courts within the Second Circuit issued a number of opinions last year holding that a relator's complaint must identify and plead the particulars of actual false claims to satisfy Rule 9(b).[49] Most recently, in ***U.S. ex rel. Bilotta v. Novartis Pharms. Corp.,*** the district court held that "in order to sufficiently plead violations of the FCA, Plaintiffs must allege the false claims themselves with sufficient particularity to satisfy Fed. R. Civ. P. 9(b); merely alleging a fraudulent underlying scheme with particularity is not enough."[50]

> Because the Complaint does not cite to a single identifiable record or billing submission they claim to be false, or give a single example of when a purportedly false claim was presented for payment by a particular defendant at a specific time, … the allegations in the Complaint are too speculative and conclusory to support an inference of a fraudulent claim…
>
> *-U.S. ex rel. Joseph v. Brattleboro Retreat*

In ***U.S. ex rel. Corporate Compliance Associates v. N.Y. Soc'y for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*** and ***U.S. ex rel. Kester v. Novartis Pharms. Corp.,*** the U.S. District Court for the Southern District of New York issued opinions explaining that the standard requiring the identification of actual false claims was more consistent with Second Circuit precedent and would likely be adopted by that circuit court.[51]

Additionally, the U.S. District Court for the District of Vermont reached a similar conclusion in ***U.S. ex rel. Joseph v. Brattleboro Retreat.****[52] Because the complaint in that case "[made] references to billing entries without identifying if and when those entries corresponded to actual claims," the district court determined that the FCA allegations were "mere speculation" in the absence of claim specifics, such as when the claims were submitted, by whom, and the appropriate reimbursement rate.

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46. 707 F.3d 451, 457 (4th Cir. 2013), *cert. denied* 134 S. Ct. 1759 (2014).
47. *Id.*
48. Brief for the U.S. as Amicus Curiae at 10, *U.S. ex rel. Nathan v. Takeda Pharm. N. America, Inc.*, 134 S. Ct. 1759 (2014) (No. 12-1349).
49. *See U.S. ex rel. Bilotta v. Novartis Pharms. Corp.,* 2014 U.S. Dist. LEXIS 139072, *25-30 (S.D.N.Y. Sept. 30, 2014); *U.S. ex rel. Corporate Compliance Associates v. New York Society for the Relief of the Ruptured & Crippled, Maintaining the Hospital for Special Surgery,* 2014 U.S. Dist. LEXIS 109786, *46-47 (S.D.N.Y. Aug. 7, 2014); *U.S. ex rel. Kester v. Novartis Pharms. Corp.,* 2014 U.S. Dist. LEXIS 74461, *36-41.
50. 2014 U.S. Dist. LEXIS 139072, at *29-30.
51. 2014 U.S. Dist. LEXIS 109786, at *46; 2014 U.S. Dist. LEXIS 74461, at *38-39.
52. 2014 U.S. Dist. LEXIS 110154, *23-28 (D. Vt. Aug. 10, 2014).

*Denotes matter handled by Bass, Berry & Sims attorneys.

Cases Requiring Only a Reliable Indicia of the Submission of False Claims. In ***Foglia v. Rental Ventures Mgmt., LLC,*** the Third Circuit followed the lead of other circuits that have adopted a more flexible approach to Rule 9(b), and upheld a whistleblower's complaint where the allegations supported a "strong inference" of the submission of actual false claims.[53] The complaint alleged that a dialysis care services company harvested a drug using leftover portions from previously used vials, but billed the government as if it were using entirely new vials of the drug. The complaint contained no details of actual false claims. Although the possibility existed that the company was not overcharging the government because it was re-using the drug as allowed by HHS-OIG, the Third Circuit accepted as true the whistleblower's allegation that the company did not comply with all HHS-OIG requirements when harvesting the drug. Therefore, the Third Circuit held that the allegations in the complaint supported an inference that the company submitted false claims, because the company would have no incentive to risk exposure to liability for failure to comply with HHS-OIG requirements unless there was a financial incentive stemming from overcharging the government.

Prior to ***Foglia,*** the Third Circuit had not ruled on the appropriate standard regarding the pleading of actual false claims. The Eighth and Eleventh Circuits, however, issued opinions last year that appeared to depart from prior decisions by those Circuits. In ***U.S. ex rel. Thayer v. Planned Parenthood of the Heartland,*** the Eighth Circuit upheld a complaint alleging FCA violations, even though the complaint did not identify actual false claims.[54] The Eighth Circuit distinguished a prior opinion in which it had applied the stricter standard, noting that the relator in that case "had no direct connection to the hospital's billing or claims department and could only speculate that false claims were submitted," whereas the relator in ***Thayer*** "was the center manager for two of [defendant's] clinics, oversaw [defendant's] billing systems, and was able to plead personal, first-hand knowledge of [defendant's] submission of false claims." Therefore, the Eighth Circuit concluded, the relator's allegations satisfied Rule 9(b), as those allegations amounted to reliable indicia to support a strong inference that false claims were actually submitted.

In ***U.S. ex rel. Mastej v. Health Mgmt. Assocs.,*** the Eleventh Circuit applied a "nuanced, case-by-case approach" to the Rule 9(b) pleading standard, under which "a relator with direct, first-hand knowledge of the defendants' submission of false claims gained through her employment with the defendants may have a sufficient basis for asserting that the defendants actually submitted false claims."[55] The Eleventh Circuit distinguished prior decisions applying a stricter standard, where the relator did not have the necessary personal knowledge.[56] In ***Mastej,*** the Eleventh Circuit noted that the relator was the vice-president of the defendant company and later CEO of one of its hospitals, and accordingly "he had direct information about . . . billings, revenues and payor mix, and he was in the very meetings where Medicare patients and the submission of claims to Medicare were discussed." The allegations in the complaint, therefore, contained sufficiently detailed allegations to satisfy the Rule 9(b) standard.

Pleading the Circumstances of Fraud

A number of courts continued to scrutinize pleadings to determine whether they sufficiently plead the circumstances of a fraudulent scheme – the "who, what, when, where, and how" of the alleged fraud. The Eighth Circuit's decision in ***United States v. Health Mgmt. Assocs.,*** provided a succinct overview of a complaint that sufficiently had pleaded the circumstances of the alleged fraud under Rule 9(b).[57] The relator alleged that the defendant engaged in a kickback scheme by paying for certain physicians' golf trips and providing "on call" pay for procedures that were not actually performed at the relevant facility. The Eighth Circuit explained that the complaint pleaded "the financial incentive scheme in great detail" by giving "the names of the doctors who received the incentives, the names of the Defendants' employees who negotiated the incentives with the doctors, precisely what the incentives were, and why they were illegal."

In ***U.S. ex rel. Ruscher v. Omnicare, Inc.,*** the district court provided a detailed overview of whether a complaint's allegations sufficiently pleaded the circumstances of fraud.[58] The relator's allegations were based on an alleged

53. 754 F.3d at 156-58.
54. 765 F.3d at 917-21.
55. 2014 U.S. App. LEXIS 20921, at *27-28.
56. *See id.* at *25-29, 35-44; *U.S. ex rel. Clausen v. Lab Corp. of Am., Inc.,* 290 F.3d 1301, 1311-14 (applying "identification" standard).
57. 2014 U.S. App. LEXIS 20921, at *12-19 (11th Cir. Oct. 30, 2014).
58. 2014 U.S. Dist. LEXIS 79885, *35 (S.D. Tex. June 12, 2014) (inducement sufficiently alleged by statements that debt forgiveness was provided "in an effort to retain its business," and that the defendant "sought to gain the business" or "was attempting to acquire the business" and had a "concern . . . with soliciting and retaining the lucrative Medicaid and Medicare Part D business."); *see also U.S. ex rel. Bilotta v. Novartis Pharms. Corp.,* 2014 U.S. Dist. LEXIS 139072, *74-75 (S.D.N.Y Sept. 20, 2014) (Rule 9(b) satisfied by complaint alleging kickback scheme by a pharmaceutical company that "particulariz[ed] the nature of speaker events" at issue and identified the "increased prescription-writing" for particular drugs during the same time frame).

scheme through which the defendant forgave accounts receivable on key clients' smaller Medicare Part D business, in exchange for the clients engaging the defendant in connection with their higher volume Medicare Part A business. The district court held that the complaint adequately alleged inducement – or the "'what' and the 'how'" of the alleged fraud – by alleging that, in exchange for debt forgiveness, the defendant expected to gain business from the beneficiaries. The complaint also sufficiently identified "who" was involved in the scheme by alleging the role played by the CEO and others in senior management, as well as eight of the defendant's "most favored" clients that benefited from the alleged scheme.[59] Finally, the district court held that the complaint sufficiently identified the "when" for kickbacks paid during a three-year period during which the relator worked for the defendant.[60]

Developments Concerning Falsity and Knowledge

Courts have continued to grapple with questions of falsity, materiality, and knowledge with respect to the assertion of FCA claims. The resolution of these questions is often determinative of whether the relator can pursue FCA allegations against a healthcare provider.

False Certification Theory of Liability

In ***U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.,***[61] the Seventh Circuit overturned a multi-million dollar jury verdict concerning false claims allegedly submitted for skilled nursing services. At trial, the relators presented two overarching theories of liability under the FCA—"worthless services" and false certification. As to the relators' worthless services allegations, the Seventh Circuit concluded that the relators failed to offer evidence that the defendant's services were truly or effectively worthless, providing that services that are "worth less are not 'worthless,'" and reserved ruling on the question of whether a "worthless services" theory is a separate theory of liability under the FCA.

As to the relators' false certification theory, the Seventh Circuit found that while worthless services could be evidence that a claim for reimbursement is false or fraudulent under a false certification theory of FCA liability, the evidence at trial was insufficient for the finding in that case.

U.S. ex rel. Troxler v. Warren Clinic, Inc.[62] involved allegations that the defendant clinic allowed non-physicians to obtain and record patients' History of Present Illness ("HPI"). Because the relator failed to plead a theory of falsity, the district court undertook an analysis of various possibilities. The district court rejected a theory of actual falsity because the relator had not alleged that the defendants failed to obtain or document HPI and had not asserted that the E/M codes used to bill for patient visits were inappropriate. The district court also rejected theories of falsity premised on express or implied false certification. The relator failed to identify any false certification premised upon the requirements of a particular statute, regulation or contract by defendants that made the gathering of HPI by physicians a prerequisite to payment and the fact that the medical necessity of an E/M service could not be determined without appropriate documentation in the patient's record. The district court concluded by noting that "liability [under the FCA] does not arise merely because a false statement is included within a claim, but rather the claim itself must be false or fraudulent."

Worthless Services as Establishing Falsity

In addition to alleging violations of conditions of payment, whistleblowers are increasingly bringing cases under a worthless services theory.

Perhaps one of the most significant worthless services cases to be decided in 2014 was ***Absher,*** in which the Seventh Circuit vacated the lower court's $28 million jury verdict and remanded the case with instructions that

59. 2014 U.S. Dist. LEXIS 79885, at *38-44; *see also Thayer,* 765 F.3d at 919, 920 (relator sufficiently alleged the "who" of certain schemes by providing "the names of the individuals that instructed her to carry out these schemes," but failed with regard to allegations of an upcoding scheme because she did not allege "who or how many physicians engaged in upcoding"); *U.S. ex rel. Bilotta v. Novartis Pharmaceuticals Corp.,* 2014 U.S. Dist. LEXIS 139072, *74-75 (Rule 9(b) satisfied when doctors involved in alleged kickback scheme were identified by name and the complaint identified specific claims for prescriptions they wrote).

60. 2014 U.S. Dist. LEXIS 79885, at *44-51; *see also Thayer,* 765 F.3d at 919, 920 (complaint sufficiently alleged the "when" of certain schemes by providing "the two year time period in which these schemes took place," but failed with regard to allegations of an upcoding scheme because it did not allege "when or how often upcoding took place at the various clinics"); 2014 U.S. Dist. LEXIS 139072, at *74-75 (Rule 9(b) satisfied when complaint specified time frame in which doctors involved in alleged kickback scheme attended events at issue).

61. 764 F.3d 699 (7th Cir. 2014).

62. 2014 U.S. Dist. LEXIS 157377 (N.D. Okla. Nov. 5, 2014).

> The "worthless services" theory of FCA liability, which a few of our sister circuits have adopted, allows a *qui tam* relator to bring claims for violations of the FCA premised on the theory that the defendant received reimbursement for products or services that were worthless.... It is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. That is, a "diminished value" of services theory does not satisfy this standard. Services that are "worth less" are not "worthless."
>
> *–U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*

judgment be entered for Momence.[63] The relators alleged that Momence submitted thousands of claims to Medicaid and Medicare for services that were so deficient that they constituted worthless services.[64] At trial, the district court instructed the jury on a diminished value theory, stating that "if Uncle Sam paid Momence 200 bucks and they only got $120 worth of value, then Momence defrauded them of $80 worth of services."[65] On appeal, the Seventh Circuit disagreed with the jury instruction, stating that "[s]ervices that are 'worth less' are not worthless," and that relators failed to offer evidence demonstrating that the services provided by Momence were "truly or effectively 'worthless.'"[66] Because the court found that the services provided by Momence were not worthless, it did not address the issue of whether a worthless services theory is a separate theory of liability.[67]

However, in ***Acad. Health,*** the district court found that the services provided by the defendant were so deficient that there was a factual dispute as to whether they could be considered worthless.[68] Both the government and the relator alleged that the defendant submitted claims for worthless services at its facility in Mississippi.[69] The relator pleaded additional claims including an FCA claim that defendant submitted claims for worthless services at other facilities nationwide.[70] The defendant moved to dismiss the complaint based on the public disclosure bar and failure to plead the fraud with the requisite particularity. The court dismissed the relator's worthless services allegations under the public disclosure bar[71] but upheld the government's complaint-in-intervention for the worthless services provided at the Mississippi facility.[72] The court rejected the defendant's argument that because it was reimbursed on a per diem basis, the government must show that the entire bundle of services billed was worthless, and instead, held that "a service can be worthless because it is deficient in nature even if the service was provided."[73]

Pleading Knowledge

In ***U.S. ex rel. Bilotta v. Novartis Pharms. Corp.,*** the government alleged that Novartis Pharmaceuticals paid kickbacks to physicians in the nature of lavish dinners and honoraria for sham speaker events in order to induce the doctors to write more prescriptions for its drugs.[74] The district court concluded that the government had sufficiently pleaded representative examples of false claims in order for the larger fraud scheme to pass muster under the pleading standards, finding it impractical to require that all claims over the alleged nine-year scheme be pleaded with particularity. In determining that the government had adequately pleaded knowledge of the underlying kickback scheme, the district court relied on the physicians' knowledge of the sham

63. 764 F.3d 699, 702 (7th Cir. 2014).
64. *Id.* at 704.
65. *Id.* at 709.
66. *Id.* at 710.
67. *Id.*
68. 2014 U.S. Dist. LEXIS 93185 (S.D. Miss. July 9, 2014).
69. *Id.* at *19-21, 42-69.
70. *Id.* at *7-41.
71. *Id.* at *108.
72. *Id.* at *161-162.
73. *Id.* at 153.
74. 2014 U.S. Dist. LEXIS 139072 (S.D.N.Y. Sept. 30, 2014).

nature of the speaker events, and the identified physicians' prescriptions for Novartis drugs significantly increased after they attended and/or spoke at the events. The district court found knowledge adequately pleaded for FCA purposes because the evidence "raise[d] a strong inference that Novartis . . . acted with actual knowledge. . . .or, at the very least, in deliberate ignorance or reckless disregard of the fact [it was causing submissions of false claims to federal and New York healthcare programs]." Specifically, evidence showed that the purpose of the speaker events was not to disseminate medical or scientific information to doctors, but rather to reward those who prescribed large quantities of Novartis drugs and to encourage other doctors to prescribe more. Further, after internally tracking the efficacy of its speaker events through "return-on-investment" studies and finding the strategy had successfully induced prescription writing, Novartis made the speaker events one of its key promotional activities.

When Are False Statements Material?

The materiality of a particular statement or action with respect to the government's decision to pay a claim continues to be an important issue in determining FCA liability. There should be no FCA liability based on pure regulatory violations if those violations are immaterial to the government's decision to pay a claim. Courts have drawn a clear distinction between violations of conditions of participation in the federal healthcare program—which are not material to a government's decision to reimburse for claims submitted—and violations of conditions of payment, which support FCA claims.

Within recent years, courts have focused considerable attention on this issue. For example, in ***U.S. ex rel. Williams v. Renal Care Group,**** the Sixth Circuit reversed summary judgment in favor of the government and entered judgment in favor of the defendant, holding that a violation of a condition of participation cannot form the basis of an FCA action.[75] The Sixth Circuit explained that the FCA should not be used to "police technical compliance with complex federal regulations."[76] The Sixth Circuit reaffirmed this holding soon afterward, in ***U.S. ex rel. Hobbs v. Medquest Assocs.,**** explaining that the appropriate remedy for regulatory violations does not require the "extraordinary remedies" of the FCA, but rather are best addressed by administrative sanctions.[77] Later that same year, the Eighth Circuit, in ***U.S. ex rel. Ketroser v. Mayo Foundation,*** affirmed the dismissal of a *qui tam* action, holding that the relator "alleged nothing more than regulatory noncompliance, which fails to state a claim because the FCA does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions."[78]

> "Even assuming that Defendants submitted CMS-855 forms and made a false certification or misrepresentation with the requisite scienter, to be actionable, the certification must also be material and have caused the government to pay a claim."
>
> *–U.S. ex rel. Rector v. Bon Secours Richmond Health Corp.*

This past year, courts continued to endorse this principle. In ***U.S. ex rel. Rostholder v. Omnicare, Inc.,*** the Fourth Circuit affirmed the dismissal of FCA allegations premised on claims submitted for allegedly adulterated drugs, reasoning that compliance with FDA safety regulations is not made a "precondition to reimbursement" under the Medicare and Medicaid statutes: "The relevant statutes do not provide that when an already-approved drug has been produced or packaged in violation of FDA safety regulations, that particular drug may not be the proper subject of a reimbursement request under Medicare and Medicaid."[79] The Fourth Circuit emphasized that relators "must allege both materiality and a false statement or fraudulent course of conduct as distinct elements of an FCA claim." Further, the Fourth Circuit observed that "were we to accept relator's theory of liability based merely on regulatory violations we would sanction use of the FCA as a sweeping

75. 696 F.3d 518 (6th Cir. 2012).
76. *Id.* at 532.
77. 711 F.3d 707, 713 (6th Cir. 2013).
78. 729 F.3d 825, 829 (8th Cir. 2013) (internal quotation marks omitted).
79. 2014 U.S. App. LEXIS 3269 (4th Cir. 2014).

*Denotes matter handled by Bass, Berry & Sims attorneys.

mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government . . . ."

The district court's opinion in ***Virginia v. Quest Diagnostics, Inc.,*** also addressed the issue of whether an FCA claim could be based on a condition of participation.[80] The district court discussed allegations that a laboratory company had violated the FCA by overcharging Virginia Medicaid in violation of a state regulation and paying kickbacks to private insurers in violation of the federal Stark law. The relator asserted a false certification theory on the defendant's Participation Agreement with Virginia Medicaid. The district court rejected the relator's argument that certification of compliance with state regulations and the state Participation Agreement could form the basis of an FCA claim.

In ***U.S. ex rel. Rector v. Bon Secours Richmond Health Corp.,*** the relator relied on the defendant's previous submission of a CMS Medicare Enrollment form, which included a certification that the provider would remain in compliance with Medicare laws, regulations and program instructions, to argue that claims submitted by the defendant in violation of the AKS triggered FCA liability.[81] Rejecting this argument, the district court held that, even assuming that the defendants submitted the enrollment forms with the requisite scienter and that the forms constituted a false certification, the enrollment form was not considered to be material to the government's decision to pay a claim. Rather, CMS Medicare enrollment forms are a condition of participation and may not be used as a basis for an FCA action.

In contrast, in ***U.S. v. Millennium Radiology, Inc.,*** the district court held that a defendant's certification of compliance with the terms of its provider agreements was sufficient to trigger FCA liability.[82] The relator alleged that Millennium entered into exclusive referral agreements and performed marketing services and provided a medical director free of charge in exchange for patient referrals, in violation of the AKS. The relator argued that because the defendants certified in their provider agreements that their claims were in compliance with the AKS and FCA, any claims submitted by the defendant to the government for payment were false. Noting that it previously held that similar allegations certifying compliance with the AKS were a condition of payment, the district court denied the defendant's motion to dismiss.

The district court's opinion in ***U.S. ex rel. Williams v. Health Mgmt. Assocs.*** involved allegations that several hospitals in Georgia and South Carolina paid clinics that provided prenatal care to undocumented mothers to refer the mothers to their hospital for the birth of their children, in violation of the AKS.[83] The relator alleged that by entering into provider agreements, the defendants agreed not to pay remuneration for the referral of Medicaid patients and that billing Medicaid for services rendered to the patients violated the AKS, and consequently, the FCA. The district court found that the relator's allegations stated an FCA claims as a matter of law and denied the defendants' motion to dismiss.

In ***U.S. ex rel. Ligai v. ETS Lindren Inc.,*** the relators alleged that the defendants submitted thousands of claims for payment for calibration work using instruments and laboratories that did not meet certain industry specifications or standards, and that the defendants falsely certified compliance with industry standards.[84] The district court found that relator's false certification theory failed because the relator failed to identify a statute, regulation or contract provision requiring the defendants to certify compliance with the industry standards. The district court held that the defendants' alleged failure to adhere to the standards set by the American Association of Laboratory Accreditation was a condition of participation, not a condition of payment and that "[the relator] cannot base an FCA cause of action on this theory."

Cases within the First Circuit provided further insight on what the First Circuit had called the "artificial categories" of false claims used by other circuits, such as "legally false" and "factually false" claims and "express certification" as compared with "implied certification."[85] The relators in ***U.S. ex rel. Escobar v. Universal Health Servs., Inc.,*** argued that these cases also meant the First Circuit no longer recognized the distinction between

80. 2014 U.S. Dist. LEXIS 69023 (E.D. Va. May 13, 2014).
81. 2014 U.S. Dist. LEXIS 52161, *30 (E.D. Va. Apr. 14, 2014).
82. 2014 U.S. Dist. LEXIS 138549 (S.D. Ohio Sept. 30, 2014).
83. 2014 U.S. Dist. LEXIS 85273, *4 (M.D. Ga. June 24, 2014).
84. 2014 U.S. Dist. LEXIS 129164, *4-5 (S. D. Tex. Sept. 16, 2014).
85. *See, e.g., U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.,* 647 F.3d 377, 385 (1st Cir. 2011).

conditions of payment and conditions of participation, arguing that the "sole consideration in determin[ing] whether a regulatory violation amounts to a false claim" is materiality.[86] The district court disagreed. After finding that none of the staffing and credentialing regulations allegedly violated were conditions of payment, the court found no need to conduct a materiality analysis: "Only after reaching the determination that [a regulation is a condition of payment] does the Court move on to its analysis of materiality."

In ***U.S. ex rel. Simpson v. Bayer Corp.,*** a case that examined FCA allegations predicated on alleged off-label promotion of a drug in violation of the Federal Food, Drug and Cosmetic Act ("FDCA"), the relator argued that her claims were viable without reliance on a false certification theory because her "primary theory of liability . . . is based on the evident materiality of misbranding to the government, and not solely on false certification."[87] The district court noted that, although the two concepts overlap, falsity and materiality are distinct, and the relator must show the defendant had failed to comply with a statute or regulation that was a condition of payment. While the government may take misbranding seriously, "allegations concerning the materiality of the FDCA's misbranding provisions to the Government do not allege the existence of a condition of payment." After finding that the relator had not plausibly alleged the defendant to have certified compliance with any statute or regulation that was a condition of payment, the district court dismissed all FCA counts.

In ***Troxler*** (discussed above), the district court noted that for false certification claims in the Tenth Circuit, materiality is a concept that is distinct, in name if not in treatment, from the concept of falsity: "In cases involving a false certification theory . . . the claim is actionable only if it leads the government to make a payment which it would not otherwise have made *and* the false statement was material to the government's decision to pay."[88] The Tenth Circuit, however, has not yet taken a position on whether materiality is a requirement for more garden-variety factual falsity claims under the FCA.

> "[T]he WSLA does not toll the statute of limitations for relators when the government is not involved, especially when those cases do not involve military or war-related contracts...."
>
> *–U.S. ex rel. Bergman v. Abbott Laboratories*

FCA STATUTE OF LIMITATIONS

In a closely watched case, the question of whether the Wartime Suspension of Limitations Act ("WSLA"), 18 U.S.C. § 3287, tolls the FCA's six-year statute of limitations will be taken up by the U.S. Supreme Court in the coming year. The Supreme Court is scheduled to hear arguments on the issue in January 2015.

On July 1, 2014, the Supreme Court granted certiorari[89] to review the Fourth Circuit's opinion in ***U.S. ex rel. Carter v. Halliburton Co.***[90] In ***Carter,*** the Fourth Circuit overturned the district court's holding that the WSLA was inapplicable to FCA cases when the government did not intervene, holding that the WSLA applies to: (1) both criminal and civil actions; (2) actions where the U.S. is not a party; and (3) relator-initiated FCA actions. The Fourth Circuit determined that the WSLA tolled the limitations period for the relator's FCA claims regarding fraudulent billing for services provided to military forces in Iraq—claims that otherwise would have been barred by the FCA's six-year statute of limitations—because the U.S. has been "at war" with Iraq since October 11, 2002. If applied in FCA actions concerning healthcare providers, the reasoning of the Fourth Circuit in ***Carter*** would threaten to expose providers to open-ended FCA liability, so long as the U.S. is involved in some type of declared military conflict. The Supreme Court's opinion is expected to have a significant impact on the viability of applying the WSLA's tolling provision in FCA cases.

86. 2014 U.S. Dist. LEXIS 40098 (D. Mass. Mar. 16, 2014).
87. 2014 U.S. Dist. LEXIS 51342 (D.N.J. Apr. 11, 2014).
88. *U.S. ex rel. Troxler v. Warren Clinic, Inc.,* 2014 U.S. Dist. LEXIS 157377, *10 (N.D. Okla. Nov. 5, 2014) (emphasis supplied) (internal citation omitted).
89. *Kellogg Brown & Root Services, Inc. v. U.S. ex rel. Carter,* No. 12-1497.
90. 710 F.3d 171 (4th Cir. 2013).

Leading up to the Supreme Court's consideration of this issue, a number of recent district court cases have declined to broadly interpret the reach of the WSLA's tolling provision. In ***U.S. ex rel. Amy Bergman,*** the U.S. District Court for the Eastern District of Pennsylvania relied on the dissent in ***Carter*** and the holding in ***U.S. ex rel. Emanuele v. Medicor Associates,***[91] concluding that "the WSLA does not toll the statute of limitations for relators when the government is not involved, especially when those cases do not involve military or war-related contracts…"[92]

REVERSE FALSE CLAIMS CASES

Known as addressing "reverse false claims," § 3729(a)(1)(G) provides for FCA liability where a defendant either: (1) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay money to the government; or (2) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay money to the government. Like claims asserted under §§ 3729(a)(1)(A) and (B), reverse false claims allegations are subject to the heightened pleading standards of Rule 9(b).

Last year, a number of reverse false claims complaints were dismissed for failure to plead in accordance with Rule 9(b)'s heightened pleading requirements.[93] For example, in ***U.S. ex rel. Joseph v. Brattleboro Retreat,****** the district court dismissed the relator's reverse false claims allegations because those allegations failed to meet the heightened pleading standard under Rule 9(b).[94] The district court explained that the relator's allegations failed to explain how the defendant's alleged conduct actually corresponded to fraudulent retention of overpayments, failed to adequately describe the overpayment amounts, and failed to show that the defendant had knowledge of the alleged overpayments.

> Relators have filed more than 3,000 new *qui tam* lawsuits over the last five years.

In ***U.S. ex rel. Ligai v. ETS-Lindgren Inc.,*** the relator alleged that the defendant received overpayments because it failed to alert "its customers" of past performance errors, made false prior certifications and failed to recall faulty equipment.[95] The district court dismissed the reverse false claims allegations, describing those allegations as a "recasting" of the underlying false claims allegations.[96] The district court noted that redundant false claims of this nature are not actionable under § 3729(a)(1)(G).[97]

DEVELOPMENTS REGARDING DAMAGES

As more FCA cases are litigated, courts are reviewing damages allegations, theories and calculations with more scrutiny. In ***U.S. ex rel. McBride v. Makar,*** the district court ordered a new trial on the issue of damages, which had been awarded against a defendant physician as a default judgment after the physician filed for bankruptcy.[98] The default judgment of almost $90 million was based upon a spreadsheet of claims provided by relator. In granting the physician's motion to set aside the judgment, the district court held that the relator had failed to plead his damages theory in his complaint sufficiently to include all claims on the spreadsheet, and allowed both the relator and the physician 90 days in which to conduct discovery on the damages amount.

Damages theories continue to be watched closely in ***U.S. ex rel. Bunk v. Birkart Globistics GmbH & Co.*** In this bid-rigging FCA case, the district court rejected

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91. 2013 U.S. Dist. LEXIS 104650 (W.D. Pa. July 26, 2013).

*Denotes matter handled by Bass, Berry & Sims attorneys.

92. 995 F. Supp. 2d at 377. In *U.S. ex rel. Landis v. Tailwind Sports Corp.,* the district court rejected the applicability of the WSLA's tolling provision in FCA cases following the 1986 FCA amendments. 2014 U.S. Dist. LEXIS 83313 (D.C. June 19, 2014). The district court concluded that the WSLA only applies to charges that "include fraud as an essential ingredient," and, following the 1986 amendments to the FCA, the D.C. Circuit "does not require proof of fraud as an 'essential element'" in FCA actions. Accordingly, the district court held that "the WSLA [did] not [toll] the running of the FCA's [statute of limitations]…." But, in *U.S. ex rel. Carroll v. Planned Parenthood Gulf Coast, Inc.,* which was a *qui tam* action in which both Texas and the U.S. declined to intervene, the district court concluded that the WSLA tolled the FCA's statute of limitations and permitted otherwise time-barred claims to be pursued by the relator. 2014 U.S. Dist. LEXIS 66385, *31 (S.D. Tex. May 14, 2014).

93. *See, e.g., Si v. Laogai Research Found.,* 2014 U.S. Dist. LEXIS 146079 (D.D.C. October 14, 2014) (dismissing reverse false claims allegations because even when applying the broader Fraud Enforcement and Recovery Act ("FERA") "obligation" definition, the relator failed to sufficiently plead what monetary obligation the defendant owed the government); *U.S. ex rel. Heesch v. Agnostic Physicians Grp.,* P.C., 2014 U.S. Dist. LEXIS 71171 (S.D. Ala. Apr. 15, 2014) (dismissing reverse false claims allegations because the government failed to provide specific factual support to their claim and therefore did not meet the particularity requirements); *U.S. ex rel. Rector v. Bon Secours Richmond Health Corp.,* 2014 U.S. Dist. LEXIS 52161 (E.D. Va. April 14, 2014) (dismissing reverse false claims allegations because relator failed to identify the source of money that defendant needed to repay to the government).

94. 2014 U.S. Dist. LEXIS 110154 (D. Vt. Aug. 8, 2014).

95. 2014 U.S. Dist. LEXIS 129164 (S.D. Tex. Sept. 16, 2014).

96. *Id.* at *38.

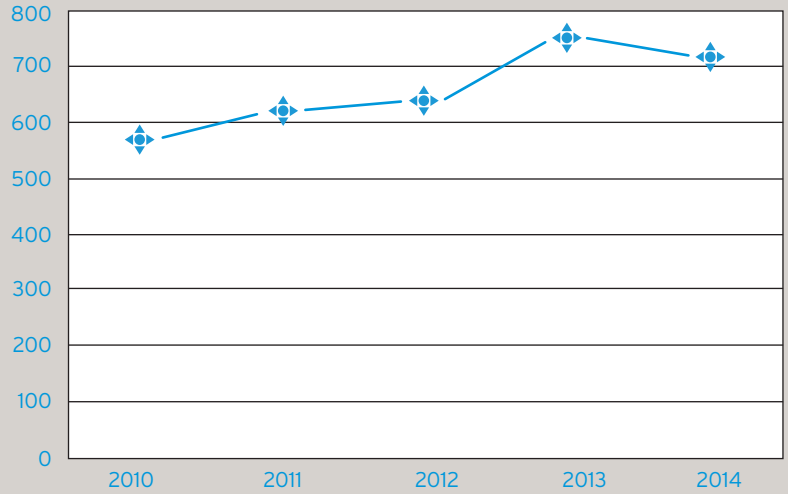
97. *Id.*

98. 2014 U.S. Dist. LEXIS 147614 (M.D. Fla. Oct. 15, 2014).

the defendants' argument that the government's expert failed to indicate that the expert would rely on a particular theory of damages.[99] The district court concluded that because the language provided in the government's complaint revealed its theory, and its initial disclosures discussed the damages theory and indicated that the quantification of damages would be provided by the expert, that defendants had sufficient notice. This district court, however, did exclude certain of the government's exhibits from evidence because the government failed to provide the defendants with access to the database from which the information summarized on the charts was compiled.

Last year also produced a follow-up ruling to a significant damages decision from 2013. In its decision in ***U.S. ex rel. Bunk v. Gosselin World Wide Moving, N.V.,*** the Fourth Circuit remanded an FCA government contract case after deciding that the government could proceed with its FCA claims against defendants, and that with respect to a single FCA action brought separately by relator, the district court did have discretion to impose lesser penalties to avoid the imposition of an excessive fine under the Eighth Amendment.[100] After remand, the government's case was tried and the jury returned a verdict against the defendants, awarding more than $100 million in damages. The district court granted the defendants' motion for a new trial, concluding that the government's theory of liability was unprecedented and untenable, and that its expert's methodology for calculating loss was not reliable and should have been excluded.

NUMBER OF NEW *QUI TAM* LAWSUITS FILED BY YEAR (FY 2010-2014)



DEVELOPMENTS REGARDING RELATORS

Considering the First-to-File Rule

The first-to-file rule provides that a relator cannot maintain a *qui tam* action if a different relator already has filed a pending *qui tam* complaint regarding the same allegations. Failure to satisfy the first-to-file rule is a jurisdictional bar to proceeding with FCA claims in the subsequent case. As more and more relators pursue FCA recoveries, case law is developing with respect to who brings allegations to the government first, and therefore, would be entitled to any FCA recovery. Importantly, courts have rejected the requirement that the related suits be identical in order for subsequent suits to be barred, and have enforced the first-to-file rule in order to avoid parasitic or opportunistic suits.

The First Circuit vigorously applied the first-to-file bar in 2014. In ***U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corp.,*** the First Circuit held that a subsequent FCA suit was barred by the first-to-file rule when the second suit was based on the same essential facts as the earlier filed complaint, even if the second suit provided more detailed allegations.[101] The First Circuit held that the "essential facts" standard required enough information to provide the government with sufficient notice to initiate the investigation into the alleged fraud. The First Circuit already had reached a similar holding in ***U.S. ex rel. Wilson v. Bristol-Meyers Squibb,*** concluding that the first-to-file rule would bar a second case, even if alleging somewhat different information.[102] The First Circuit reasoned that once the government is informed of the essential facts, it has enough information to proceed with the investigation.

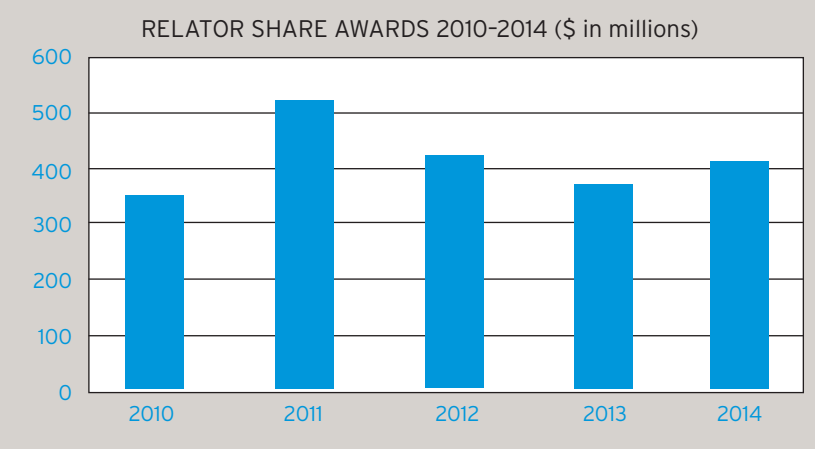
Other courts reached similar conclusions. The Fifth Circuit, in ***U.S. ex rel. Johnson v. Planned Parenthood of Houston & Southeast Tex.,*** rejected a

99. 2014 U.S. Dist. LEXIS 90398 (E.D. Va. June 30, 2014).
100. 741 F.3d 390 (4th Cir. 2013).
101. 2014 U.S. App. LEXIS 22564 (1st Cir. Dec. 1, 2014).
102. 750 F.3d 111 (1st Cir. 2014).

second complaint because the previously filed complaint alleged the same fraudulent scheme.[103] Like the First Circuit, the Fifth Circuit evaluated the "essential facts," and held that the proper focus in applying the first-to-file bar was on whether any investigation in the first case would uncover the same fraudulent activity in the second complaint. The second relator argued that because the language discussing the fraudulent conduct in the settlement agreement resolving the first case was different from the second complaint's allegations, that the second suit was not barred. The Fifth Circuit, however, focused on the allegations contained in the complaints, rather than the information found in the settlement agreement, which it deemed "irrelevant."

In ***U.S. ex rel. Carter v. Halliburton Co.,*** the district court held that the first-to-file bar applies even when the first suit is on appeal, as the case is still "pending" for purposes of the FCA.[104] The district court held that, even though the relator's earlier complaint was on appeal, the first-to-file bar still precluded the filing of the relator's subsequent complaint. In effect, the district court held that a relator could act as his own jurisdictional bar to the second suit in that circumstance.

The D.C. Circuit's holding in ***U.S. ex rel. Shea v. Cellco P'ship.,*** created a split of authority regarding the question of whether a dismissed action could be considered as pending such that the first-to-file bar would apply.[105] After the first FCA action had been settled with the government, the same relator filed a new suit, alleging that the allegations were unrelated to the first suit because they involved different contracts and agencies, and would give rise to a different investigation. The D.C. Circuit disagreed, holding that the complaints were sufficiently related such that the first case would adequately alert the government to the possibility of the scheme alleged in the second suit. The D.C. Circuit also concluded that even though the relator's earlier suit was over, it refused to interpret "pending" to mean an active case; rather it concluded that "pending" simply refers to the first case. In reaching this conclusion, the D.C. Circuit acknowledged that it was disagreeing with the



Seventh, Tenth and Fourth Circuits, which have held that the first-to-file rule applies only when the earlier action is still pending.[106]

FCA Retaliation Claims

Employer-Employee Relationship

The FCA retaliation provision prohibits employers from taking adverse action against employees who have engaged in protected activity under the FCA. This past year, the district court in ***Wichansky v. Zowine*** provided additional guidance on what constitutes an employer-employee relationship for an FCA retaliation claim.[107] In granting the defendant's motion to dismiss, the district court held that a de facto employer relationship was insufficient for an FCA retaliation cause of action, and an employee could not state a claim against his employer for acts done by individual co-employees acting without authorization of the company. The district court specifically rejected the notion that wrongful conduct by a corporate employee should be imputed onto the corporation when the corporation received a benefit, noting "[t]o the contrary, it generally is accepted that wrongful action taken by corporate officers or employees without authorization make them liable to the corporation."

103. 570 F. App'x 386 (5th Cir. 2014).
104. 19 F. Supp. 3d 655 (E.D. Va. 2014).
105. 748 F.3d 338 (D.C. Cir. 2014).
106. *U.S. ex rel. Chovanec v. Apria Healthcare Grp., Inc., 606 F.3d 361 (7th Cir. 2010); In re Natural Gas Royalties ex rel. U.S. v. Exxon Co.,* 566 F.3d 956 (10th Cir. 2009); *U.S. ex rel. May v. Purdue Pharma L.P.,* 737 F.3d 908 (4th Cir. 2013).
107. 2014 U.S. Dist. LEXIS 156632 (D. Ariz. Nov. 4, 2014).

There is a general consensus among district courts that a plaintiff cannot bring a retaliation claim against a supervisor in his/her individual capacity under the FCA. For example, district courts in both ***Rangarjan v. John Hopkins Health Sys. Corp.*** and ***U.S. ex rel. Sadr v. Pediatric Cardiology Associates, PC.,*** reached that conclusion.[108] The district court in ***Si v. Laogai Research,*** however, reached an opposite conclusion in applying the pre-FERA FCA retaliation provision, holding that a relator could bring a retaliation claim under the FCA against his supervisor in his individual capacity if the relator could pierce the corporate veil and show that the supervisor had control over the organization.[109]

Defining "Protected Activity"

A whistleblower alleging a retaliation claim under the FCA must show: (1) that the employee engaged in protected activity; (2) the defendant knew about the employee's protected activity; (3) the defendant took an adverse employment action against the employee; and (4) there was a causal connection between the protected activity and the adverse employment action.

In past years, courts have grappled with the definition of "protected activity," and last year was no different. The district court's holding in ***Fannie Mae v. K.O. Realty Inc.*** provides useful guidance on what constitutes protected activity, where the district court held that the FCA's protections against retaliation do not apply when the retaliation claim is not against the party alleged to have committed the underlying FCA violation.[110]

In ***U.S. ex rel. Portilla v. Riverview Post Acute Care Ctr.,*** the district court reaffirmed the principle that a relator's protected activity must focus on matters that could lead to a viable FCA action.[111] There, the relator alleged that her employment was terminated for raising concerns that the nursing facility was providing inadequate care to patients and falsifying records to avoid liability. The district court held that relator's actions were "administrative, regulatory whistleblowing," not fraud whistleblowing, and that her conduct would not have placed the defendants on notice that she was concerned with billing practices or Medicare/Medicaid Fraud.

The district court's holding in ***U.S. ex rel. Tran. V. Computer Scis. Corp.*** further limited the definition of "protected activity," by concluding that mere refusal to participate in fraudulent activity did not "trigger the protections of the FCA retaliation provision."[112] The district court explained that not only does mere refusal to participate "not equate with the kind of affirmative activity that the text of the statute conveys," but not a single court has held that the refusal to participate in allegedly fraudulent conduct by itself constitutes protected activity.

Arbitrability of Retaliation Claims

Although the use of arbitration provisions in employment agreements continues to grow, employers may find that they are not broad enough to capture FCA claims. In ***U.S. ex rel. Paige v. BAE Sys. Tech.,*** the Sixth Circuit concluded that an employment agreement that required arbitration for "any dispute arising from [the employment agreement]" and "any dispute, which arising under the terms of [the employment agreement]" did not require FCA retaliation claims to be arbitrated.[113] According to the Sixth Circuit, a retaliation action under the FCA did not depend on whether the terms of the employment agreement were violated; rather it was a separate statutory action that would exist regardless of whether there was an employment agreement. The Sixth Circuit did note, however, that other cases have held that a more broadly worded arbitration provision may capture FCA retaliation claims.

Statute of Limitations for Retaliation Claims

In ***Weslowski v. Zugibe,*** the district court provided guidance on when the three-year statute of limitation begins to run for FCA retaliation claims.[114] In ***Weslowski,*** the plaintiff attempted to bring a retaliation action against his employer more than three years after his resignation, arguing that his resignation was conditional and his last day of employment was within the three-year statute of limitation. The district court rejected the plaintiff's "continuing violation" theory of liability and held that the FCA retaliation provision only applies to retaliatory conduct that occurred while the relator was employed. Because the only retaliatory conduct that occurred within

108. 2014 U.S. Dist. LEXIS 163049 (D. Md. Nov. 21 2014); No. 1:13-cv-00077 (E.D. Va. Jan. 23, 2014).
109. 2014 U.S. Dist. LEXIS 146079 (D.D.C. Oct. 14, 2014).
110. 2014 U.S. Dist. LEXIS 110193 (N.D. Tex. Aug. 8, 2014).
111. 2014 U.S. Dist. LECIS 44002 (D. N.J. Mar. 31, 2014).
112. 2014 U.S. Dist. LEXIS 90757, *82. (D.D.C. July 3, 2014). In *Absher* (discussed above), the Seventh Circuit concluded that the relators had not engaged in protected activity because there was no evidence that their actions related to investigating or reporting suspected fraud by the defendant. *Absher,* 764 F.3d 699, 715,716 (7th Cir. 2014).
113. 566 Fed. App'x 500 (6th Cir. 2014).
114. 2014 U.S. Dist. Lexis 44041 (S.D.N.Y).

the statute of limitations time period was after he was terminated, his FCA retaliation claim was dismissed. The district court also rejected the plaintiff's attempt to rely on the WSLA tolling provisions.

DISCOVERY DEVELOPMENTS IN FCA CASES

The previous year produced a number of significant discovery decisions that address the availability of the attorney-client privilege and work product protection in FCA cases. While the D.C. Circuit issued a highly anticipated decision reaffirming a protective approach to the attorney-client privilege when a communication may have overlapping legal and non-legal purposes, district courts were less willing to sustain a claim of privilege or work product protection, particularly in the context of an alleged waiver, in several other cases.

Broad Formulation of the Attorney-Client Privilege Primary Purpose Test

In ***In re Kellogg Brown & Root (KBR),*** the D.C. Circuit reversed the district court's decision narrowly interpreting the primary purpose test, which requires that a communication be made for the primary purpose of obtaining or rendering legal advice in order for the attorney-client privilege to apply.[115] The relator sought documents generated by a government contractor in connection with an internal investigation conducted pursuant to the company's compliance policies. As a government contractor, the company also was required to maintain a business ethics and compliance program that provided a mechanism for internal reporting and disclosure of certain types of misconduct.

The D.C. Circuit rejected the district court's holding that the privilege did not apply to documents generated during the internal investigation because the primary purpose of the communications was not to obtain legal advice due to the fact that the investigations were undertaken pursuant to regulatory law and corporate policy. The D.C. Circuit held that "[s]o long as obtaining or providing legal advice was *one of the significant purposes* of the internal investigation, the attorney-client privilege applies, even if there were also other purposes for the investigation and even if the investigation was mandated by regulation rather than simply an exercise of company discretion."

> "So long as obtaining or providing legal advice was one of the significant purposes of the internal investigation, the attorney-client privilege applies, even if there were also other purposes for the investigation and even if the investigation was mandated by regulation rather than simply an exercise of company discretion."
>
> *–In re Kellogg Brown & Root, Inc.*

In applying this broader formulation of the primary purpose test, the D.C. Circuit provided an important protection to companies which are required by law to maintain robust compliance programs, including healthcare providers, such that in-house lawyers simultaneously engage in communications that have overlapping legal and compliance purposes.

Overcoming Government Work Product Protection in FCA Cases with Prior or Parallel Criminal Investigations

In ***U.S. ex rel. Landis v. Tailwind Sports Corp.,*** the district court outlined guidance that provides persuasive authority to defendants seeking discovery of work product generated during a criminal investigation that is shared with government lawyers building a parallel or subsequent civil case.[116] This reasoning could provide meaningful protections to companies as they face the anticipated increase in parallel criminal and civil reviews of FCA cases.

At issue was information generated by federal agents conducting an investigation into the alleged use of performance enhancing drugs in professional cycling. While the criminal investigation was ongoing, Floyd

115. *U.S. ex rel. Barko v. Halliburton Co.,* 2014 U.S. Dist. LEXIS 36490, *8 (D.D.C. Mar. 6, 2014).

116. The district court indicated that it had insufficient evidence to rule on the motion to compel on a document by document basis and directed the government to provide justification for its privilege assertions. The district court continued to offer "guidance," however, "based on its review of the parties' briefing and the applicable case law." 2014 U.S. Dist. LEXIS 138965, at *11 (D.D.C. Sept. 30, 2014). *See* Remarks by Assistant Attorney General for the Criminal Division Leslie R. Caldwell at TAF Education Fund Conference (Sept. 17, 2014), *available at* http://www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-taxpayers-against (announcing increased coordination between Criminal and Civil Divisions and parallel review of new *qui tam* complaints).

Landis, Lance Armstrong's former teammate on the Postal Service professional cycling team, filed a *qui tam* complaint against Armstrong and others, and the government subsequently intervened. During discovery in the civil case, the government revealed, through inadvertent disclosure, that it had received memoranda produced by law enforcement during the criminal investigation.

Armstrong sought production of the memoranda, arguing that, to the extent the work product doctrine applied, the protection could be overcome because he had a substantial need based on the fact that the relevant events occurred 15 years ago. The district court agreed that Armstrong had shown substantial need, but for different reasons. The district court explained that "[t]he civil lawyers litigating this *qui tam* action have received a substantial advantage from having access to the fruits of the prior criminal investigation." Because the statements provided to law enforcement included "critical sources of evidence for *both* sides," the district court concluded that, "[p]articularly in *qui tam* actions, fairness dictates that both sides have equal access to relevant witness statements developed by law enforcement in prior or parallel criminal investigations." Thus, the district court indicated that any memoranda from the criminal investigation that constituted "fact" work product and was shared with the attorneys in the civil case should be produced.

Cautionary Cases on Privilege Waiver

Last year, several district courts expressed unwillingness to excuse waiver of a privilege when a defendant made certain disclosures as part of its strategy in responding to inquiries or allegations. These cases serve as cautionary tales to clients as they contemplate a strategy for cooperating with government investigations and crafting defenses to allegations.

In ***U.S. ex rel. Garbe v. Kmart Corp.,*** the district court refused to apply the selective-waiver doctrine in a civil case, when a company provided attorney work product to government regulators in connection with a prior investigation. The defendant had provided the document at issue with "the primary motivation [of appearing] cooperative in order to hopefully obtain a more favorable result in the investigation. . . ."[117] Kmart argued that it had "selectively waived" the work product protection with regard to the federal government, such that the protection still applied against the relator in the civil case. The district court concluded, however, that selective waiver was not appropriate because "both the federal government and Relator are adversaries of K-Mart under essentially the same circumstances." The district court further emphasized, "K-Mart made a strategic calculation; did the potential risk of waiver of work product protection outweigh the potential benefit it would receive by appearing cooperative with the federal government? K-Mart concluded that the potential benefit outweighed the risk."

In ***U.S. ex rel. Barker v. Columbus Regional Healthcare System,*** the district court concluded that the defendant waived its attorney-client privilege by inserting its knowledge of the law into the proceedings.[118] In its answer to an FCA complaint alleging false certifications of the AKS and the Stark law, the defendant raised as an affirmative defense that its actions were undertaken in good faith and constituted conduct that was lawful, proper, justified or privileged. The district court held that the attorney-client privilege was not available to documents regarding the transactions at issue because "when a defendant affirmatively asserts a good faith belief that its conduct was lawful, it injects the issue of its knowledge of the law into the case and thereby waives the attorney-client privilege."

High Evidentiary Standards in Establishing Privilege

Finally, one district court has reminded attorneys and clients that privilege claims must be supported with detailed evidence to satisfy each element of the privilege asserted. In ***U.S. ex rel. Schaengold v. Memorial Health,*** a district court refused to find that a document was privileged because the supporting declaration "fail[ed] to show who exactly sent the [document], whether the *primary* purpose of the communication was for legal advice, or whether the communication was indeed confidential."[119] In dicta, the court also explained that similar evidentiary standards applied to the defendant's attempt to establish factors relevant to assessing whether a waiver is excused. For example, the court explained that in order to address the sufficiency of a privilege review, the defendant could not rely on a "naked assertion" of a privilege review, but rather must establish "when the

117. 2014 U.S. Dist. LEXIS 73261, *3-4 (N.D. Ill. May 29, 2014).
118. 2014 U.S. Dist. LEXIS 120504, *6 (M.D. Ga. Aug. 29, 2014).
119. 2014 U.S. Dist. LEXIS 156595, at *9 (S.D. Ga. Nov. 5, 2014).

review occurred, how much time [counsel] took to review the documents, what [certain] documents were reviewed, and other basic details of the review process."

JUDICIAL REVIEW OF SETTLEMENTS

While relators and the government may share the same interest during the investigation and prosecution of an FCA action, their respective interests may diverge during settlement negotiations and courts may have to step in to determine a fair and appropriate result.

In ***U.S. ex rel. Peterson v. Sanborn Map Co.,*** the district court resolved issues regarding the enforcement of the terms of a settlement agreement over the relator's objections and a dispute regarding the relator's percentage share of the proceeds of the settlement.[120] In enforcing the terms of the settlement agreement and rejecting the relator's efforts to alter the scope of the previously agreed upon release, the district court rejected the relator's argument that the scope of the release had not been agreed upon by the parties. The district court explained that although the government and the relator had continued to negotiate certain terms of the settlement agreement, the scope of release language was "independent of and outside the scope of the parties' agreement" to modify other terms of the agreement.

In considering the relator's request for a share of the settlement proceeds, the district court ultimately awarded the relator 19 percent instead of the 25 percent he sought. For its part, the government argued that the relator should have received the minimum of 15 percent under the FCA, because the relator's participation was not substantial and the relator made the investigation more difficult and increased the risk of litigation. According to the government, the relator delayed reporting and filing the complaint, publicized the case in violation of the seal and unreasonably opposed settlement.

120. 2014 U.S. Dist. LEXIS 13471 (E.D. Mo. Feb. 4, 2014).

CASES TO WATCH

During the previous year, there were many noteworthy developments in healthcare fraud and abuse cases. Three of these developments are discussed below.

Use of Statistical Extrapolation To Establish Liability

For many years, creative relators' counsel and the government have sought to push the bounds of theories of liability under the FCA. We saw this last year, as district courts in Florida grappled with the issue of whether violations of the Stark law could taint Medicaid claims and serve as a basis for FCA liability.

During the previous year, ***U.S. ex rel. Martin v. Life Care Centers of America,*** pending in the U.S. District Court for the Eastern District of Tennessee, has been one of the most closely watched cases.[121] Last year, the district court issued important rulings concerning Life Care's motion for partial summary judgment and to exclude the government's expert testimony regarding the government's intended use of statistical sampling to establish liability over an extrapolated universe of claims. These rulings potentially will have significant influence on how relators and the government will pursue theories of liability against healthcare providers in future FCA actions.

The government alleged that Life Care billed for services that were medically unreasonable, unnecessary, and unskilled in its skilled nursing facilities. According to the government's complaint, Life Care fostered a corporate environment that pressured employees to bill at excessively high levels for all patients, regardless of medical need, and incentivized high reimbursement through bonuses/awards, plans of action for low-performers and quick retaliation against whistleblowers.

Life Care's partial summary judgment motion attempted to head off the government's novel attempt to use statistical sampling—not to determine damages, but to establish underlying FCA liability. The government sought to use a random sample of 400 admissions from 82 Life Care facilities between 2006 and 2012 where Medicare was the primary payer and more than 65 percent of those facilities' rehabilitation therapy days were at the Ultra-High Resource Utilization Group ("RUG") level of reimbursement. The government intended to extrapolate its findings from this sample to the entire universe of patient admissions from these facilities, including 54,396 patient admissions, comprising 154,621 total claims, to make "estimates on the total number of claims which were submitted for non-covered services and the total amount of overpayments made by Medicare."

> "The Government has statistical evidence regarding all of the Government's universe of 2,181 claims. Statistical evidence is evidence."
> *- U.S. ex rel. Paradies v. Aseracare, Inc.*

The district court held that where there was a large universe of potential claims, making a claim-by-claim review impracticable, statistical sampling is a "legally viable mechanism which the Government may employ in attempting to prove the FCA claims in this action." The district court noted that there is no specific prohibition against the use of statistical sampling in the FCA, and that Congress could have precluded its use but had not done so. The district court examined the application of sampling to each of the elements of FCA claims:

Regarding the identification of specific false claims, the district court found that the government would not be required to specify with detail all of the unidentified claims for which it sought to impose

121. 2014 U.S. Dist. LEXIS 142657 (E.D. Tenn. Sept. 29, 2014).

liability, where the number of claims makes it impracticable to identify and review each claim and statement.

Regarding the falsity of claims, the district court rejected Life Care's argument that an individualized determination is necessary due to the subjective and patient-specific nature of the medical necessity issue, noting that sampling has been used in litigation "for decades" and that Life Care's argument simply "highlights the very nature of statistical sampling: that a smaller portion of claims will be used to draw an inference about a larger, not entirely identical, populations of claims."

Regarding knowledge, the district court determined that the government's statistical sampling was not reliant on a "collective knowledge theory"—typically rejected as a viable theory in FCA cases—because the government will be attempting to meet the scienter requirement in each submitted claim with evidence of Life Care's "corporate practices and pressure" and "then extrapolate the total number of claims to the relevant universe."

Regarding materiality, the district court rejected Life Care's argument that the government must show that the unskilled therapy was sufficient to reduce the RUG level billed to Medicare, because materiality focuses on "the *potential* effect" of any false statement, not its actual effect.

The district court noted that several of Life Care's arguments were "compelling," but that such arguments should be considered by a jury rather than the court. In that regard, the district court noted that Life Care can still attack the weight to be given to any extrapolated evidence through several methods (e.g., cross-examination, competing witnesses/experts).

There can be little doubt that providers increasingly will encounter attempts by relators and the government to apply statistical sampling in hopes of extrapolating liability over a broader set of claims.[122]

FCA Liability Based on Retention of Overpayments

On June 27, 2014, DOJ filed its complaint-in-intervention in the FCA action against Continuum Health Partners, alleging that the health system failed to return overpayments to the federal healthcare programs in a timely manner.[123] Providers are familiar with PPACA's amendment to the FCA, which established that the failure to return an overpayment from Medicare or Medicaid within 60 days after identification of that overpayment will result in possible FCA liability. For its part, CMS has yet to finalize regulations regarding the identification, reporting and returning of such overpayments. Nonetheless, DOJ's lawsuit against Continuum Health marks one of the first cases in which the government has intervened under 31 U.S.C. § 3729(a)(1)(G), alleging that a provider failed to timely return overpayments under PPACA's 60-day time limit.

In its complaint-in-intervention, DOJ alleged that Continuum Health identified overpayments resulting from a "software compatibility issue," which erroneously indicated that additional payments could be sought from Medicaid as a secondary payer. The relator worked for Continuum Health within its revenue cycle operations and Continuum Health allegedly asked that he ascertain which claims had been improperly submitted as a result of the software error. The relator allegedly identified more than 900 claims in an amount of $1 million in overpayments caused by the software error.

According to DOJ, Continuum Health took no action with respect to the work performed by the relator and then fraudulently delayed in repaying the overpayments and did so with respect to more than 300 claims only after receiving a Civil Investigative Demand from DOJ. DOJ's complaint-in-intervention asserts a single claim for relief under § 3729(a)(1)(G).

The case against Continuum Health marks the first instance in which DOJ has intervened in an FCA action against a provider for the failure to return overpayments timely since the PPACA amendments to the FCA. The allegations against Continuum Health are noteworthy due to the fact that DOJ's complaint-in-intervention includes no allegations that Continuum Health knowingly submitted improper or fraudulent claims; rather, the allegations

122. See *U.S. ex rel. Paradies v. Aseracare, Inc.,* 2014 U.S. Dist. LEXIS 167970 (N.D. Ala. Dec. 4, 2014) (denying motion for summary judgment and noting that "[t]he Government has statistical evidence regarding all of the Government's universe of 2,181 claims. Statistical evidence is evidence.").
123. *U.S. ex rel. Kane v. Healthfirst, Inc.,* Civ. No. 11-2325 (S.D.N.Y).

focus solely on the fact that Continuum Health allegedly improperly retained the overpayments received as a result of an admitted billing error.

Continuum Health has filed a motion to dismiss this action and providers should watch this action closely to monitor arguments made by DOJ in support of its claims under § 3729(a)(1)(G).

Continued Focus on Anti-Kickback Statute Concerning Pharmaceutical Companies

DOJ has continued to aggressively pursue pharmaceutical companies in connection with allegations that those companies have provided inducements to healthcare providers in an effort to influence drugs dispensed to patients. Rebates, incentive programs, educational grants, speaker programs and other financial support offered to providers by pharmaceutical companies have drawn scrutiny from DOJ based on the concern that these arrangements are nothing more than thinly-disguised kickbacks paid to providers.

In a number of recent cases, DOJ has focused on internal company communications and communications between pharmaceutical companies and providers to support allegations that these companies allegedly violated the AKS, which makes it illegal to pay any remuneration to induce referrals of items or services covered by the federal healthcare programs.[124] DOJ also noted situations in which pharmaceutical companies allegedly violated their own internal policies concerning arrangements such as speaking programs or tracked the return on investment in connection with these programs.

DOJ undoubtedly will continue to focus on areas of potential fraud and abuse relating to the marketing of drugs and devices and the offering of any sort of remuneration by pharmaceutical companies to healthcare providers. Whether healthcare providers have blatantly offered goods, services, payments or other benefits to induce referrals, or whether such remuneration has been packaged as consulting fees, grants or studies, healthcare providers should expect continued scrutiny of such remuneration as a possible violation of the AKS and, consequently, the FCA.

124. *See U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.,* Civ. No. 11-cv-08196 (S.D.N.Y.); *U.S. ex rel. Bilotta v. Novartis Pharmaceuticals Corp.*, Civ. No. 11-cv-00071 (S.D.N.Y.); *U.S. ex rel. Spetter v. Abbott Labs.,* No. 10-cv-00006 (W.D. Va.); *U.S. ex rel. McCoyd v. Abbott Labs.,* No. 07-cv-00081 (W.D. Va.).

STARK LAW/ANTI-KICKBACK STATUTE

As a result of a number of self-disclosures and settlements involving alleged Stark and Anti-Kickback Statute violations, several themes emerged last year concerning these statutes.

Through these self-disclosures and settlements, several themes emerged regarding Stark and Anti-Kickback enforcement.

Physician Enforcement

Enforcement authorities pursuing Stark and AKS claims traditionally have focused on hospitals, laboratories and other healthcare entities, while physicians often escaped enforcement action except in egregious cases. Last year, however, saw a shift in this trend, as enforcement authorities also pursued physicians as "phase two" of an investigation in cases involving Stark and AKS schemes.

For example, Devender Batra, M.D., and Belmont Cardiology, Inc., agreed to pay $1 million to resolve allegations involving improper compensation arrangements between Dr. Batra, East Ohio Regional Hospital and Ohio Valley Medical Center.[125] The investigation into the alleged Stark and FCA violations involving Dr. Batra followed a 2011 settlement with the hospitals after the hospitals self-disclosed noncompliant compensation arrangements involving Dr. Batra and Belmont Cardiology, Inc.[126]

Similarly, in October 2014, the United States settled with two cardiologists for $380,000 regarding allegations that the physician-owners of Cumberland Clinic violated the FCA by entering into sham management agreements with Saint Joseph Hospital.[127] This action followed the $16.5 million settlement entered into by the hospital in January 2014.

Competitors

Settlements reached last year also serve as a reminder that the pool of potential *qui tam* relators is not limited to current and former employees, but often can include competitors. Optim Healthcare reached a $4 million settlement to resolve allegations that it performed and billed for financially-motivated surgical procedures at its remote hospital in violation of the Stark law.[128] The whistleblower in the case was a former executive of a competing healthcare company.

A federal jury in ***Ameritox, Ltd. v. Millennium Laboratories, Inc.,*** awarded more than $15 million to a competitor of Millennium Laboratories, after the competitor alleged that Millennium's nationwide marketing strategy for its urine drug testing practices violated unfair competition laws.[129] In an interesting twist, the competitor, Ameritox, Ltd., used Stark and AKS as a predicate for legal challenges *outside* of the FCA. The jury determined that the provision of free point-of-care drug testing cups constituted illegal remuneration, violating Stark and AKS.

Stark: Self-Disclosure Backlog

Perhaps one reason for the seeming reduction of the litigation of Stark claims is the growing use of the Self-Referral Disclosure Protocol ("SRDP") to resolve Stark violations, particularly with respect to technical violations. When CMS first implemented its self-disclosure process in 2010, it underestimated the volume of disclosures it would receive. CMS has struggled with the burden of review since

125. *See* http://www.justice.gov/usao/wvn/news/2014/april/batra.html.
126. *See* http://www.justice.gov/usao/wvn/news/2011/september/ovmc.html.
127. *See* http://www.justice.gov/opa/pr/kentucky-cardiologists-agree-pay-380000-settle-false-claims-act-allegations-based-illegal.
128. *U.S. ex rel. Schaengold v. Tattnall Hosp. Co.,* No. 4:11-cv-166 (S.D. Ga. Aug. 13, 2014).
129. *Ameritox, Ltd. v. Millennium Labs., Inc.,* No. 8:11-cv-00775 (M.D. Fl. Sept. 15, 2014). A judge subsequently reduced the punitive damages awarded by the jury by $3.5 million.

it first implemented the self-disclosure protocol in 2010, resulting in significant delays to resolution. Some estimate the agency has completed only 10 percent of the current volume of disclosures received.[130] Based on its experience administering the SRDP in the first three years, CMS revised its estimates in 2014 by doubling the average number of self-disclosures it anticipates receiving annually and increasing the estimated burden per disclosure from 24 to 50 hours.[131] Recently, CMS requested comments on its intent to establish an expedited SRDP review process for certain disclosures that have no indicia of fraud and that involve common arrangements, such as leasing and personal service arrangements.[132] The CMS proposal, which is currently pending, incorporates ideas originally considered by Congress in 2013.[133]

Stark: Settlements Extending Reach to Medicaid

Settlements of FCA claims were not surprising outcomes after recent court rulings finding that violations of Stark tainted claims submitted for reimbursement under Medicaid. In ***U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center and Halifax Staffing, Inc.,*** Halifax Hospital Medical Center reached a settlement for $85 million concerning such allegations.[134]

Similarly, in ***U.S. ex rel. Schubert v. All Children's Health System,*** the defendant agreed to pay $7 million to settle FCA allegations by submitting claims to Medicaid tainted by violations of Stark after the district court denied its motion to dismiss the case.[135] Although it declined to intervene, the United States filed a Statement of Interest in connection with the case, making clear its position that the Stark law applies to claims submitted to the Medicaid program.

Stark: Compensating Physicians

Physician compensation continued to receive intense scrutiny last year. The United States intervened in ***U.S. ex rel. Schaengold v. Memorial Health, Inc.*** with respect to allegations that the hospital had entered into employment arrangements with three physicians in connection with the purchase of the physicians' practice that exceeded fair market value, took into account the volume or value of referrals, and were not commercially reasonable.[136] The government alleges that that the hospital considered referrals to the hospital in purchasing the practice and establishing the physician compensation, pointing to the projected and actual substantial losses related to these employed physicians. The district court ruled that the claims could proceed against the hospital, but not the parent health system. This case will be one to watch this year, as it continues the debate about whether and under what circumstances purchasing and operating a physician practice or employing physicians at a financial loss is commercially unreasonable and outside the employment exception under Stark.

A personal services arrangement came under fire in ***U.S. ex rel. Heesch v. Diagnostic Physicians Group,*** which ultimately settled for $24.5 million.[137] Allegations involved long-standing compensation arrangements between a health system and physicians group established as part of the group's purchase. The arrangements allegedly violated Stark by basing payment on a percentage of Infirmary's revenues, which included Medicare payments for tests and procedures referred by DPG physicians.

Finally, a group practice of cardiologists with offices throughout central and northern New York agreed to pay $1.3 million in August 2014 to resolve allegations that, for an 11-month period, it violated the FCA and Stark by knowingly compensating its physician-partners based on the volume or value of that physician's referrals for nuclear scans and CT scans that were not personally performed by the referring physician.[138] This case is notable for being one of the first cases in which Stark enforcement veered into physician compensation solely *within* a group practice, an area in which enforcement has historically been minimal.

130. Joe Carlson, *Curing Technical Violations,* Modern Healthcare (June 22, 2013) *available at* http://www.modernhealthcare.com/article/20130622/MAGAZINE/306229970.
131. CMS, Physician Self-Referral Disclosure Protocol: *Supporting Statement,* issued in connection with 79 Fed. Reg. 25,133 (May 2, 2014), *available at* http://www.reginfo.gov/public/do/DownloadDocument?documentID=475651&version=0.
132. 79 Fed. Reg. 25,133 (May 2, 2014); *Supporting Statement.*
133. H.R. 3776, 113th Cong. (1st Sess. 2013), or the Stark Administrative Simplification Act, would have established a fixed penalty for technical violations of the Stark law; the Discussion Draft of the Protecting the Integrity of Medicare Act of 2014, incorporated many of the changes proposed by H.R. 3776, but the version of the bill formally introduced in Congress (H.R. 5780, 113th Cong. (2nd Sess. 2014)) deleted in its entirety the provision regarding technical violations of the Stark law.
134. *U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr. et al.,* Civ. No. 09-cv-1002 (M.D. Fla. July 23, 2014).
135. *U.S. ex rel. Schubert v. All Children's Health Sys.,* Civ. No. 8:11-cv-01687(M.D. Fla. Apr. 16, 2014).
136. (S.D. Ga. Dec. 8, 2014).
137. No. 1:11-cv-00364-KD-B (S.D. Ala. Sept. 4, 2014).
138. *See* http://www.justice.gov/usao/nyn/news/2024-3992-618127744.pdf.

Kickbacks: Settlements and Discount Safe Harbors

DaVita Healthcare Partners, Inc., agreed to pay $389 million to resolve alleged AKS violations regarding the use of a joint venture business model to induce patient referrals to its dialysis clinics.[139] The whistleblower, a former DaVita financial analyst, alleged that DaVita engaged in a nationwide scheme to improperly induce referrals to its facilities by selling shares to physicians in existing DaVita dialysis centers for below-market rates, buying shares in physician-owned dialysis centers for above-market rates, giving physicians kickbacks masked as profits from joint ventures, and paying physicians to refrain from building competing dialysis centers. As part of its Corporate Integrity Agreement with HHS-OIG, DaVita agreed to unwind 11 joint ventures and to refrain from entering into certain partial divestiture joint ventures.[140]

Pharmacy supplier Omnicare, Inc. agreed to pay $124.2 million to resolve allegations that Omnicare entered into below-cost, per diem pricing contracts to supply prescription medication and other pharmaceutical drugs to skilled nursing facilities and their resident patients in return for the facilities' continued selection of Omnicare as their pharmacy provider. In addition, Omnicare allegedly offered and provided prompt payment discounts as an inducement to the facilities, regardless of whether payment was actually prompt. Notably, the relator elected to pursue the case after the United States declined to intervene in both of the settled *qui tam* lawsuits, and negotiated the settlement with Omnicare, which was approved by the DOJ.[141]

139. *U.S. ex rel. David Barbetta v. DaVita, Inc.*, No. 09-cv-02175 (D. Colo. Oct. 22, 2014).
140. DaVita Press Release (Oct. 22, 2014), http://phx.corporate-ir.net/phoenix.zhtml?c=76556&p=irol-newsArticle&ID=1980553.
141. *U.S. ex rel. Gale v. Omnicare, Inc.* No. 1:10-cv-00127 (N.D. Ohio Aug. 11, 2014); *U.S. ex rel. Silver v. Omnicare, Inc.*, No. 1:11-cv-01326 (D. N.J. Aug. 11, 2014).

MEDICARE CONTRACTORS AND RELATED LITIGATION

Frustration with the performance of the RACs continued this year, as calls for reform, a backlog of provider appeals for RACs and other claims appeals and government contracting restructuring coincided with the original RAC contracts expiring in February 2014.

CMS used the reprocurement period as an opportunity to reform certain parts of the RAC program, but effectively introduced more questions than answers.

RAC Contract Reprocurement Process Halted

CMS proposed changes to the RAC program as part of the RAC contract reprocurement process, including delaying payment to RACs until allegedly improper claims pass the second level of appeal and creating an additional national RAC solely for home health and durable medical equipment matters.

In ***CGI Federal Inc., v. United States,*** CGI Federal Inc. ("CGI"), a RAC for one of the CMS regions, asserted that CMS violated Federal Acquisition Regulation ("FAR") Part 8 by adding a provision that prolonged the time in which RACs would receive payment for appealed claims.[142] In the Requests for Quotations[143] ("RFQs") issued in January 2014, CMS altered the original process to require RACs to wait until after the second level of appeal rather than at the time of collection to invoice CMS. The Court of Federal Claims initially ruled in CMS' favor, but subsequently granted CGI's motion to stay the ruling, pending CGI's appeal, and enjoined CMS from awarding RAC contracts for the regions involved in CGI's bid protest.[144] In the meantime, CMS has not awarded new RAC contracts for the remaining regions. Instead, CMS extended its contracts with existing RAC contractors, allowing for a limited scope of audits through August 2016.[145] As RACs wait to learn whether CMS may alter the applicable payment scheme, the injunction on new RAC contracts renders both the future of the RAC payment mechanism and the status of the RAC program itself ambiguous.

Calls for Reform of RAC Program

CMS' efforts at reforming the RAC program come amidst comments by congressional leaders for CMS to ensure that RACs are "identifying real claim coding and medical documentation errors" and continued calls for reform by the American Hospital Association ("AHA"). In ***American Hosp. Ass'n v. Burwell,*** the AHA's efforts to mount legal challenges to CMS' policy decisions implemented by the RACs proved unsuccessful this year. On September 17, 2014, the district court dismissed the AHA's lawsuit, which sought to challenge CMS's refusal to reimburse hospitals for Part B services where RACs denied hospitals' Part A inpatient claims for reasonable and necessary care.[146] In granting HHS's motion to dismiss, the district court held that it lacked subject matter jurisdiction, explaining that under the Medicare Act, it could not review the challenged policies, including CMS' failure to create an exception to the one-year time limit for rebilling, because they did not constitute a "final decision . . . after a hearing" as required by statute.[147]

The AHA's unsuccessful litigation, however, did not slow down continued calls for reform. In a letter to HHS, congressional leaders also voiced concerns that RAC denials of inpatient stays, up to three years after services were rendered, require Medicare beneficiaries to pay higher out-of-pocket expenses under Medicare Part B and make them liable for post-acute care

142. *CGI Federal Inc. v. United States,* 118 Fed. Cl. 337 (Cl. Ct. Aug. 22, 2014).
143. A Request for Quotation is a type of bidding solicitation in which suppliers or vendors are invited to provide a cost quote for the completion of a particular project or program.
144. *CGI Federal Inc. v. United States,* No. 14-355C (U.S. Claims Sept. 2, 2014).
145. http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Recent_Updates.html.
146. *American Hosp. Ass'n et al. v. Burwell,* 2014 U.S. LEXIS 129787 (D.D.C. Sept. 17, 2014).
147. *Id.*

> "[T]he unprecedented growth in claim appeals continues to exceed the available adjudication resources to address appeals...."
>
> *–79 Fed. Reg. 394*

services no longer covered as a result of reclassification of the hospital care.[148] Congressional leaders and the AHA both cited a 2012 report issued by HHS to note that 72 percent of hospital-appealed RAC denials are overturned at the Administrative Law Judge ("ALJ") hearing level.[149]

In a recently released report, the AHA referenced this statistic as evidence that the RACs are inappropriately and inaccurately denying payments to hospitals, reducing hospital resources and redirecting funds from patient care to the appeals process.[150] Members of Congress and the AHA also criticized CMS's payment structure with the RACs, a central issue in the CGI case, with Congress suggesting RACs receive a retainer fee similar to other government contractors in lieu of the current contingency fee arrangement. On December 3, 2014, the American Medical Association ("AMA") echoed the concerns of Congress and the AHA in a letter to CMS Administrator Marilyn Tavenner, urging CMS to, among other things, implement financial penalties against RACs for inaccurate findings.[151]

Medicare Claims Appeals Backlog Continues While CMS Offers Potential Settlement Options to Resolve Pending Appeals

Appeals of Medicare claims denials continued to challenge providers as CMS introduced several efforts to streamline what many have argued is a broken process.

In December 2013, the Office of Medicare Hearings and Appeals ("OMHA") announced that it would temporarily suspend the assignment of most new requests for ALJ hearings as of July 15, 2013 due to the extensive backlog of claim appeals. On May 22, 2014, the AHA and three associated hospitals filed suit against HHS to compel the agency to meet the statutory deadlines for administrative claim denials for Medicare reimbursement.[152]

The AHA contended that significant delays in the Medicare appeals process, which "far exceed statutory timeframes," has caused great harm to providers of Medicare services, such as the plaintiff hospitals, and was clearly contrary to a statutory mandate requiring timely adjudication. On December 18, 2014, the district court dismissed the AHA's suit, stating that while it sympathizes with the plight of providers who must wait years to resolve their Medicare appeals, the delays are "not so egregious as to warrant intervention."[153] In lieu of using its mandamus power, the Court left what it described as essentially a fiscal and political problem for Congress and HHS to address.

To aid in alleviating the significant backlog noted in the AHA lawsuit, on August 29, 2014, CMS announced a settlement offer to acute care hospitals and critical access hospitals ("CAHs") to resolve pending appeals of claim denials by RACs and Quality Improvement Organizations ("QIOs") related to certain inpatient claims.[154] The proposed settlement offer allowed any acute care hospital or CAH willing to waive its right to request an appeal to recoup partial payment of claims equal to 68 percent of the net payable amount of the claims in controversy. Hospitals could not choose to settle some claims and continue to appeal others. Certain hospitals could be excluded from the settlement program based on pending FCA litigation or investigations. The deadline for hospitals to request settlement through Administrative Agreement Requests was on or prior to October 31, 2014.

In addition to the inpatient status settlement program, CMS introduced two other mechanisms for reducing the backlog at the ALJ level: the **Settlement Conference Facilitation ("SCF") Pilot Program** for Part B providers and suppliers and the **Statistical Sampling Pilot Program.** Under the SCF Pilot Program, Part B providers or suppliers can negotiate with CMS to reach

148. Letter to K. Sebelius (Feb. 10, 2014), at http://www.aha.org/content/14/140210-let-congress-hhs.pdf.
149. *See id; see also* OIG, "Improvements are Needed at the Administrative Law Judge Level of Medicare Appeals," OEI-02-10-00340, (Nov. 2012), at http://oig.hhs.gov/oei/reports/oei-02-10-00340.pdf (last accessed on Dec. 15, 2014).
150. *See* Amer. Hosp. Ass'n, *RAC Audit Reform is Essential to Fix Urgent, Critical Problems*, at http://www.aha.org/content/14/issuebrief-rac.pdf.
151. American Medical Association Letter to Marilyn B. Tavenner, CMS Administrator (Dec. 4, 2014), at http://mb.cision.com/Public/373/9691232/b40542e4f58ec822.pdf.
152. *Amer. Hosp. Ass'n v. Kathleen Sebelius,* No. 14-cv-851 (D.D.C. May 22, 2014).
153. *Am. Hosp. Ass'n et al. v. Burwell,* 2014 U.S. Dist. LEXIS 174738 (D.D.C. Dec. 18, 2014).
154. *See* Medicare Learning Network, *CMS Offers Settlement to Acute Care Hospitals and CAHs to Resolve Appeals of Patient Status Denials,* at https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2014-08-29-eNews-SE.html.

mutually agreeable settlements to their claims pending at the ALJ level. Eligible claims must include all ALJ requests filed at the ALJ level in 2013 and not be currently assigned to an ALJ. If the negotiations are unsuccessful, the appealed claims remain at the ALJ level of appeal in the order originally received.[155] CMS is not required to pay interest on any claims settled under the SCF program. Settlement under the SCF program may allow Part B providers and suppliers to resolve their appeals in a more timely manner without waiting years for the appeals process during which CMS recoups the money for the claims at issue.

The **Statistical Sampling Pilot Program** enables Part A and B providers and suppliers to resolve large amounts of pending ALJ appeals by requesting extrapolation from a random sampling of the claims from the universe of claims agreed upon during a pre-hearing conference.[156] The random sampling of claims will be reviewed by an ALJ at a hearing. The ALJ's final decision on the sample claims will be applied to the universe of pending claims. To be eligible for this program, a provider or supplier must have at least 250 eligible claims either assigned to an ALJ or with ALJ hearing requests filed between April 1, 2013 and June 30, 2013. Unlike the SCF program, a provider or supplier taking part in the Statistical Sampling Pilot Program cannot revert back to the normal ALJ appeals process after the pre-hearing conference order if it is unhappy with the ALJ's determination.

CMS Makes Changes to MAC Expectations in Appeals Process

CMS also recently established changes impacting the appeals process. Effective October 27, 2014, CMS implemented a new section to Chapter 3 of the Medicare Program Integrity Manual, instructing the Medicare Administrative Contractors ("MACs") to support their medical review decisions through the ALJ level of appeal.[157] MACs are now expected to provide support for CMS' defense of medical review decisions at the ALJ level, whether or not those decisions were originally made by a MAC, a RAC or other Medicare audit contractors. MACs are expected to assign a physician to participate at ALJ hearings and to oversee the ALJ hearing support process for their own claim determinations. The new manual provisions require MACs to coordinate with the QIC, the adjudicator for the second level of appeal, during the ALJ hearing process, including communication of all scheduled ALJ hearings to ensure timely determination of whether to participate in the ALJ hearing. Regardless of whether a MAC is a participant or party to an ALJ appeal, the MAC must be prepared to discuss details related to the facts of each claim under appeal, the relevant coverage policies and payment requirements, and, for extrapolation cases, the background on how the provider/supplier was selected for review, the case adjudications and the extrapolation process.

Unified Program Integrity Contractor Contract Procurement Underway

In an effort to consolidate its auditing program and prevent overlapping audits, CMS has plans to create new audit entities called **Unified Program Integrity Contractors ("UPICs"),** which will take on auditing responsibilities of ZPICs, Medicaid Integrity Contractors ("MICs"), and Program Safeguard Contractors ("PSCs") in a nationwide effort to streamline review of claims. Responses to CMS' draft Statement of Work for organizations to bid on UPIC contracts were due to CMS on June 9, 2014 with a projected contract award date in the third quarter of fiscal year 2015.[158] After transition and implementation, UPICs will likely not be active and fully operational until 2016.

CMS hopes this consolidation will result in increased data transparency to integrity contractors, improved contractor accountability through a national strategy, and more data on healthcare providers' claims and payments. UPICs will perform complicated data analysis, data matching and prepayment and post-payment reviews on Medicare-only claims, Medicaid-only claims, and Medicare-Medicaid claims, and other claims information, managed care data, and private sector data. The UPICs will operate in five regional jurisdictions. At this time, it is anticipated that UPICs will limit their review to claims under Medicare Parts A and B for fraud, abuse and waste. The new UPICs will completely replace MICs and likely ZPICs, although the other contractor types will continue to exist.

155. *See* CMS Settlement Conference Facilitation Pilot, *at* http://www.hhs.gov/omha/OMHA%20Settlement%20Conference%20Facilitation/settlement_conference_facilitation_pilot.html.
156. *Statistical Sampling Pilot Program Fact Sheet,* Office of Medicare Hearings and Appeals, at http://www.hhs.gov/omha/OMHA%20Statistical%20Sampling/statistical_sampling_fact_sheet.pdf.
157. CMS Manual System, Pub. 100-08 Medicare Program Integrity, Transmittal 543, Change Request 8501 (Issued Date: September 26, 2014), at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R543PI.pdf.
158. Centers for Medicare & Medicaid Services: Unified Program Integrity Contractor (UPIC) Umbrella Statement of Work (USOW). Draft. April 24, 2014, at https://www.fbo.gov/index?s=opportunity&mode=form&id=9c934f3a36040d859958816a3d60c30f&tab=core&_cview=0.

Challenges to Use of Statistical Sampling in Claims Audits

Recent cases also provided insight on legal challenges to Medicare contractors' use of statistical sampling in calculating overpayments. On February 17, 2014, in ***John Balko & Assocs. v. Sec'y, U.S. HHS,*** the Third Circuit addressed judicial review of extrapolated overpayment determinations by HHS.[159] Following an audit where extrapolation was used to calculate an overpayment, Balko argued that the contractor did not meet the requirement of 42 U.S.C. § 1395ddd(f)(3), which required an administrative finding of a provider's continuous or high level payment errors or a determination that educational intervention did not correct the issue before using extrapolation to calculate an overpayment. Not persuaded by Balko's arguments, the Third Circuit upheld the district court's granting of summary judgment and held that the statute clearly precludes judicial review of the Secretary's determination that a provider had a sustained or high rate of payment error and the Secretary's decision was supported by substantial evidence.

Similarly, two district courts also upheld the use of statistical sampling to calculate extrapolated overpayment amounts resulting from audits conducted by Medicare contractors.[160] Despite these unfavorable decisions, the use of statistical sampling to calculate extrapolated overpayment demands will continue to hotly be contested by providers defending adverse Medicare contractor audit results.

159. *John Balko & Assocs. v. Sec'y,* U.S. HHS, 555 Fed. Appx. 188, 189 (3d Cir. 2014).

160. *See Schuldt Chiropractic Wellness Center v. Sebelius,* 2014 U.S. Dist. LEXIS 7767 (D. Neb. Jan. 22, 2014) (upholding validity of ZPIC's overpayment extrapolation); *Becker v. Sebelius,* 2014 U.S. Dist. LEXIS 81968 (D.N.J. June 13, 2014) (affirming Medicare Appeals Council decision finding that the statistical sample and extrapolation calculation performed by a PSC were valid).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

A large portion of the government's success in healthcare fraud enforcement matters can be attributed to its focus on the pharmaceutical and medical device industries.

Last year, these industries witnessed DOJ teaming up with the FDA to hold entities liable for violations of Current Good Manufacturing Practices ("cGMP"); the FDA ramping up its scrutiny of compound pharmacies; DOJ and OIG remaining unrelenting in their desire to hold executives criminally liable for corporate misconduct; and DOJ bringing its first FCA case against a physician-owned distributor ("POD"). The government also continued to use traditional enforcement tactics, including pursuing AKS violations involving inappropriate remuneration arrangements with physicians and bringing FCA actions based on off-label marketing. Likewise, DOJ and OIG demonstrated their continued commitment to using non-monetary techniques to promote corporate compliance.

Trending Upward: The DOJ and FDA Enforcement Partnership

DOJ continued to work closely with the FDA to hold pharmaceutical and medical device companies accountable for substandard manufacturing practices and the distribution of adulterated products that threaten the health and safety of the public. In 2013, Deputy Assistant Attorney General for the Consumer Protection Branch of the Civil Division, Maame Ewusi-Mensah Frimpong, announced that the government would be "taking an especially hard look whenever patients are placed at an unacceptably high risk of harm by . . . violations of current good manufacturing practices."[161] Echoing those sentiments, in a December 2014 press conference, Acting Assistant Attorney General for the Civil Division, Joyce Branda, remarked that food and drug manufacturers "have a responsibility to make sure their products are produced under suitable conditions, and with appropriate and truthful labeling. And they have a responsibility above all to make sure that what leaves their factories and warehouses and clinics is safe."[162] With the government clear about its focus, it is more important than ever that the industry understand its manufacturing obligations.

DOJ (and whistleblowers) may, in theory, use cGMP violations as the basis for pursuing FCA liability. In such situations, DOJ would assert that the manufacturer caused the submission of false claims because the drugs or devices being distributed were "adulterated."

In February 2014, however, the Fourth Circuit held that non-compliance with cGMPs alone is not enough to serve as the basis for FCA liability, because adhering to cGMPs is not a precondition for reimbursement under Medicare or Medicaid.[163] In ***U.S. ex rel. Rostholder v. Omnicare, Inc.,*** the relator alleged that Omnicare had inappropriately packaged penicillin and non-penicillin products in the same location without adequate separation and cross-contamination controls. In affirming the dismissal of the case against Omnicare, the Fourth Circuit reasoned that false claims had not been submitted because FDA approval is the relevant precondition for reimbursement and there is no authority that indicates adulterated drugs lose their approved status.

Compound Pharmacy Enforcement

In November 2013, Congress empowered the FDA with oversight authority over compound pharmacies that produce sterile drugs in batches for hospitals and physicians (referred to as "outsourcing facilities") and instituted requirements that such facilities meet the cGMP requirements

161. *See* http://www.justice.gov/iso/opa/civil/speeches/2013/civ-speech-130129.html.
162. *See* http://www.justice.gov/opa/speech/acting-assistant-attorney-general-joyce-r-branda-civil-division-delivers-remarks-new.
163. *U.S. ex rel. Rostholder v. Omnicare, Inc.,* 745 F.3d 694 (4th Cir. 2014), cert. denied, No. 13-1411 (U.S. Oct. 6, 2014).

referenced above.[164] Last year, armed with this new authority, the FDA issued more than 25 warning letters to compounding pharmacies where violations were identified, which was more warning letters than had been sent to compounding pharmacies in the previous five years.[165] Additionally, increased inspections resulted in 25 recalls issued by compounding pharmacies in fiscal year 2014, up from three in 2012.[166]

Holding Individual Bad Actors Accountable

In the previous year, several high-ranking DOJ officials announced that the Criminal Division and Civil Division, along with foreign prosecutors, would be increasing their coordination to prosecute criminally culpable corporate executives and employees. On September 17, 2014, Principle Deputy Assistant Attorney General for the Criminal Division Marshall Miller told the Global Investigation Review Program that "[c]orporations do not act criminally, but for the actions of individuals. The Criminal Division intends to prosecute those individuals, whether they're sitting on a sales desk or in a corporate suite."[167]

Throughout the year, DOJ made good on its promise. For example, on November 13, 2014, an indictment was filed against Vascular Solutions Inc. ("VSI") and its CEO Howard Root, charging eight counts of introducing adulterated and misbranded medical devices into interstate commerce and one count of conspiracy to conceal the illicit activities.[168] VSI's Vari-Lase product was approved by the FDA for treatment of "superficial veins." It is alleged that, from 2007 to 2014, Root directed a sales initiative to promote the product for the removal of "perforator" veins, which are deeper in the skin and riskier to treat with a laser. Over that time period, Root allegedly conspired with others in the company to conceal their illegal promotion activities, ignoring explicit warnings from the FDA about the safety of Vari-Lase to treat perforator veins. It is worth noting that in July 2014, VSI paid $520,000 to resolve FCA civil liability stemming from the same behavior.

Similarly, on December 17, 2014, Barry Steinlight, the owner and president of Raw Deal, a New Jersey-based dietary supplement manufacturing company, pleaded guilty to one count of conspiracy to commit wire fraud based on a scheme he orchestrated involving diluted and adulterated dietary ingredients and supplements.[169] Steinlight disclosed that, between 2009 and 2013, he instructed employees to incorporate "fillers" into Raw Deal products and not to include the fillers on the certificate of analysis' list of ingredients provided to customers. Moreover, Steinlight told his employees to falsely certify that the Raw Deal products were kosher or organic. As part of his plea agreement, Steinlight agreed to forfeit $1 million in profits. Steinlight faces a maximum of five years in prison and a fine up to $250,000, or twice the gain or loss caused by the offense.

> "Corporations do not act criminally, but for the actions of individuals. The Criminal Division intends to prosecute those individuals, whether they're sitting on a sales desk or in a corporate suite."
>
> *–Remarks by Principle Deputy Assistant Attorney General for the Criminal Division Marshall Miller*

DOJ's First FCA Action against PODs and Physician Investors

On March 26, 2013, OIG released a Special Fraud Alert, entitled ***"Special Fraud Alert: Physician-Owned Entities,"*** regarding AKS concerns related to physicians holding ownership interests in companies that derive revenues from the sales of medical devices used by the physician-owners for their patients.[170] The OIG called the POD arrangement "inherently suspect" under the AKS and discouraged its use. Although it took more than a year after the OIG's warning, DOJ brought its first FCA case against a POD in 2014.

164. Drug Quality and Security Act, 113 P.L. 54, 127 Stat. 587.
165. *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm.
166. *See* http://www.usatoday.com/story/news/nation/2014/10/07/compounding-pharmacy-recalls-inspections-contamination/16472741/.
167. *See* http://www.justice.gov/opa/speech/remarks-principal-deputy-assistant-attorney-general-criminal-division-marshall-l-miller.
168. *See* http://www.justice.gov/opa/pr/vascular-solutions-inc-and-its-ceo-charged-selling-unapproved-medical-devices-and-conspiring.
169. *See* http://www.justice.gov/opa/pr/owner-dietary-supplement-company-pleads-guilty-multi-million-dollar-scheme-adulterate-dietary.
170. *See* http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

On September 8, 2014, DOJ filed a complaint against Dr. Aria Sabit, a Michigan neurosurgeon, Reliance Medical Systems, a spinal implant company; Apex Medical Technologies; Kronos Spinal Technologies, two of Reliance's distributorships; and Brett Berry, John Hoffman and Adam Pike (Reliance's owners) alleging that their arrangement violates the AKS and FCA.[171]

In ***United States v. Reliance Med Sys., LLC,*** the government alleges that Berry and Pike formed Reliance in January 2006, and, since its formation, they have owned and operated 14 affiliated PODs, including Kronos and Apex.[172] The PODs sold implants to hospitals at a markup, so the implants could be used in procedures performed by the PODs physician-owners. In particular, the government alleges that Reliance used Apex to impermissibly provide kickbacks to Dr. Sabit for using Reliance implants in his procedures. The complaint claims that before his April 2010 investment in Apex, Dr. Sabit had never used Reliance implants. Between May 2010 and July 2012, after his investment, it is alleged that Dr. Sabit used Reliance implants in 90 percent of his spinal fusion procedures and was paid more than $430,000 by Apex. The government also claims that the arrangement encouraged Dr. Sabit to perform medically unnecessary surgeries in violation of the FCA – a claim also raised in a separate *qui tam*.

(It is worth noting that Reliance may have aroused the ire of DOJ and OIG in October 2013, when it unsuccessfully brought a lawsuit against OIG, claiming that its characterization of PODs in the Special Fraud Alert violated their First Amendment and due process rights because it harmed their ability to communicate with investors.[173])

Focus on Pharmaceutical and Medical Device Kickback Arrangements with Physicians

Enforcement agencies continued to resolve numerous cases alleging inappropriate remuneration arrangements between pharmaceutical or medical device companies and healthcare providers in violation of the AKS. For example, on January 9, 2014, CareFusion Corp., the California-based pharmaceutical manufacturer and medical device company, agreed to a $40.1 million settlement to resolve allegations that, among other things, it paid kickbacks to physicians to use their product, ChloraPrep.[174] In particular, it was alleged that, in 2008, CareFusion paid the co-chair of the Safe Practices Committee of the National Quality Forum, Dr. Charles Denham, $11.6 million to induce him to recommend ChloraPrep to healthcare providers.

Similarly, on March 11, 2014, subsidiaries of the Israeli pharmaceutical giant, Teva Pharmaceuticals Industries Ltd., agreed to pay the state of Illinois and the federal government $27.6 million to resolve allegations that the entities violated the FCA by offering kickbacks to a physician to prescribe their generic version of clozapine, an anti-psychotic medication, to Medicare and Medicaid beneficiaries.[175] The company paid the physician $50,000 as part of a "consulting agreement" and provided all-expense-paid vacations for the physician and his family.

Likewise, on October 29, 2014, EBI LLC, d/b/a Biomet Spine and Bone Health Technologies and Biomet Inc., agreed to pay $6.07 million to settle allegations that the company violated the FCA by, among other things, paying kickbacks to physicians' staff to encourage them to persuade doctors to utilize EBI's bone growth simulator product.[176] The government alleged that the defendants paid office staff members through personal service agreements, and that the arrangement resulted in the submission of false billings to Medicare, as well as other federal healthcare programs.

Enforcement Agencies Continued Targeting Off-Label Promotion

As in years past, state and federal enforcement agencies continued to target pharmaceutical companies promoting drugs for off-label purposes. The FDCA and corresponding FDA regulations prohibit off-label promotion.[177] Once a drug has been approved, it may not be marketed or promoted for any use not specified in an application and approved by FDA. The sale and promotion of drugs or medical devices for "off-label" or "unapproved uses" can implicate liability under FCA or FDCA. Most enforcement has been in

171. *See* http://www.justice.gov/opa/pr/united-states-pursues-claims-against-neurosurgeon-spinal-implant-company-physician-owned.
172. *See* Complaint ¶¶ 81,83, *United States v. Reliance Med. Sys., LLC,* (C.D. Cal. Sept. 8, 2014) (No. 14-6979).
173. *See Complaint, Reliance Med. Sys., LLC v. United States,* (C.D. Cal. Sept. 8, 2014) (No. 13-7451).
174. *See* http://www.justice.gov/opa/pr/carefusion-pay-government-401-million-resolve-allegations-include-more-11-million-kickbacks.
175. *See* http://www.justice.gov/opa/pr/pharmaceutical-company-pay-276-million-settle-allegations-involving-false-billings-federal.
176. *See* http://www.justice.gov/opa/pr/biomet-companies-pay-over-6-million-resolve-false-claims-act-allegations-concerning-bone.
177. 21 U.S.C. §§ 301-96.

the pharmaceutical space; however, device companies are not immune from liability. Some case examples are set forth below.

On February 21, 2014, Endo Health Solutions, and its subsidiary Endo Pharmaceuticals, Inc. (collectively, "Endo") agreed to a $192 million settlement to resolve both criminal and FCA civil liability. The government alleged that Endo marketed its Lidoderm product for unapproved uses and, as a result, Endo's marketing behavior caused false claims to be submitted to federal healthcare programs because physicians prescribed Lidoderm to patients for unapproved uses not covered under the programs.[178] Lidoderm was approved by the FDA for the sole purpose of pain relief associated with a shingles complication known as post-herpetic neuralgia ("PHN"). It was alleged that Endo intended the product to be used for non-PHN purposes, but the product was misbranded under the FDCA because its labeling did not have sufficient directions for the alternative uses. Additionally, Endo sales representatives were encouraged to instruct physicians on how to use Lidoderm for the unapproved uses. OIG required Endo to enter into an extensive five-year corporate integrity agreement ("CIA") with OIG.

Likewise, on April 16, 2014, Astellas Pharma US Inc., entered into a $7.3 million settlement to resolve FCA claims based on allegations that it promoted and marketed its product Mycamine for unapproved uses.[179] The government alleged that Astellas knowingly promoted and marketed the drug for pediatric use, which was not a medically accepted indication and, therefore, not covered by the federal healthcare programs. During that time, Mycamine was approved only to treat severe Candida infections in adults or to prevent such infections in adults undergoing stem cell transplants.

Similarly, on September 24, 2014, Shire Pharmaceuticals agreed to a $56.5 million settlement with the federal government and several states to resolve FCA liability related to its marketing and promotion of several drugs, including ADHD medications Adderall XR, Vyvanse and Daytrana.[180] The government alleged that Shire inappropriately promoted Adderall XR for uses unsupported by clinical data and exaggerated its efficacy when compared to alternative treatments. Shire also allegedly promoted Adderall XR for treating conduct disorder, an indication not approved by the FDA, and sales representatives made false and misleading statements about the "abuseability" and effectiveness of Vyvanse. Shire agreed to enter into a five-year CIA with OIG.

Use of Non-Monetary Penalties to Promote Compliance

In addition to the monetary settlements and penalties discussed above, DOJ and OIG recommitted themselves to using non-monetary penalties to encourage entities to operate in a compliant manner. On June 5, 2014, at the American Bar Association's 10th National Institute on the Civil False Claims Act and Qui Tam Enforcement, Stuart F. Delery, Assistant Attorney General for the Civil Division, stated that to promote compliance and implementation of best practices, the DOJ has "put a renewed emphasis on non-monetary remedial measures that will help us to prevent misconduct from happening again."[181] Delery specifically noted how effective CIAs implemented in conjunction with OIG oversight had been at accomplishing that goal.

178. *See* http://www.justice.gov/opa/pr/endo-pharmaceuticals-and-endo-health-solutions-pay-1927-million-resolve-criminal-and-civil.
179. *See* http://www.justice.gov/opa/pr/astellas-pharma-us-inc-pay-73-million-resolve-false-claims-act-allegations-relating-marketing.
180. *See* http://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug.
181. *See* http://www.justice.gov/iso/opa/civil/speeches/2014/civ-speech-140605.html.

APPENDIX A - 2014 NOTABLE SETTLEMENTS

HOSPITALS AND HOSPITAL SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 17, 2013	Tenet Healthcare Corporation; affiliated entities	Tenet agreed to pay $5 million to resolve FCA allegations that Tenet paid kickbacks to doctors by allowing them to lease offices at below-market rates in exchange for patient referrals. The United States previously declined intervention. The settlement agreement was not made public until March 2014.[1]	$5 million
January 6, 2014	St. Mary Medical Center	St. Mary Medical Center agreed to pay $2.33 million to resolve FCA allegations that it administered 15 improper physician income guarantee agreements between January 2005 and August 2010. St. Mary discovered the problem independently and took corrective action immediately, including self-disclosing the violation.[2]	$2.33 million
January 28, 2014	Saint Joseph Health System, Inc. d/b/a Saint Joseph London Hospital	Saint Joseph London Hospital agreed to pay $16.5 million to resolve FCA allegations that it billed federal and state healthcare programs for numerous unnecessary cardiac procedures between January 2008 and August 2011 and that it entered into sham management agreements with certain physicians in order to induce referrals. Saint Joseph also entered into a five-year CIA with HHS-OIG in connection with the agreement.[3]	$16.5 million
March 10, 2014	Halifax Hospital Medical Center; Halifax Staffing, Inc.	Halifax Hospital Medical Center and Halifax Staffing agreed to pay $85 million to resolve FCA allegations that it violated the Stark Law by knowingly executing contracts with six oncologists that contained an incentive bonus that improperly included the value of prescription drugs and tests the oncologists ordered and Halifax billed to Medicare. The government also alleged Halifax compensated certain physicians at levels in excess of the fair market value of their work. As part of the settlement, Halifax Hospital and Halifax Staffing entered into a five-year CIA with HHS-OIG. Halifax entered into a second settlement in this *qui tam* action later in 2014 to resolve allegations as to which the government declined to intervene.[4]	$85 million
March 13, 2014	Memorial Hospital	Memorial Hospital agreed to pay $8.5 million to settle FCA allegations that it violated the Stark Law and Anti-Kickback Statute by engaging in a joint venture with a pain management physician and by entering into an arrangement with an ophthalmologist under which the ophthalmologist resold certain medical equipment to the hospital at inflated prices. Memorial self-disclosed these alleged violations to the government.[5]	$8.5 million
March 19, 2014	West Penn Allegheny Health System, Inc.	West Penn Allegheny Health System agreed to pay $1.53 million to settle FCA allegations that it leased space to physicians at below-market rates to induce referrals to West Penn. West Penn self-disclosed the alleged violations to the government.[6]	$1.53 million
March 21, 2014	Duke University Health System	Duke University Health System agreed to pay $1 million to settle FCA allegations that its hospitals wrongfully billed Medicare and Medicaid for coronary artery bypass surgeries during which physicians' assistants and graduate medical students acted as surgical assistants; and inappropriately unbundled claims related to anesthesia and cardiac services.[7]	$1 million

1. http://www.miamiherald.com/news/local/community/miami-dade/article1963695.html.
2. http://www.justice.gov/usao/pae/News/2014/January/stmary_release.htm.
3. http://www.justice.gov/usao/kye/news/2014/2014-01-28-sjhlondon.html.
4. http://www.justice.gov/opa/pr/2014/March/14-civ-252.html.
5. http://www.justice.gov/opa/pr/2014/March/14-civ-270.html.
6. http://www.justice.gov/usao/paw/news/2014/2014_march/2014_03_19_01.html.
7. http://www.justice.gov/usao/nce/press/2014/2014-mar-21.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 15, 2014	Health Management Associates, Inc.; Durant HMA, LLC d/b/a Medical Center of Southeastern Oklahoma; Durant HMA Physicians Management, LLC	Medical Center of Southeastern Oklahoma (MCSO) and its parent company, Health Management Associates, agreed to pay $1.5 million to resolve federal and state FCA allegations that MCSO and one of its physicians, Dr. Daniel Castro, billed Medicaid for sinus surgeries that were not medically indicated and for services related to surgical procedures that Dr. Castro did not perform.[8]	$1.5 million
April 21, 2014	All Children's Health System Inc.; All Children's Hospital, Inc.; Pediatric Physician Services, Inc.	All Children's Health System and its affiliates agreed to pay $7 million to resolve federal and state FCA allegations that All Children's Health System established certain compensation arrangements that exceeded fair market value and improper productivity bonuses for physicians in violation of the Stark Law. The United States previously declined to intervene in the matter.[9]	$7 million
April 25, 2014	Baptist Health System, Inc.; Baptist Neurology, Inc.; Southern Baptist Hospital of Florida, Inc.	Baptist Health System and affiliated entities agreed to pay $2.6 million to resolve FCA allegations that its subsidiary facilities billed Medicare and Medicaid for medically unnecessary services as a result of the conduct of two neurologists in Baptist's network who misdiagnosed patients with neurological disease. Despite learning of the misdiagnoses as early as October 2011, Baptist failed to disclose them to the government until September 2012.[10]	$2.6 million
April 30, 2014	Somerset Medical Center	Somerset Medical Center agreed to pay $435,640 to resolve FCA allegations that it violated the Anti-Kickback Statute by providing kickbacks to a physician group that referred a substantial number of patients to Somerset each year. The kickbacks were alleged to have been in the form of inflated rental payments for space Somerset leased from the physician group.[11]	$435,640
May 28, 2014	Ashland Hospital Corporation d/b/a King's Daughters Medical Center	King's Daughters Medical Center agreed to pay $40.9 million to resolve FCA allegations that it maintained improper financial relationships with certain employed cardiologists, billed Medicare and Medicaid for numerous medically unnecessary coronary procedures, and had physicians falsify medical records in order to justify the procedures. The hospital agreed to enter into a five-year CIA with HHS-OIG in connection with the settlement.[12]	$40.9 million
June 10, 2014	Shands Teaching Hospital & Clinics Inc.; Shands Jacksonville Medical Center Inc.; Shands Jacksonville Healthcare Inc.	Shands Healthcare agreed to pay $3.25 million to settle the remaining allegations in the *qui tam* action styled ***U.S. ex rel. Myers v. Shands Healthcare, et al.*** (M.D. Fla.) that six Shands healthcare facilities improperly billed federal healthcare programs for outpatient services that lacked physician orders or were otherwise deficient for the charges billed. The government declined to intervene as to these allegations. In July 2013, Shands paid $26 million to resolve allegations in this action as to which the government intervened—specifically, that six Shands healthcare facilities billed for inpatient services that should have been billed as outpatient services.[13]	$3.25 million
June 25, 2014	Northcross Medical Center; Mark Tuan Le, M.D.	Northcross Medical Center and Dr. Le agreed to pay $6.2 million to settle FCA allegations that Dr. Le and his practice billed Medicare and Medicaid for services that were not medically necessary, not provided, and/or provided to immediate family members, and otherwise failed to comply with Medicare and Medicaid rules and regulations from December 2007 through March 2013.[14]	$6.2 million

8. http://www.justice.gov/usao/oke/news/2014/04182014.html.
9. http://www.beckershospitalreview.com/legal-regulatory-issues/all-children-s-hospital-pediatric-physician-services-all-children-s-health-system-to-pay-7m-to-settle-stark-law-violations.html.
10. http://www.justice.gov/opa/pr/2014/May/14-civ-476.html.
11. http://www.justice.gov/usao/nj/Press/files/Somerset%20Medical%20Center%20Settlement%20PR.html.
12. http://www.justice.gov/usao/kye/news/2014/2014-05-28-KingsDaughters.html.
13. http://www.law360.com/articles/547263/shands-settles-remainder-of-26m-fca-suit.
14. http://www.justice.gov/usao/ncw/pressreleases/2014/Charlotte-2014-06-25-le.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 10, 2014	Carthage Area Hospital	Carthage Area Hospital agreed to pay $750,000 to settle FCA claims that it double-billed Medicare for operating room and ambulatory surgical services from September 2006 through June 2010.[15]	$750,000
July 21, 2014	Infirmary Health System, Inc.; Infirmary Medical Clinics, P.C.; IMC-Diagnostic and Medical Clinic, P.C.; IMC-Northside Clinic, P.C.; Diagnostic Physicians Group P.C.	Infirmary Health System ("IHS"), two IHS-affiliated clinics, and Diagnostic Physicians Group ("DPG") agreed to pay $24.5 million to resolve FCA allegations that the two IHS-affiliated clinics had an arrangement with DPG to pay a percentage of Medicare payments to DPG for tests and procedures referred to the clinics by DPG physicians, in violation of the Stark Law and Anti-Kickback Statute. In connection with the settlement, IHS and its affiliated clinics entered into a five-year CIA with HHS-OIG.[16]	$24.5 million
July 22, 2014	Halifax Hospital Medical Center; Halifax Staffing, Inc.	Halifax Hospital Medical Center and Halifax Staffing agreed to pay $1 million to resolve the remaining allegations in the *qui tam* action styled ***U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center*** (M.D. Fla.) that Halifax submitted claims for medically unnecessary inpatient services that should have been billed as outpatient services. The government declined to intervene as to these allegations. The settlement was reached just prior to a scheduled July 2014 trial.[17]	$1 million
August 4, 2014	Community Health Systems, Inc.; Community Health Systems Professional Service Corporation	Community Health Systems and its affiliates agreed to pay $98.15 million to resolve seven *qui tam* actions involving allegations that the company billed for unnecessary inpatient services that should have been billed as outpatient or observation services. As part of the agreement, CHS entered into a five-year CIA with HHS-OIG.[18]	$98.15 million
August 13, 2014	Optim Healthcare; Tattnall Hospital Company LLC d/b/a The Doctors Hospital of Tattnall; affiliated entities and individuals	Optim Healthcare agreed to pay $4 million to settle FCA allegations that Optim, through its physician-owned hospital and ambulatory surgical center, submitted false claims for procedures that were improperly inflated, misidentified in order to receive a higher rate of reimbursement and/or in violation of the Stark Law.[19]	$4 million
August 15, 2014	Albert Einstein Healthcare Network; Fornance Physician Services	Albert Einstein Healthcare Network and Fornance Physician Services agreed to pay $348,854 to resolve FCA allegations that the entities billed Medicare and Medicaid for services that were allegedly performed by a physician but were actually performed by residents where the physician was not appropriately performing teaching physician services. The physician also upcoded certain services to receive higher reimbursement and submitted other bills despite the lack of sufficient documentation to support the billable service. Albert Einstein Healthcare and Fornance disclosed these alleged violations to the government.[20]	$348,854
August 18, 2014	Carondelet Health Network d/b/a Carondelet St. Mary's Hospital; Carondelet St. Joseph's Hospital	Carondelet Health Network agreed to pay $35 million to resolve FCA allegations that the subject hospitals submitted claims for inpatient rehabilitation facility services for patients that were not appropriate for these services. Carondelet disclosed some inpatient rehabilitation overpayments to the government and made a significant repayment, prior to becoming aware of the government's investigation. While the government took these actions into account in reaching the settlement amount, it had concerns that the disclosure and repayment were not timely, complete or adequate.[21]	$35 million

15. http://www.justice.gov/usao/nyn/news/2013-3970-1892344192.pdf.
16. http://www.justice.gov/opa/pr/alabama-hospital-system-and-physician-group-agree-pay-245-million-settle-lawsuit-alleging.
17. http://www.modernhealthcare.com/article/20140714/NEWS/307149965.
18. http://www.justice.gov/opa/pr/community-health-systems-inc-pay-9815-million-resolve-false-claims-act-allegations.
19. http://www.justice.gov/usao/gas/press_releases/2014/201408014_Optim.html.
20. http://www.justice.gov/usao/pae/News/2014/August/einsteinsettlement_release.htm.
21. http://www.justice.gov/usao/az/press_releases/2014/PR_08182014_Carondelet.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 22, 2014	Banks-Jackson-Commerce Hospital and Nursing Authority d/b/a Banks Jackson Commerce Medical Center; Narisimhulu Neelagaru, M.D.	Banks Jackson Commerce Medical Center ("BJC") and Narisimhulu Neelegaru, M.D. agreed to pay $529,000 to settle FCA allegations that BJC compensated Dr. Neelegaru in a manner that violated the Stark Law. Specifically, the government alleged that in exchange for referrals of Medicare-eligible patients to BJC, BJC compensated Dr. Neelegaru for professional services and medical director services in excess of fair market value. BJC settled with the United States for $329,000 in September 2010, but the matter remained under seal until the United States settled with Dr. Neelagaru for $200,000 in September 2014, when both settlements were announced. In September 2010, in connection with the settlement, BJC agreed to enter into a five-year CIA with HHS-OIG.[22]	$529,000
October 15, 2014	Our Lady of Lourdes Memorial Hospital, Inc.	Our Lady of Lourdes Memorial Hospital, Inc. agreed to pay $3.37 million to resolve FCA allegations that it improperly billed Medicare for hyperbaric oxygen therapy services provided by a third party at a facility that did not meet federal regulations for "provider based status." The hospital discovered the improper billing during an internal review, took corrective action, and disclosed its findings to the government.[23]	$3.37 million
October 30, 2014	Dignity Health	Dignity Health agreed to pay $37 million to resolve FCA allegations that 13 of its hospitals billed for inpatient services for patients that should have been treated in an outpatient setting. The hospitals were alleged to be billing for improper inpatient services involving three groups of patients: patients undergoing elective cardiovascular procedures in scheduled surgeries that should have been billed as outpatient surgeries; patients undergoing elective, minimally-invasive kyphoplasty procedures; and patients with common medical diagnoses where admission as an inpatient was medically unnecessary. As part of the settlement, Dignity Health entered into a five-year CIA with HHS-OIG.[24]	$37 million
December 19, 2014	St. Helena Hospital	St. Helena Hospital, an acute care hospital within the Adventist Health System, agreed to pay $2.25 million to resolve FCA allegations that the hospital knowingly billed Medicare for medically unnecessary angioplasties and for inpatient angioplasty services that should have been performed in an outpatient setting.[25]	$2.25 million
December 22, 2014	Northampton Hospital Company, LLC; Northampton Hospital Corporation d/b/a Easton Hospital	Northampton Hospital Company and Easton Hospital agreed to pay $662,000 to settle FCA allegations that the hospital billed Medicare for a certain physician's urologic procedures and tests that were either not performed, only partially completed or medically unnecessary.[26]	$662,000
December 23, 2014	SpecialCare Hospital Management Corporation; Robert McNutt	SpecialCare, a company which provides administrative healthcare management services, agreed to pay $6 million to settle FCA allegations that it caused several hospitals to submit false claims to Medicare and Medicaid for inpatient detoxification services provided to patients who suffered from substance abuse issues. The government alleged that SpecialCare helped hospitals provide emergency detox services without a required state certificate; pursuant to illicit referrals; and that were medically unnecessary and/or violated professional standards of care. Two defendant hospitals in these *qui tam* actions previously entered settlement agreements in 2008 and 2012. As part of the settlement, SpecialCare and McNutt agreed to enter into a five-year CIA with HHS-OIG.[27]	$6 million

22. www.justice.gov/usao/gan/press/2014/09-22-14.html.
23. http://www.justice.gov/usao/nyn/news/2049-4040-127951232.pdf.
24. http://www.justice.gov/opa/pr/dignity-health-agrees-pay-37-million-settle-false-claims-act-allegations.
25. http://www.justice.gov/usao-ndca/pr/st-helena-hospital-agrees-pay-225-million-settle-false-claims-act-allegations.
26. http://www.justice.gov/usao-edpa/pr/easton-hospital-agrees-pay-government-662000-resolve-false-claims-act-allegations.
27. http://www.law360.com/articles/608850/hospital-manager-inks-6m-fca-deal-over-drug-abuse-care.

HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
August 4, 2014	The City of New York	The City of New York agreed to pay $1.05 million to resolve FCA allegations that the New York City Human Resource Administration ("HRA") caused various managed care organizations to provide health insurance to individuals HRA knew or should have known were ineligible to receive Medicaid benefits because the individuals had moved out of state.[28]	$1.05 million
September 9, 2014	Caremark LLC	Caremark, the pharmacy benefit management company owned by CVS, agreed to pay $6 million to resolve FCA allegations that it failed to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries who also were eligible for drug benefits under Caremark-administered private health plans.[29]	$6 million
November 6, 2014	Visiting Nurse Service of New York; VNS Choice; VNS Choice Community Care	Visiting Nurse Service of New York ("VNS") and affiliates paid $35 million to resolve FCA allegations that VNS and its affiliates improperly billed Medicaid for members whose needs did not qualify for the VNS Choice managed long-term care plan. These members were alleged to have been improperly referred by VNS-managed social adult day care centers or received services from those centers that did not qualify as "personal care services" under the contract with New York's Department of Health.[30]	$35 million

LONG-TERM CARE PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 27, 2013	CLP Healthcare Services, Inc. d/b/a Hospice Compassus	Hospice Compassus agreed to pay $3.9 million to resolve FCA allegations that it billed federal and state healthcare programs for hospice services provided to patients who were not terminally ill under Medicare and Medicaid regulations. This settlement was announced in March 2014.[31]	$3.9 million
January 17, 2014	RehabCare Group, Inc.; RehabCare Group East, Inc.; Rehab Systems of Missouri; Health Systems, Inc.	RehabCare Group, Inc. and Rehab Systems of Missouri (along with certain affiliates) agreed to pay $30 million to resolve FCA allegations that RehabCare made an arrangement with Rehab Systems to provide therapy services for residents of Rehab System's 60 nursing homes in exchange for a $400,000 to $600,000 upfront payment and a portion of the revenue from every referral, in violation of the Anti-Kickback Statute.[32]	$30 million
April 7, 2014	Alliance Rehabilitation, LLC; Active Physical Therapy Services, LLC; Thomas Bray; Rajeev Gupta; Geeta Trehan	Alliance Rehabilitation and Active Physical Therapy Services agreed to pay $2.78 million to settle FCA allegations that they billed Medicare and TRICARE for physical therapy services that were not provided or supervised by the physical therapist listed on the claim. As part of the agreement, the entities and three individuals associated with them entered into a five-year CIA with HHS-OIG.[33]	$2.78 million
April 23, 2014	Amedisys, Inc.; Amedisys Holding, LLC	Amedisys, a provider of home health services, and its affiliates agreed to pay $150 million to resolve FCA allegations that Amedisys submitted claims for services that were medically unnecessary or were provided to patients who were not homebound. The government also alleged Amedisys provided certain referring physicians with kickbacks in the form of below-market-rate coordination services, in violation of the Anti-Kickback Statute and Stark Law. As part of the settlement, Amedisys entered into a five-year CIA with HHS-OIG.[34]	$150 million

28. http://www.justice.gov/usao/nyn/news/2022-3988-1164688640.pdf.
29. http://www.justice.gov/opa/pr/caremark-will-pay-6-million-resolve-false-claims-act-allegations.
30. http://www.justice.gov/usao/nys/pressreleases/November14/VisitingNurseServiceSettlementPR.php.
31. http://www.justice.gov/usao/aln/News/March%202014/13%20Mar,%202014%20Hospice.html.
32. http://www.justice.gov/opa/pr/2014/January/14-civ-060.html.
33. http://www.justice.gov/usao/dc/news/2014/apr/14-083.html.
34. http://www.justice.gov/opa/pr/2014/April/14-civ-422.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
June 13, 2014	Foundation Health Services, Inc.; American Family Services, Inc.; Bluebonnet Healthcare, Inc.; Huntingdon Nursing Center, Inc.; Magnolia Healthcare, Inc.; Richard T. Daspit, Sr.; Rock Glen Healthcare, Inc.	Foundation Health Services and its affiliated nursing facilities agreed to pay $750,000 to resolve FCA allegations that the nursing facilities billed Medicare and Medicaid for materially substandard and/or worthless nursing services. Among other allegations, the entities allegedly did not follow appropriate fall protocols; failed to provide for activities of daily living, including bathing and feeding residents; and failed to provide a habitable living environment. The facilities also allegedly failed to employ a sufficient number and skill-level of nursing staff to provide adequate care to residents. In connection with the settlement, Foundation and the other facilities agreed to enter into a five-year CIA with HHS-OIG.[35]	$750,000
June 24, 2014	Blackhawk Lifecare Center	Blackhawk Lifecare Center, a skilled nursing facility which utilized a third-party therapy services provider, agreed to pay $500,000 to resolve FCA allegations that it submitted or caused to be submitted improper therapy services claims to the government because the claims were not justified by the residents' conditions. Blackhawk also allegedly submitted inflated cost reports to Medicaid by including the costs of the therapy services in its cost reports.[36]	$500,000
August 18, 2014	Ralex Services, Inc. d/b/a Glen Island Center for Nursing and Rehabilitation; Leah Friedman; Will-Maur Associates, LLC	Glen Island Center for Nursing and Rehabilitation, its owner and the real estate holding company of the facility agreed to pay $1.32 million to New York and $880,000 to the United States to resolve FCA allegations that the facility submitted false information in Patient Review Instrument data to inflate the level of care provided to residents and thus submitted falsely inflated claims for reimbursement to Medicaid. The defendants attempted to conceal the scheme by forging signatures and making false entries in the residents' medical records. As part of the settlement, Glen Island agreed to enter into a CIA with the New York State Office of the Medicaid Inspector General.[37]	$2.2 million
September 5, 2014	Life Care Services LLC; CoreCare V LLP d/b/a ParkVista	Life Care Services ("LCS"), a manager of skilled nursing facilities, and ParkVista, an LCS-operated SNF, agreed to pay $3.75 million to settle FCA allegations that they had submitted or caused to be submitted false claims to Medicare for unreasonable or unnecessary skilled rehabilitation therapy purportedly performed by RehabCare Group East, Inc., a subsidiary of Kindred Health. Specifically, the government alleged that LCS and ParkVista failed to prevent RehabCare practices at ParkVista and a former LCS-operated SNF intended to increase Medicare reimbursement, including: providing unreasonable and unnecessary therapy; placing patients in the highest RUG level unless it was shown the patients could not tolerate that amount of therapy; discouraging the provision of therapy in amounts lower than the minimum threshold required for the highest RUG level; arbitrarily shifting planned therapy minutes between therapy disciplines to meet RUG targets and recording rounded or estimated minutes instead of the actual amount of therapy provided.[38]	$3.75 million
September 15, 2014	A Plus Home Health; Stephen Nemerofsky; Tracy Nemerofsky	A Plus Home Health and its owners agreed to pay $1.65 million to resolve FCA allegations involving a kickback scheme whereby A Plus provided marketing jobs for at least seven physicians' spouses or significant others in exchange for referrals of Medicare beneficiaries to A Plus. The spouses and significant others did little, if any, actual marketing work and were paid, in part, based on the amount of referrals the physicians made to A Plus. The relator objected to the fairness and reasonableness of the settlement but the court granted the defendants' and government's motion to dismiss on November 5, 2014 based on the settlement. The United States previously settled with five couples that allegedly accepted similar kickbacks from A Plus.[39]	$1.65 million

35. http://www.justice.gov/usao/md/news/2014/NursingHomeChainToPay750000ToResolve.html.
36. http://www.justice.gov/usao/ian/news/2014/jun_14/6_24_14_Blackhawk.html.
37. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-22-million-settlement-new-rochelle-nursing-home-fraudulent; http://www.law360.com/articles/568606/ny-nursing-home-to-pay-2-2m-to-end medicaid-fraud-suit.
38. http://www.justice.gov/opa/pr/two-companies-pay-375-million-allegedly-causing-submission-claims-unreasonable-or-unnecessary.
39. http://www.justice.gov/opa/pr/florida-home-health-care-company-and-its-owners-agree-resolve-false-claims-act-allegations.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 15, 2014	Episcopal Ministries to the Aging, Inc.	Episcopal Ministries to the Aging ("EMA"), a not-for-profit organization that owns a skilled nursing facility, agreed to pay $1.3 million to resolve FCA allegations that it billed Medicare for unreasonable or unnecessary rehabilitation therapy purportedly provided by RehabCare Group East, Inc., a subsidiary of Kindred Healthcare. Specifically, the settlement resolved allegations that EMA failed to prevent RehabCare practices intended to increase Medicare reimbursement, including: providing unreasonable and unnecessary therapy; placing patients in the highest RUG level unless it was shown the patients could not tolerate that amount of therapy; discouraging the provision of therapy in amounts lower than the minimum threshold required for the highest RUG level; arbitrarily shifting planned therapy minutes between therapy disciplines to meet RUG targets and recording rounded or estimated minutes instead of the actual amount of therapy provided.[40]	$1.3 million
October 10, 2014	Extendicare Health Services, Inc.; Progressive Step Corporation	Extendicare Health Services, an operator of skilled nursing facilities, and its subsidiary Progressive Step Corporation, a provider of rehabilitation therapy, agreed to pay $38 million to settle FCA allegations that Extendicare billed Medicare and Medicaid for materially substandard skilled nursing services and failed to provide care that satisfied federal and state regulations and standards of care at 33 of its SNFs; and Extendicare and Progressive Step provided medically unreasonable and unnecessary rehabilitation services to Medicare Part A patients at 33 SNFs, particularly during the patients' assessment reference period, in order to bill at the highest RUG level. As part of the settlement, Extendicare agreed to enter into a five-year CIA with HHS-OIG.[41]	$38 million
October 27, 2014	Advanced Professional Home Health Care	Advanced Professional Home Health Care agreed to pay $57,000 to resolve FCA allegations that it altered physician signature dates and other information on physician orders for home healthcare services. As part of the agreement, Advanced Professional will implement a compliance program for at least two years relating to its documentation of physician orders for home health services.[42]	$57,000
November 12, 2014	CareAll Management LLC; affiliated entities	CareAll Management, a home health provider, and affiliated entities agreed to pay more than $25 million to the United States and Tennessee to settle FCA allegations that between 2006 and 2013, it overstated the severity of patients' conditions in order to increase reimbursement and billed for services that were not medically necessary or rendered to homebound patients. As part of the agreement, CareAll agreed to be bound by an enhanced and extended CIA with HHS-OIG (CareAll was already operating under a CIA related to a 2012 settlement).[43]	$25 million+
December 2, 2014	Serenity Hospice Care, LLC	Serenity Hospice Care and an affiliate agreed to pay $581,504 to settle FCA allegations that they billed Medicare for hospice services for patients who were ineligible for hospice care under Medicare regulations.[44]	$581,504

40. http://www.justice.gov/opa/pr/episcopal-ministries-aging-inc-pay-13-million-allegedly-causing-submission-claims.
41. http://www.justice.gov/opa/pr/extendicare-health-services-inc-agrees-pay-38-million-settle-false-claims-act-allegations.
42. http://www.justice.gov/usao/miw/news/2014/2014_1027_APHHC.html.
43. http://www.justice.gov/opa/pr/careall-companies-agree-pay-25-million-settle-false-claims-act-allegations.
44. http://www.justice.gov/usao/gas/press_releases/2014/20141202_Serenity.html.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 7, 2014	Hi-Tech Pharmacal Co.	Hi-Tech Pharmacal, a pharmaceutical manufacturer, agreed to pay $25 million to resolve FCA allegations that it provided inflated pricing information for its drugs to Texas Medicaid, which materially increased Medicaid's reimbursement rate for those drugs.[45]	$25 million
January 7, 2014	CareFusion Corporation	CareFusion, a pharmaceutical manufacturer and distributor, agreed to pay $40.1 million to resolve FCA allegations that it paid $11.6 million in kickbacks to a physician in order to induce him to recommend ChloraPrep, a CareFusion drug. The settlement also resolved allegations that CareFusion knowingly promoted ChloraPrep for uses not approved by the FDA, not medically indicated or altogether unsubstantiated.[46]	$40.1 million
January 8, 2014	BioScrip, Inc.	BioScrip, a specialty pharmacy, agreed to pay $15 million to resolve FCA allegations that it received kickbacks from Novartis—in the form of patient referrals and purported rebates—to push patients to continue using Exjade, a Novartis-manufactured iron reduction drug.[47]	$15 million
February 7, 2014	Berchtold USA	Berchtold, a medical device vendor, agreed to pay $3.6 million to settle FCA allegations that Berchtold overcharged the government by potentially more than $1 million in relation to a $2.4 million subcontract to sell medical equipment to military hospitals. The company purportedly submitted fabricated invoices and falsified product numbers in an attempt to satisfy certain procurement pricing requirements.[48]	$3.6 million
February 19, 2014	EndoGastric Solutions, Inc.	EndoGastric Solutions, a medical device company, agreed to pay up to $5.25 million ($2.5 million in fixed payments, up to $2.75 million in contingent payments) to resolve FCA allegations that it knowingly misled providers into submitting claims for more invasive procedures even though its device permitted providers to conduct the same procedure less invasively and paid kickbacks to certain providers for participating in seminars to induce them to use its devices. As part of the settlement, EndoGastric entered into a five-year CIA with HHS-OIG.[49]	$2.5 million (fixed); up to $2.75 million (contingent)
February 21, 2014	Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.	Endo Health Solutions and its subsidiary Endo Pharmaceuticals agreed to pay $192.7 million to resolve criminal and FCA allegations that they caused false claims to be submitted to federal programs by promoting one of its drugs for uses not approved by the FDA and, often, not medically indicated. As part of this global settlement, Endo agreed to enter into atwo and a half-year deferred prosecution agreement with DOJ and a five-year CIA with HHS-OIG.[50]	$171.9 million (civil); $20.8 million (criminal forfeiture)
February 24, 2014	H.E. Butt Grocery Company; HEB Grocery Company, LP; HEBCO GP LLC	H.E. Butt Grocery and related entities agreed to pay $12 million to the state of Texas to resolve FCA allegations that the grocery store and pharmacy chain submitted inflated usual and customary pricing information to Texas Medicaid along with its claims for reimbursement by failing to account for discounted prices it charged members in its "Rx Rewards Program."[51]	$12 million

45. https://www.texasattorneygeneral.gov/oagnews/release.php?print=1&id=4622.
46. http://www.justice.gov/opa/pr/2014/January/14-civ-021.html.
47. http://www.justice.gov/usao/nys/pressreleases/January14/NovartsBioScrip.php.
48. http://www.postandcourier.com/article/20140312/PC05/140319794; http://www.law360.com/articles/526337/faegre-baker-can-t-shed-gov-t-contract-malpractice-suit.
49. http://www.justice.gov/opa/pr/2014/February/14-civ-173.html.
50. http://www.justice.gov/opa/pr/2014/February/14-civ-187.html.
51. http://www.news-journal.com/business/grocer-pays-million-in-whistleblower-case/article_bb9c387e-a14e-53eb-91ab-c3f472ced2e3.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
February 27, 2014	Omnicare, Inc.	Omnicare agreed to pay $4.19 million to resolve FCA allegations that it solicited and received kickbacks from drug manufacturer Amgen, Inc. in return for implementing "therapeutic interchange" programs designed to switch Medicaid beneficiaries from a competitor drug to Amgen's product Aransesp. Amgen previously settled with the government in April 2013.[52]	$4.19 million
March 11, 2014	IVAX LLC; Teva Pharmaceuticals USA, Inc.	Pharmaceutical manufacturers Teva Pharmaceuticals and IVAX agreed to pay $27.7 million to resolve FCA allegations that they made payments to a physician through a series of "consulting agreements" and all-expenses-paid trips in order to induce him to prescribe a Teva drug. The physician became the largest prescriber of the drug and the scheme resulted in the submission of thousands of false claims to Medicare Part D and Illinois Medicaid.[53]	$27.7 million
April 16, 2014	Astellas Pharma US Inc.	Astellas Pharma agreed to pay $7.3 million to resolve FCA allegations that, between 2005 and 2010, it knowingly marketed and promoted the sale of the drug Mycamine for pediatric use, which was not an approved use for Mycamine at the time and, therefore, not covered by federal healthcare programs.[54]	$7.3 million
May 28, 2014	Medtronic, Inc.	Medtronic, a medical device manufacturer, agreed to pay $10 million to resolve FCA allegations that it caused providers to submit false claims to the government by inducing physicians to use its products through kickback payments in the form of speaking fees, free business plans and tickets to sporting events. In September 2014, Medtronic agreed to pay a total of $362,362 to 46 states and D.C. to resolve similar FCA allegations.[55]	$10 million
June 25, 2014	Omnicare, Inc.	Omnicare and its affiliates agreed to pay $124 million to resolve FCA allegations in two *qui tam* actions styled ***U.S. ex rel. Gale v. Omnicare, Inc.*** (N.D. Ohio) and ***U.S. ex rel. Silver v. Omnicare, et al.*** (D.N.J.), relating to a "swapping" kickback scheme Omnicare purportedly engaged in whereby it provided 22 SNFs with discounts on Medicare Part A prescription drugs in exchange for the referral of Medicare Part D patients. The government declined to intervene in these matters (though the government later intervened in ***Gale,*** when Omnicare moved to disqualify the relator after reaching a preliminary settlement agreement with relator in October 2013).[56]	$124 million
July 22, 2014	American International Biotechnology, LLC; Jason Hoover	American International Biotechnology ("AIB") agreed to pay $343,739 to settle FCA allegations that it billed Medicare for genetic tests that were improperly referred to AIB as a result of an AIB contract sales agent falsely marketing the tests to a medical practice and offering to pay per-patient kickbacks to an employee of the medical practice.[57]	$343,739
July 28, 2014	Vascular Solutions, Inc.	Vascular Solutions ("VSI"), which markets and sells medical devices that treat varicose veins with laser therapy, agreed to pay $520,000 to resolve FCA allegations that it caused false claims to be submitted for its "Short Kit" medical device by marketing the kit for the sealing of perforator veins without FDA approval. In November 2014, VSI and its CEO were criminally indicted for allegedly conspiring to defraud the United States by concealing the illegal sales activity and for introducing adulterated and misbranded devices into interstate commerce.[58]	$520,000

52. http://www.justice.gov/opa/pr/omnicare-pay-government-419-million-resolve-false-claims-act-allegations-kickbacks.
53. http://www.justice.gov/opa/pr/2014/March/14-civ-251.html.
54. http://www.justice.gov/opa/pr/2014/April/14-civ-391.html.
55. http://www.justice.gov/opa/pr/2014/May/14-civ-571.html; http://www.ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-medtronic-medicaid-violations.
56. http://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving.
57. http://www.justice.gov/usao/paw/news/2014/2014_july/2014_07_22_01.html.
58. http://www.justice.gov/opa/pr/vascular-solutions-inc-pay-520000-resolve-false-claims-allegations-relating-medical-device; http://www.justice.gov/opa/pr/vascular-solutions-inc-and-its-ceo-charged-selling-unapproved-medical-devices-and-conspiring.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
August 8, 2014	McKesson Corporation	McKesson, a pharmaceutical distributor, agreed to pay $18 million to resolve FCA allegations that it failed to comply with the shipping and handling requirements of its vaccine distribution contract with the CDC. The government alleged that McKesson improperly set monitors designed to detect when air temperatures inside shipping boxes moved outside a range considered safe for shipping vaccines and knowingly submitted false claims to the CDC that it had complied with its contractual obligations.[59]	$18 million
August 21, 2014	Smith & Nephew, Inc.	Smith & Nephew, a medical device manufacturer, agreed to pay $11.3 million to resolve allegations in the *qui tam* action styled ***U.S. ex rel. Cox v. Smith & Nephew, Inc.*** (W.D. Tenn.) that the company violated the FCA and Trade Agreements Act by selling products to the United States that had a country of origin that had not executed a trade agreement with the United States. In 2008, Smith & Nephew voluntarily disclosed to the government that some of its medical devices did not comply with country-of-origin regulations. The government initially declined to intervene in the matter.[60]	$11.3 million
August 29, 2014	Omni Surgical, L.P. d/b/a Spine 360; Jamie Gottlieb, M.D.	Spine 360, a manufacturer of spinal surgery devices, and Jamie Gottlieb, M.D., a spinal surgeon, agreed to pay $2.6 million to resolve FCA allegations that Spine 360 paid illegal kickbacks to Dr. Gottlieb to induce him to use the company's products. In addition, Spine 360 allegedly falsified financial documents in order to cover up the illegal scheme.[61]	$2.6 million
September 24, 2014	Enzo Biochem, Inc.; Enzo Clinical Laboratories	Enzo Biochem and one of its subsidiaries agreed to pay $3.51 million to resolve FCA allegations that Enzo employees input diagnosis codes—that they believed were most likely to secure reimbursement from CMS—into claim forms without going back to the physician to obtain the missing code and subsequently submitted the claims for payment to CMS.[62]	$3.51 million
September 24, 2014	Shire Pharmaceuticals LLC	Shire Pharmaceuticals agreed to pay $56.5 million to resolve FCA allegations that Shire improperly marketed and promoted several of its drugs, including Adderall XR, Vyvanse and Daytrana. For example, the government contended that Shire illegally promoted Adderall XR by asserting that Adderall XR was superior to all other ADHD drugs and would "normalize" patients, despite a lack of clinical data sufficient to support such a claim; and promoting Adderall XR for treating conduct disorder, an indication for use unapproved by the FDA. As part of this settlement, Shire agreed to enter into a five-year CIA with HHS-OIG.[63]	$56.5 million
October 9, 2014	Sorkin's Rx Ltd. d/b/a CareMed Pharmaceutical Services	CareMed Pharmaceutical Services, a specialty pharmacy, agreed to pay $10 million to resolve FCA allegations that company representatives made false statements to insurance companies to secure prior authorization for drug coverage by fabricating Medicare beneficiaries' patient information and pretending to be from prescribing physicians' offices when calling insurers. The settlement also resolves allegations that the pharmacy engaged in double billing of unused doses of two drugs and submitted claims for automatic refills of medications that were not actually dispensed.[64]	$10 million
October 15, 2014	Organon USA Inc.	Organon, a pharmaceutical company now owned by Merck, agreed to pay $31 million to settle FCA allegations—involving nearly every state Medicaid program—that Organon underpaid Medicaid rebates; paid illegal kickbacks to nursing homes in the form of market share discounts and rebates to encourage the use of two of its drugs over competing antidepressants; and promoted certain other drugs for non-approved uses.[65]	$31 million

59. http://www.justice.gov/opa/pr/mckesson-corp-pay-18-million-resolve-false-claims-allegations-related-shipping-services.
60. http://www.law360.com/articles/573721/smith-nephew-to-pay-8m-to-settle-fca-suit-with-va.
61. http://www.justice.gov/opa/pr/manufacturer-spinal-devices-and-surgeon-pay-united-states-26-million-settle-alleged-kickback.
62. http://www.justice.gov/usao/nye/pr/September14/2014Sep24c.php.
63. http://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug.
64. http://www.justice.gov/usao/nys/pressreleases/October14/CareMedSettlementPR.php.
65. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-31-million-national-medicaid-settlement-pharmaceutical.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 29, 2014	EBI LLC d/b/a Biomet Spine and Bone Health Technologies; Biomet, Inc.	Biomet Spine and Bone Health Technologies and Biomet agreed to pay $6.07 million to resolve FCA allegations that they paid staff at physicians' offices for seven years purportedly pursuant to personal service agreements in order to induce the physicians to use their bone growth stimulators, in violation of the Anti-Kickback Statute.[66]	$6.07 million
November 4, 2014	Biotronik, Inc.	Biotronik agreed to pay $4.9 million to settle FCA allegations that it paid implanting physicians illegal remuneration in the form of repeated expensive meals and monthly payments for service on a nonexistent physician advisory board in order to induce the physicians to start or continue using Biotronik devices, thus causing hospitals and ASCs to submit false claims to Medicare and Medicaid for the devices.[67]	$4.9 million
December 1, 2014	North Atlantic Medical Supplies Inc. d/b/a Regional Home Care, Inc.	Regional Home Care agreed to pay $852,378 to settle FCA allegations that it submitted claims to Medicare and Medicaid for respiratory therapy services provided by unlicensed personnel, in violation of Massachusetts regulations. The government alleged that, even after North Atlantic Medical Supplies ("NAMS") was informed by the Massachusetts Department of Public Health that its practice was illegal, NAMS did not stop the practice and continued to bill Medicare and Medicaid for these services.[68]	$852,378
December 3, 2014	Rite Aid Corporation	Rite Aid agreed pay $2.99 million to resolve FCA allegations that it offered illegal payments in the form of gift cards to induce Medicare and Medicaid beneficiaries to transfer their prescriptions to Rite Aid pharmacies.[69]	$2.99 million
December 8, 2014	OtisMed Corporation; Charlie Chi	Device manufacturer OtisMed and its CEO, Charlie Chi, agreed to pay more than $80 million to resolve criminal and FCA allegations that they distributed unapproved cutting guides into interstate commerce while its application to the FDA for clearance to market the device was pending and after the application was denied. The government also alleged that OtisMed encouraged healthcare providers to submit claims for MRIs that were not reimbursable because they were not for diagnostic use, but rather were performed solely to provide data for the creation of an OtisMed device. OtisMed agreed to be excluded from participating in federal healthcare programs for 20 years. Chi pleaded guilty to criminal charges related to the unapproved distribution of the cutting guides. As part of the settlement, Stryker, which acquired OtisMed during this timeframe, agreed to conduct a review and audit regarding whether other marketed devices have the appropriate FDA approvals and share the results of that audit with the government, as well as to submit annual certifications regarding the effectiveness of its compliance program.[70]	$41.15 million (civil) $39.56 million (criminal fines and forfeiture)

PHYSICIANS AND OTHER PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 7, 2014	Abhijit Deshpande, M.D.; Pinnacle Health Care	Dr. Deshpande and Pinnacle Health Care agreed to pay $89,965.38 to resolve allegations that they submitted claims for certain sleep medicine services and tests that were either not provided by a licensed physician, duplicative or performed by someone not associated with Dr. Deshpande or Pinnacle.[71]	$89,965.38
January 10, 2014	Michael R. Barr; Norman J. Pfaadt	Michael Barr and Norman Pfaadt, former HealthEssentials Solutions executives, agreed to pay $1.0 million and $20,000, respectively, to resolve FCA allegations that Barr and Pfaadt pressured HealthEssentials staff to bill for services that were inflated or not medically necessary in connection with a larger scheme which HealthEssentials settled in 2008.[72]	$1.02 million

66. http://www.justice.gov/opa/pr/biomet-companies-pay-over-6-million-resolve-false-claims-act-allegations-concerning-bone.
67. http://www.justice.gov/opa/pr/biotronik-inc-pay-49-million-resolve-claims-company-paid-kickbacks-physicians.
68. http://www.justice.gov/opa/pr/government-settles-false-claims-act-allegations-against-oxygen-and-sleep-therapy-company.
69. http://www.justice.gov/usao/cac/Pressroom/2014/155.html.
70. http://www.justice.gov/usao/nj/Press/files/Otismed%20News%20Release.html.
71. http://www.justice.gov/usao/wae/news/2014/2014_01_07_Deshpande.html.
72. http://www.justice.gov/opa/pr/former-healthessentials-solutions-inc-executives-pay-more-1-million-resolve-allegations.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 10, 2014	Stanley J. Swierzewski, M.D.	Dr. Swierzewski, a urologist, agreed to pay $300,000 to settle FCA allegations that he improperly billed Medicare at the doctor's rate for services provided by physician's assistants working without the doctor's supervision.[73]	$300,000
January 24, 2014	Tennessee Orthopaedic Clinics P.C.; Appalachian Orthopaedic Clinics P.C.	Tennessee Orthopaedic Clinics and Appalachian Orthopaedic Clinics agreed to pay $1.3 million and $550,000, respectively, in order to resolve FCA allegations that they knowingly billed state and federal healthcare programs for reimported osteoarthritis medications with uses not approved in the United States.[74]	$1.85 million
February 7, 2014	Addixxion Recovery of Kentucky LLC d/b/a SelfRefind; PremierTox 2.0 LLC; Bryan Wood, M.D.; Robin Peavler, M.D.	SelfRefind, a chain of addiction treatment clinics, PremierTox 2.0 and two physician owners of SelfRefind agreed to pay $15.8 million to resolve FCA allegations that they billed Medicare and Medicaid for urine tests that were medically unnecessary or were more expensive than the actual tests performed. After becoming owners of PremierTox, Drs. Wood and Peavler allegedly referred all drug screens completed at SelfRefind to PremierTox for additional comprehensive screening that was often unnecessary or more expensive than suitable alternative tests. As part of the settlement, PremierTox agreed to enter into a five-year CIA with HHS-OIG.[75]	$15.8 million
February 18, 2014	A.I.M. Center, Inc.	A.I.M. Center, a community mental health facility, agreed to pay $800,000 to resolve FCA allegations that it upcoded psychosocial rehabilitation services provided to Medicaid beneficiaries and knowingly concealed overpayments resulting from double billing for services already included in per-diem rates. In connection with the agreement, A.I.M. Center entered into a five-year CIA with HHS-OIG.[76]	$800,000
February 18, 2014	Engage Medical, Inc. and Sanjay Puri; Advanced Cardiology Center and Pankaj Lal, M.D., Mubashar Choudry, M.D., and Moshin Ijaz, M.D.; Kenilworth Internists, P.A. and Reva Gill, M.D.; Sureth Muttath, M.D.	Engage Medical, a medical billing company, and three of Engage's client medical practices agreed to pay $3.3 million, collectively, to resolve allegations that Engage double billed federal and state healthcare programs for nuclear stress tests by using both the code for nuclear stress tests and a code for a repeated or distinct test, when in fact the test was not repeated and no distinct service was performed. Pursuant to this arrangement, Engage sought referrals from general practitioners, promising them a portion of the double payment. Engage is also alleged to have improperly unbundled certain interpretive services already included in the code for the nuclear stress tests.[77]	$3.3 million
February 20, 2014	Diagnostic Imaging Group, LLC; Doshi Diagnostic Imaging Services, P.C.	Diagnostic Imaging Group and its subsidiary Doshi Diagnostic Imaging Services agreed to pay $15.5 million to resolve FCA allegations that Diagnostic Imaging Group submitted claims to Medicare for imaging or interpretive services that were never performed, billed for medically unnecessary tests as part of a test-bundling scheme and paid kickbacks to physicians for referrals in the form of a payment ostensibly for supervising patients who underwent nuclear stress tests. Diagnostic Imaging Group also entered into a five-year CIA with HHS-OIG as part of the agreement.[78]	$15.5 million
February 25, 2014	Steven Chun, M.D.; Sarasota Pain Associates, P.A.	Steven Chun, M.D. and his pain clinic agreed to pay $750,000 to resolve FCA allegations that Dr. Chun systematically and inappropriately upcoded routine patient visits to the highest level possible and submitted claims for examinations he never conducted. Under the terms of the agreement, Dr. Chun and Sarasota Pain Associates entered into a three-year CIA with HHS-OIG.[79]	$750,000

73. http://www.masslive.com/news/index.ssf/2014/01/longmeadow_urologist_agrees_to.html; http://medbill.net/2014/01/longmeadow-urologist-agrees-to-settle-for-fraud-allegations.
74. http://www.justice.gov/opa/pr/2014/January/14-civ-076.html.
75. http://www.justice.gov/usao/kye/news/2014/2014-02-10-premiertox.html.
76. http://www.tn.gov/attorneygeneral/press/2014/pr14-04.html.
77. http://www.justice.gov/usao/md/news/2014/ThreeMedicalGroupsAndAMedicalBillingCompanyAgreeToPay3340979ToResolveInvestigationInto.html.
78. http://www.justice.gov/opa/pr/2014/February/14-civ-200.html.
79. http://www.justice.gov/usao/flm/press/2014/Feb/20140225_Chun.html.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
March 12, 2014	American Family Care, Inc.	American Family Care, a network of walk-in medical clinics, agreed to pay $1.2 million to resolve FCA allegations that it knowingly submitted false claims to Medicare by selecting Evaluation and Management codes reflecting a level of services that exceeded those actually provided. As part of the settlement, American Family Care and its affiliates entered into a five-year CIA with HHS-OIG.[80]	$1.2 million
March 13, 2014	John Arthur Kiely, M.D.	John Arthur Kiely, M.D. agreed to pay $1.4 million to resolve FCA allegations that he submitted claims to Medicare and Medicaid for laser eye procedures that fell outside of the requisite standard of care and were not medically necessary. Under the terms of the settlement, Dr. Kiely also agreed to a 20-year exclusion from federal healthcare programs.[81]	$1.4 million
March 21, 2014	Valley Heart Consultants, P.A.; Carlos Mego, M.D.; Subbarao Yarra, M.D.	Valley Heart Consultants and two physicians agreed to pay $3.9 million to resolve FCA allegations that between January 2004 and September 2010, they billed Medicare and Medicaid for nuclear stress tests that were substandard, conducted by non-licensed individuals, and medically unnecessary. Under the terms of the settlement, the parties agreed to enter into a five-year CIA with HHS-OIG.[82]	$3.9 million
April 1, 2014	CRC Health Corporation; CRC Health Group, Inc.; CRC Health Tennessee*	CRC Health Corporation and its subsidiaries agreed to pay $9.2 million to resolve FCA allegations that one of its substance abuse treatment facilities billed Tennessee's Medicaid program for therapy services that either were not provided or were provided by therapists who were not licensed to practice in Tennessee. The government also alleged that the facility failed to make a licensed psychiatrist available to patients at the facility or to maintain patient-staffing ratios, as required by Tennessee regulations; billed for Medicaid patients in excess of the state-licensed bed capacity at the facility; and double-billed for substance abuse medications provided to patients at the facility.[83]	$9.2 million
April 14, 2014	Hope Cancer Institute; Raj Sadasivan, M.D.	Hope Cancer Institute and its owner Dr. Raj Sadasivan agreed to pay $2.9 million to resolve FCA allegations that the Institute submitted claims to federal healthcare programs for chemotherapy drugs that were not provided to beneficiaries. Dr. Sadasivan allegedly instructed employees of the Institute to bill for a predetermined amount of cancer drugs at certain dosage levels, when lower dosages of these drugs were actually provided to beneficiaries.[84]	$2.9 million
April 17, 2014	Belmont Cardiology, Inc.; Devender Batra, M.D.	Belmont Cardiology and Devander Batra, M.D. agreed to pay $1 million to settle allegations that they caused two hospitals to submit fraudulent claims to Medicare as a result of Belmont Cardiology and Dr. Batra entering into an improper compensation arrangement.[85]	$1 million
May 14, 2014	Wasfi A. Makar, M.D.; American Cancer Treatment Centers	On May 14, a federal district judge issued an $89.6 million default judgment against Dr. Makar, the former owner of American Cancer Treatment Centers, concluding a *qui tam* action styled ***U.S. ex rel. McBride v. Makar, et al.*** (M.D. Fla.) alleging that Dr. Makar directed employees at the treatment centers to perform and bill for daily imaging procedures that were medically unnecessary. On October 15, 2014, the court vacated the default judgment and granted a new trial on damages, upon concluding that the damages award was calculated based on allegedly fraudulent claims that were outside the scope of the original complaint. The United States previously declined to intervene in this matter.[86]	$89.6 million (default judgment); new trial subsequently granted on damages

80. http://www.justice.gov/opa/pr/2014/March/14-civ-281.html.
81. http://www.justice.gov/usao/md/news/2014/OphthalmologistAgreesToPay1.4MillionAndTo20YearVoluntaryExclusionFromFederalProgramsTo.html.
82. http://www.justice.gov/usao/txs/1News/Releases/2014%20March/140321%20-%20Mego%20and%20Yarra.html.
83. http://www.justice.gov/opa/pr/2014/April/14-civ-395.html.
84. http://www.justice.gov/opa/pr/2014/April/14-civ-378.html.
85. http://www.justice.gov/usao/wvn/news/2014/april/batra.html.
86. https://www.law360.com/articles/587804.

*Denotes matter handled by Bass, Berry & Sims attorneys.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
May 21, 2014	Calloway Laboratories, Inc.	Calloway Laboratories agreed to pay $4.67 million to settle allegations that it falsely billed Medicare and Medicaid for urine testing services that were never actually ordered. Specifically, Calloway Laboratories routinely billed using a code designated for covered pathology services in addition to the code for urine drug testing, even though treating healthcare providers did not deem pathology services necessary or knowingly order the service. Calloway Laboratories also entered into a five-year CIA with HHS-OIG as part of the settlement.[87]	$4.67 million
May 29, 2014	First Call Ambulance Service, LLC	First Call Ambulance Service agreed to pay $500,000 to resolve allegations that it submitted false claims to Medicaid for advanced life support services that were not medically necessary or not actually provided in order to receive higher rates of reimbursement. As part of the agreement, First Call entered into a five-year CIA with HHS-OIG.[88]	$500,000
June 3, 2014	Elizabethtown Hematology Oncology, PLC; Yusuf K. Deshmukh, M.D.; Rafiq Ur Rahman, M.D.	Elizabethtown Hematology Oncology and its owners agreed to pay $3.73 million to resolve allegations that they submitted or caused to be submitted false claims for unnecessary and improperly extended chemotherapy infusion treatment and for unnecessary office visit evaluations for infusion therapy treatments. In connection with the settlement, the clinic and Dr. Deshmukh agreed to enter into a three-year CIA with the HHS-OIG.[89]	$3.73 million
August 14, 2014	Cardiovascular Specialists, P.C., d/b/a New York Heart Center	New York Heart Center ("NYHC") agreed to pay $1.33 million to settle FCA allegations that it compensated NYHC partner-physicians in a manner that accounted for their volume or value of referrals for nuclear and CT scans, in violation of the Stark Law.[90]	$1.33 million
August 24, 2014	Sleep Medicine Center, Inc.; Hubert Michael Zachary, M.D.; George Restea M.D.	Sleep Medicine Center ("SMC") and Hubert Michael Zachary, M.D. agreed to pay $200,000 to resolve FCA allegations that they billed for sleep studies and psychological testing that were not medically necessary, conducted by appropriately licensed individuals or actually performed. As part of the settlement, SMC and Dr. Zachary agreed to be excluded from participation in federal healthcare programs for eight years. On September 4, George Restea, M.D., Medical Director of SMC, agreed to pay $90,324 to resolve similar FCA allegations that the government contended were the result of his failure to supervise the center as he agreed to do.[91]	$290,324
August 28, 2014	Bostwick Laboratories	Bostwick Laboratories agreed to pay $6.05 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Daugherty v. Bostwick Laboratories, et al.*** (S.D. Ohio) that it improperly billed Medicare and Medicaid for tests and services referred in violation of the Anti-Kickback Statute and for tests performed without a doctor's order or consent. The United States previously declined to intervene in the matter.[92]	$6.05 million
September 2, 2014	Meridian Surgical Partners, LLC; Meridian Surgical Partners-Florida II, LLC; Treasure Coast Surgery Center, LLC; William Byron; Anesthesia Advantage, LLC; Treasure Coast Surgery, Inc.*	Meridian Surgical Partners and its subsidiaries agreed to pay $3.3 million to the United States to resolve FCA allegations that Meridian paid certain physicians above fair market value for their ownership interests in an ambulatory surgery center subsequently sold shares to new physicians at below fair market value in order to induce patient referrals. The United States previously declined intervention in the action.[93]	$3.3 million

87. http://www.justice.gov/usao/wvs/press_releases/May2014/attachments/0521141_Calloway_Settlement.html.
88. http://www.justice.gov/usao/tnm/pressReleases/2014/5-29-14.html.
89. http://www.justice.gov/usao-wdky/pr/owners-elizabethtown-hematology-oncology-plc-agree-pay-over-37-million-settle-false.
90. http://www.justice.gov/usao/nyn/news/2024-3992-618127744.pdf.
91. http://www.justice.gov/usao/flm/press/2014/Sep/20140911_Sleep%20Clinic.html.
92. http://www.natlawreview.com/article/bostwick-laboratories-agrees-to-pay-us-government-605-million-allegedly-violating-an.
93. http://www.law360.com/articles/575838/surgical-chain-pays-5m-to-end-fca-kickbacks-suit.

*Denotes matter handled by Bass, Berry & Sims attorneys.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 14, 2014	Medical Billing Service, Inc.	Medical Billing Service agreed to pay $1.95 million to resolve FCA allegations that it changed diagnosis codes on claims to Medicare and Medicaid in order to get rejected claims paid on behalf of radiologists.[94]	$1.95 million
October 14, 2014	Complete Imaging Solutions, LLC d/b/a Houston Diagnostics; Rahul Dhawan*	Houston Diagnostics, its affiliate centers and its owner agreed to pay $1.45 million to settle FCA allegations that Houston Diagnostics engaged in improper financial relationships with referring doctors and billed Medicare using the provider number of a physician who neither gave his authorization nor was involved in providing the billed services.[95]	$1.45 million
October 14, 2014	One Step Diagnostic, Inc.; Fuad Rehman Cochinwala	Arising from the same *qui tam* action as the above settlement, One Step Diagnostic and owner Fuad Rehman Cochinwala agreed to pay $1.2 million to resolve FCA allegations that they violated the Stark Law by entering into sham consulting and medical director agreements with physicians who referred patients to One Step Diagnostic Centers. As part of the settlement, One Step Diagnostic and Cochinwala agreed to enter into a five-year CIA with HHS-OIG.[96]	$1.2 million
October 21, 2014	Satyabrata Chatterjee, M.D.; Ashwini Anand, M.D.	Satyabrata Chatterjee, M.D. and Ashwini Anand, M.D.—cardiologists and joint owners of a physician group—agreed to pay $380,000 to settle FCA allegations that they entered into sham agreements with St. Joseph Hospital to be paid for management services they never performed in exchange for referring cardiology procedures and other healthcare services exclusively to St. Joseph, in violation of the Anti-Kickback Statute and Stark Law. As part of the settlement, Drs. Chatterjee and Anand agreed to enter into three-year integrity agreements with HHS-OIG. Earlier in the year, St. Joseph's reached a settlement agreement with the government to resolve related allegations.[97]	$380,000
October 22, 2014	DaVita Healthcare Partners, Inc.	DaVita Healthcare Partners agreed to pay $400 million (including $39 million in civil forfeiture) to resolve federal and state FCA allegations that—in order to induce referrals of patients to its dialysis clinics—it paid kickbacks in the form of lucrative joint venture opportunities to physicians or physician groups with large patient populations with renal disease; paid physicians to serve as medical directors of the joint venture clinics; and entered into agreements with physicians in which the physicians agreed not to compete with the clinics and which bound all the physicians in a practice group. DaVita entered into a five-year CIA with HHS-OIG in connection with the settlement. The DaVita settlement was the largest FCA settlement in 2014.[98]	$400 million
October 28, 2014	Columbia University; International Center for Aids Care and Treatment Programs	Columbia University and one of its affiliated public health programs, *International Center for Aids Care and Treatment Programs* ("ICAP"), agreed to pay $9.02 million to settle FCA allegations that ICAP submitted false claims to the government under federal AIDS research grants. The government alleged Columbia improperly charged work to government grants for several years by knowingly failing to use a suitable means of verifying whether the wages it paid employees of ICAP were based on actual work done, as required under the grant terms.[99]	$9.02 million

94. http://www.justice.gov/usao/gan/press/2014/10-14-14.html.
95. http://www.justice.gov/opa/pr/operators-houston-area-diagnostic-centers-agree-pay-26-million-settle-alleged-false-claims.
96. http://www.justice.gov/opa/pr/operators-houston-area-diagnostic-centers-agree-pay-26-million-settle-alleged-false-claims.
97. http://www.justice.gov/opa/pr/kentucky-cardiologists-agree-pay-380000-settle-false-claims-act-allegations-based-illegal.
98. http://www.justice.gov/opa/pr/davita-pay-350-million-resolve-allegations-illegal-kickbacks; http://www.law360.com/articles/589613/davita-finalizes-400m-settlement-over-kickback-claims.
99. http://www.justice.gov/usao/nys/pressreleases/October14/ColumbiaICAPsettlementPR.php.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 30, 2014	Charles L. Bennett, M.D.	Dr. Charles L. Bennett, a former cancer research physician at Northwestern University, agreed to pay $475,000 to resolve allegations that he submitted false claims under NIH research grants for reimbursement for professional and consulting services, food, hotels, travel, conference registration fees and other expenses that benefitted Dr. Bennett and his family and friends. Northwestern settled its portion of the lawsuit in July 2013.[100]	$475,000
October 30, 2014	Ocean Dental, P.C.	Ocean Dental agreed to pay $5.05 million to resolve FCA allegations that it submitted false claims to Medicaid for more dental restorations than were actually performed or for work that was never actually performed at all. In connection with the settlement, Ocean Dental entered into a five-year CIA with HHS-OIG.[101]	$5.05 million
November 4, 2014	Borio Chiropractic Health Center; Joseph Borio	Joseph Borio, the owner of a chiropractic center, agreed to pay $376,436 to settle FCA allegations that he improperly upcoded services and falsely certified that his services were medically necessary. As part of the settlement, Borio entered into a three-year CIA with HHS-OIG.[102]	$376,436
November 19, 2014	Santa Clarita Surgery Center; Narinder S. Grewal, M.D.	Pain clinic Santa Clarita Surgery Center and its owner agreed to pay $1.2 million to resolve FCA allegations that they submitted fraudulent claims to federal and state healthcare programs for upcoded medical services.[103]	$1.2 million
November 24, 2014	Gilbert Lederman, M.D.	Gilbert Lederman, M.D., former Chief of Radiation Oncology at Staten Island University Hospital ("SIUH"), agreed to pay $2.35 million to resolve allegations that he submitted or caused to be submitted claims for an experimental cancer treatment not eligible for reimbursement by Medicare. SIUH settled its portion of the matter for $25 million in September 2008.[104]	$2.35 million
December 12, 2014	VMG Pulmonary and Sleep Institute; Marivic Villa, M.D.	VMG Pulmonary and Sleep Institute and its physician/owner agreed to pay $250,000 to settle FCA allegations that they billed for services that were not medically necessary and were performed by unlicensed, uncredentialed, and unsupervised employees.[105]	$250,000
December 15, 2014	The Research Foundation for the State University of New York	State University of New York agreed to pay $3.75 million to settle FCA allegations that its Center for Development of Human Services ("CDHS") submitted false statements in connection with its state contract to perform audits designed to measure errors in local determinations as to which state residents were eligible to receive Medicaid and Children's Health Insurance Program benefits. Because of CDHS' alleged data manipulation, the audits did not serve their purpose as random samples.[106]	$3.75 million

100. http://www.fbi.gov/chicago/press-releases/2014/former-northwestern-physician-to-pay-the-united-states-475-000-to-settle-cancer-research-grant-fraud-claims.
101. http://www.justice.gov/usao/okw/news/2014/2014_10_31.html.
102. http://www.fbi.gov/albany/press-releases/2014/cicero-chiropractor-settles-civil-health-care-fraud-claims.
103. http://www.justice.gov/usao/cac/Pressroom/2014/153.html.
104. http://www.reuters.com/article/2014/11/24/us-healthcare-settlement-lederman-idUSKCN0J824D20141124.
105. http://www.justice.gov/usao/flm/press/2014/Dec/20141121_VMG.html.
106. http://justice.gov/usao/nyn/news/2085-4111-597320192.pdf.

APPENDIX B: INTERVENED CASES (PRIOR TO SETTLEMENT)

DATE OF INTERVENTION/ FILING	CASE STYLE	FCA ALLEGATIONS	STATUS
January 2, 2014	***U.S. ex rel. Garcia v. Louisiana Sleep Diagnostics, LLC,*** No. 12-1225 (W.D. La.)	***Sleep Diagnostics Company.*** The United States intervened in the relator's litigation, initiated in May 2012, as to allegations that Louisiana Sleep Diagnostics submitted claims to Medicare for services that were not reimbursable because the services were performed either at undisclosed locations and/or at locations other than the location billed. The government declined to intervene at the time as to the relator's allegations regarding the submission of false claims to TRICARE.[1]	Government withdrew its intervention on June 3, 2014. Relator is proceeding in discovery on all claims
February 18, 2014	***U.S. ex rel. Williams v. Health Management Associates, Inc., et al.,*** No. 09-130 (M.D. Ga.)	***Hospital and Hospital Health System.*** The lawsuit, initiated in December 2009, alleges that hospitals owned by ("HMA") and Tenet Healthcare paid kickbacks to Hispanic Medical Management d/b/a Clinica de la Mama and related entities in return for referrals of low-income pregnant women for labor and delivery services reimbursable by Medicaid. The government has opened a parallel criminal investigation against the defendants. In 2013, the United States intervened in eight whistleblower lawsuits against HMA.[2]	Stayed pending completion of parallel criminal investigation
March 24, 2014	***U.S. ex rel. Stephens v. Malik, et al.,*** No. 12-306 (N.D. Ind.)	***Home Health Provider and Physician.*** The United States intervened in the relator's litigation, initiated in August 2012, as to allegations that Defendant Dr. Arshad Malik referred Medicare patients to Defendant Prime Health Care Services, a home health agency which is owned by Defendant Afzal Malik, Dr. Malik's brother, in violation of the Stark Law. The United States declined to intervene as to the relator's allegations regarding the submission of inflated claims.[3]	In discovery; parties have until May 18, 2015 to file dispositive motions
April 2, 2014	***U.S. ex rel. Clyde, et al. v. Orbit Medical, et al.***, No. 10-297 (D. Utah)	***Medical Equipment Supplier.*** The lawsuit, initiated in April 2010, alleges that Orbit Medical and one of its principals, Jake Kilgore, falsified medical records that are used to support payment claims for power wheelchairs. In a parallel criminal proceeding, Kilgore was indicted in 2013 for healthcare fraud, false statements related to healthcare and wire fraud based on factually similar allegations. The government has also opened a criminal investigation of Orbit Medical.[4]	Stayed pending completion of parallel criminal proceeding against Jake Kilgore and criminal investigation of Orbit Medical
April 17, 2014	***U.S. ex rel. Madany, et al. v. Shahab, et al.,*** No. 09-13693 (E.D. Mich.)	***Home Health Providers.*** The United States intervened in the relators' litigation, initiated in September 2009, as to allegations that 24 individual defendants and eight home health providers engaged in a scheme to bill Medicare for home health services that were not rendered, or if rendered were medically unnecessary, and that were based on physician referrals induced by kickbacks and improper financial relationships. In particular, the defendants are alleged to have paid kickbacks to physicians, marketers and patients, and falsified certifications and patient visit notes, in order to secure Medicare reimbursement. The government intervened against only some of the defendants named in the relators' complaint; the remaining defendants were voluntarily dismissed.[5]	Complaint in Intervention filed; some Answers have been filed

1. PACER, http://www.pacer.gov (registration required).
2. http://www.justice.gov/opa/pr/government-intervenes-lawsuit-against-tenet-healthcare-corp-and-georgia-hospital-owned-health.
3. http://posttrib.chicagotribune.com/news/lake/26722731-418/merrillville-doc-brother-face-8m-in-fines-in-medicaid-complaint.html#.VL7rGEfF-Ks.
4. http://www.justice.gov/opa/pr/government-intervenes-lawsuit-against-medical-equipment-supplier-orbit-medical-inc-and-former.
5. PACER, http://www.pacer.gov (registration required).

DATE OF INTERVENTION/ FILING	CASE STYLE	FCA ALLEGATIONS	STATUS
June 23, 2014	***U.S. ex rel. Schaengold v. Mem'l Health, Inc., et al.,*** No. 11-58 (S.D. Ga.)	***Hospital and Physician Practice.*** The United States intervened in the relator's litigation, initiated in March 2011, as to allegations that Memorial Health and its subsidiaries entered into compensation agreements with Eisenhower Medical Associates physicians in violation of the Stark Law, resulting in affirmative and reverse FCA liability. The United States declined to intervene as to other alleged violations of the Stark Law and Anti-Kickback Statute.[9]	Partial MTD of reverse false claim count granted in part as to several defendants
June 27, 2014	***U.S. ex rel. Kane v. Continuum Health Partners, Inc., et al.,*** No. 11-2325 (S.D.N.Y.)	***Hospitals and Hospital System.*** The United States intervened in the relator's litigation, initiated in April 2011, as to allegations that the defendants, which were previously part of a network of non-profit hospitals operated and coordinated by Continuum, delayed in returning nearly $1 million in Medicaid overpayments for almost two years after they discovered the overpayments.[6]	Pending MTD
July 2, 2014	***U.S. ex rel. Savitch, et al. v. Sabit, et al.,*** No. 13-3363 (C.D. Cal.)	***Physician and Medical Device Companies.*** The United States intervened in the ***Savitch*** lawsuit, initiated in May 2013, as to allegations that Dr. Sabit performed medically unnecessary spinal fusion surgeries. The government declined to intervene as to allegations against Defendants Dr. Abou-Samra and Community Memorial Health System, though its investigation of these defendants continues.	Pending motions for stay until completion of parallel criminal proceeding against Dr. Sabit and of criminal investigation of Reliance Defendants
September 8, 2014	***U.S. v. Reliance Medical Sys., LLC, et al.,*** No. 14-6979 (C.D. Cal.)	The United States subsequently filed a separate lawsuit against Dr. Sabit, Reliance Medical Systems, two Reliance distributors and their non-physician owners alleging that Reliance, through its distributors, paid physicians, including Dr. Sabit, to induce them to use Reliance spinal implants when performing surgeries, in violation of the Anti-Kickback Statute. On November 21, 2014, the government filed a criminal complaint against Dr. Sabit for healthcare fraud and performing medically unnecessary spinal fusion surgeries.[7]	Pending MTD in ***Reliance*** matter
August 6, 2014	***U.S. ex rel. Cretney-Tsosie v. Creekside Hospice II, LLC, et al.,*** No. 13-167 (D. Nev.) ***U.S. ex rel. Lepera v. Skilled Healthcare, LLC, et al.,*** No. 13-1283 (D. Nev.)	***Hospice Entities.*** The United States intervened in the relators' litigation, initiated in April 2012 ***(Cretney-Tsosie)*** and August 2013 ***(Lepera),*** as to allegations that Creekside and Skilled Healthcare enrolled patients in hospice care who were not terminally ill and falsified documents to support patients' hospice eligibility. The ***Cretney-Tsosie*** lawsuit and ***Lepera*** lawsuit have been consolidated into one action.[8]	Complaint in Intervention filed
August 25, 2014	***U.S. ex rel. Fowler, et al. v. Evercare Hospice, Inc., et al.,*** No. 11-642 (D. Colo.) ***U.S. ex rel. Rice v. Evercare Hospice, Inc.,*** No. 14-1647 (D. Colo.)	***Hospice Entity.*** The United States intervened in this consolidated action, initiated in March 2011 ***(Fowler)*** and June 2013 ***(Rice),*** as to the relators' allegations that Evercare Hospice submitted claims for hospice services provided to patients who were not terminally ill, as a result of, among other actions, management pressuring employees and physicians to admit and retain patients who were not terminally ill and challenging or disregarding physicians' decisions that patients should be discharged.[10]	Defendants have until January 30, 2015 to answer Complaint in Intervention and Relators' Complaint

6. http://www.justice.gov/usao/nys/pressreleases/June14/ContinuumHealthPartnersincLawsuotPR.php.
7. http://www.justice.gov/opa/pr/united-states-pursues-claims-against-neurosurgeon-spinal-implant-company-physician-owned.
8. http://www.justice.gov/opa/pr/united-states-files-false-claims-act-lawsuit-against-las-vegas-hospice-and-related-entities.
9. http://www.courthousenews.com/2014/12/16/hospital-faces-liability-over-medicare-payments.htm.
10. http://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-against-evercare-hospice-and-palliative.

DATE OF INTERVENTION/ FILING	CASE STYLE	FCA ALLEGATIONS	STATUS
August 29, 2014	***U.S. v. The Arba Group, et al.,*** No. 14-3946 (N.D. Cal.)	***Nursing and Rehab Facility.*** The United States filed a civil FCA action against the owners, operators, and manager of Country Villa Watsonville East Nursing Center and Country Villa Watsonville West Nursing and Rehabilitation Center, alleging that the defendants provided materially substandard and/or worthless services to residents of the nursing homes as a result of persistent and severe overmedication.[11]	Defendants have until March 2, 2015 to answer the Complaint
September 11, 2014	***U.S. ex rel. Nichols v. The Sleep Medicine Ctr., et al.***, No. 12-1080 (M.D. Fla.)	***Sleep Clinic Physicians.*** The United States intervened in the relator's litigation, initiated in October 2012, as to allegations that The Sleep Medicine Center billed for services that were medically unnecessary, not conducted by appropriately licensed individuals or never actually performed. The Court dismissed the claims against The Sleep Medicine Center, its owner-manager and its medical director in October 2014, pursuant to a settlement agreement with the government. The government is proceeding against two other physicians as to allegations that despite certifying they would supervise the clinic, the physicians only lent their names—in exchange for compensation—so that the clinic could bill federal healthcare programs. Specifically, the physicians agreed to act as medical directors and staff physicians at the center, but merely signed documents without reviewing them or actually seeing any patients.[12]	Complaint in Intervention filed
October 27, 2014	***U.S. ex rel. Forcier, et al. v. Computer Sciences Corp., et al.,*** No. 12-1750 (S.D.N.Y.)	***IT Company and Municipality.*** The lawsuit, initiated in March 2012, alleges that Computer Sciences Corp. and the City of New York engaged in billing fraud schemes that utilized computer programs to automatically alter billing data (e.g., circumventing requirement that Medicaid be billed after private insurance coverage is exhausted), resulting in the submission of false claims to Medicaid.[13]	Pending MTD
November 17, 2014	***U.S. ex rel. Becker, et al. v. Proctor, et al.,*** No. 11-14214 (S.D. Fla.)	***Surgeon and Ambulatory Surgery Center ("ASC").*** The United States intervened in the relators' litigation, initiated in May 2011, as to allegations that Dr. Proctor billed Medicare for medically unnecessary skin cancer surgeries. Grove Place Surgery Center, an ASC which Dr. Proctor manages, is also a defendant in the lawsuit. The United States declined to intervene as to allegations against other entities affiliated with Dr. Proctor.[14]	Complaint in Intervention filed
December 22, 2014	***U.S. ex rel. Doe v. Institute of Cardiovascular Excellence, PLLC, et al.,*** No. 11-406 (M.D. Fla.) ***U.S. ex rel. Taylor, et al. v. Institute of Cardiovascular Excellence,*** No. 14-1454 (M.D. Fla.)	***Cardiologist and Practice Group.*** The United States intervened in two lawsuits, initiated in July 2011 and June 2013, against Dr. Asad Qamar, a Florida cardiologist, and his physician group, the Institute for Cardiovascular Excellence, alleging that the defendants performed medically unnecessary peripheral artery interventions and paid kickbacks to patients by routinely waiving the 20 percent Medicare copayment, regardless of the patients' financial need.[15]	Government has until April 21, 2015 to serve its complaint in ***Doe*** and until April 29, 2015 to serve its complaint in ***Taylor***

11. http://www.justice.gov/usao-ndca/pr/united-states-sues-nursing-home-owners-and-operators-and-their-manager-under-false.
12. http://www.justice.gov/usao/flm/press/2014/Sep/20140911_Sleep%20Clinic.html.
13. http://www.justice.gov/usao/nys/pressreleases/October14/CSCandCityofNewYorkSuitPR.php.
14. http://www.justice.gov/usao/fls/PressReleases/2014/141121-01.html.
15. http://www.justice.gov/opa/pr/government-intervenes-lawsuit-against-florida-cardiologist-alleging-unnecessary-peripheral.

ABOUT BASS, BERRY & SIMS PLC

The Bass, Berry & Sims Healthcare Fraud Task Force represents healthcare providers in connection with fraud and abuse matters, including responding to governmental inquiries by the U.S. DOJ and U.S. Attorneys' Offices, the Office of Inspector General of the U.S. Department of Health and Human Services, federal program safeguard contractors, and various states' Attorneys General offices. We have a track record of successfully representing providers in related FCA litigation, including multiple declinations and dismissals in FCA *qui tam* cases in 2014 alone. We routinely counsel healthcare providers on implementing state-of-the-art compliance programs and assist clients in navigating self-disclosure and other compliance-related projects.

The firm's healthcare fraud and abuse practice is led by former members of the U.S. DOJ and a number of former Assistant U.S. Attorneys with significant experience handling healthcare fraud matters. Our attorneys are frequent speakers on healthcare fraud and abuse topics and two of our members serve as Adjunct Professors of Law at Vanderbilt University Law School teaching Healthcare Fraud and Abuse. For more information, please visit our website at http://www.bassberry.com/healthcare-fraud.

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With our base in Nashville, the nation's healthcare capital, and our office in Washington, D.C., our healthcare fraud and abuse attorneys stay abreast of recent developments in healthcare regulations; fraud and abuse laws; and the agencies that enforce them. The following attorneys contributed to authoring this Healthcare Fraud and Abuse Review of 2014.

Matthew Curley represents healthcare providers in connection with civil and criminal investigations by federal and state regulators and in related FCA litigation. Matt previously was Assistant U.S. Attorney with the U.S. Attorney's Office for the Middle District of Tennessee, where he served as Civil Chief and coordinated enforcement efforts arising under the FCA. He is an adjunct professor at Vanderbilt School of Law, teaching Healthcare Fraud and Abuse.

Wallace Dietz is chair of the firm's Compliance & Government Investigations Practice Group. His practice includes representing healthcare companies facing whistleblower lawsuits under the FCA or other regulatory violations and conducting internal and government investigations. Wally has notable successes negotiating with the DOJ, FTC, various states regulators, and other government agencies.

Anna Grizzle focuses her practice exclusively on helping healthcare clients address enforcement and compliance issues and in responding to legal and regulatory violations. Anna advises on the reporting and repayment of overpayments and in responding to payor audits and has advised a number of healthcare clients in self-disclosures, including disclosures made through the physician self-referral (Stark) and HHS-OIG disclosure protocols.

John Kelly is the Managing Partner of the firm's Washington, D.C. office and is an experienced trial lawyer, who represents healthcare providers, life sciences companies, and individuals in investigations and enforcement actions concerning the FCA, Anti-Kickback Statute, Stark Law, and the FDCA. John previously served as a prosecutor with DOJ where he held a number of leadership positions, including Assistant Chief for Healthcare Fraud, Criminal Division, Fraud Section; Lead Prosecutor, Medicare Fraud Strike Force; and Chief of Staff and Deputy Director of EOUSA.

Lisa Rivera focuses her practice on advising healthcare providers on matters related to civil and criminal healthcare fraud and abuse, as well as government investigations and enforcement. Lisa previously served for 13 years as an Assistant U.S. Attorney, with the last 10 years in the U.S. Attorney's Office for the Middle District of Tennessee, where she was the Civil and Criminal Healthcare Fraud Coordinator and responsible for the coordination of all criminal and civil healthcare fraud investigations and cases.

Brian Roark leads the firm's Healthcare Fraud Task Force and represents healthcare clients facing governmental investigations and related litigation under the FCA. He is an adjunct professor at Vanderbilt School of Law, teaching Healthcare Fraud and Abuse.

Danielle Sloane represents life science and healthcare clients navigate federal and state healthcare laws and regulations and frequently advises clients on compliance, fraud and abuse, and operational matters, including self-disclosures, voluntary repayments, overpayments, compliance plans and audits, and internal investigations. Danielle also advises transactional clients on structuring joint ventures, transactions and lends regulatory expertise to due diligence reviews of healthcare targets.

Angela Bergman represents clients in investigations and litigation related to compliance and alleged FCA violations, including hospital billing practices, medical necessity issues, and other fraud and abuse matters.

Courtney Bumpers represents individuals and entities in connection with government investigations and related litigation. Courtney previously was as an Assistant U.S. Attorney with the U.S. Attorney's Office for the Western District of North Carolina.

Taylor Chenery focuses his practice on government compliance and investigations and related FCA litigation. Taylor previously was a law clerk for the Hon. Samuel H. Mays, Jr., of the United States District Court for the Western District of Tennessee.

John Eason represents clients in government investigations conducted by DOJ and in healthcare fraud and abuse actions arising under the FCA. John previously was a law clerk for the Hon. Anita Brody of the United States District Court for the Eastern District of Pennsylvania.

Lindsey Fetzer focuses her practice on white collar and corporate compliance matters, including healthcare fraud and abuse issues. Lindsey has represented clients in foreign and domestic matters involving DOJ, the SEC, and other primary enforcement agencies.

Kiel Fisher represents clients responding to compliance-related claims and investigations arising under the FCA, Stark Law or Anti-Kickback Statute violations.

Lauren Gaffney represents healthcare clients concerning regulatory compliance and healthcare fraud matters, and has advised clients concerning self-disclosures and in connection with responding to audits and appeals by government contractors.

Kaitlin Harvie represents healthcare providers in connection with internal investigations and related proceedings, focusing on issues of healthcare fraud and abuse. She also has counseled a number of clients on compliance-related matters.

Shuchi Parikh represents healthcare providers in connection with internal investigations and related proceedings. Shuchi previously clerked for the Court of Appeals for the District of Columbia and served as an intern with DOJ's Civil Frauds Section and with the Office for General Counsel for CMS.

Robert Platt represents clients in government and internal investigations in matters involving DOJ, the SEC and other agencies.

Molly Ruberg represents healthcare providers in connection with internal investigations and related proceedings. Molly previously was a law clerk for the Hon. John G. Heyburn II of the United States District Court for the Western District of Kentucky.

Amy Sanders represents healthcare providers in connection with operational, regulatory and transactional matters and has written extensively on PPACA.

Julia Tamulis advises healthcare providers on Medicare appeals and hearings related to reimbursement denials, and provides guidance on governmental investigations of healthcare providers concerning potential fraud and abuse matters. Julia previously was as an attorney-advisor for HHS's Departmental Appeals Board.

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