

HEALTHCARE FRAUD AND ABUSE REVIEW 2012



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A LOOK BACK...A LOOK AHEAD

The previous year saw another record-setting recovery by the federal government in its efforts to combat healthcare fraud and abuse. Late last year, the U.S. Department of Justice (DOJ) announced that it had recovered \$4.9 billion in settlements and judgments in civil cases involving fraud against the government in FY 2012.¹

DOJ opened 885 new civil healthcare fraud investigations in FY 2012 and had 1,023 civil healthcare fraud matters pending at the end of that fiscal year.² DOJ also saw a record 647 *qui tam* lawsuits filed during the previous fiscal year and recovered \$3.3 billion in lawsuits filed by relators under the False Claims Act (FCA) during that same period.³

The federal government also aggressively pursued recovery on behalf of the United States in criminal healthcare fraud actions. DOJ announced a number of high-profile settlements involving record-setting criminal fines, including the payment of \$1 billion by GlaxoSmithKline as part of a plea agreement stemming from misbranded drugs and the failure to report drug safety information⁴ and the payment of nearly \$700 million in fines and forfeited assets by Abbott Labs resulting from allegations of misbranding.⁵

DOJ also opened 1,131 new criminal healthcare fraud investigations during FY 2012 and had 2,032 healthcare fraud criminal investigations pending at the

end of that fiscal year. DOJ also filed criminal charges in 452 cases involving 892 defendants during that time.⁶

The work of the Medicare Fraud Strike Force also resulted in the two largest healthcare fraud take-downs in the history of the Strike Force. In May 2012, DOJ announced that charges had been filed against 107 individuals for approximately \$452 million in false billings for a variety of alleged fraud schemes involving various medical treatments and services such as home healthcare, mental health services, psychotherapy, physical and occupational therapy, durable medical equipment (DME) and ambulance services.⁷ And, in October 2012, DOJ announced that charges had been filed against 91 individuals for approximately \$430 million in false billing related to home healthcare, mental healthcare, and ambulance transportation.⁸

For its part, the Office of the Inspector General for the U.S. Department of Health and Human Services (HHS/OIG) excluded 3,131 individuals and

¹ See <http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html>.

² See <https://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf>.

³ See generally http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf (Oct. 24, 2012).

⁴ See <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>. The GlaxoSmithKline criminal fines were part of a \$3 billion settlement resolving both criminal and civil allegations.

⁵ See www.justice.gov/opa/pr/2012/May/12-civ-585.html. The Abbot Labs criminal fines were part of a \$1.6 billion settlement resolving both criminal and civil allegations.

⁶ See <https://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf>.

⁷ See www.justice.gov/opa/pr/2012/May/12-ag-568.html.

⁸ See www.justice.gov/opa/pr/2012/October/12-ag-1205.html.

entities during FY 2012.⁹ These exclusions predominantly resulted from criminal convictions related to Medicare and Medicaid and other healthcare programs, patient abuse and neglect, and licensure revocations.

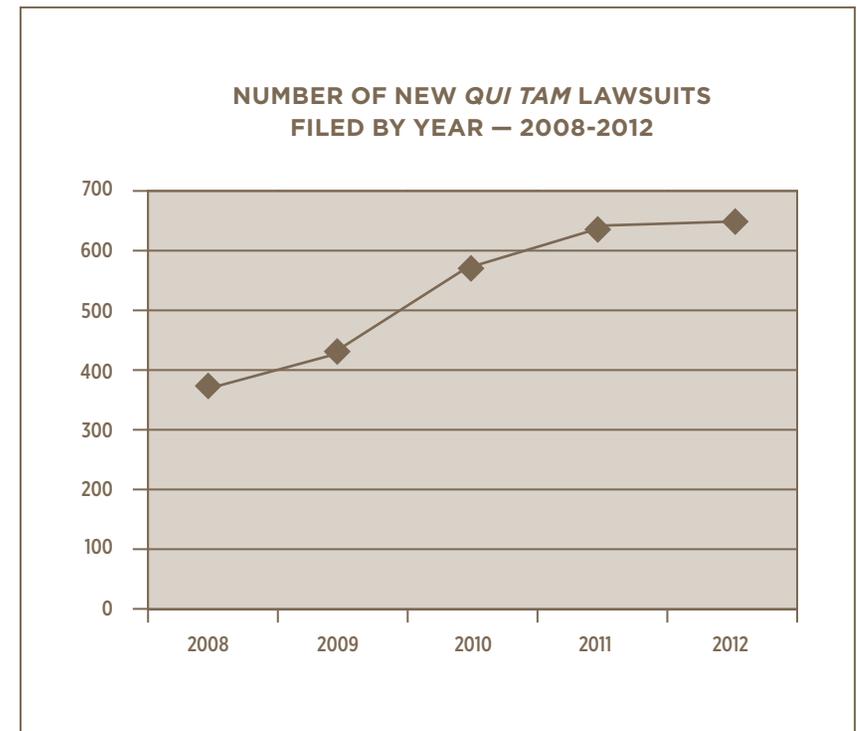
Last year's record-setting recoveries were not the only healthcare fraud-related, news-worthy events on the part of the federal government. In September 2012, U.S. Attorney General Eric Holder and HHS Secretary Kathleen Sebelius delivered a letter to the hospital community citing "troubling indications" that healthcare providers have been using electronic health records technology "to obtain payments to which they are not entitled."¹⁰ Their letter noted the possibility of "cloning" of medical records and the use of electronic health records to facilitate "upcoding" of the intensity of care or sensitivity of a patient's condition as a means to inflate reimbursement.

There were also a number of important decisions by federal courts in health-care-related civil and criminal litigation. While courts continued to grapple with the pleading standards for claims arising under the FCA, those cases do not stand alone in their significance. Courts tackled public disclosure bar issues and made important rulings on damages and penalties under the FCA. Courts also looked at issues arising under the physician self-referral law (Stark) and the Anti-Kickback Statute.

The coming year undoubtedly will see a continued focus and devotion of resources by the federal government on combatting healthcare fraud and abuse. And, there is little reason to think that last year's record-setting flood of *qui tam* lawsuits filed by relators will slow this year. If anything, providers should expect a continued increase in the number of *qui tam* lawsuits filed and a similar increase in the number of proactive investigations initiated by DOJ and HHS/OIG.

It also is anticipated that HHS/OIG will make increased use of its exclusion authority and is expected to provide updated guidance on that authority. We

likewise expect aggressive activity by CMS program integrity contractors, even as providers press their challenge to overzealous RACs in a lawsuit filed late last year.



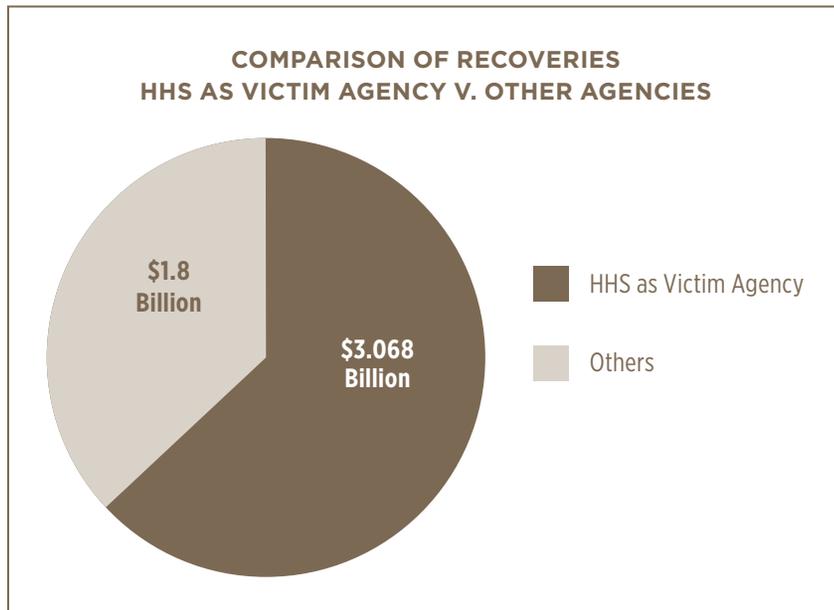
We hope this Healthcare Fraud and Abuse Review of 2012 will assist healthcare providers in staying abreast of legal developments in this area and offer some insight as to what providers might see in the coming year. One thing is for certain, attorneys and healthcare providers alike can expect a very busy 2013.

⁹ See <https://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf>.

¹⁰ Letter of E. Holder and K. Sebelius to Amer. Hosp. Ass'n, et al., dated September 24, 2012; see also Letter from Amer. Hosp. Ass'n to E. Holder and K. Sebelius, located at <http://www.aha.org/advocacy-issues/letter/2012/121112-let-hhs-doj.pdf>.

NOTEWORTHY SETTLEMENTS

The overwhelming majority of recoveries in civil actions alleging fraud against the government involve allegations of healthcare fraud against the federal healthcare programs. In fact, more than 62 percent of the government’s recovery is in civil fraud matters involving healthcare providers.



The previous year witnessed many healthcare fraud-related FCA settlements arising from *qui tam* litigation, federal and state investigations, and self-disclosures. Those settlements reveal several trends in healthcare fraud enforcement that are likely to continue into 2013. Appendix A to this Healthcare Fraud and Abuse Review contains a detailed breakdown of the noteworthy settlements referenced in the trends discussed below.

The critical point in the life of a federal healthcare fraud investigation stemming from the filing of a *qui tam* lawsuit often times is when the government makes its decision to intervene in a particular case. Last year, the amount recovered by the federal government through settlements and judgments in intervened *qui tam* cases dwarfed recoveries in cases in which the United States declined intervention. In settlements and judgments arising from intervened cases, the government collected more than \$3.33 billion in FY 2012 compared with only \$29.39 million recovered in declined cases during that time. Given the consequences of the intervention decision, providers facing a *qui tam* lawsuit must make every effort to convince the government to decline intervention in these cases.

**COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES
SETTLEMENTS AND JUDGEMENTS**

Year	Intervened Cases	Declined Cases
2008	\$1.03 Billion	\$12.68 Million
2009	\$1.96 Billion	\$33.78 Million
2010	\$2.32 Billion	\$100.99 Million
2011	\$2.64 Billion	\$173.11 Million
2012	\$3.33 Billion	\$29.39 Million

HOSPITAL SYSTEMS AND HOSPITALS

Settlements involving FCA claims against hospitals during 2012 most often involved resolution of claims for improper billing for one-day stays and short stays. Allegations faced by hospitals frequently involved billing Medicare or Medicaid for services on an inpatient basis that the government alleged should have been billed as outpatient treatment or as observation status.¹¹ In those cases, the alleged improper characterization of patient admission status was often times supported by the allegation that patients were admitted and billed as inpatients and were discharged from the hospital in less than 24 hours. Last year also witnessed settlements over the characterization of specific procedures as inpatient, rather than outpatient.

We have every reason to believe that the federal government's enforcement efforts will continue to focus on investigating allegations of improper short stay admissions. Hospitals would be well served to review admissions data proactively for trends that might suggest that further investigation of admissions practices is warranted.

> The federal government will continue its focus on improper short-stay hospital admissions in 2013.

FCA liability premised on violations of Stark and the Anti-Kickback Statute continued to make up a significant portion of hospital settlements in 2012 as well.

Notable settlements involved instances of alleged improper financial arrangements including free office space and free service arrangements, below-market lease agreements, and above-market rent paid by a hospital to physician groups in order to allow the physicians to meet mortgage obligations.¹² Other notable settlements involved improper recruitment agreements that compensated physician practice groups in amounts greater than the incidental costs of a recruited physician's start-up, and paid physician practice groups advances on income guarantees even where the physician generated profits.

Last year also witnessed several hospital settlements involving allegations of upcoding, medically unnecessary care and/or inadequate documentation. These settlements often included allegations that hospitals billed for services performed by inadequately licensed staff and/or not in the presence of an attending physician, and allegations that hospitals failed to obtain the appropriate medical necessity documentation.¹³

HOSPICE, HOME HEALTH AND OTHER PROVIDERS

Hospice companies were a frequent target of federal investigation and *qui tam* litigation in 2012. Last year's hospice settlements followed a common pattern involving allegations that companies billed federal healthcare programs for medically unnecessary care because the beneficiaries failed to meet medical necessity criteria. In most instances, patients allegedly lacked the required prognosis of six months or fewer to live.¹⁴

¹¹ See Appendix A; see, e.g., <http://www.justice.gov/usao/co/news/2012/jan/1-5-12.html>.

¹² See Appendix A; see, e.g., <http://www.timesfreepress.com/news/2012/aug/24/memorial-health-care-to-pay-13-million>.

¹³ See Appendix A; see, e.g., http://www.justice.gov/usao/pae/News/2012/May/temple,kubacki_release.htm; <http://www.justice.gov/usao/tnm/pressReleases/2012/6-29-12.html>.

¹⁴ See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2012/November/12-civ-1401.html>.

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

There were several trends in pharmaceutical-related FCA settlements last year. Several pharmaceutical companies settled FCA liability with the federal government resulting from the misreporting of drug prices to reduce drug rebate obligations or due to the resulting overpayment.¹⁵

The greatest number of settlements involved allegations of off-label promotion of drugs and devices. Indeed, the previous year saw record-setting civil settlements of FCA liability upwards of \$2 billion in such cases.¹⁶ In addition to off-label allegations, these settlements frequently involved resolution of alleged violations of the Anti-Kickback Statute stemming from physician inducements such as compensated travel and entertainment, including tickets to sporting events, dinners, ski and spa outings, sham consulting agreements, sham royalty agreements, and sham research grants.¹⁷

¹⁵ See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2012/April/12-civ-539.html>.

¹⁶ See <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>.

¹⁷ See Appendix A; see, e.g., <http://www.justice.gov/opa/pr/2012/December/12-civ-1547.html>.

FALSE CLAIMS ACT UPDATE

With the ever-increasing number of pending *qui tam* cases, federal district and appellate courts explored a number of significant FCA issues during the past year.

These cases considered the FCA's public disclosure bar, the pleading standards required by Rule 9(b), the pleading of falsity and materiality, and how courts should determine the limits of damages and penalties sought by the government in these cases, among other issues. While there is no single trend to be identified by these cases, it is reasonable to assume that future court decisions will reflect the purpose of recent FCA amendments, which were largely intended to reduce or eliminate obstacles that relators face in pleading FCA claims.

> In 2012, relators filed 647 *qui tam* lawsuits, 412 of which involved HHS as the victim agency.

Courts also grappled with a number of issues unique to relators. If recent FCA amendments have been designed to ease the path for relators asserting FCA

claims, courts have been much less forgiving when relators have come into possession of a provider's privileged information.

RETROACTIVITY OF FERA

Late last year, the Sixth Circuit held that certain FCA amendments included in the Fraud Enforcement and Recovery Act (FERA) should be applied retroactively. In *Sanders v. Allison Engine Co.*, the Sixth Circuit considered whether the retroactivity language in § 4(f)(1) of FERA, providing that the changes to § 3729(a)(2) (now codified at § 3729(a)(1)(B)) would apply to all "claims under the [FCA]" pending on or before June 7, 2008, applied to all civil actions under the FCA that were pending on June 7, 2008.¹⁸ In concluding that FERA's amendments to the FCA applied retroactively to such cases, the Sixth Circuit deepened the divide among the circuit courts that have considered this issue.¹⁹

Given the implications of the decisions reached by the divided circuits, there is a strong possibility that this issue will be taken up by the U.S. Supreme Court.

¹⁸ 2012 U.S. App. LEXIS 26738 (6th Cir. Nov. 2, 2012).

¹⁹ *Id.* at *23-25 (discussing the split among the Second and Seventh Circuits (which have held FERA to apply retroactively to actions pending as of June 7, 2008), the Ninth and Eleventh Circuits (which have held FERA to apply retroactively to "claims" (i.e., demands for payment) pending as of June 7, 2008), and the Fifth Circuit (which appears to have taken both positions)).

Should the Supreme Court affirm the Sixth Circuit’s interpretation of FERA’s retroactivity, it would significantly impact the possible exposure faced by providers for FCA cases pending as of June 7, 2008.

THE FCA’S PUBLIC DISCLOSURE BAR

The FCA’s public disclosure bar prevents a relator from filing a *qui tam* complaint based on information that was previously publicly disclosed, thereby discouraging parasitic lawsuits based on publicly available information.

Although recent U.S. Supreme Court precedent has interpreted the public disclosure bar broadly, Congress narrowed its scope through the Patient Protection and Affordable Care Act. Decisions rendered in 2012 considering the public disclosure bar make clear that courts continue to wrestle with defining the bar’s outer limits.

What Constitutes a Public Disclosure?

Courts continue to take varying approaches in dealing with the fundamental issue of what constitutes a “public disclosure.” Though not in the context of a healthcare fraud action, in *U.S. ex rel. Jones v. Collegiate Funding Servs., Inc.*, the Fourth Circuit issued an opinion of note for providers. The Fourth Circuit considered allegations that a student loan provider violated federal regulations and laws in its practices, causing the federal government to guarantee the resulting student loans.²⁰ Among the exhibits offered by the student loan provider in support of its motion to dismiss were SEC filings, which it argued were “administrative reports” for the purposes of the public disclosure bar.²¹ Though the Fourth Circuit noted that documents received by a federal agency do not

constitute administrative reports standing alone, the student loan provider’s SEC filings “were reasonably determined to be administrative reports because they were submitted under the SEC’s administrative regulatory requirements of the company. . . . While these documents were not authored by the SEC or created under their supervision, they were produced at the request of and were made public by the SEC in the course of carrying out its activities as a federal agency.”²² As such, the SEC filings were considered public disclosures.

Although the U.S. Supreme Court has held that documents produced in response to a Freedom of Information Act (FOIA) request can qualify as a “public disclosure,”²³ the Ninth Circuit held last year that a document or information does not constitute a public disclosure under the FCA simply because it is available through a FOIA request. In *Berg v. Honeywell Int’l, Inc.*, the Ninth Circuit concluded that the document or information must actually be requested and produced in order to constitute a public disclosure.²⁴ In rejecting application of the public disclosure bar, the Ninth Circuit explained, “the reports were ‘theoretically or potentially available’ to the public prior to Relators’ suit, but they were not ‘actually’ available and were not publicly disclosed under the FCA.”²⁵

When Are a Relator’s Allegations “Based Upon” Publicly Disclosed “Allegations or Transactions?”

The scope of the FCA’s public disclosure bar often turns on a court’s interpretation of whether a relator’s allegations are “based upon” or are “substantially similar to” previous public disclosures.

In *United States v. Rush Univ. Med. Ctr.*, the Seventh Circuit held that a GAO report disclosing an industry-wide practice of billing for unsupervised

²⁰ 469 Fed. App’x 244 (4th Cir. 2012).

²¹ *Id.* at 256.

²² *Id.* at 257.

²³ See *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 131 S. Ct. 1885 (2011).

²⁴ 2012 U.S. App. LEXIS 25897 (9th Cir. Dec. 19, 2012).

²⁵ *Id.* at *4 (citation omitted).

residents' work was too general to bar relators' more detailed allegations that outlined how a particular hospital had implemented a specific scheme to improperly bill for services provided by such residents.²⁶ Although the GAO report had previously disclosed allegations that hospitals commonly billed the government for unsupervised work by residents, the Seventh Circuit explained that relator's new allegations were more specific because they described the details of how the hospital consistently permitted teaching physicians to "supervise" multiple operations simultaneously, thereby preventing them from effectively supervising all of the services provided by the residents.²⁷

Relators' allegations in *Rush Univ. Med. Ctr.* were determined not to be substantially similar to the previous disclosures because relators "allege[d] a kind of deceit that the GAO report does not attribute to *any* teaching hospital. . . . [N]o one who read the GAO report, or followed the progress of the PATH audits, would know or even suspect that Rush University was misrepresenting the 'immediate availability' of teaching physicians during concurrently scheduled procedures."²⁸ The Seventh Circuit noted that relators' allegations provided new, more specific information than had been previously disclosed and that "boosting the level of generality in order to wipe out *qui tam* suits that rest on genuinely new and material information is not sound."²⁹

In *U.S. ex rel. Black v. Health & Hosp. Corp.*, the Fourth Circuit reaffirmed its trend toward a broader interpretation of the public disclosure bar's "based upon" standard. Although the Fourth Circuit had previously interpreted the public disclosure bar to prohibit only those allegations that were "actually derived" from the previous disclosures, its decision in *Black* reaffirmed a prior holding that "the public disclosure bar 'encompasses actions even *partly based*

upon prior public disclosures.'"³⁰ Under that interpretation, the Fourth Circuit held that previous public disclosures had extensively disclosed "concern with the UPL/IGT financing scheme used by the states to take advantage of aggregate" upper payment limits under Medicaid and that "the Amended Complaint essentially parrots the concerns outlined in the 2007 Proposed Rule; tracks the public debate surrounding the issue; and borrows heavily from CMS' publicly disclosed concerns with the UPL/IGT program."³¹

Unlike the Seventh Circuit in *Rush Univ. Med. Ctr.*, the Fourth Circuit in *Black* held that the relator failed to plead allegations that were not included within the scope of the broad previous public disclosures. As such, the relator's allegations were based at least partly on the previous disclosures and were subject to dismissal.

Two separate cases considering the public disclosure bar also emerged from the U.S. District Court for the Southern District of Florida. In *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, the relator alleged that Tenet hospitals accepted patient referrals from physicians who leased space from the hospitals at below-market rental rates and accepted other improper benefits, all in violation of Stark and the Anti-Kickback Statute.³² The district court rejected Tenet's argument that the relator's allegations should be dismissed because the real estate firm that was marketing the sale of Tenet's medical office buildings had previously publicly disclosed the information underlying relator's *qui tam* complaint.

The district court noted that the public disclosures were limited to basic information about the medical buildings and stated that "'facts' which are

²⁶ 680 F.3d 933 (7th Cir. 2012).

²⁷ *Id.* at 935.

²⁸ *Id.* at 935-36.

²⁹ *Id.* at 936.

³⁰ 2012 U.S. App. LEXIS 17398, *26 (4th Cir. Aug. 17, 2012) (quoting *U.S. ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 351-52 (4th Cir. 2009)).

³¹ *Id.* at *12, *27.

³² 2012 U.S. Dist. LEXIS 96434 (S.D. Fla. July 12, 2012).

presented as innocuous financial data that do not on the surface suggest fraud cannot be equated with ‘allegations or transactions’ that do.”³³ The district court underscored the significance of the FCA’s reference to “allegations or transactions” and held that the public disclosure bar is not triggered by the disclosure of innocuous financial data that does not allege or suggest wrongdoing and does not, therefore, put the government on notice of potential fraudulent activity.³⁴

In *U.S. ex rel. Osheroff v. Humana, Inc.*, the relator similarly argued that the relevant public disclosures revealed only innocuous information that did not amount to “allegations or transactions” under the public disclosure bar.³⁵ The district court rejected that argument and distinguished the case from *Tenet*, pointing out that the public disclosures revealed information that, if true, clearly implicated the restrictions contained in the Anti-Kickback Statute and the Civil Monetary Penalties Law.³⁶ Because the public disclosures revealed that Humana may have offered improper benefits to Medicare beneficiaries, those disclosures “were sufficient to bring the [Humana’s] alleged fraud to the Government’s attention.”³⁷

The district court also rejected the relator’s argument that the complaint should survive dismissal because it added significant detail to the previously disclosed information. Although acknowledging that the additional allegations and transactions provided by relator might be relevant to the Humana’s anticipated affirmative defenses, the district court held that those additional allegations were “not essential to [the] relator’s claims” and “merely add to the allegations that were already in the public domain.”³⁸ As such, the relator’s claims were still “based upon” and “substantially the same” as the

public disclosures and, therefore, were subject to dismissal.³⁹

In *U.S. ex rel. Colquitt v. Abbott Labs.*, the U.S. District Court for the Northern District of Texas explained that “the key for determining whether allegations or transactions have been publicly disclosed is whether ‘the critical elements of the fraudulent transaction were in the public domain.’”⁴⁰ In *Colquitt*, the relator alleged that Abbot Labs fraudulently obtained FDA approval for medical devices by misrepresenting how they would be used and marketed, which led to the submission of false claims for reimbursement with respect to those devices. The district court held that “allegations or transactions” had been previously publicly disclosed through 510(k) summaries filed with the FDA, which both “disclose[d] the alleged false statements” by misrepresenting the intended use of the device and disclosed “the alleged true state of affairs” by containing information relating to the size and dimensions of the device that revealed the falsity of the stated intended use. As such, the critical elements of the supposed fraudulent transaction were in the public domain.

Relator as Original Source

Courts also have been divided on the issue of whether a relator who would otherwise qualify as an “original source” under the public disclosure bar must provide his or her allegations to the government before filing suit or, more restrictively, before the relevant public disclosure occurs.

Perhaps signaling a move away from requiring disclosure to the government before the public disclosure has occurred, in *U.S. ex rel. Davis v. Dist. of Columbia*, the D.C. Circuit held that a relator must only provide information

³³ *Id.* at *12.

³⁴ *Id.* at *12-15.

³⁵ 2012 U.S. Dist. LEXIS 139949 (S.D. Fla. Sept. 28, 2012).

³⁶ *Id.* at *29-31.

³⁷ *Id.* at *31.

³⁸ *Id.* at *37-38.

³⁹ *Id.* at *38.

⁴⁰ 864 F. Supp. 2d 499, 519 (N.D. Tex. 2012) (citations omitted).

to the government prior to *filing suit*.⁴¹ In *Davis*, the D.C. Circuit specifically rejected the argument that a relator's value is lost after the public disclosure occurs. "Importantly, the relator's information can be different and more valuable to the government than the information underlying the public disclosure, which might be nothing more than speculation or rumors. . . . The relator may have an eyewitness account or important documents supporting the public allegation, but not available from any other source, which could aid the government."⁴²

The D.C. Circuit's opinion in *Davis* overruled prior cases that required a relator to disclose to the government before the public disclosure occurred. Because other circuits have adopted similar reasoning, at times even explicitly relying on that previous precedent from the D.C. Circuit, it remains to be seen whether other courts will follow suit and similarly alter their interpretation of the public disclosure bar's disclosure requirement.⁴³

In *Colquitt*, the district court clarified that "[a]lthough a relator need not be the original source of every element of his claims," a relator must be an original source with respect to each of the various claims that he alleges.⁴⁴ The relator in *Colquitt* asserted both fraudulent inducement and off-label promotion claims against Abbott Labs. The district court concluded that the relator was an original source as to the fraudulent inducement claims, because the dimensions and physical characteristics of the medical devices at issue "were available to any member of the public who wanted to find them," and, therefore, the relator's knowledge was not independent of the public disclosures, but

instead "depend[ed] and relie[d] on public disclosures."⁴⁵ The relator, however, did possess independent knowledge with respect to his off-label promotion claims because he obtained that information through his personal experience working with Abbott Labs and "because th[at] information was not publicly disclosed" in the sources identified by the defendants.⁴⁶ The relator's "knowledge [was] also 'direct' because it was gained first hand from his experience as an Abbott employee."⁴⁷ In addition, as in *Davis*, the district court in *Colquitt* explicitly rejected Abbott Labs' argument that a relator must provide his information to the government before the public disclosure occurs, holding that disclosure to the government after the allegations have been publicly disclosed but before filing suit is sufficient under the public disclosure bar.⁴⁸

In its opinion in *Black*, the Fourth Circuit clarified that relators bear the burden of establishing that they qualify as an original source under the public disclosure bar. The Fourth Circuit explained that relator's "purported status as the 'original source' must rest on more than a guessing game."⁴⁹ "In order to achieve original source status, [relator] must prove beyond a preponderance of the evidence that he has 'direct and independent knowledge of the information on which his allegations are based and has voluntarily provided the information to the Government.'"⁵⁰ The Fourth Circuit affirmed the district court's granting of the hospital's motion to dismiss "[d]ue to the 'glaring lack of evidence' of [relator's] direct and independent knowledge."⁵¹

In *Little v. Shell Exploration & Prod. Co.*, the Fifth Circuit joined the Ninth Circuit in holding that a federal employee whose official duties include

⁴¹ 679 F.3d 832 (D.C. Cir. 2012).

⁴² *Id.* at 838 (citation omitted).

⁴³ See, e.g., *U.S. ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 942-43 (6th Cir. 1997) (adopting the "D.C. Circuit's approach" that a relator must disclose information to the government before filing suit under the FCA).

⁴⁴ 864 F. Supp. 2d at 525.

⁴⁵ *Id.*

⁴⁶ *Id.* at 525-26.

⁴⁷ *Id.* at 526.

⁴⁸ See *id.* at 527-29.

⁴⁹ 2012 U.S. App. LEXIS 17398, at *30.

⁵⁰ *Id.* at *29 (quoting 31 U.S.C. § 3730(e)(4)(B)).

⁵¹ *Id.* at *30-31 (citation omitted).

investigating fraud on behalf of the government by definition cannot qualify as an original source under the public disclosure bar.⁵² The Fifth Circuit noted that a relator must voluntarily provide the information underlying his claims to the government in order to qualify as an original source and held that “the fact that a relator ‘was employed specifically to disclose fraud is sufficient to render his disclosures nonvoluntary.’”⁵³

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 *qui tam* complaint.⁵⁴ Although courts disagree about whether a previous complaint can bar a subsequent complaint if the former is somehow legally deficient, decisions in 2012 suggest a potential trend away from requiring the previous complaint to satisfy the same legal standards as the subsequent complaint in order for the first-to-file rule to apply.

In *U.S. ex rel. Banignan v. Organon USA Inc.*, the U.S. District Court for the District of Massachusetts held that a deficient complaint *can* bar a subsequent complaint.⁵⁵ The district court declined to hold that the first-to-file bar required a showing that the previously-filed complaint was sufficient under Rule 9(b), as “[i]mposing this additional requirement would frustrate the purpose of the first-to-file bar by raising the threshold for it to apply.”⁵⁶ The district court also held that the previous complaint barred some elements of the subsequent

relators’ complaint even though the previous complaint did not name Organon as a defendant.⁵⁷ The earlier complaint named one of Organon’s drugs as part of the alleged kickback scheme, which the district court deemed “the equivalent” of naming the manufacturer Organon itself and sufficient to “put the government on the trail of the alleged fraud against” Organon.⁵⁸

In *U.S. ex rel. Sandager v. Dell Mktg., L.P.*, the U.S. District Court for the District of Minnesota likewise held that a previous complaint need not comply with Rule 9(b)’s heightened pleading requirement in order to bar a subsequent complaint under the first-to-file rule. “The ultimate question is whether the Government had a basis on which to investigate the fraudulent scheme. That standard may be met even if the first-filed complaint is technically deficient.”⁵⁹

The Tenth Circuit also weighed in last year on a first-to-file issue in *U.S. ex rel. Wickliffe v. EMC Corp.*⁶⁰ In *Wickliffe*, the government sought to dismiss relators’ complaint under both the first-to-file rule and under 31 § U.S.C. 3730(c)(2)(A). Relators argued that the previously-filed complaint was insufficient under Rule 9(b) and, thus, could not operate to preclude their complaint.⁶¹ Although the Eighth Circuit decided the case under § 3730(c)(2)(A), it “admit[ted] to being uneasy with the parties’ suggestion that Rule 9(b)’s particularity requirement should be applied to the first-to-file bar.”⁶² The Eighth Circuit expressed concern that such a rule might require district courts to evaluate complaints filed in other courts, which could ultimately lead to disparate analyses.⁶³ Ultimately, the Eighth Circuit cited the government’s “valid interest in

⁵² 690 F.3d 282, 294 (5th Cir. 2012).

⁵³ *Id.* (quoting *U.S. ex rel. Fine v. Chevron, U.S.A.*, 72 F.3d 740, 744 (9th Cir. 1995)).

⁵⁴ 31 U.S.C. § 3730(b)(5).

⁵⁵ 2012 U.S. Dist. LEXIS 76130, *20 n.17 (D. Mass. June 1, 2012) (citing *U.S. ex rel. Batiste v. SLM Corp.*, 740 F. Supp. 2d 98, 104 (D.D.C. 2010)).

⁵⁶ *Id.*

⁵⁷ *Id.* at *24-25.

⁵⁸ *Id.* at *24-26; see also *U.S. ex rel. Heineman-Guta v. Guidant Corp.*, 2012 U.S. Dist. LEXIS 92702 (D. Mass. July 5, 2012) (adopting the reasoning in *Batiste* and holding that a previously-filed complaint does not need to satisfy Rule 9(b)’s heightened pleading requirement in order to bar a later-filed *qui tam* complaint).

⁵⁹ 2012 U.S. Dist. LEXIS 59714, *26-27 (D. Minn. Apr. 26, 2012).

⁶⁰ 473 Fed. App’x 849 (10th Cir. 2012).

⁶¹ *Id.* at 851.

⁶² *Id.*

⁶³ *Id.* (citing *Batiste*, 659 F.3d at 1210).

ending duplicative litigation involving resolved claims” and the fact that the government had become aware of the claims prior to the relators’ complaint as sufficient justification for dismissing the relators’ claims.⁶⁴

DEVELOPMENTS IN FCA PLEADING STANDARDS

Pleading Fraud with Particularity under Rule 9(b)

Courts have continued to grapple with the types of FCA allegations that satisfy the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure; in other words, the pleading of the “who, what, when, where, and how” of the alleged fraud.

The Eleventh Circuit issued two opinions analyzing FCA allegations under Rule 9(b)’s pleading standard. In *U.S. ex rel. Matheny v. Medco Health Solutions, Inc.*, relators alleged a reverse false claims theory of liability and asserted that the defendants had improperly retained and attempted to conceal approximately \$69 million in overpayments from the government.⁶⁵ The Eleventh Circuit held that relators satisfied Rule 9(b) by alleging “exactly which documents” containing false statements were submitted to the government, “exactly which sentence” of the documents was false, “who was responsible,” “when the

Certification was submitted,” “how the statement misled the government,” and “what the Defendants gained as a result.”⁶⁶ The Eleventh Circuit distinguished the case from a prominent line of Eleventh Circuit precedent analyzing FCA allegations under Rule 9(b), stating that “[t]his is not a case like *Clausen* and its progeny, in which the complaint failed to allege any factual specifics identifying the existence or submission of an actual false claim.”⁶⁷

Although not a healthcare case, the Eleventh Circuit’s opinion in *U.S. ex rel. Klusmeier v. Bell Constructors, Inc.* (issued the day before the Eleventh Circuit’s opinion in *Matheny*) reaffirmed the requirement that a *qui tam* relator must establish that an actual false claim was submitted to the government for payment.⁶⁸ The Eleventh Circuit acknowledged that relators had provided details about how the defendant violated its contracts with the government and when the defendant submitted monthly invoices to the government, but held that “[r]elators fail[ed] to establish that the contract violations actually resulted in the submission of false claims.”⁶⁹ The Eleventh Circuit noted that Rule 9(b) does not permit a relator to speculate that because the defendant had violated the contract in some instances and because it had submitted some invoices to the government for payment, “false claims ‘must have been submitted, were likely submitted or should have been submitted. . . .’”⁷⁰ The Eleventh Circuit also noted that relators lacked the type of inside, personal knowledge about the defendant’s submission of false claims to the government that normally will support an FCA complaint.⁷¹

⁶⁴ *Id.* at 853-54.

⁶⁵ 671 F.3d 1217 (11th Cir. 2012).

⁶⁶ *Id.* at 1225.

⁶⁷ *Id.* (citing *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002)).

⁶⁸ 2012 U.S. App. LEXIS 3370 (11th Cir. Feb. 21, 2012).

⁶⁹ *Id.* at *8-9.

⁷⁰ *Id.* at *9 (quoting *Clausen*, 290 F.3d at 1311).

⁷¹ In three separate cases relying on the Eleventh Circuit’s opinion in *Clausen*, the U.S. District Court for the District of Massachusetts reiterated that relators must show that a false claim was actually presented to the government. See *U.S. ex rel. Provuncher v. AngioScore, Inc.*, 2012 U.S. Dist. LEXIS 60390, *9 (D. Mass. May 1, 2012); see also *U.S. ex rel. Tessitore v. Infomedics Inc.*, 847 F. Supp. 2d 256, 264 (D. Mass. 2012) (dismissing the relator’s allegations where the relator failed to identify any individual “responsible for filing a false claim” or “any false claim that was submitted, including the date or amount of any such claim or the government program to which it was submitted”); *U.S. ex rel. Banignan v. Organon USA, Inc.*, 2012 U.S. Dist. LEXIS 76130, *52-53 (D. Mass. June 1, 2012) (dismissing FCA allegations for failure to satisfy the “presentment requirement” of identifying with particularity actual false claims for payment under Rule 9(b)).

In *U.S. ex rel. Wilson v. Crestwood Healthcare, L.P.*, the U.S. District Court for the Northern District of Alabama dismissed a *qui tam* complaint alleging violations of Stark and the Anti-Kickback Statute stemming from improper payments under physician lease agreements while the defendant was under a corporate integrity agreement. The district court explained that while the complaint provided a “detailed explanation of the illegal scheme that, he alleges, precipitated false claims,” the complaint failed under Rule 9(b) because it provided “no details” regarding any actual false claims submitted to the government.⁷²

In *Colquitt*, the district court employed a more flexible pleading standard under Rule 9(b).⁷³ The district court stated that the typical requirement of pleading “the time, place and contents of a false representation, as well as the identity of the person making the misrepresentation and what that person obtained thereby . . . is not a straitjacket for Rule 9(b).”⁷⁴ Although relator failed to allege the payment of specific claims, the district court nevertheless held that relator’s off-label promotion allegations against Abbott Labs satisfied Rule 9(b) because relator identified specific instances of the alleged off-label promotion and described how Abbott Labs prepared and distributed to healthcare providers reimbursement guides that instructed how to seek reimbursement from the government for the alleged off-label use.⁷⁵

In *U.S. ex rel. Raynor v. Natl. Rural Utilities Coop. Finance, Corp.*, a non-healthcare fraud *qui tam*, the Eighth Circuit affirmed a district court’s dismissal of a *qui tam* complaint for failure to satisfy the requirement of Rule 9(b) to plead how the fraud actually occurred with the requisite particularity.⁷⁶ The Eighth Circuit explained that the relator’s “conclusory” or “summar[y]” allegations

lacked any specifics “regarding the fraudulent nature of any of the alleged acts of any Defendant.”⁷⁷

And, in *U.S. ex rel. Grenadyor v. Ukranian Village Pharmacy, Inc.*, the pleading deficiency was not the failure to identify specific false claims or how the alleged improper conduct occurred; rather, relator’s failure to plead “who” engaged in the conduct at issue required dismissal of the FCA claims.⁷⁸ The district court cited relator’s failure to link any of the alleged wrongful conduct – which included kickbacks to physicians, prescription recycling, falsified customer copay records being issued to customers, and the use of another pharmacy’s billing number – to any specific patient or physician. Relator’s failure to identify “who” committed the fraud caused the complaint to fail under Rule 9(b).

Developments Concerning Falsity and Knowledge

Courts issued a number of important decisions concerning the questions of falsity and knowledge. For example, courts continued to consider how far the FCA reaches beyond claims that directly contain false statements. In *U.S. ex rel. Jones v. Brigham & Women’s Hospital*, the First Circuit held that FCA liability could attach to a grant application, submitted to the National Institute on Aging that relied on study data that had allegedly been falsified.⁷⁹ According to the First Circuit, the requirement of falsity was satisfied because “[a] number of statements in the Application demonstrate reliance on the study’s conclusions and therefore necessarily implicate the allegedly false data.”⁸⁰

In the absence of an explicit false representation, a claim also can be

⁷² 2012 U.S. Dist. LEXIS 69763, *22-23 (N.D. Ala. May 18, 2012).

⁷³ See *Colquitt*, 864 F. Supp. 2d at 533-537.

⁷⁴ *Id.* at 533.

⁷⁵ *Id.* at 533-34.

⁷⁶ 690 F.3d 951, 956 (8th Cir. 2012).

⁷⁷ *Id.*

⁷⁸ 2012 U.S. Dist. LEXIS 126100 (N.D. Ill. Sept. 5, 2012).

⁷⁹ 678 F.3d 72 (1st Cir. 2012).

⁸⁰ *Id.* at 86.

considered false when its submission carries with it the implicit representation that a provider is lawfully entitled to the payment sought, when in fact the provider is not. In such cases, there is often a dispute over the elements of falsity and knowledge. These two elements are sometimes interrelated, particularly when the alleged falsity stems from the defendant's purported failure to comply with a complex regulatory regime.

In its opinion in *U.S. ex rel. Williams v. Renal Care Group*, the Sixth Circuit provided significant insight as to the type of proof required to show falsity and knowledge under the FCA.⁸¹ In considering those issues in a case involving the propriety of billing by a diabetes supply company, the Sixth Circuit reversed the district court's grant of summary judgment in favor of the United States and vacated the \$83 million award of damages and penalties against the defendants. The Sixth Circuit then took the extraordinary step of entering summary judgment on behalf of the defendants with respect to the two primary FCA counts brought by the government.

In considering the question of falsity, the Sixth Circuit characterized the government's argument as an "obsessive[]" focus on the fact that the defendants pursued reimbursement for diabetic supply services "for the sole purpose of increasing its profit margins." The Sixth Circuit had little difficulty in rejecting this motive as providing proof that the claims submitted by the defendant supply company were false. When examined in the context of the regulatory framework at issue, the Court's reasoning could not have been clearer: "Why a business

> "Why a business ought to be punished solely for seeking to maximize profits escapes us."
- *U.S. ex rel. Williams v. Renal Care Group*

ought to be punished solely for seeking to maximize profits escapes us."⁸²

The Sixth Circuit then tackled the question of the type of proof required to show that a defendant acted "knowingly" under the FCA, where the government argues that a defendant acts with reckless disregard of the fact that the submission of the claims at issue violated Medicare regulations. In what is likely to be the most important takeaway from the opinion, the Sixth Circuit held that the defendants were not in reckless disregard of the truth or falsity of their claims where the defendants: (1) consistently sought clarification of whether billing for the claims at issue was proper; (2) followed industry practice in attempting to decipher ambiguous regulations; (3) were forthright with the government regarding the business practices surrounding the claims at issue; and (4) sought guidance from outside counsel on the manner in which the regulations at issue should be interpreted. As the Sixth Circuit unequivocally concluded, "[t]o deem such behavior 'reckless disregard' of controlling statutes and regulations imposes a burden on government contractors far higher than what Congress intended" in amending the FCA to allow reckless disregard to satisfy the FCA's knowledge requirement.⁸³

When False Statements Are Material

In addition to raising issues of falsity and knowledge, the alleged failure to comply with a complex regulatory regime may also raise issues of materiality. In addition to considering issues of falsity and knowledge, the Sixth Circuit's opinion in *Renal Care Group* evaluated whether a supposed violation of a condition of participation could render a claim materially false. The Sixth Circuit had little difficulty in reaching the conclusion that the violation of a condition of participation does not render a claim materially false under the FCA and, therefore, cannot lead to FCA liability. The Court's reasoning was straightforward: "[t]he False Claims Act is not a vehicle to police technical compliance with complex federal regulations."⁸⁴

⁸¹ 696 F.3d 518 (6th Cir. 2012).

⁸² *Id.* at 529.

⁸³ *Id.* at 530-31.

⁸⁴ *Id.* at 532.

The Fifth Circuit also tackled whether a regulatory requirement was a condition of payment or merely a condition of participation in *Gonzalez v. Fresenius Medical Care North America*.⁸⁵ In *Gonzalez*, relator alleged that Fresenius had falsely certified compliance with “the Anti-Kickback Act, the Stark Law, and a host of federal and state regulations that govern dialysis facilities” when it submitted its annual cost reports. “Evidence adduced at trial showed that, although the cost reports were a condition of Medicare participation and failure to submit accurate cost reports would trigger Medicare’s remedial scheme, the cost reports would not cause payment to be withheld.”⁸⁶ Relator did not “offer any evidence that a statute or Medicare regulation conditioned payment on the cost report’s certification.”⁸⁷ The Fifth Circuit noted that, in light of this evidence, the “cost reports would present a difficult basis for FCA liability.” Ultimately, however, the Fifth Circuit resolved the case by noting that there was insufficient evidence of an underlying violation of the Anti-Kickback Statute and the Stark Law.⁸⁸

And, while courts have noted that the FCA does not necessarily reach all regulatory noncompliance, in *U.S. ex rel. Onnen v. Sioux Falls Independent School Dist. No. 49-5*, the Eighth Circuit emphasized that there is nothing about a complex regulatory regime that “precludes the Attorney General from suing under the FCA when the government has been damaged by a materially false or fraudulent claim for payment or by use of a record or statement in a materially false claim.”⁸⁹ Instead, “[t]he scope of regulatory requirements and sanctions may affect the fact-intensive issue of whether a specific type of regulatory non-compliance resulted in a materially false claim for a specific government payment. The issue is often complex and may require inquiry into whether a regulatory requirement was a precondition to the government payment or merely a condition of continuing participation in a government program.”⁹⁰

As the government and relators continue to pursue unique theories of FCA liability against providers, questions of materiality no doubt will continue to be at the forefront of hotly contested issues at the pleading stage of FCA cases.

DEVELOPMENTS IN FCA DAMAGES AND PENALTIES

The federal government and relators continue to aggressively seek recovery for damages premised on the theory that the government received no value by virtue of the defendant’s submission of false claims. The D.C. and Second Circuits have been the latest courts to take up the question of how FCA damages should be determined.

The D.C. Circuit Reinforces Damages Approach

During the previous year, the D.C. Circuit issued its second important decision on damages under the FCA within the prior two years. Previously, in *United States v. Science Applications International Corp. (SAIC)*, the D.C. Circuit held that the value of services provided to the government must be considered when determining damages under the FCA.⁹¹ At trial, the DOJ successfully convinced the district court that single damages should equal the amount paid by the government in excess of what it would have paid had it known of the false certification, regardless of the actual value of goods or services provided to the government. Typically, this approach means that a defendant will be liable for the full amount paid by the government pursuant to the false certification. The D.C. Circuit reversed, and held that the fact-finder must apply a “benefit-of-the-bargain framework” under which the government can recover the full amounts paid “only where the

⁸⁵ 689 F.3d 470 (5th Cir. 2012).

⁸⁶ *Id.* at 475-76.

⁸⁷ *Id.*

⁸⁸ *Id.* at 476.

⁸⁹ 688 F.3d 410, 415 (8th Cir. 2012)

⁹⁰ *Id.* at 414-15.

⁹¹ 626 F.3d 1257 (D.C. Cir. 2010).

government proves that it received no value from the product delivered.”⁹²

In *U.S. ex rel. Davis v. District of Columbia*, the D.C. Circuit reemphasized its approach in *SAIC*.⁹³ In *Davis*, the relator alleged that the federal government should have paid nothing for Medicaid services provided by the District of Columbia because the defendant did not maintain records sufficient to support the services provided (as was required by Medicaid). There was no allegation, however, that the defendant had failed to provide services to the government, or even that the value of the services was less than the government believed it had purchased. Accordingly, the D.C. Circuit affirmed the dismissal of relator’s treble damages and conspiracy claims, stating “[a] server’s failure to bring a receipt after dinner cause no harm when you know you’ve been properly charged. The same is true here: The government got what it paid for and there are no damages.”⁹⁴ The D.C. Circuit, however, did allow for the possibility that relator could recover a share of any statutory penalties.

Second Circuit Considers FCA Damages Standard

Following the D.C. Circuit’s opinion in *Davis*, the Second Circuit held that where a defendant fails to provide services that conform to its contract with the government, the government may be able to recover the full amount paid to the defendant. In *U.S. ex rel. Feldman v. van Gorp*, a physician and Cornell University Medical Center had applied for and received a grant from the National Institute of Health (NIH) to fund a fellowship program that would study the neuropsychology of HIV and AIDS.⁹⁵ The application to NIH identified key faculty members who would be involved in the program and stated that the fellowship would emphasize training with HIV and AIDS patients. The application was resubmitted in subsequent years with little alteration.

According to relator, who was one of the fellows selected to participate in the program, “out of the 165 clinical cases that the fellows saw during their fellowship, only three involved HIV-positive patients.”⁹⁶ Additionally, the relator alleged that several key faculty members identified in the applications did not contribute to the program. After a jury found defendants liable under the FCA for certain applications, the district court awarded actual damages in treble the amount NIH paid pursuant to the false applications.

Defendants appealed, arguing that the district court erred in awarding the government the full amount of the grant, rather than deducting the value of the training that was actually delivered. The Second Circuit rejected defendants’ argument, stating that the government did not merely receive *less* than it bargained for (which likely would have resulted in a “benefit-of-the-bargain” approach similar to that in *Davis*); rather, the government “did not get the ‘neuropsychology with a strong emphasis upon research training with HIV/AIDS’ program it bargained for at all.”⁹⁷ Because “[t]he government bargained for something qualitatively, but not quantifiably, different from what it received,” the appropriate measure of damages was the total amount paid by the government pursuant to the false applications.⁹⁸

Limiting FCA Penalties in the Absence of Actual Damages

In *U.S. ex rel. Bunk v. Birkart Globistics GmbH & Co.*, the U.S. District Court for the Eastern District of Virginia held that where statutory penalties are grossly disproportional to any harm caused by the defendants, the penalties may be unconstitutional. Relator alleged that bidders on a U.S. Department of Defense contract had entered into a price-fixing agreement prior to submitting their bids. At trial, the jury agreed and concluded that the winning contractor

⁹² *Id.* at 1279.

⁹³ 679 F.3d 832 (D.C. Cir. 2012).

⁹⁴ *Id.* at 840.

⁹⁵ 697 F.3d 78 (2d Cir. 2012).

⁹⁶ *Id.* at 83.

⁹⁷ *Id.* at 91.

⁹⁸ *Id.* at 90.

had falsely certified that there had been no such collusion.⁹⁹ The contractor's 9,136 invoices allegedly were false, leading to a minimum civil penalty of \$50,248,000 (i.e., \$5,500 x 9,136). Defendants challenged the penalty as an excessive fine prohibited by the Eighth Amendment.

The district court first analyzed whether the government had, in fact, been harmed. The district court engaged in an analysis similar to that employed by the D.C. Circuit in *Davis*: the amount of damages under the FCA is equal to "the amount the government paid over and above what the government would have paid if not for the fraudulent activity."¹⁰⁰ Neither relator, nor the government (which had intervened), however, had presented evidence that "any bidder would have offered or the government would have accepted" a lower bid than the bid submitted by the defendant.¹⁰¹ Furthermore, there was no allegation that the services provided by the defendants were deficient in any way. Thus, the district court concluded that the evidence was "insufficient to quantify in any meaningful way any economic harm sustained by the government . . ."¹⁰² For good measure, the district court also criticized the rote multiplication of invoices to calculate the statutory penalty: "Defendants' false [bid] did not necessarily cause or correspond to any particular number of invoices that [defendant] would ultimately file; and there could have been substantially more or fewer invoices than actually filed without any real difference in Defendants' overall level of culpability."¹⁰³

Having determined that the government did not sustain any damages, the district court also held that an assessment of more than \$50 million in statutory penalties would be "grossly disproportionate" to the non-existent harm, such that the penalties would violate the Excessive Fines Clause of

the Eighth Amendment to the Constitution. Among other reasons, the court noted that an assessment of \$50 million in penalties obviously could not be expressed as a multiple of damages where there are no damages.¹⁰⁴ Furthermore, after concluding that a \$50 million civil penalty was unconstitutional, the court determined that the FCA left the court with no discretion to impose a lesser civil penalty. Thus, the district court determined that it was "left with no other option than to refuse to enforce the civil penalty provision of the FCA."¹⁰⁵

While this case is currently on appeal to the Fourth Circuit, the reasoning upon which the district court relies does offer some hope for providers facing penalties that might be grossly disproportionate to possible damages.

DEVELOPMENTS REGARDING RELATORS: USE OF PRIVILEGED INFORMATION AND INELIGIBLE RELATORS

With the ever-increasing numbers of *qui tam* lawsuits filed by relators seeking recovery on behalf of the United States, relators have enjoyed a steady and significant increase in the statutorily-mandated relator share awards resulting from successful judgments and settlements. Between 2008 and 2012, relators have recovered more than \$1.8 billion in relator share awards.

As the number of *qui tam* cases continues to increase, courts now are routinely considering issues unique to relators and their eligibility to pursue recovery in FCA cases. Cases during the previous year have highlighted the significant

⁹⁹ 2012 U.S. Dist. LEXIS 18445 (E.D. Va. Feb. 14, 2012).

¹⁰⁰ *Id.* at *24.

¹⁰¹ *Id.* at *23.

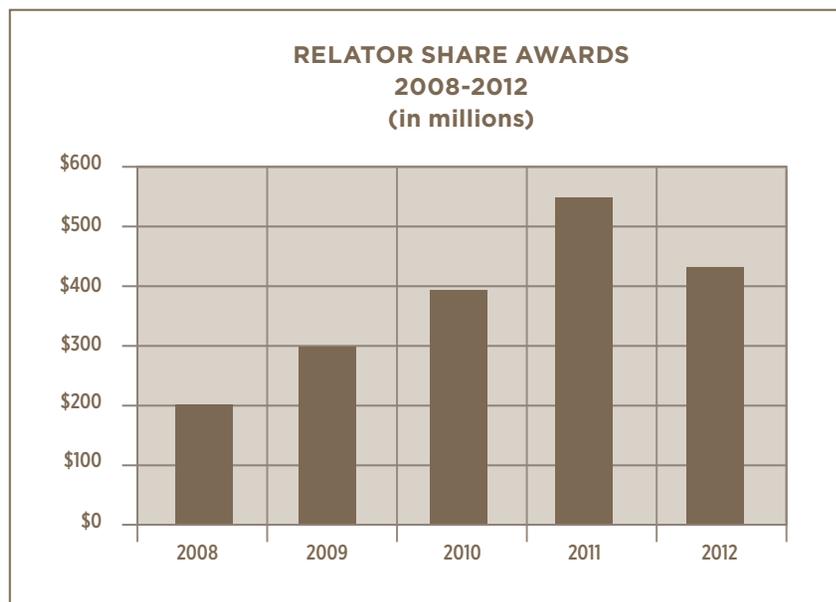
¹⁰² *Id.* at *29.

¹⁰³ *Id.* at *35.

¹⁰⁴ *Id.* at *38.

¹⁰⁵ *Id.* at *47.

risk that can arise from a relator's reliance on privileged information in the pursuit of a *qui tam* action. Companies should be aware of these risks, and defense counsel should be ready to move swiftly to seek appropriate relief should such a situation arise.



On August 23, 2012, the U.S. Court of Appeals for the Second Circuit heard oral argument in *U.S. ex rel. Fair Laboratory Practices Associates v. Quest Diagnostics, Inc.*, on the question of whether a former general counsel can bring a *qui tam* action against his previous employer. The Second Circuit is reviewing a March 2011 decision by the U.S. District Court of the Southern District of New York, which dismissed the suit and disqualified the relator,

its general partners, and its counsel from the case and any future case based on the same facts.¹⁰⁶

In *Quest Diagnostics*, the relator was a general partnership of three former executives, including the former general counsel, of a Quest Diagnostics subsidiary, formed for the singular purpose of filing an FCA action against Quest Diagnostics alleging violations of the Anti-Kickback Statute. Based on information obtained from special discovery, defendants moved for dismissal, asserting that the former general counsel violated the New York Code of Professional Responsibility through his participation as a relator. In granting defendants' motion and dismissing the action, the district court held that the former general counsel, as a general partner of relator, "represent[ed] another person, the United States, in a matter substantially related and materially adverse to his former representation of [the Quest Diagnostics subsidiary], without his client's consent," in direct violation of the New York Code.¹⁰⁷

The district court rejected relator's argument that the former general counsel's disclosures should be permitted as necessary to prevent a future crime or fraud - an exception to an attorney's duty of confidentiality. The district court explained that, even though the former general counsel may have believed defendants were intending to commit a crime when the complaint was filed in 2005, relator failed to articulate how the former general counsel's disclosures - which reached back to at least 1996 - were needed to prevent any future crime or fraud. Because the disclosures had been going on since the creation of the general partnership and because their scope was unknown, the court found the entire partnership tainted and disqualified it, its general partners and their counsel.¹⁰⁸

The Second Circuit's decision in *Quest Diagnostics* likely will have important ramifications concerning the scope of the crime-fraud exception to the duty

¹⁰⁶ 2011 U.S. Dist. LEXIS 37014 (S.D.N.Y. Apr. 5, 2011).

¹⁰⁷ *Id.* at *27.

¹⁰⁸ *Id.* at *39-46.

of confidentiality, as well as a relator's ability to rely on privileged information in a *qui tam* action.¹⁰⁹

In *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*, the U.S. District Court for the District of Arizona also considered a relator's use of privileged and confidential information in pursuing a *qui tam* action against the holder of the privilege.¹¹⁰ The relator was a former chief compliance officer for IASIS Healthcare and took numerous privileged and confidential materials with him upon leaving his employment with IASIS Healthcare. The relator subsequently provided those documents to his counsel in preparation for filing a *qui tam* action against the company.

> **“*Qui Tam* Counsel did engage in misconduct by withholding IASIS’s documents and failing to seek either a court ruling while the case was sealed or failing to contact IASIS after the seal was lifted.”**
- *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*

Although the documents were eventually returned and the action dismissed for failing to state a claim, the district court considered IASIS Healthcare's motion for sanctions against relator's counsel based on their mishandling of the privileged documents. In granting the motion, the district court held that relator's attorneys had breached two ethical duties subsequent to receiving the privileged materials: (1) while the complaint was sealed and IASIS Healthcare could not be contacted, counsel failed to seek a ruling from the

district court about the privileged documents; and (2) after the complaint was unsealed, counsel failed to initiate any contact with IASIS Healthcare, but instead “feigned ignorance” in response to IASIS Healthcare's initial letter demanding the documents' return. As a result, the district court ordered relator's counsel to pay attorneys' fees and costs associated with its attempt to retrieve the privileged documents.

JUDICIAL REVIEW OF SETTLEMENTS

The FCA provides the federal government with considerable discretion in determining whether to dismiss a *qui tam* action. In certain contexts, this discretion may be nearly unfettered. In *U.S. ex rel. Schweizer v. Océ N.V.*, however, the D.C. Circuit determined that the government's discretion was not unlimited.¹¹¹

In *Océ*, after the federal government, which had not intervened in the action, and the defendants reached an agreement to settle the claims at issue, those parties moved to dismiss those claims. The relator then filed an objection to the settlement. While the district court dismissed the settled claims after hearing, it did so pursuant to 31 U.S.C. § 3730(c)(2)(A) without reviewing the settlement. The D.C. Circuit reversed, concluding that the federal government could not settle a *qui tam* action over the objection of a relator without a determination by a district court that the proposed settlement was fair, adequate and reasonable under the circumstances, as required by 31 U.S.C. § 3730(c)(2)(B).¹¹²

It remains to be seen whether the D.C. Circuit's decision in *Océ* will complicate settlement efforts for providers and whether it will strengthen the hand of relators in the context of settlement negotiations.

¹⁰⁹ See, e.g., *U.S. ex rel. NPT Assocs. v. Lab. Corp. of Amer. Holdings*, 2012 U.S. Dist. LEXIS 169028 (S.D.N.Y. Nov. 28, 2012) (permitting discovery on the issue of whether the relator should be disqualified due to knowledge potentially obtained via former counsel).

¹¹⁰ 2012 U.S. Dist. LEXIS 6896 (D. Ariz. Jan. 10, 2012).

¹¹¹ 677 F.3d 1228 (D.C. Cir. 2012).

¹¹² *Id.* at 1233-37.

CASES TO WATCH

While there are a number of healthcare-related cases that likely will garner attention during the coming year, there are a few that likely will be of particular interest to healthcare providers and practitioners.

PRESERVATION OF EVIDENCE

In *U.S. ex rel. Baker v. Community Health Systems, Inc.*, the U.S. District Court for the District of New Mexico affirmed a federal magistrate judge's decision that the federal government acted in bad faith in connection with the destruction of documents of certain CMS officials and failed to take timely action to recover those documents.¹¹³ The district court rejected the government's objections to the finding that the government's litigation hold was untimely and inadequate and determined that defendants were precluded from access to documents that would allow them to present evidence in support of their defense.

> “This Court finds that conduct [by the Government] egregious enough to warrant these sanctions as appropriate and necessary.”
- *U.S. ex rel. Baker v. Community Health Sys., Inc*

The district court was critical of the government's failure to preserve electronically stored data once a litigation hold was in place, including a

failure to collect certain employees' data and a failure to halt auto-deletion of computer files and emails following the departure of certain employees. According to the district court, the government's failure to preserve certain documents and electronic data reflected a “‘lackadaisical attitude’ with which the Government approached its ongoing duty to monitor the litigation hold.”¹¹⁴ The district court also accepted the magistrate judge's recommendation of sanctions against the government, which required the government to produce documents related to the lost electronic data and other documents without regard to claims of privilege or work product protection. The decision also contemplates the possibility of further forensic examination to recover lost data and information, and an award of attorneys' fees and costs to defendants associated with their motion for sanctions. This matter remains pending before the district court.

THE SCOPE OF THE ATTORNEY-CLIENT PRIVILEGE IN COMPLIANCE MATTERS

In *U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, the government alleged that the hospital's employment arrangements with certain neurosurgeons and medical oncologists violated Stark because the compensation exceeded fair market value, took into account the volume or value of the doctors'

¹¹³ 2012 U.S. Dist. LEXIS 144892 (D.N.M. Oct. 3, 2012).

¹¹⁴ *Id.* at *12-13.

referrals, and were either never signed or signed after the effective date of the employment agreements.¹¹⁵

During the course of discovery, the hospital sought to withhold various categories of documents from production on privilege grounds. In considering a motion to compel production by the hospital, the district court denied several of the hospital's privilege claims. The district court explained that "simply funneling non-privileged information through an attorney does not automatically encase the document in privilege."¹¹⁶

Points from the district court's opinion worth note include:

- Communications between the company and in-house counsel are not presumed privileged; rather, the company must demonstrate that the purpose and intent of those communications was to seek legal assistance and the information conveyed related to the assistance sought;
- Copying in-house counsel on an email does not render the communication privileged unless the communication was primarily for the purpose of seeking or rendering legal advice;
- The hospital's compliance log, which tracked compliance issues that needed to be investigated, was not privileged, even though the log was clearly marked as privileged and confidential and the hospital's compliance officer testified that the log was maintained to facilitate discussions with the hospital's general counsel regarding litigation risk and potential exposure from reported incidents. The district court ruled that the log did not evidence a request for legal assistance or the transmission of legal advice, and so was not privileged;

- Audits and reviews performed by the hospital's compliance department, case management department, finance department, and any department other than the legal department generally were not privileged because the primary purpose of documents generated in the reviews was not seeking or providing legal advice; and
- The district court ordered the hospital to produce two emails between the finance department and legal department under the "crime-fraud exception" finding that the hospital was engaged in fraudulent conduct, when the finance department sought assistance from the legal department to allow the hospital to make certain payments to the oncologists.

In sum, providers should not assume that a communication is privileged simply because the communication is labeled privileged or because counsel is copied on the communication. Additionally, audits or reviews of areas of significant exposure should be performed under the direction and active participation of counsel to leave no doubt that they are privileged.

CIVIL INVESTIGATIVE DEMANDS

In *United States v. Kernan Hosp.*, the hospital filed a petition to set aside a Civil Investigative Demand (CID) that the United States had served on the hospital after the district court dismissed without prejudice its FCA complaint for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b).¹¹⁷ In granting the hospital's petition, the district court rejected the government's argument that the CID was necessary to cure

¹¹⁵ 2012 U.S. Dist. LEXIS 158944 (M.D. Fla. Nov. 6, 2012).

¹¹⁶ *Id.* at *9.

¹¹⁷ 2012 U.S. Dist. LEXIS 165688 (D. Md. Nov. 20, 2012).

deficiencies in its original fraud allegations. Before filing its initial complaint, the government initiated an investigation of alleged upcoding on the part of the hospital and served a subpoena on the hospital, to which the hospital responded, and obtained testimony pursuant to a separate CID.

In reaching its decision, the district court considered the statutory limitations of the CID provisions of the FCA. While the district court concluded that the FCA authorized the government to issue a CID “before commencing a civil proceeding under § 3730(a) or other false claims law,” the district court found the FCA to be silent on the question of whether the government could issue a CID *after* commencing an action. In reviewing relevant legislative history, the district court concluded that service of a CID after commencement of litigation no longer serves the FCA’s purpose. Accordingly, the district court determined that government may no longer exercise its CID authority under § 3733 after suit has been filed.¹¹⁸

As the federal government’s use of CIDs continues to increase, we can expect much more litigation surrounding the limits of the government’s authority to use this very powerful tool in furtherance of its FCA investigations.

¹¹⁸ *Id.* at 15-20.

STARK/ANTI-KICKBACK STATUTE

During the prior year, a number of key cases have offered insight as to how courts will interpret the myriad of complexities that come with interpreting and applying Stark and the Anti-Kickback Statute and the implementing regulations of these statutes. We expect courts in the upcoming year to continue to tackle challenging issues under Stark and the Anti-Kickback Statute.

U.S. EX REL. DRAKEFORD V. TUOMEY HEALTHCARE SYS.

The Fourth Circuit examined issues related to Stark in *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*¹¹⁹ In *Tuomey*, the relator and the government alleged, among other things, that Tuomey had entered exclusive contracts with a specialist physician for outpatient services at Tuomey, which were initiated after other specialists had considered relocating their outpatient procedures from Tuomey to their offices. The Fourth Circuit remanded the case on Seventh Amendment grounds, but addressed two Stark issues that it determined were likely to recur on remand.¹²⁰

First, the Fourth Circuit concluded that the facility component of services personally performed by the physicians pursuant to the contracts, for which Tuomey (a hospital) billed a facility fee to Medicare, constituted “a referral” within the meaning of Stark; thus, any such referrals in the context of a financial relationship must meet an exception to Stark.

Second, the Fourth Circuit addressed whether an arrangement that takes into account anticipated referrals implicates the “volume or value” standard under Stark such that the arrangement qualifies as “indirect compensation arrangement.”¹²¹ Tuomey argued that the inquiry should be “whether the physicians’ compensation takes into account the volume or value of referrals, not whether the parties considered referrals when deciding whether to enter the contracts in the first place.”

Based upon references to “anticipated” referrals both in the regulatory definition of “fair market value” and in official agency commentary, the Fourth Circuit concluded that where anticipated referrals are taken into consideration, the volume or value standard has been implicated. The Fourth Circuit explained that “[a]t bottom, the Stark Law and [its implementing regulations] seek to ensure that hospitals and other healthcare providers compensate physicians only for the work or services they actually perform, not for their ability to generate other revenues for the provider through referrals.”¹²² As a result,

¹¹⁹ 675 F.3d 394 (4th Cir. 2012).

¹²⁰ *Id.* at 405-06.

¹²¹ *Id.*

¹²² *Id.* at 409.

Tuomey ultimately would need to show that “the physician’s compensation must not take into account the volume or value of *anticipated referrals*.”¹²³ Thus, the Fourth Circuit stated that the jury question on remand should be “whether the contracts, on their face, took into account the value or volume of anticipated referrals.” The Fourth Circuit also indicated that “compensation arrangements that take into account anticipated referrals do not meet the fair market value standard.”¹²⁴

U.S. EX REL. ARMFIELD V. GILLS

In *U.S. ex rel. Armfield v. Gills*, the U.S. District Court for the Middle District of Florida denied relators’ summary judgment motion contending that the arrangements and contracts at issue failed to comply with the regulatory safe harbors to the Anti-Kickback Statute.¹²⁵ The arrangements at issue involved a space lease, an equipment lease and a services agreement where a physician would conduct her medical practice, which consisted of providing pre-operative examinations referred to her by Dr. Gills and other physicians at St. Luke’s Cataract and Laser Institute and St. Luke’s Surgical Center.

After a detailed review of the safe harbor requirements for each type of agreement and a review of the terms of each of the three agreements at issue, the district court agreed with the defendants that each agreement fell within a safe harbor to the Anti-Kickback Statute and, thus, the payments pursuant to those agreements were not prohibited “remuneration” within the meaning of the Anti-Kickback Statute.

In denying relators’ motion for summary judgment, the district court commented that “[t]he safe harbor provisions are intended to offer the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the

physician and all of the remuneration to be received for those services” and that “[t]he [r]ental [a]greements in this case provide that transparency and verifiability.”¹²⁶

BROWN V. TETHYS BIOSCIENCE, INC.

In *Brown v. Tethys Bioscience, Inc.*, several former Tethys pharmaceutical sales representatives filed a lawsuit against Tethys Bioscience claiming, among other things, that they were wrongfully terminated for refusing to honor Tethys’ “illegal and unethical” requests. When the sales representatives were unable to meet sales goals, they were allegedly told by management to “do what it takes, do whatever you have to” to generate sales of its new product. In particular, the sales representatives were allegedly told by Tethys management to use gift cards and other enticements to obtain sales.

According to Tethys, the practice of using gift cards to generate sales was not approved or encouraged by Tethys. Importantly, Tethys also discouraged Medicare and Medicaid sales and purportedly did not want any test coming from Medicare or Medicaid. Tethys allegedly told its salespeople that Medicare and Medicaid tests would not count towards sales goals, and to have a conversation “with our doctors and tell them that this test is not for Medicare/Medicaid patients.”

In a retaliatory discharge claim, the sales representatives alleged that Tethys’ direction regarding the use of gift cards violated both Stark and the Anti-Kickback Statute. The district court rejected both claims noting that in both instances, Tethys specifically deterred the salespeople from trying to obtain Medicare and Medicaid business – a necessary element to establish both Stark and Anti-Kickback violations.¹²⁷

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ 2012 U.S. Dist. LEXIS 154749 (M.D. Fla. Oct. 29, 2012).

¹²⁶ *Id.* at *25 (internal quotes and citation excluded).

¹²⁷ 2012 U.S. Dist. LEXIS 141268 (S.D. W. Va. Oct. 1, 2012).

MEDICARE CONTRACTORS AND RELATED LITIGATION

There was significant litigation concerning issues related to Medicare contractors during the previous year. In the case that has perhaps garnered the most media attention, the American Hospital Association (AHA) filed suit against HHS, alleging that CMS has wrongfully refused to pay hospital providers for care provided by hospitals to Medicare patients.¹²⁸

In *Amer. Hosp. Ass'n v. Sebelius*, the AHA's complaint challenges CMS' refusal to pay hospitals for covered, medically necessary care after RACs determine that the care should have been provided on an outpatient, rather than an inpatient, basis. The AHA's lawsuit calls into question such payment denials as an alleged violation of federal law requiring reimbursement for patient care. The district court has set a briefing schedule with respect to motions for summary judgment that will be completed in July 2013.

Providers found themselves on the losing end of a number of other cases challenging the actions of Medicare contractors. In *Palomar Medical Center v. Sebelius*, the Ninth Circuit affirmed the decision that there was no administrative or judicial right to review a RAC's decision to reopen Medicare claims.¹²⁹ This decision is a significant setback to providers. It affords contractors nearly unfettered ability to reopen claims and essentially guts a provider's ability to challenge contractor decisions to reopen claims under the "good cause" requirement.

In *Nichole Med. Equip. & Supply, Inc. v. Tricenturion, Inc.*, the Third Circuit upheld the district court's dismissal of an action brought by a DME provider against a Medicare contractor because the provider failed to exhaust administrative remedies prior to filing a suit and because the contractors were entitled to immunity because their official duties gave them the discretion

> **"The Medicare program has been refusing to pay hospitals for hundreds of millions of dollars' worth of care provided to patients, even though all agree that the care provided was reasonable and medically necessary as the Medicare Act requires."
- Amended Compl., *Amer. Hosp. Ass'n v. Sebelius***

¹²⁸ *Amer. Hosp. Ass'n v. Sebelius*, No. 1:12-cv-01770-CKK (D.D.C.).

¹²⁹ 693 F.3d 1151 (9th Cir. 2012).

to withhold payments and recoup alleged overpayments.¹³⁰ While providers may contemplate whether recourse exists against contractors for the denial of claims if the claims are ultimately allowed in the appeals process, the Third Circuit's opinion makes clear that any efforts at such recourse would certainly face an uphill battle.

Finally, during the previous year, a number of district courts considered providers' efforts to challenge Medicare contractors' decisions to use statistical sampling and extrapolation. Each of these cases ruled against providers, most notably on the ground that the contractors' decisions to use extrapolation could not be judicially reviewed based upon the applicable statute governing the use of extrapolation.¹³¹

If the previous year is any indication, we expect that litigation surrounding Medicare contractors will continue to be intense and we anticipate additional significant decisions with respect to these issues in the upcoming year.

¹³⁰ 694 F.3d 340 (3d Cir. 2012).

¹³¹ *Balko v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 (W.D. Penn. Dec. 28, 2012); *Gentiva Healthcare Corp. v. Sebelius*, 857 F. Supp. 2d 1 (D.D.C. 2012); *Anghel v. Sebelius*, 2012 U.S. Dist. LEXIS 176838 (E.D.N.Y. Dec. 13, 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. July 18, 2012); *Morgan v. Sebelius*, 2012 U.S. Dist. LEXIS 51695 (S.D. W. Va. Apr. 12, 2012); *Transynd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 (S.D. Tex. Mar. 27, 2012).

PHARMACEUTICAL AND DEVICE DEVELOPMENTS

Perhaps the most significant decision in the area of pharmaceuticals and medical devices resulted from the Second Circuit's consideration of a criminal conviction of a pharmaceutical sales representative stemming from his promotion of a drug for an off-label use. In *United States v. Caronia*, the Second Circuit reversed the conviction, determining that the conviction under the Food Drug and Cosmetic Act (FDCA) violated the sales representative's First Amendment right of free speech.¹³²

There was no question that the sales representative promoted the drug at issue for unapproved indications in violation of the FDCA. And, the government's theory of prosecution identified his speech alone as part of the illegal conspiracy and the illegal conduct at issue. The sales representative was convicted by the jury and the district court sentenced him to one year probation and 100 hours of community service. The district court denied a pre-trial motion to dismiss and the post-trial motion for acquittal.

The Second Circuit vacated the sales representative's conviction, concluding that the government prosecuted the sales representative solely for off-label promotion and the district court instructed the jury that it could convict on that theory alone. The Second Circuit rejected the government's argument that the off-label promotion was used only as evidence of intent as simply untrue and belied by the government's arguments and conduct at trial.

> **“The government has not established a ‘reasonable fit’ among its interests in drug safety and public health, the lawfulness of off-label use, and its construction of the FDCA to prohibit off-label promotion.”**
- *United States v. Caronia*

After reviewing the U.S. Supreme Court's decision in *Sorrell v. IMS Health, Inc.*, which held that speech in aid of pharmaceutical marketing was a form of expression protected by the First Amendment, the Second Circuit determined

¹³² 2012 U.S. App. LEXIS 24831 (2d Cir. Dec. 3, 2012).

that the speech restriction at issue was content- and speaker-based and failed heightened scrutiny.¹³³ Even if the criminal prohibition of off-label promotion were to be evaluated under the *Central Hudson's* less rigorous intermediate test, the Second Circuit determined that the restriction would fail that test as well.¹³⁴

Government prosecution of misbranding resulting from off-label promotion has been a long-standing tool in the government's effort to combat healthcare fraud and has been a key component in some of the largest healthcare fraud settlements on record. It remains to be seen whether the Second Circuit's opinion in *Caronia* will materially impact the government's effort in this regard.

¹³³ *Id.* at *32-36.

¹³⁴ *Id.* at *45-47.

Appendix A - 2012 Notable Settlements

HOSPITALS AND HOSPITAL SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 5, 2012	Denver Health and Hospital Authority d/b/a Denver Health Medical Center	On January 5, 2012, Denver Health and Hospital Authority d/b/a Denver Health Medical Center agreed to pay \$6.3 million to resolve FCA allegations that it admitted and billed federal healthcare programs for patients as inpatient when the patients should have been billed as outpatient or observation status. ¹³⁵	\$6.3 million
January 23, 2012	Cayuga Medical Center at Ithaca, Inc.	On January 23, 2012, Cayuga Medical Center at Ithaca, Inc. in New York, agreed to pay \$3.1 million to resolve FCA allegations that it violated the Stark law by entering into improper physician recruitment agreements, paying physician practices greater amounts than the incidental costs of the recruited physicians, and paying advances on income even where the recruited physician was profitable, in exchange for Medicare referrals. ¹³⁶	\$3.1 million
February 7, 2012	Various Hospitals	Currently, DOJ has settled FCA claims with 40 hospitals related to kyphoplasty treatment. In February 2012, 14 hospitals agreed to pay \$12 million to settle FCA allegations related to kyphoplasty spinal fracture treatment. The government alleged that the hospitals inflated unnecessary bills to Medicare by treating the procedure as inpatient rather than outpatient procedure. ¹³⁷	\$12 million
February 13, 2012	Rhode Island Hospital	On February 13, 2012, Rhode Island Hospital agreed to pay \$5.3 million to resolve FCA allegations that it billed for medically unnecessary overnight stays for Gamma Knife treatments. ¹³⁸	\$5.3 million

¹³⁵ <http://www.justice.gov/usao/co/news/2012/jan/1-5-12.html>

¹³⁶ <http://www.justice.gov/usao/nyn/news/1561-3073-2777472.pdf>

¹³⁷ <http://www.justice.gov/opa/pr/2012/February/12-civ-173.html>

¹³⁸ <http://www.justice.gov/usao/ri/news/2012/feb2012/rihos.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 10, 2012	Tenet Healthcare Corporation	On April 10, 2012, resulting from a disclosure under its Corporate Integrity Agreement (CIA), Tenet Healthcare Corporation agreed to pay \$42.8 million to resolve FCA allegations that its inpatient rehabilitation facilities billed medically unnecessary services for Medicare patients that did not meet the standard for admission. ¹³⁹	\$42.8 million
April 13, 2012	CHRISTUS Health; CHRISTUS Spohn Health System Corporation; CHRISTUS Spohn Hospital Alice; CHRISTUS Spohn Hospital Beeville; CHRISTUS Spohn Hospital Corpus Christi-Memorial; CHRISTUS Spohn Hospital Corpus Christi-Shoreline; CHRISTUS Spohn Hospital Kleberg	On April 13, 2012, CHRISTUS Health and six of its Texas hospitals agreed to pay \$5.1 million to resolve FCA allegations that all six hospitals used inpatient codes for billing federal healthcare programs that should have been outpatient. The hospitals allegedly billed outpatient surgeries as inpatient when patients were discharged in less than 24 hours. ¹⁴⁰	\$5.1 million
April 23, 2012	BHC Sierra Vista Hospital, Inc. d/b/a Sierra Vista Hospital; Psychiatric Solutions, Inc.; Universal Health Services, Inc.	On April 23, 2012, Psychiatric Solutions Inc. and Universal Health Services Inc. agreed to pay \$3.5 million to resolve FCA allegations that its Sierra Vista Hospital facility billed for outpatient treatment when patients only attended sporadically, and to resolve allegations that it violated conditions of payment for failure to (1) obtain approval for inpatient care, (2) document individual outpatient therapy sessions, (3) obtain physician orders for lab work, and (4) obtain physician certification for certain admissions. As a result, Sierra Vista Hospital also entered a five-year CIA with HHS/OIG. ¹⁴¹	\$3.5 million

¹³⁹ <http://www.justice.gov/opa/pr/2012/April/12-civ-446.html>

¹⁴⁰ <http://www.justice.gov/usao/txs/1News/Releases/2012%20June/120614%20Christus%20Spohn.html>

¹⁴¹ <http://www.justice.gov/usao/cae/news/docs/2012/05-01-12PSISettlement.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
May 4, 2012	Lenox Hill Hospital	On May 4, 2012, Lenox Hill Hospital agreed to pay \$11.75 million to settle FCA allegations that it inflated charges for services to Medicare patients to obtain larger supplemental reimbursement (outlier payments) that Medicare pays to hospitals and providers in cases where the cost of care is unusually high. ¹⁴²	\$11.75 million
May 14, 2012	Pennsylvania's Academic Medical Center; Temple University Physicians; Temple University School of Medicine; and Temple University-Of The Commonwealth System of Higher Education	On May 14, 2012, resulting from a self-disclosure that followed the August 2011 criminal conviction of Dr. Joseph Kubacki for healthcare fraud, Pennsylvania's Academic Medical Center, Temple University Physicians, Temple University School of Medicine, and Temple University-Of The Commonwealth System of Higher Education agreed to pay \$412,474 to resolve FCA liability for allegedly billing Medicare for services performed by residents as if the physician was present when he was not. The hospital also settled for billing Medicare for plastic surgery services that were not performed by or in the presence of attending physicians. ¹⁴³	\$412,474 ¹⁴⁴
June 14, 2012	AHS Hospital Corp., Atlantic Health System, Inc. and Overlook Hospital	On June 14, 2012, AHS Hospital Corp., Atlantic Health System, Inc. and Overlook Hospital agreed to pay \$9 million to settle allegations that it violated the FCA by overbilling Medicare for patients treated on an inpatient basis who should have been treated as outpatient or observation. As a result, AHS also entered a five-year CIA with HHS/OIG. ¹⁴⁵	\$9 million
June 22, 2012	Maury Regional Hospital d/b/a Maury Regional Medical Center and Lewis Health Center	On June 22, 2012, resulting from a self-disclosure, Tennessee-based Maury Regional Hospital d/b/a Maury Regional Medical Center and Lewis Health Center agreed to pay \$3.6 million to resolve FCA liability for (1) allegedly billing for ambulance services that were not medically necessary or where medical necessity was not documented, (2) failure to obtain physician certification statements for ambulance trips, (3) documenting incorrect transport levels and mileage, and (4) failure to obtain required signatures. ¹⁴⁶	\$3.6 million

¹⁴² <http://www.justice.gov/usao/nys/pressreleases/May12/lenoxhillsettlement.html>

¹⁴³ http://www.justice.gov/usao/pae/News/2012/May/temple,kubacki_release.htm

¹⁴⁴ <http://www.modernhealthcare.com/article/20120515/NEWS/305159969>

¹⁴⁵ <http://www.justice.gov/opa/pr/2012/June/12-civ-789.html>

¹⁴⁶ <http://www.justice.gov/usao/tnm/pressReleases/2012/6-29-12.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 2, 2012	NextCare, Inc.	On July 2, 2012, NextCare, Inc. – a practice management company that operates a chain of urgent-care facilities – entered into a \$10 million settlement to resolve allegations that the company billed Medicare for medically unnecessary allergy, H1N1 virus, and respiratory panel testing and engaged in artificially inflating claims (upcoding). ¹⁴⁷	\$10 million
August 23, 2012	Memorial Health Care System, Inc.	On August 23, 2012, Memorial Health Care System, Inc., in Chattanooga, Tennessee, agreed to pay \$1.3 million to resolve FCA liability ¹⁴⁸ for alleged Stark violations through financial arrangements with physician groups, including below-market lease agreements and the provision of office space and services, offered to allegedly provide financial benefits to physicians in exchange for referrals. ¹⁴⁹	\$1.3 million
August 24, 2012	Pacific Health Corporation; Health Investment Corporation; Los Angeles Metropolitan Medical Center; Newport Specialty Hospital (formerly known as Tustin Hospital and Medical Center); and Anaheim General Hospital	On August 24, 2012, Pacific Health Corporation and its hospitals agreed to pay \$16.5 million to resolve FCA allegations. The hospitals were accused of violating the AKS by paying “recruiters” to transport homeless Medicare and Medicaid beneficiaries by ambulance from Skid Row in Los Angeles to hospitals for medically unnecessary treatment that was then billed to Medicare or Medi-Cal. Los Angeles Doctors Hospital Inc. also entered a guilty plea and PHC entered a deferred prosecution agreement. ¹⁵⁰	\$16.5 million

¹⁴⁷ <http://www.justice.gov/opa/pr/2012/July/12-civ-843.html>

¹⁴⁸ <http://www.justice.gov/usao/tne/news/2012/August/082312%20Settlement%20Agreement%20Memorial%20Health%20Care%20System.html>

¹⁴⁹ <http://www.timesfreepress.com/news/2012/aug/24/memorial-health-care-to-pay-13-million/>

¹⁵⁰ <http://www.fbi.gov/losangeles/press-releases/2012/pacific-health-corporation-and-three-of-its-southland-hospitals-agree-to-pay-16.5-million-in-cases-stemming-from-illegal-kickback-scheme>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 19, 2012	HCA, Inc. and Parkridge Medical Center	On September 19, 2012, HCA, Inc. and Parkridge Medical Center agreed to pay \$16.5 million to settle FCA allegations that it gave financial benefits to doctors in exchange for patient referrals. The hospital allegedly entered into financial transactions with the physician group Diagnostic Associates of Chattanooga in order to provide compensation in exchange for referrals. The transactions included above-market rent for office space leased by Parkridge from Diagnostic Associates to assist physicians in the group to meet mortgage obligations and to help release the physicians from a separate lease obligation. Parkridge also entered a five-year CIA with the HHS/OIG. ¹⁵¹	\$16.5 million
November 5, 2012	Freeman Health System	On November 5, 2012, as the result of a self-disclosure, Missouri-based Freeman Health System agreed to pay \$9.3 million to resolve FCA allegations that it violated the Stark law. Freeman allegedly provided incentive pay to approximately 70 physicians employed at clinics based on the revenue generated by the physicians' referrals for diagnostic testing and other services performed at the Freeman-owned clinics. This allegedly created an incentive to refer such procedures to Freeman and Freeman then billed Medicare for the services. ¹⁵²	\$9.3 million
November 13, 2012	Baylor Health System; Baylor University Medical Center; and HealthTexas Provider Network	On November 13, 2012, Texas-based Baylor Health System, Baylor University Medical Center, and HealthTexas Provider Network agreed to pay \$907,355 to resolve FCA allegations that it filed false claims for radiation oncology services. Baylor allegedly double billed Medicare for services, billed for a higher level of service when a lower and less expensive level of service should have been billed, billed for procedures without supporting documentation in the medical record, and billed radiation treatment delivery without corroboration of a supervising physician. ¹⁵³	\$907,355

¹⁵¹ <http://www.justice.gov/opa/pr/2012/September/12-civ-1133.html>

¹⁵² <http://www.justice.gov/opa/pr/2012/November/12-civ-1320.html>

¹⁵³ <http://www.justice.gov/opa/pr/2012/November/12-civ-1413.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
November 20, 2012	Morton Plant Mease Health Care, Inc.; Morton Plant Hospital; St. Joseph's Hospital; Morton Plant North Bay Hospital; St. Anthony's Hospital; Mease Countryside Hospital; and Mease Dunedin Hospital	On November 20, 2012, as the result of a <i>qui tam</i> , Florida-based Morton Plant Mease Health Care, Inc. and its hospitals agreed to pay \$10.1 million to the federal government to resolve allegations that they violated the FCA. The hospital group allegedly overbilled for interventional cardiac and vascular procedures performed on Medicare patients as inpatient when they should have been billed as outpatient or observation. ¹⁵⁴	\$10.1 million
December 20, 2012	WakeMed Health and Hospitals	On December 20, 2012, North Carolina-based WakeMed Health and Hospitals (WakeMed) agreed to pay \$8 million to resolve FCA allegations. WakedMed allegedly billed for procedures performed on Medicare patients as inpatient when they should have been billed as outpatient because the patients were discharge in less than 24 hours. The provider also entered into a deferred prosecution agreement. ¹⁵⁵ *In early 2013, the North Carolina District Court rejected the WakeMed settlement agreement and deferred prosecution agreement, arguing it is not severe enough. ¹⁵⁶	\$8 million*

¹⁵⁴ <http://www.justice.gov/opa/pr/2012/November/12-civ-1391.html>

¹⁵⁵ <http://www.justice.gov/usao/nce/press/2012/2012-dec-19.html>

¹⁵⁶ <http://www.beckershospitalreview.com/legal-regulatory-issues/judge-wakemed-settlement-proposal-too-small-for-false-claims-allegations.html>

HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 3, 2012	WellCare Health Plans Inc.	On April 3, 2012, WellCare Health Plans Inc., a Florida-based managed care organization, agreed to pay \$137.5 million to resolve FCA allegations that WellCare had falsely inflated claimed expenses in order to avoid returning money to Medicaid, falsified patient records, knowingly retained overpayments, and engaged in marketing abuses by cherry-picking healthy patients. ¹⁵⁷	\$137.5 million

¹⁵⁷ http://www.justice.gov/usao/flm/press/2012/apr/20120403_WellCare.html

HOSPICE, HOME HEALTH AND OTHER PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
February 17, 2012	Odyssey Healthcare, Inc.	On February 15, 2012, hospice company Odyssey Healthcare, Inc., agreed to pay \$25 million to resolve allegations that it submitted false claims to federal programs for medically unnecessary continuous home care services billed at a higher rate than routine care services. As a result, Odyssey entered into a CIA with HHS/OIG. ¹⁵⁸	\$25 million
March 23, 2012	LifeWatch Services, Inc.	On March 23, 2012, Chicago-based LifeWatch Services, Inc., settled with the government for \$18.5 million to resolve allegations that it improperly billed for ambulatory cardiac telemetry (ACT) services because it billed for non-reimbursable mild or moderate palpitations. LifeWatch also allegedly provided services of full-time employees to hospitals for free in exchange for referrals of monitoring services in violation of the AKS. ¹⁵⁹	\$18.5 million
April 3, 2012	Radiotherapy Clinics of Georgia	On April 3, 2012, Radiotherapy Clinics of Georgia agreed to pay \$3.8 million to settle allegations that it billed for prostate cancer treatments that were not medically necessary and overbilled for consults and pre-plans that were either not medically necessary or that were not reviewed by a physician. ¹⁶⁰	\$3.8 million

¹⁵⁸ <http://www.justice.gov/opa/pr/2012/March/12-civ-272.html>; <http://www.prnewswire.com/news-releases/odyssey-hospice-announces-agreements-with-department-of-justice-and-office-of-inspector-general-139545938.html>

¹⁵⁹ <http://www.justice.gov/opa/pr/2012/March/12-civ-369.html>

¹⁶⁰ <http://www.justice.gov/opa/pr/2012/April/12-civ-426.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 23, 2012	Apex Medical Group, P.C, d/b/a Nephrology Consultants; Extracorporeal Technologies, Inc.; Fort Sanders Kidney Center, Inc.; Naseemul Siddiqi, M.D.	On April 23, 2012, Tennessee-based Nephrology Consultants agreed to pay \$4.4 million to resolve FCA allegations that it submitted bills to federal programs for physician services that were upcoded and submitted inaccurate claims for dialysis services. ¹⁶¹	\$4.4 million
June 5, 2012	Hospice Care of Kansas, LLC and Voyager HospiceCare, Inc.	On June 5, 2012, Hospice Care of Kansas, LLC and Voyager HospiceCare, Inc., agreed to pay \$6.1 million to resolve FCA allegations that they billed federal programs for ineligible hospice services because patients did not have a medical prognosis of six months or less, and improper delays in discharges and misleading documentation resulting from employee payment based on patient census levels. ¹⁶²	\$6.1 million
July 3, 2012	DaVita, Inc.	On July 3, 2012, DaVita, Inc., the largest operator of dialysis clinics in the United States, agreed to pay \$55 million to settle FCA allegations that DaVita fraudulently billed for free supplies of an anemia drug. ¹⁶³	\$55 million
July 16, 2012	Fairmont Diagnostic Center; Jack L. Baker; and Open MRI, Inc.	On July 16, 2012, Texas-based Fairmont Diagnostic Center, Jack L. Baker, and Open MRI, Inc. agreed to pay \$650,000 to resolve FCA allegations that they violated state laws, the AKS, and the Stark law through entering into sham personal services agreements for medical directorships that took into account the value of referrals, and by entering into contracts to pay the salaries of employees in physician offices that took into account the value of referrals. Jack Baker has submitted to a voluntarily suspension from the healthcare programs for six years. ¹⁶⁴	\$650,000

¹⁶¹ <http://www.justice.gov/usao/tne/news/2012/May/050312%20Apex%20Settlement.html>

¹⁶² <http://www.justice.gov/opa/pr/2012/June/12-civ-768.html>

¹⁶³ <http://www.law360.com/articles/356484>

¹⁶⁴ <http://www.justice.gov/usao/txs/1News/Releases/2012%20August/120814%20Baker.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 17, 2012	AHH Historic Inc. f/k/a Altus Healthcare and Hospice, Inc.	On July 17, 2012, AHH Historic Inc. f/k/a Altus Healthcare and Hospice, Inc. agreed to pay \$555,572 to settle FCA allegations that it submitted bills to the federal government for medically unnecessary services because patients did not qualify for the second-highest level of hospice reimbursement – general inpatient care – because the patients did not meet medical necessity requirement of a need for pain control or acute or chronic system management that could not be managed in another setting. ¹⁶⁵	\$555,572
August 10, 2012	CareAll Management, LLC, f/k/a Diversified Health Management, Inc.; CareAll, Inc.; Professional Home Health Care, LLC; The James W. CareAll Family Trust; University Home Health, LLC; VIP Home Nursing and Rehabilitation Services	On August 10, 2012, CareAll settled allegations it violated the FCA for \$9.4 million. The Government alleged that CareAll violated the FCA through submission of false cost reports because CareAll hid a relationship between its management company and its home health agencies. Had the relationship been disclosed, the Medicare reimbursement to the management company would have been lower. ¹⁶⁶	\$9.4 million
November 20, 2012	Harmony Care Hospice, Inc.	On November 20, 2012, South Carolina-based Harmony Care Hospice, Inc., and its CEO/Owner agreed to pay \$1.3 million to settle FCA allegations that the company submitted bills to Medicare for medically unnecessary services because beneficiaries were ineligible for hospice care because they did not have a terminal prognosis of six months or less. ¹⁶⁷	\$1.3 million
December 17, 2012	American Sleep Medicine, LLC	On December 17, 2012, independent diagnostic testing facility American Sleep Medicine, LLC, agreed to pay \$15.1 million to resolve allegations it violated the FCA by billing Medicare for sleep diagnostic services not eligible for reimbursement because the procedures were performed by unlicensed or uncertified technicians. ¹⁶⁸	\$15.1 million

¹⁶⁵ <http://www.fbi.gov/atlanta/press-releases/2012/altus-healthcare-hospice-settles-allegations-of-inappropriate-use-of-inpatient-hospice>

¹⁶⁶ <http://www.justice.gov/opa/pr/2012/August/12-civ-997.html>

¹⁶⁷ <http://www.justice.gov/opa/pr/2012/November/12-civ-1401.html>

¹⁶⁸ <http://www.justice.gov/opa/pr/2013/January/13-civ-006.html>

PHARMACEUTICAL AND DEVICE COMPANIES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
February 8, 2012	Dava Pharmaceuticals	On February 8, 2012, Dava Pharmaceuticals agreed to pay \$11 million to resolve allegations of misreporting drug prices in order to reduce its Medicaid drug rebate obligations. ¹⁶⁹	\$11 million
February 27, 2012	Mylan, Inc.	On February 27, 2012, generic drug manufacturer Mylan, Inc. agreed to pay \$57 million to resolve FCA allegations related to false reporting of Average Wholesale Price (AWP) for some of its prescription drugs, causing Medicaid to overpay for certain drugs. ¹⁷⁰	\$57 million
March 23, 2012	EUSA Pharma	On March 23, 2012, EUSA Pharma agreed to pay \$180,000 to settle FCA allegations that it encouraged physicians to submit inflated claims to Medicare for imaging scans. ¹⁷¹	\$180,000
April 13, 2012	AmMed Direct LLC	On April 13, 2012, AmMed Direct LLC agreed to pay \$18 million to resolve allegations that it submitted false claims for diabetic testing supplies. AmMed allegedly advertised free cookbooks to induce Medicare beneficiaries to contact AmMed. Once contacted, AmMed attempted to sell the beneficiaries Medicare supplies. When beneficiaries tried to return the supplies, AmMed failed to timely refund Medicare. ¹⁷²	\$18 million

¹⁶⁹ <http://www.justice.gov/opa/pr/2012/February/12-civ-182.html>

¹⁷⁰ <http://www.bloomberg.com/news/2012-02-28/mylan-to-pay-57-million-to-settle-drug-overpricing-claims-1.html>

¹⁷¹ <http://www.fbi.gov/washingtondc/press-releases/2012/pennsylvania-based-eusa-pharma-usa-inc.-to-pay-u.s.-180-000-for-allegedly-submitting-inflated-claims-to-medicare>

¹⁷² <http://www.justice.gov/usao/tnm/pressReleases/2012/4-13-12.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 26, 2012	McKesson Corporation	On April 26, 2012, McKesson Corporation, a large drug wholesaler, agreed to pay more than \$190 million to the federal government to resolve allegations that it violated the FCA through inflated pricing information related to the AWP for some of its prescription drugs, causing Medicaid to overpay. ¹⁷³	\$190 million
May 7, 2012	Abbott Laboratories Inc.	On May 7, 2012, Abbott Laboratories Inc. agreed to pay \$1.5 billion to resolve criminal and civil liability with the federal government, 45 states, and the District of Columbia. Abbott's FCA civil settlement amounted to \$800 million to resolve allegations that the company engaged in off-label marketing and promotion. As a result, Abbott entered into a CIA with HHS/OIG. Under the CIA, Abbott agreed not to compensate its sales force for off-label sales, and agreed its executives will certify compliance with the CIA. ¹⁷⁴	\$800 million
May 31, 2012	St. Jude Medical	On May 31, 2012, St. Jude Medical agreed to pay \$3.65 million to resolve FCA allegations that it overcharged the Veterans Administration and the Department of Defense for implantable cardiac devices (ICD) by marketing that the devices were covered by warranties but then failed to grant appropriate credits under the warranties so that invoices submitted to the government overstated the cost of replacement ICDs. ¹⁷⁵	\$3.65 million
June 7, 2012	Orthofix Inc. and Orthofix International NV	On June 7, 2012, medical device manufacturer Orthofix Inc. and Orthofix International NV, agreed to pay \$34 million to resolve FCA allegations that it misstated costs resulting in overpayments, waived patient co-payments, paid kickbacks to physicians to induce the use of their products, caused the submission of falsified certificates of medical necessity, and failed to advise patients of their right to rent rather than buy the products. ¹⁷⁶	\$34 million

¹⁷³ <http://www.justice.gov/opa/pr/2012/April/12-civ-539.html>

¹⁷⁴ <http://www.justice.gov/opa/pr/2012/May/12-civ-585.html>

¹⁷⁵ <http://www.justice.gov/opa/pr/2012/May/12-civ-694.html>

¹⁷⁶ <http://www.justice.gov/opa/pr/2012/June/12-civ-724.html>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 2, 2012	GlaxoSmithKline LLC	On July 2, 2012, GlaxoSmithKline LLC (GSK) agreed to pay \$3 billion to resolve criminal and civil allegations that the company engaged in off-label promotion and paid kickbacks to physicians, failed to report certain safety data to the FDA, and engaged in false price reporting practices in violation of the FCA. GSK's civil FCA settlement amounted to \$2 billion. GSK entered into a five-year CIA with HHS/OIG. Under the CIA, GSK agreed that executives must forfeit up to three years of annual performance pay if found to be involved in significant misconduct, agreed that executives will certify compliance, and agreed to abolish compensation based on sales goals for its sales force. ¹⁷⁷	\$2 billion
October 25, 2012	Boehringer Ingelheim Pharmaceuticals, Inc.	On October 25, 2012, Connecticut-based Boehringer Ingelheim Pharmaceuticals, Inc. agreed to pay \$95 million to resolve FCA allegations that it engaged in off-label drug promotion and illegal kickbacks with four of its prescription drugs, including promotion of off-label uses, off-label doses, and making unsubstantiated efficacy claims. ¹⁷⁸	\$95 million
November 2, 2012	Blackstone Medical, Inc.	On November 2, 2012, Orthofix Inc.'s parent company, Orthofix International NV, agreed to pay \$30 million to resolve FCA allegations that its subsidiary, Blackstone Medical, Inc., paid kickbacks to spinal surgeons in the form of compensated travel and entertainment, sham consulting agreements, sham royalty agreements, and sham research grants, in order to induce them to implant Orthofix-manufactured products. ¹⁷⁹	\$30 million
November 9, 2012	Pfizer, Inc.	On November 9, 2012, Pfizer, Inc., a pharmaceutical company, announced that it had agreed in principle with the DOJ to pay \$257 million to resolve FCA allegations that it promoted an organ transplant drug for off-label uses. ¹⁸⁰	\$257 million

¹⁷⁷ <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>

¹⁷⁸ <http://www.justice.gov/opa/pr/2012/October/12-civ-1291.html>

¹⁷⁹ <http://www.justice.gov/opa/pr/2012/November/12-civ-1309.html>

¹⁸⁰ <http://www.nasdaq.com/article/pfizer-to-plead-guilty-in-rapamune-settlement-20121109-00917>

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 6, 2012	Healthpoint Ltd. and DFB Pharmaceuticals	On December 6, 2012, Texas-based Healthpoint Ltd. and DFB Pharmaceuticals agreed to pay up to \$48 million to resolve FCA allegations that it allegedly marketed a drug without FDA approval and where the safety and efficacy data for the drug was insufficient, and misrepresented the unapproved status of the drug to the government in seeking Medicare and Medicaid reimbursement. ¹⁸¹	\$48 million
December 19, 2012	Amgen Inc.	On December 19, 2012, Amgen Inc. agreed to pay \$762 million to resolve criminal and FCA liability related to the marketing and promotion of certain drugs. Amgen agreed to pay \$612 million to resolve civil FCA allegations that Amgen engaged in off-label promotion for uses and doses that were not approved by the FDA, offering kickbacks to healthcare providers, and false price reporting practices. ¹⁸²	\$612 million
December 19, 2012	Sanofi-Aventis U.S. Inc. and Sanofi-Aventis U.S. LLC	On December 19, 2012, Sanofi-Aventis U.S. Inc. and Sanofi-Aventis U.S. LLC agreed to pay \$109 million to resolve FCA allegations that it violated the AKS by providing physicians with free units of Hyalgan, a knee injection, to induce them to purchase and prescribe the product, and that the government paid inflated prices for Hyalgan because Sanofi-Aventis submitted false average sales price reports for Hyalgan that did not take into account free units distributed by its sales representatives to physicians, when Hyalgan was purchased. ¹⁸³	\$109 million
December 27, 2012	Victory Pharma, Inc.	On December 27, 2012, Victory Pharma, Inc., a San Diego-based pharmaceutical company, agreed to pay \$11.4 million to settle FCA allegations that it paid doctors illegal kickbacks to encourage them to prescribe the company's products, including tickets to sporting events, dinners, ski and spa outings, and paying physicians to allow sales representatives to "shadow" them. ¹⁸⁴	\$11.4 million

¹⁸¹ <http://www.justice.gov/opa/pr/2012/December/12-civ-1459.html>

¹⁸² <http://www.fbi.gov/newyork/press-releases/2012/amgen-inc.-pleads-guilty-to-federal-charge-in-brooklyn-pays-762-million-to-resolve-criminal-liability-and-false-claims-act-allegations>

¹⁸³ <http://www.justice.gov/opa/pr/2012/December/12-civ-1526.html>

¹⁸⁴ <http://www.justice.gov/opa/pr/2012/December/12-civ-1547.html>

ABOUT BASS, BERRY & SIMS PLC

Founded in 1922, Bass, Berry & Sims represents numerous Fortune 500 and other domestic and international companies in complex corporate transactions, disputes and compliance matters. Our work for preeminent organizations includes serving as regulatory auditor for the New York Stock Exchange, representing one of the largest healthcare companies in the world in a \$33 billion leveraged buyout (at the time, the largest in U.S. history), as well as serving as the SEC-approved monitor for a Big Four accounting firm.

ABOUT OUR HEALTHCARE FRAUD AND ABUSE PRACTICE

Led by our Compliance and Government Investigations Practice Group and our Healthcare Fraud Task Force, our firm routinely 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. Our attorneys also have extensive experience in successfully representing providers in related FCA litigation. And, we routinely counsel healthcare providers on implementing state-of-the-art compliance programs.

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 *Health Care Fraud and Abuse*. For more information, please visit our website at <http://www.bassberry.com/healthcare-fraud>.

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