# Healthcare Fraud and Abuse Review
# 2015

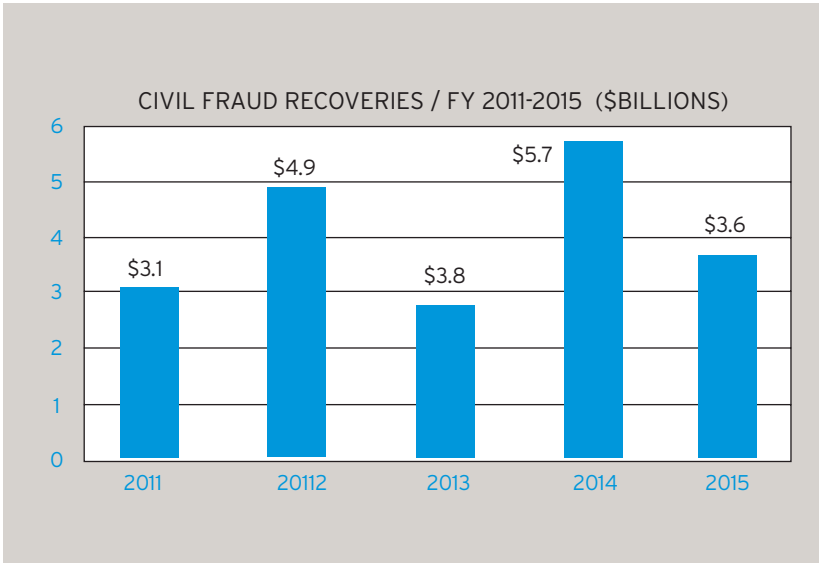
BASS BERRY + SIMS PLC

# A LOOK BACK...A LOOK AHEAD

**For the first time in recent history, the previous year's healthcare fraud headlines were noteworthy as much for legal developments and U.S. Department of Justice ("DOJ") pronouncements as they were for the healthcare fraud recovery haul by the government.**

To be sure, DOJ enjoyed yet another banner year of civil and criminal healthcare fraud enforcement results. During the fiscal year ending September 30, 2015 ("FY 2015"), the federal government racked up nearly $3.6 billion in civil fraud recoveries, marking the eleventh straight year in which such recoveries exceeded $1 billion.[1]

Nearly $2 billion of last year's civil recoveries related to matters involving false claims against the federal healthcare programs in violation of the False Claims Act ("FCA").[2] During the last five years, civil recoveries involving the federal healthcare programs have exceeded $12.5 billion. As will be detailed further in our Review, a significant amount of last year's civil recoveries involved *qui tam* actions raising issues of medical necessity and improper financial relationships between hospitals and doctors. In contrast to years past, only a fraction of the recoveries involved matters concerning the pharmaceutical industry.[3]




**In FY 2015, the United States recovered $3.6 billion in fraud-related civil settlements and judgments.**

Whistleblowers filed 632 new *qui tam* lawsuits under the FCA in FY 2015, which was more than a 10% drop compared to the previous year.[4] This marked the fifth straight year, however, in which relators filed more than 600 new *qui tam* lawsuits and brought the tally of the total number of *qui tam* lawsuits filed during that time period to nearly 3,400. And, whistleblowers recovered a record breaking $598 million as their share of the proceeds in *qui tam* judgments and settlements in FY 2015, bringing their total recoveries during the past five years to more than $2.4 billion.[5]

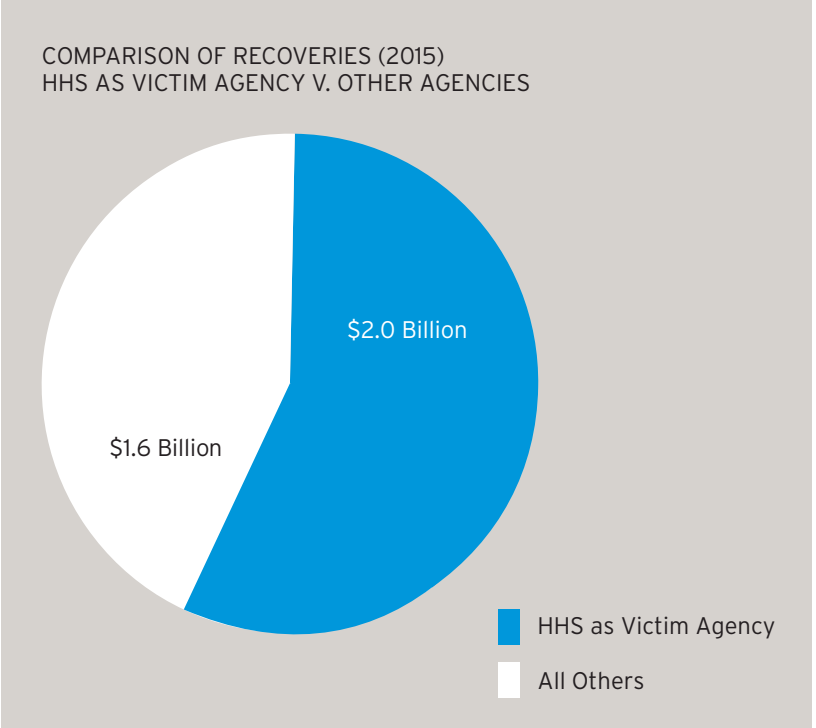
In addition to civil fraud recoveries, DOJ announced a number of high profile criminal enforcement actions and results. In June 2015, the Medicare Fraud Strike Force led the largest single takedown in its history, which resulted in charges against 243 defendants, including doctors, nurses and other licensed healthcare professionals. The takedown was part of a coordinated nationwide

1. http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.
2. http://www.justice.gov/opa/file/796866/download.
3. http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.
4. http://www.justice.gov/opa/file/796866/download.
5. *Id.*

operation across 17 federal districts and involved an estimated $700 million in false billings of government healthcare programs.[6] The Strike Force also racked up a number of convictions of healthcare providers, ranging from physicians,[7] administrators,[8] home health,[9] durable medical equipment[10] and ancillary service providers.[11]

Health and Human Services Office of Inspector General ("HHS-OIG") reported expected recoveries of more than $3.25 billion, consisting of nearly $1.13 billion in audit receivables and about $2.2 billion in investigative receivables.[12] HHS-OIG reported 925 criminal actions against individuals or entities that had engaged in crimes against federal healthcare programs and 682 civil actions, including lawsuits alleging false claims and unjust-enrichment, seeking civil monetary penalties and administrative recoveries related to provider self-disclosures. HHS-OIG also excluded more than 4,000 individuals and entities from participation in federal healthcare programs. Overall, HHS-OIG reported $20.6 billion in estimated savings resulting from legislative, regulatory and administrative actions.

In June 2015, HHS-OIG released a Portfolio Report, which summarized nearly 10 years' worth of investigations and audits regarding Medicare Part D.[13] This Report was intended to synthesize numerous past HHS-OIG reports that have identified weaknesses in Part D program integrity. The Report focused, in particular, on weaknesses in the use of data to identify vulnerabilities and highlighted the fact that Part D remains vulnerable to fraud.




6. http://www.justice.gov/opa/pr/national-medicare-fraud-takedown-results-charges-against-243-individuals-approximately-712.
7. *See, e.g.*, http://www.justice.gov/opa/pr/new-orleans-doctors-and-registered-nurse-sentenced-roles-50-million-fraud-scheme (physicians sentenced to 80 and 64 months, respectively, and ordered to pay more than $11 million in resti tution for role in home health agency fraud scheme involving unnecessary services); http://www.justice.gov/opa/pr/physician-sentenced-72-months-prison-role-detroit-area-medicare-fraud-scheme (physician sentenced to 72 months for role in healthcare fraud scheme involving in-home physician services); http://www.justice.gov/opa/pr/medical-director-and-three-therapists-sentenced-their-roles-63-million-miami-health-care (physician sentenced to 192 months in prison stemming from role in healthcare fraud scheme involving kickbacks to assisted living facility owners); http://www.justice.gov/opa/pr/detroit-area-doctor-sentenced-45-years-prison-providing-medically-unnec-essary-chemotherapy (physician owner and operator of cancer treatment center sentenced to 45 years in prison for role in providing medically unnecessary chemotherapy to patients and soliciting kickbacks from home health and hospice providers for referrals of patients).
8. *See, e.g.*, http://www.justice.gov/opa/pr/home-health-care-agency-owner-sentenced-80-months-directing-detroit-area-medicare-fraud (home health agency owner sentenced to 80 months stemming from $7 million healthcare fraud scheme involving unnecessary services); http://www.justice.gov/opa/pr/new-orleans-office-manager-sentenced-role-50-million-fraud-scheme (home health agency office manager sentenced to 48 months in prison and ordered to pay $14 million in restitution for role in healthcare fraud scheme involving kickbacks to recruiters and unnecessary services); http://www.justice.gov/opa/pr/owner-detroit-home-health-care-companies-sentenced-80-months-prison-role-126-million-fraud (owner of home health agency sentenced to 80 months in prison for role in $12.65 million Medicare fraud and tax scheme involving unnecessary services).
9. *See, e.g.*, http://www.justice.gov/opa/pr/assistant-administrator-riverside-general-hospital-sentenced-40-years-prison-116-million (hospital administrator sentenced to 40 years in prison for role in $116 million Medicare fraud scheme involving medically unnecessary services and kickbacks)
10. *See, e.g.*, http://www.justice.gov/opa/pr/owner-houston-durable-medical-equipment-health-care-companies-sentenced-34-million-medicare (owner of durable medical equipment ("DME") company sentenced to 63 months for role in $2 million healthcare fraud scheme involving substitution of DME products for more expensive products billed to Medicare); http://www.justice.gov/opa/pr/former-owner-medical-equipment-supply-company-sentenced-35-million-medicare-and-medi-cal (owner of medical supply company sentenced to 97 months in prison for role in $3.5 million healthcare fraud scheme involving medically unnecessary services).
11. *See, e.g.*, http://www.justice.gov/opa/pr/miami-area-pharmacy-owner-sentenced-42-months-prison-role-15-million-medicare-part-d-fraud (pharmacy owner sentenced to 42 months in prison for role in Part D healthcare fraud scheme involving fraudulent prescriptions); http://www.justice.gov/opa/pr/ambulance-company-manager-sentenced-87-months-prison-55-million-medicare-fraud-scheme (ambulance company manager sentenced to 78 months in prison for role in healthcare fraud scheme involving medically unnecessary ambulance transports).
12. http://oig.hhs.gov/newsroom/news-releases/2015/sarfall2015.asp.
13. http://oig.hhs.gov/oei/reports/oei-03-15-00180.asp.

Statistics summarizing recoveries told only part of the story regarding the government's healthcare fraud efforts last year. In November 2015, DOJ released a memorandum concerning "Individual Accountability for Corporate Wrongdoing," which is commonly referred to as the "Yates Memo," in recognition of its author Deputy Attorney General Sally Yates.[14] The Yates Memo formalizes a message DOJ officials have been clearly forecasting during the last several years; namely, that DOJ will seek to hold individuals who are responsible for corporate wrongdoing accountable for their actions. The Yates Memo includes a number of directives regarding cooperation credit and the expectation that those seeking such credit will provide a full disclosure of all facts regarding individuals involved in the alleged wrongdoing. Notably, the FCA was the only statute specifically referenced in the Yates Memo and undoubtedly healthcare providers in the midst of investigations will be grappling with the consequences of the Yates Memo in the coming years.

Last year, a number of key legal developments concerning the FCA emerged, which practitioners and healthcare providers will be tracking closely. In perhaps the most noteworthy, the U.S. Supreme Court granted *certiorari* to consider the legal viability and scope of the implied certification theory of falsity under the FCA.[15] Given the split among the circuits regarding whether and to what extent a provider's implied certification of compliance with an underlying requirement may establish an FCA violation, the Supreme Court will have the opportunity to provide some much needed clarity on this issue.

We hope our firm's annual Healthcare Fraud and Abuse Review will assist healthcare providers in staying abreast of legal developments relevant to their business and will offer insight as to what providers might see during the coming year. Given last year's developments, there can be no question that the government will continue to aggressively pursue enforcement initiatives and that courts increasingly will be called upon to evaluate key legal issues bearing on civil and criminal enforcement of healthcare fraud.

14. http://www.justice.gov/dag/file/769036/download.
15. http://www.supremecourt.gov/qp/15-00007qp.pdf.

# NOTEWORTHY SETTLEMENTS

## Resolutions in healthcare fraud cases accounted for more than half of the $3.5 billion in FCA recoveries obtained by DOJ in FY 2015.

While this is the fourth year in a row that FCA recoveries have exceeded $3.5 billion, total recoveries are down from the record-setting $5.69 billion in settlements and judgments recovered in 2014, which were largely due to blockbuster settlements with major banks following the housing and mortgage crisis. This year's $1.9 billion in recoveries from the healthcare industry represents a slight decrease from last year, though these numbers reflect only federal recoveries and do not take into account additional amounts recovered by state enforcement agencies for Medicaid losses.[16]

The vast majority of FCA investigations continue to arise from allegations raised in *qui tam* complaints filed by whistleblowers. Historically, the bulk of recoveries in FCA lawsuits initiated by relators have come from cases in which the United States intervenes. This year, however, the recoveries were distributed more evenly between intervened and non-intervened *qui tam* cases, with non-intervened cases accounting for approximately 40% of recoveries in FCA cases generated by *qui tam* lawsuits.[17] Such numbers undoubtedly will encourage the relators' bar to continue to aggressively litigate declined cases.

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

COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES - SETTLEMENTS AND JUDGMENTS (2011-2015)

| Year | Intervened Cases | Declined Cases |
|---|---|---|
| 2011 | $2.65 billion | $173.89 million |
| 2012 | $3.30 billion | $44.97 million |
| 2013 | $2.88 billion | $125.82 million |
| 2014 | $2.98 billion | $80.53 million |
| 2015 | $1.76 billion | $1.15 billion |

### HOSPITALS AND HEALTH SYSTEMS

Last year featured several notable settlements involving hospitals resolving FCA allegations. The majority of these settlements related to allegations involving improper physician compensation and billing for medically unreasonable or unnecessary procedures.

***Physician Compensation.*** Perhaps the most noteworthy settlement events last year were the significant number of settlements involving physician compensation. Remarkably, records for physician compensation settlements were set and broken within a several week span. The wave of these settlements began in September 2015, when DOJ announced a $25 million settlement resolving allegations that Columbus Regional Healthcare System paid excessive compensation to a referring physician. Just weeks later, DOJ announced a record-breaking $69.5 million physician compensation settlement with North Broward Hospital District to resolve similar allegations. That record lasted less than one week, as DOJ almost doubled the Broward settlement when it announced a $118.7 million settlement with Adventist Health Systems involving physician compensation issues. In October 2015, Tuomey Healthcare Systems resolved a $237 million judgment against it for improperly compensating referring physicians. That settlement called for Tuomey to pay $72.4 million and be acquired by Palmetto Health. To end the year, DOJ announced a final settlement of $9.8 million paid by Memorial Health Inc. in Savannah, Georgia, to resolve allegations that Memorial paid physicians above fair market value compensation that took into account referrals to the hospital. In each of these announcements, DOJ stressed that physician compensation arrangements will remain a top enforcement priority.

16. http://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015.
17. *See id.*

***Medically Unnecessary Procedures.*** Another theme found in several substantial settlements during the past year involved allegations of medically unnecessary procedures. These settlements focused on both hospitals and laboratories and emphasized invasive procedures involving the heart or spine. Yet, the largest settlement resolved allegations relating to lab testing. Millennium Health LLC, one of the nation's largest drug-testing laboratories, agreed to pay $256 million to resolve allegations that it billed for medically unnecessary lab testing and for providing free test cups to physicians in exchange for referrals. The government characterized Millennium's failure to tailor tests to individual patients' needs as a problematic "standing order" that caused unnecessary testing.

## LONG-TERM CARE

Long-term care providers, including hospice providers, skilled nursing facilities and home health companies, continued to face intense enforcement scrutiny in the past year. The increase in settlements across these industries demonstrates that DOJ continues to view long-term care providers as high-priority enforcement targets.

***Hospice Providers.*** The number of hospice settlements increased substantially last year. After a handful of hospice settlements in 2014, DOJ reached settlements with at least nine hospice providers in FY 2015 in almost as many different federal districts. Most of these cases involved allegations that providers had billed Medicare for hospice services for patients who were not eligible for hospice care or had submitted claims for higher levels of care than were appropriate. Other cases, however, involved claims that the providers failed to meet certain conditions of payment, such as following patients' plans of care with regard to the number of nurse visits per week, or failed to document a valid basis for the initial start of hospice care and/or subsequent hospice coverage.[18]

***Skilled Nursing Facilities.*** SNF settlements included several record-setting cases involving violations of the Anti-Kickback Statute ("AKS"). Last June, in the largest settlement involving alleged violations of the AKS by a SNF, Hebrew Home Health Network paid $17 million and entered a five-year Corporate Integrity Agreement ("CIA") to resolve allegations that it provided improper payments to its medical directors in exchange for referrals of Medicare SNF patients. Earlier in the year, Regent Management Services resolved allegations that it received kickbacks from ambulance companies in exchange for awarding rights to Medicare and Medicaid transport referrals, which is believed to be the first settlement to hold accountable medical institutions rather than ambulance companies involved in these types of "swapping" arrangements.[19]

A number of other settlements involving SNFs included allegations of medically unnecessary services. These cases alleged that providers manipulated patients' Resource Utilization Group ("RUG") levels, such as by providing lower levels of care after the initial assessment reference period, by placing patients in the highest RUG level unless it was shown that patients could not tolerate such therapy, arbitrarily shifting therapy minutes between therapy disciplines to meet RUG targets, and recording rounded or estimated minutes instead of the actual amount of therapy provided. Other SNF settlements included allegations that a facility failed to obtain required physician certifications or recertifications or failed to provide patient care activities reflected in patient records or as required by physician orders.[20]

***Home Health Companies.*** Enforcement activity also remained robust in the home health context. FCA settlements with home health providers involved a wide range of issues, including billing for medically unnecessary services, AKS violations, failure to comply with requirements such as completing initial certification and "face-to-face" assessments, and billing for services provided by an individual excluded from federal and state healthcare programs.[21]

## PHARMACEUTICALS AND MEDICAL DEVICE COMPANIES

Pharmaceutical and medical device industries were also targets for government enforcement last year. Several settlements resolved allegations that companies marketed their products for uses that were not approved by the Food and Drug Administration ("FDA") or pharmacies and practitioners received kickbacks in exchange for increasing certain prescriptions. Most notably, Novartis agreed to pay $390 million to settle allegations that it provided unlawful rebates to specialty pharmacies in order to boost prescription refills for Novartis products. The settlement also requires Novartis to extend an existing CIA for five years and add more burdensome provisions to that agreement.

18. *See* Appendix A.
19. *Id.*
20. *Id.*
21. *Id.*

# ISSUES TO WATCH

**There are a number of key issues that will drive the government's enforcement efforts in the coming year and that will have a significant impact on how healthcare fraud matters are pursued by relators asserting FCA claims and are defended on behalf of healthcare providers.**

**Individual Liability**

In late 2014, DOJ's Criminal Division announced its increased "commitment to criminal investigations and prosecutions that stem from allegations in [FCA] lawsuits."[22] DOJ explained that the Criminal Division had "implemented a new procedure so that all new *qui tam* complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed." Given the number of criminal convictions that have originated from the investigation of the allegations set forth in civil *qui tam* lawsuits, DOJ's announcement of its increased focus on *qui tam* lawsuits as a source for the investigation of criminal wrongdoing was noteworthy.

Building on that announcement, the Yates Memo provided new guidance that outlined DOJ's increased focus on individual accountability during civil and criminal investigations of corporate wrongdoing.[23] The principles announced in the Yates Memo serve as the basis for revisions to the U.S. Attorney's Manual ("USAM") – particularly the section outlining the Principles of Federal Prosecution of Business Organizations – released November 16, 2015.[24]

The Yates Memo outlines six "key steps" to guide DOJ's investigations of corporate misconduct:

1. As a "threshold requirement" to receiving any cooperation credit in civil or criminal matters, corporations must provide all relevant facts relating to the individuals responsible for or involved in the corporate misconduct, regardless of their position in the company.

2. Prosecutors are instructed to "focus on individuals from the inception of the investigation."

3. Continuing with DOJ's focus in recent years on facilitating coordination between DOJ attorneys handling criminal and civil matters, the Yates Memo directs those attorneys involved in corporate investigations to be in routine communication with each other.

4. "Absent extraordinary circumstances" resolutions with companies may not provide protection to individuals from criminal or civil liability, such as through agreements to dismiss charges against or provide immunity for individual officers or employees.

5. Resolutions with corporate targets should not be obtained without a clear plan to resolve related individual cases within the statute of limitations period and any declinations regarding individuals should be clearly memorialized.

6. In determining whether to bring suit against an individual, civil attorneys must evaluate factors beyond the individual's ability to pay.

The Yates Memo formalizes a message DOJ officials have been clearly forecasting during the last several years; namely, that individuals responsible for corporate wrongdoing will be held accountable. Furthermore, most of the principles outlined in the Yates Memo and accompanying changes to the USAM remain consistent with DOJ's prior procedures and expectations relating to the investigation and prosecution of white collar cases. Nevertheless, the Yates Memo will impact the considerations companies must make in conducting their investigations and responding to evidence of wrongdoing.

22. http://www.justice.gov/opa/speech/remarks-assistant-attorney-general-criminal-division-leslie-r-caldwell-taxpayers-against.
23. http://www.justice.gov/dag/file/769036/download.
24. http://www.justice.gov/usam/usam-9-28000-principles-federal-prosecution-business-organizations#9-28.720 (revised Nov. 16, 2015).

Most significantly, the Yates Memo changes the manner in which the thoroughness of a factual disclosure is evaluated for cooperation credit by mandating that a company identify all individuals "involved in and responsible for" the wrongdoing. DOJ's expectation that companies disclose all factual information is not novel; as Ms. Yates herself recently put it, "[w]hat is new is the consequence of not" disclosing all relevant facts about individuals. She further explained, "[i]n the past, cooperation credit was a sliding scale of sorts and companies could still receive at least some credit for cooperation, even if they failed to fully disclose all facts about individuals. That has changed now."[25]

This distinction is particularly important for companies that submit claims to the federal government, and thus, face scrutiny under the FCA. Notably, the FCA was the only statute explicitly referenced in the Yates Memo, as it noted DOJ's position that full disclosure of all facts regarding individuals is required to establish "full cooperation" that may qualify a defendant for reduced damages under the FCA.

In determining the extent to which a company intends on cooperating with a government investigation, the company must be mindful that DOJ may view any efforts of cooperation as "coming up short," if the company is not willing to identify the individuals relevant to the misconduct. Consequently, the thoroughness of the disclosure has not only become a threshold issue for DOJ in evaluating a company's cooperation, but may become the primary consideration for companies in developing their position with regard to cooperation in an investigation.

**The Future of the FCA's Implied Certification Theory of Falsity**

In December 2015, the U.S. Supreme Court granted the petition for writ of *certiorari* in ***Universal Health Services, Inc. v. Escobar*** and will consider whether and to what extent the implied certification theory is a viable theory of falsity under the FCA.[26] This case undoubtedly will be one of the most closely watched FCA cases to be argued before the Supreme Court since the 1986 amendments to the FCA.

> "The rules have just changed. Effective today, if a company wants any consideration for its cooperation, it must give up the individuals, no matter where they sit within the company."
>
> *Deputy Attorney General Sally Quillian Yates*

In the absence of a statutory definition of "falsity," courts have grappled with how to define the FCA's reach in determining what constitutes a false or fraudulent claim. To this end, a number of courts have fashioned distinctions between "factually" false and "legally" false claims and have further subdivided "legally" false claims based on whether those claims are premised on "implied" or "express" certification of compliance with conditions of payment.[27] To complicate things further, there is a division among some courts regarding whether the conditions of payment upon which an implied certification theory of liability must be expressly identified as such.[28] Still other courts are yet to have adopted such distinctions or have rejected the foregoing distinctions in their entirety.[29] Given the wide divergence of views on this issue, the Supreme Court's willingness to consider the viability of the implied certification theory of liability is significant.

In the underlying opinion, the First Circuit considered whether a mental health provider's failure to meet certain state regulations rendered claims submitted by the provider false for purposes of the FCA. The district court had dismissed the relators' complaint in its entirety and in doing so, drew a distinction between requirements imposed on providers as preconditions to reimbursement and those imposed as preconditions of participation in the program in the first instance. In reversing the district court's dismissal of the relators' FCA claims, the First Circuit found that any distinction between a condition of participation

25. http://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-american-banking-0.
26. ___ S. Ct. ___, 2015 WL 4078340 (Dec. 4, 2015).
27. *See, e.g., U.S. ex rel. Conner v. Salina Reg'l Health Ctr.*, Inc., 543 F.32d 1211, 1217 (10th Cir. 2008).
28. *Compare Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); Mikes v. Straus, 274 F.3d 687, 702 (2d Cir. 2001), with *U.S. ex rel. Hutcheson v. Blackstone*, 647 F.3d 377, 386-88 (1st Cir. 2011); *U.S. ex rel. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015); *U.S. ex rel. Davis v. SAIC*, 626 F.3d 1257, 1269-70 (D.C. Cir. 2010).
29. *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015); *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010).

and a condition of payment was irrelevant to the analysis. Rather, the First Circuit concluded that the relator had adequately pleaded falsity despite the fact that none of the regulations at issue implicated conditions of payment. In doing so, the First Circuit reiterated its prior holding in ***Hutcheson*** that preconditions of payment may be found in sources such as statues, regulations and contracts and "need not be expressly designated." To this end, the inquiry is "fact intensive" and "context specific" and requires a "close reading of the foundational documents, or statutes and regulations" at issue.[30]

Wider acceptance of the First Circuit's approach would open the door for relators to premise FCA claims on virtually any regulatory violation given the "fact intensive" inquiry required by ***Hutcheson*** and ***Escobar***. Whether the Supreme Court outright rejects implied certification as a basis of FCA liability or merely limits its use to situations where the regulation expressly preconditions payment on compliance, either result would provide some level of comfort for healthcare providers given the "blunt instrument" the FCA has become in policing regulatory violations that otherwise would be left to administrative oversight.[31]

> "Unlawful financial arrangements between health care providers and their referral sources raise concerns about physician independence and objectivity. Patients are entitled to be sure that the care they receive is based on their actual medical needs rather than the financial interests of their physician."
>
> *DOJ Press Release, Adventist Health System Settlement*

**Physician Compensation in the Crosshairs**

A trio of FCA settlements involving physician arrangements announced in September 2015 leave little doubt that such arrangements will continue to be squarely within the government's enforcement crosshairs in the coming year. The allegations in these matters and magnitude of the settlement dollars at issue offer important lessons for hospitals to consider in structuring compliant physician compensation arrangements. These record breaking settlements share common themes: (1) payment of compensation above fair market value ("FMV"), (2) compensation leading to significant losses generated by employed physicians or physician groups, and (3) tracking of referrals as part of compensation analysis. DOJ has noted that the presence of these factors may indicate an arrangement that runs afoul of the Stark Law and the AKS. Relators have recognized this shift and increasingly are alleging impropriety based on above FMV compensation in combination with net losses and referral tracking.

For example, in ***U.S. ex rel. Payne v. Adventist Health System/Sunbelt, Inc.***, Adventist allegedly aggressively purchased physician practices and employed physicians resulting in above-FMV compensation and losses totaling $21.7 million and kept track of the value of referrals received from the employed physicians and pressured underperforming physicians to refer additional patients to their employing hospitals.[32]

Similarly, in ***U.S. ex rel. Reilly v. North Broward Hospital District***, North Broward Hospital District allegedly over-compensated physicians, which resulted in a net loss from the employed physician practice groups of more than $17 million.[33] Broward Health was allegedly able to offset losses through roughly $28 million in profits generated by the resulting physician referrals and secretly tracked referral data to determine whether to provide higher compensation to its physicians.[34]

In ***U.S. ex rel. Barker v. Columbus Regional Healthcare System Inc.***, Columbus Regional Healthcare System paid a physician more than twice the amount of the collections and revenue Columbus Regional received for the services he

30. *Escobar*, 780 F.3d at 512-13.
31. *Mikes*, 274 F.3d at 699.
32. *U.S. ex rel. Payne v. Adventist Health System/Sunbelt, Inc.*, No. 3;12-CV-856-W, (W.D.N.C), Am. Compl. ¶¶ 143 – 146; 150, 170, 189-90.
33. *U.S. ex rel. Reilly v. North Broward Hospital District*, No. 10-60590 (S.D. Fla.), Relator's 3d Am. Compl. ¶¶ 200-05.
34. *Id.* at ¶ 200, 220.

personally performed.[35] The complaint further alleged that "the only way [this compensation arrangement] makes sense is if [Columbus Regional] determined his compensation by indirectly calculating the financial benefits to [Columbus Regional] of the designated health services ("DHS") [the physician] referred to the Defendant."[36]

DOJ has taken the stance that the presence of these factors may be evidence of an arrangement that violates the Stark Law and the AKS. Relators also have been quick to realize this shift and increasingly have premised liability on above FMV compensation, net losses and the tracking of referrals.[37] As this enforcement trend continues, hospitals should carefully scrutinize proposed arrangements with referral sources and ensure that these arrangements are at FMV and supported by a legitimate business need separate from any potential referral revenue.

### Medical Necessity of Long-Term Care Services

The previous year saw the continued trend of an increasing number of FCA cases based on the theory that long-term care services (*e.g.,* skilled nursing, home health or hospice) provided to patients were medically unnecessary, and therefore, the healthcare provider submitted false claims in connection with those services.[38]

The falsity alleged in these cases often turns on contentious reviews of medical records by experts, with the parties arguing over whether proof of an objective falsehood necessary to establish falsity exists. In many cases, however, the intent required to establish a violation of the FCA (actual knowledge, deliberate ignorance or reckless disregard of the truth or falsity of the information) is derived not from any particular patient's medical records, but rather from other business records of the defendant. These records might include budgets or benchmarking relative to future services, or the tracking of performance across a larger population of patients to allow for comparison against prior forecasts.

It is common for plaintiffs in FCA cases to point to a provider's stated "goals" or "benchmarks" as pressure on the provider's employees to provide medically unnecessary services. Not surprisingly, when providers track performance against those goals, benchmarks or budgets, or evaluate employees relative to those standards, such conduct likewise is highlighted as evidence of wrongdoing.

While it may be tempting for a court to allow FCA claims to proceed in the face of such allegations, at least one district court rejected this line of argument during the previous year. In ***U.S. ex rel. Lawson v. Aegis Therapies, Inc.***, DOJ had asserted that a skilled nursing provider knowingly submitted false claims by pointing to the provider's utilization benchmarking and documentation instructions to therapists.[39] The district court recognized that there are very legitimate business reasons for a healthcare provider to create budgets, establish goals and benchmarks, and to evaluate performance relative to the foregoing. As the district court explained, prudent business practices demand tracking of such information in order to evaluate effective delivery of care to patients, staffing needs, patient demographics, relational dynamics among clinicians and the overall business climate.

As more cases proceed against long-term care providers challenging the medical necessity of the care provided to patients, it will be increasingly important for courts to distinguish between legitimate business practices and those practices that actually evidence wrongful conduct.

### Appellate Consideration of Statistical Sampling

Last year, we covered in depth the government's use of statistical sampling to establish liability across a broad universe of claims in FCA cases and in particular, the district court's opinion in ***U.S. ex rel. Martin v. Life Care Centers of America***, in which the district court rejected a motion to exclude the government's expert testimony regarding the intended use of statistical sampling to establish liability over an extrapolated universe of claims. Since that time, a number of other

35. *U.S. ex rel. Barker v. Columbus Regional Healthcare System*, No. 4:12-cv-108 (M.D. Ga.); *U.S. ex rel. Barker v. Columbus Regional Healthcare System*, No. 4:14-cv-304 (M.D. Ga.); *see also* http://www.justice.gov/opa/pr/georgia-hospital-system-and-physician-pay-more-25-million-settle-alleged-false-claims-act-and.
36. *Id.*
37. Unless otherwise noted, the United States did not file a complaint in intervention or otherwise take a position on the sufficiency of the allegations related to potential practice losses and tracking of referrals.
38. *See, e.g., U.S. ex rel. Hayward v. SavaSeniorCare, LLC*, No. 3:11-cv-0821 (M.D. Tenn.), United States' Consolidated Complaint in Intervention, dated Oct. 26, 2015 (Dkt. No. 241); *U.S. ex rel. HCR ManorCare, Inc.*, No. 1:09-cv-00013 (E.D. Va.), United States' Consolidated Complaint in Intervention, dated April 10, 2015 (Dkt. No. 324).
39. 2015 WL 1541491 (S.D. Ga. Mar. 31, 2015).

district courts have considered the issue of whether such evidence may be used to establish liability by either the government or relators.[40]

In the coming year, an appellate court may very well have the first opportunity to consider the use of statistical sampling to establish liability in FCA cases. In ***U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.***, the district court certified two issues for interlocutory appeal to the Fourth Circuit in connection with FCA claims asserted by relators against a chain of nursing homes regarding hospice services provided to patients, including whether relators should be permitted to rely upon statistical sampling to establish liability and damages across a universe of claims and whether the government had an unfettered right to approve or reject a proposed settlement of FCA claims between a relator and defendant.[41]

On the question of sampling, the district court explained that "each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary." As such, consideration of "that question for each of the patients involved in this action is a highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart for each individual patient." In the district court's view, the foregoing rendered the particular case unsuitable for the use of sampling.[42]

Over the government's opposition, the Fourth Circuit agreed to hear both of the issues certified by the district court for interlocutory appeal, and this matter is expected to be heard in mid-2016. It is possible that the Fourth Circuit could avoid the question of statistical sampling by focusing solely on the question of the government's rights relative to proposed FCA settlements; however, we expect that such a result would be unlikely given the fact that the Fourth Circuit agreed to hear both issues on appeal. Healthcare providers should closely watch this appeal, as an appellate decision considering the issue of statistical sampling will have a significant impact on FCA cases involving issues of medical necessity across large numbers of claims.

40. *See U.S. ex rel. Paradies v. Aseracare, Inc.*, 2014 U.S. Dist. LEXIS 167970 (N.D. Ala. Dec. 4, 2014) (denying motion for summary judgment and noting that "[t]he Government has statistical evidence regarding all of the Government's universe of 2,181 claims. Statistical evidence is evidence."); *U.S. ex rel. Guardiola v. Renown Health*, 2015 WL 5123375 (D. Nev. Sept. 1, 2015) (issuing discovery ruling regarding the underlying data universe relevant to relator's use of statistical sampling); *U.S. ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 WL 1926417 (M.D. Fla. Apr. 28, 2015) (granting relator's motion to admit expert testimony based on statistical sampling that had not been undertaken by relator as of the date of the motion).
41. 2015 WL 3903695 (D.S.C. July 6, 2015).
42. *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 15-238 (4th Cir.).

# FALSE CLAIMS ACT UPDATE

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

As in previous years, there continue to be a number of legal developments involving the FCA that will greatly impact the government's enforcement efforts.

## THE FCA'S PUBLIC DISCLOSURE BAR

The FCA's public disclosure bar prevents a relator from filing a *qui tam* complaint based on information previously disclosed to the public, thereby dissuading parasitic lawsuits based on publicly available information. In response to cases expanding the reach of the FCA's public disclosure bar, amendments to the FCA set forth in the Patient Protection and Affordable Care Act ("PPACA") pared back its scope in favor of relators. Since those amendments, courts have worked to define the parameters of the public disclosure bar, including when to apply the amended version of the public disclosure bar, whether the bar as amended by PPACA is no longer jurisdictional in nature, what disclosures are sufficient to trigger the bar, and how a relator can qualify as an "original source" under the statute.

### Whether the Public Disclosure Bar Remains Jurisdictional

Last year, courts again considered whether the public disclosure bar should no longer be considered a jurisdictional bar as a result of PPACA's amendments to the FCA, but instead a basis for dismissal under Rule 12(b)(6). Most courts have continued to conclude that the amended public disclosure bar is no longer jurisdictional in nature.

In ***U.S. ex rel. Osheroff v. Humana, Inc.***, the Eleventh Circuit found that the district court improperly assumed that the amended public disclosure bar was jurisdictional and held that defendants' motion to dismiss should be treated as motion made under Rule 12(b)(6).[43] The Eleventh Circuit stated that the "plain language of the new provision commands this interpretation" because (1) it instructs courts to dismiss an action when the provision applies; (2) Congress removed the prior language that rendered the bar jurisdictional in nature; (3) Congress did not remove similar jurisdictional language from surrounding provisions; and (4) the amended section also provides that the government can oppose dismissal, permitting the case to move forward even if the public disclosure bar would otherwise apply.

Other courts generally reached the same conclusion as was reached in ***Osheroff***.[44] In ***United States v. Sandford-Brown, Ltd.***, however, the Seventh Circuit labeled the amended public disclosure provision as a "jurisdictional bar"[45] and at least one district court in the Seventh Circuit found itself bound by this determination.[46]

Notably, despite the procedural and substantive differences between a jurisdictional bar and the grounds for dismissal under Rule 12(b)(6), in considering documents outside of the complaint for the public disclosure analysis, courts often found any differences to be immaterial.[47]

43. 776 F.3d 805, 810-11 (11th Cir. 2015).
44. *See, e.g., U.S. ex rel. Shea v. Verizon Commc'ns, Inc.*, 2015 WL 7769624, at *5 (D.D.C. Oct. 6, 2015); *U.S. ex rel. Solomon v. Lockheed Martin Corp.*, 2015 WL 6956578, at *1 (N.D. Tex. Nov. 10, 2015); *U.S. ex rel. Moore v. Pennrose Properties, LLC*, 2015 WL 1358034, at *5 (S.D. Ohio Mar. 24, 2015); *U.S. ex rel. Rockey v. Ear Inst. of Chicago, LLC*, 92 F. Supp. 3d 804, 814 (N.D. Ill. 2015).
45. 788 F.3d 696, 703 (7th Cir. 2015).
46. *See Carmel v. CVS Caremark Corp.*, 2015 WL 3962532, at *4 (N.D. Ill. June 26, 2015) ("[B]ecause I am bound by the court's ruling in *Sanford-Brown*, I conclude that I must continue to view the public disclosure bar as jurisdictional in nature, regardless of how other courts of appeals characterize it or how the parties have framed the argument.").
47. *U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 256 (D. Mass. 2015) ("Given that courts are often willing to take judicial notice of matters that are public in nature, the procedural vehicle for seeking dismissal ultimately may not matter all that much."); Osheroff, 776 F.3d at 811 (detailing the extrinsic documents that can be considered for a Rule 12(b)(6) motion and noting "all of the evidence at issue here was properly before the district court, regardless of which Rule 12 standard applies."); *U.S. ex rel. Carter v. Bridgepoint Educ., Inc.*, 2015 WL 4892259, at *3 (S.D. Cal. Aug. 17, 2015) (same); *U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 2015 WL 4577341, at *6 n.4 (D. Mass. July 29, 2015) ("The Court nevertheless notes that since the standard of review for failure to state a claim under Fed. R. Civ. P. 12(b)(6) is similar to that accorded under Fed. R. Civ. P. 12(b)(1), this is largely a distinction without a difference.").

### Whether to Apply the Public Disclosure Bar as Amended by PPACA

Because PPACA narrowed the language of the public disclosure bar in certain respects, whether the public disclosure bar applies and effectively precludes the allegations at issue in an FCA lawsuit sometimes depends on which version of the statute is applied. As such, the determination of which version to apply can have a substantial impact on the success of a defendant's reliance on the public disclosure bar to defeat a relator's FCA allegations. Although some courts in the past have determined which version of the statute to apply based on the date of the filing of the original complaint, the majority approach now seems to entail applying the version of the statute in place when the underlying conduct occurred.

This trend remained last year with the Third Circuit (***U.S. ex rel. Judd v. Quest Diagnostics Inc.***) and Sixth Circuit (***U.S. ex rel. Antoon v. Cleveland Clinic Foundation***) holding that the pre-PPACA version of the public disclosure bar applies where the underlying conduct occurred before the amendment despite the fact that the complaints in those actions were filed after PPACA's enactment.[48] In ***U.S. ex rel. Bogina v. Medline Industries, Inc.*** and ***U.S. ex rel. Shea v. Verizon Communications, Inc.***, the underlying conduct straddled PPACA's enactment, and the district court in both cases applied the earlier version of the public disclosure bar to conduct before PPACA's enactment and the amended version of the bar to conduct post-dating the enactment.[49]

Courts continued to grapple with the question of what constitutes the "underlying conduct" for purposes of deciding which version of the public disclosure bar to apply. For example, in ***U.S. ex rel. Wilhelm v. Molina Healthcare,*** the district court held that the relevant conduct for determining the version of the public disclosure bar to be applied was the submission of the alleged false claims.[50] Yet, in ***U.S. ex rel. Carter v. Bridgepoint Education, Inc.***, where the alleged submission of false claims spanned both versions of the public disclosure bar, the district court only applied the pre-PPACA version because "the majority of and the most important aspects of the allegedly fraudulent conduct" occurred before the amendment—including the public disclosures and the signature of a program agreement.[51] In ***U.S. ex rel. Moore v. Pennrose Properties, LLC***, the district court held that "the truly determinative factor" is the date of the "fraudulent conduct" on which the action is based, "[a]lthough the date of the filing of a complaint may be relevant to the question" of which version applies.[52]

Some courts applied the amended version of the public disclosure bar to conduct post-dating *and* pre-dating PPACA's enactment. In ***Sanford-Brown***, where the complaint was filed after PPACA's enactment, the Seventh Circuit stated that the amended version of the public disclosure bar "controls" the entirety of the case which straddled PPACA's enactment.[53] A similar result was reached in ***U.S. ex rel. Winkelman v. CVS Caremark Corp.***, where the district court stated only that because "[j]urisdiction is determined based on whether it existed at the time the plaintiff filed the original complaint," the amended version applies to the entire lawsuit (even though the court subsequently observed that the amended version is not a jurisdictional bar).[54]

### When Are Disclosures Sufficient to Bar FCA Allegations?

Courts continued a trend of specifically defining how or to whom information must be disseminated in order to constitute a "public disclosure," often narrowing the scope of the public disclosure bar, which marked a shift away from decisions favorable to providers toward a more nuanced and specific application of the public disclosure bar. Determining what disclosures are sufficient to bar FCA allegations most often arose in the context of analyzing disclosures made to government or regulatory entities.

***U.S. ex rel. Wilson v. Graham County Soil & Water Conservation Dist.***, a case that has been before the Fourth Circuit three times and the U.S. Supreme Court twice, involved allegations of fraud against the government with respect

48. 2015 WL 5025447, at *2-3 (3d Cir. Aug. 26, 2015); 788 F.3d 605, 614-15 (6th Cir. 2015).
49. 2015 WL 1396190, at *2 (N.D. Ill. Mar. 24, 2015); 2015 WL 7769624, at *5 (D.D.C. Oct. 6, 2015).
50. 2015 WL 5562313, at *6-7 (S.D. Fla. Sept. 22, 2015).
51. 2015 WL 4892259, at *3 (S.D. Cal. Aug. 17, 2015).
52. 2015 WL 1358034, at *5-6 (S.D. Ohio Mar. 24, 2015).
53. *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 703 (7th Cir. 2015). One district court in the Seventh Circuit subsequently minimalized the import of Sanford-Brown, noting that prior precedent in the Seventh Circuit and elsewhere holds that "the version of the statute in force when the events underlying the suit took place controls," in applying the pre-PPACA version of the public disclosure bar to conduct occurring before the amendment. *U.S. ex rel. Bellevue v. Universal Health Servs. of Hartgrove Inc.*, 2015 WL 5873292, at *2-3 (N.D. Ill. Oct. 5, 2015).
54. 2015 WL 4577341, at *9-10 (D. Mass. July 29, 2015); *see also U.S. ex rel. Rockey v. Ear Institute of Chicago, LLC*. 92 F. Supp. 3d 804, 812, 814 (N.D. Ill. 2015) (applying amended version even where conduct "presumably" went back to October 2008).

to an Emergency Watershed Protection Program.[55] The district court found that the relator's allegations were previously publicly disclosed in an audit report prepared by county auditors and in an investigation report prepared by the USDA and dismissed the relator's complaint.[56] The Fourth Circuit reversed the district court on the grounds that the reports at issue were not "publicly" disclosed because they were disclosed only to government agencies. The Fourth Circuit held that "a 'public disclosure' requires that there be some act of disclosure *outside the government*."[57] The Fourth Circuit noted that "the Government is not the equivalent of the public domain" and that "nothing in the record suggests that either report actually reached the public domain."[58] Notably, the Fourth Circuit clarified that the fact that the reports were accessible to the public through public information laws did not affect its analysis because the reports were never actually requested by or disclosed to the public.[59]

Citing ***Wilson***, the Sixth Circuit issued a similar opinion three weeks later in ***U.S. ex rel. Whipple v. Chattanooga-Hamilton County Hospital Authority***.* In that case, the district court granted partial summary judgment in favor of the defendant on the grounds that the relator's allegations were previously publicly disclosed through a government audit and investigation.[60] The Sixth Circuit reversed the district court, holding that disclosure of allegations only to the government or its contractors was not sufficiently "public" to trigger the public disclosure bar. The Sixth Circuit reasoned that the relevant disclosures were made only to the government, its agents and the defendant's own consultant, which were subject to confidentiality obligations to the defendant, and that the public disclosure bar requires a broader disclosure to the public. According to the Sixth Circuit, to hold otherwise would be to render the term "public" superfluous.[61]

In ***U.S. ex rel. Little v. Shell Exploration & Production Co.***, two federal auditors filed a *qui tam* suit based on allegations learned during the course of their official duties.[62] The district court granted summary judgment for a second time in favor of the defendants on public disclosure grounds, holding that the "substance" of the *qui tam* complaint previously was publicly disclosed through public comments, administrative and court decisions, and a government audit and investigation.[63] The Fifth Circuit reversed the district court, re-affirming its previous holding in the case that disclosures that were "never disseminated into the public domain" were not "proper subjects for analysis" under the public disclosure bar.[64] Limiting its analysis only to information disclosed beyond the defendants and the government, the Fifth Circuit held that the remaining disclosures did not disclose the substance of the allegations in the relators' *qui tam* complaint.[65]

Although federal appellate courts remain split on the issue of what type of disclosure is sufficient to trigger the public disclosure bar, the opinions in both ***Wilson*** and ***Whipple*** note that the approach adopted by the Seventh Circuit is increasingly becoming an isolated, minority approach.[66] The Seventh Circuit is the only court to hold that disclosure of information to "a competent public official" who has "managerial responsibility" for the type of fraudulent claim alleged is sufficient to bar FCA allegations.[67] But, the Second Circuit has held that disclosure to "innocent employees" of the defendant company—not considered disclosure to the public at large—can suffice as a "public disclosure" for purposes of the FCA.[68] Thus far, the Supreme Court has declined the opportunity to address this circuit split.

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

55. 777 F.3d 691, 693 (4th Cir. 2015).
56. *Id.* at 694-95.
57. *Id.* at 697 (quoting *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 728 (1st Cir. 2007), abrogated on other grounds, Allison Engine v. *U.S. ex rel. Sanders,* 553 U.S. 662 (2008)).
58. *Id.* at 697.
59. *Id.* at 698.
60. 782 F.3d 260 (6th Cir. 2015).
61. *Id.* at 268-69.
62. 602 F. App'x 959, 962-63 (5th Circuit 2015).
63. 2014 WL 869326, *1-3 (S.D. Tex. Mar. 5, 2014).
64. 602 F. App'x at 974.
65. *Id.* at 966-74. After reversing the district court for the second time with respect to the public disclosure issue, the Fifth Circuit remanded the case with direction to the Chief Judge of the Southern District of Texas to reassign the case to a different district judge. *Id.* at 976.
66. *See Wilson,* 777 F.3d at 697; *Whipple*, 782 F.3d at 268.
67. *See U.S. ex rel. Mathews v. Bank of Farmington*, 166 F.3d 853, 861 (7th Cir. 1999), *overruled on other grounds, Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009).
68. *See U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 322-23 (2d Cir. 1992).

**When Is a Relator an Original Source?**

Last year, courts continued to clarify the requirements for a relator to be considered an original source, and thus exempted from the public disclosure bar, under the FCA's pre-PPACA and post-PPACA versions. In these cases, courts focused, in particular, on the requirements that a relator have "direct and independent knowledge of the information on which the allegations are based" (pre-PPACA) and "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" (post-PPACA).

The Third and Sixth Circuits made significant rulings regarding the type of knowledge that a relator must possess to have "direct knowledge" to qualify as an original source under the pre-PPACA statute. In ***U.S. ex rel. Antoon v. Cleveland Clinic Foundation***, the Sixth Circuit held that "proof of first-hand knowledge of fraud" is "not a necessary component" to establishing direct knowledge and that "direct knowledge is knowledge gained by relator's own efforts and not acquired from labor of others."[69] This case-by-case determination is controlled by the character of the relator's discovery and investigation. The Sixth Circuit found that the relator did not qualify as an original source because the "heart" of his FCA claim was founded on a review of medical records and he could only "speculate" about whether a physician was personally involved in the surgery that formed the basis of his fraud allegations. "Mere suspicion" that fraudulent activity resulted based on a review of medical records did not entitle the relator to original source status. In ***United States v. Express Scripts***, the Third Circuit held that the relator lacked direct knowledge where his allegations arose only from conducting an "eyeball comparison of two publicly available price listings" and relying on his "years of experience" in the pharmaceutical industry.[70]

In interpreting when a relator "materially adds" to publicly disclosed information under the amended FCA, courts have focused not on the nature of the relator's discovery and investigation, but instead on qualitatively comparing a relator's allegations and the publicly disclosed information. This generally has narrowed the circumstances under which a relator qualifies as an original source.

In ***Osheroff***, the Eleventh Circuit provided its first interpretation of when a relator "materially adds" to publicly disclosed information.[71] The *qui tam* suit alleged FCA liability based on violations of the AKS as a result of clinics providing free exercise classes, transportation and other perks to patients. Public disclosures detailed many of these perks, but the relator contended he was an original source because he added details about the frequency and type of services provided—showing they were more than nominal in value—and because he conducted his own investigation of the clinics' programs. The Eleventh Circuit disagreed, explaining that the relator's information did not "materially add" to the publicly disclosed information because the disclosures "were already sufficient to give rise to an inference that the clinics were providing illegal remuneration to patients."

Similarly, in ***U.S. ex rel. Rockey v. Ear Institute of Chicago***, the district court rejected the relator's argument that he qualified as an original source by alleging "numerous detailed examples" of improper physician billing not previously disclosed, because the "isolated examples" did not materially add to the "comprehensive mea culpa" letter sent to Medicare by one of the defendant's physicians.[72]

In ***U.S. ex rel. Winkelman v. CVS Caremark Corp.***, the relators argued they were original sources because they provided details on how an alleged scheme to inflate usual and customary prescription drug prices was carried out, including that a relator "saw first-hand how CVS implemented" a generic drug discount program and that during an audit a relator "observed that CVS' usual and customary prices were higher" than the program prices.[73] The district court held that the relators failed to "materially add" to the public disclosures because their first-hand observations did not constitute "qualitatively different information" from that already publicly disclosed "concerning the nature" of the alleged drug pricing scheme—specifically, the fact that CVS was not charging the government the generic drug discount program prices,

69. 788 F.3d 605, 614-15 (6th Cir. 2015).
70. 602 Fed. App'x 880, 882 (3rd Cir. 2015).
71. 776 F.3d 805, 815 (11th Cir. 2015).
72. 92 F. Supp. 3d 804, 817 (N.D. Ill. 2015).
73. 2015 WL 4577341, at *9-10 (D. Mass. July 29, 2015).

and thus was not treating the program prices as usual and customary prices, had already been publicly reported in the media and in congressional hearings and reports.

Finally, courts diverged on the question of whether a relator's status as an original source is temporally limited to when her "direct and independent knowledge" begins and ends. In ***U.S. ex rel. Galmines v. Novartis Pharmaceuticals Corp.,*** the district court held there is no such strict time limitation as "the limitation on a relator's ability to recover for additional periods of time [for the same underlying scheme] is not the original source bar but the pleading requirements and the discretionary powers of the court over discovery."[74] The district court reasoned that the time period of the fraud is not a "material fact" for the FCA's first-to-file bar, so it would "bedevil judicial reasoning" to conclude it is "nonetheless a critical element for original-source purposes."

Yet, in ***U.S. ex rel. Gravett v. Methodist Medical Center***, the district court found that the relator had direct and independent knowledge regarding the fraudulent scheme during the time of his employment with the defendant, but that he was not an original source outside that time period because "it is not possible for [the relator] to have direct knowledge of the specific patients and treatments provided after his termination from employment[,] as he would not have been present to personally observe these situations, and he offers no other basis" to support the finding that he had direct knowledge of such situations.[75]

## DEVELOPMENTS IN FCA PLEADING STANDARDS

### Pleading with Particularity under Rule 9(b)

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

#### *Pleading Actual Claims*

The question of whether relators must plead particular facts regarding actual false claims continues to divide courts. Some courts, including the First, Fourth and Sixth Circuits, have taken the view that a relator must identify and plead the specific details of actual false claims.[76] The Third, Fifth, Seventh and Ninth Circuits, by contrast, have held that a complaint may satisfy the requirements of Rule 9(b), if it alleges a fraudulent scheme to submit false claims, so long as the allegations contain "reliable indicia" to support a "strong inference" that false claims were submitted.[77] Courts within the Eighth, Tenth and Eleventh Circuits have decided cases that have appeared to reach different conclusions on this question.[78]

***Cases Requiring the Identification of Specific False Claims.*** In the past, the First Circuit has shifted between requiring the identification of a specific false claim and applying a more flexible standard.[79] Last year, the First Circuit explained its approach as requiring "relators to connect allegations of fraud to *particular* false claims for payment, rather than a fraudulent scheme in the abstract."[80] In ***U.S. ex rel. Escobar v. Universal Health Services, Inc.***, the First Circuit held the relators had "succeeded in linking their allegations of fraud to specific claims for payment" by alleging "twenty-seven separate dates on which claims were submitted in connection with [a specific patient's] care, each time including the relevant billing codes, amount invoiced, and the name of the [defendant's] staff member who provided the treatment for which reimbursement was sought." Furthermore, the First Circuit determined the allegations with regard to one patient were sufficiently particular to allow other allegations to proceed that pertained to claims for services rendered to other

74. 88 F. Supp. 3d 447, 454-55 (E.D. Pa. 2015).
75. 82 F. Supp. 3d 835, 840-41 (C.D. Ill. 2015).
76. *See, e.g., U.S. ex rel. Escobar v. Universal Health Services, Inc.* 780 F.3d 504, 515 (1st Cir. 2015); *U.S. ex rel. Nathan v. Takeda Pharm. N. Am. Inc.*, 707 F. 3d 451, 457 (4th Cir. 2013); *U.S. ex rel. Bledsoe v. Cmty. Health Sys.*, Inc., 501 F.3d 493, 504 (6th Cir. 2007).
77. *See Forglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 155-57 (3d Cir. 2014); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009); Ebeid v. Lungwitz, 616 F.3d 993, 998-99 (9th Cir. 2010).
78. *Compare U.S. ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 560 (8th Cir. 2008) (same), *and U.S. ex rel. Sikkenga v. Regence BlueCross BlueShield*, 472 F.3d 702, 727-28 (10th Cir. 2006) (same), *and Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009) (same) *with U.S. ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 916-19 (8th Cir. 2014) (same), *and U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010) (same), *and U.S. ex rel. Mastej v. Health Mgmt. Assocs.*, 591 Fed. Appx. 693, 703 (11th Cir. Oct. 30, 2014) (same).
79. *Compare U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004) (applying strict standard) abrogated on other grounds, Allison Engine Co. v. *U.S. ex rel.* Sanders, 553 U.S. 662 (2008), *with U.S. ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009) (applying flexible standard).
80. 780 F.3d at 515 (emphasis added).

patients by the relevant staff members.[81] It appears that the First Circuit now will require relators to identify specific claims to satisfy Rule 9(b), but these representative claims will enable allegations regarding other claims to proceed, if they are rendered fraudulent by the same alleged scheme.[82]

A number of district courts have dismissed cases this year for failure to plead a specific false claim. For example, in ***U.S. ex rel. Prather v. Brookdale Senior Living Communities., Inc.,**** the district court dismissed the relator's amended complaint, which included only "generally delineated circumstances" of individual patients' receipt of home health services. The district court explained the complaint lacked details about the basis of the claim for payment, the form or method used to submit the claim, any corporate authorization for the claim and any amount paid to the defendants by the government in response to the claims.[83]

Some of the courts that dismissed cases due to the relators' failure to plead specific details of false claims acknowledged that certain circumstances may call for a relaxed pleading standard, such as "when relevant facts are not accessible to the pleader."[84] Nevertheless, highlighting the narrow circumstances in which relaxing the standard would be appropriate, these courts all refused to apply a more lenient standard in the particular cases.[85]

***Cases Requiring Only a Reliable Indicia of the Submission of False Claims.*** In other cases, courts have applied a more lenient standard for Rule 9(b) and have allowed the pleading of the submission of a false claim by providing reliable indicia that a claim was submitted, rather than by requiring the identification of a specific false claim.

Relators in a pair of cases from the Middle District of Florida succeeded in satisfying Rule 9(b) under the relaxed standard. In ***U.S. ex rel. Space Coast Medical Associates, LLP***, the district court held relators had pleaded "sufficient indicia of reliability that claims were submitted" by alleging "particularized knowledge of the Defendants' billing process and of alleged fraudulent bills," as well as "individual Medicare patients who received treatment."[86] In ***U.S. ex rel. Bingham v. Baycare Health System***, the district court applied even more lenience. In a case based on alleged Stark Law and AKS violations, the district court held that Rule 9(b) was satisfied when the relator alleged only the fraudulent scheme and, relying on Centers for Medicare & Medicaid Services ("CMS") data, the defendant's revenue from Medicare claims and the names of the physicians at issue. The district court explained the lenient standard was appropriate because the nature of the alleged fraud did not rely on the contents of particular bills due to the fact that the improper relationships tainted every claim submitted as a result of referrals at issue.[87]

Other courts applied the relaxed standard, but nonetheless rejected the relators' complaints as insufficiently pleaded. In ***U.S. ex rel. Judd v. Quest Diagnostics Inc.***, the Third Circuit announced its "adoption" of the "more nuanced reading of the heightened pleading requirements of Rule 9(b)" and held that the relator's allegations failed because the relator provided "no reason to believe" that the defendant "submitted claims for Medicare reimbursement in connection with its kickbacks."[88] Similarly, in ***U.S. ex rel. Britton v. Lincare Inc.***, the Eleventh Circuit issued a per curiam opinion affirming the district court's dismissal of the relator's complaint for failure to plead fraud with particularity under Rule 9(b). The Eleventh Circuit explained the relator was "unable to muster any facts

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

81. *Id.* (emphasis added).
82. *See* also *U.S. ex rel. Cieszyski v. LifeWatch Servs., Inc.*, 2015 WL 6153937 at *3 n.5, 12 (N.D. Ill. Oct. 19, 2015) ("specific examples," which included patient names, procedure dates and the claim amounts, names of relevant staff members, or allegations that payment was received, but concerned only submissions to Medicare were sufficient to allow claims to proceed regarding other government insurers because "the alleged fraudulent scheme is identical").
83. 2015 WL 6812581, at *16-18 (M.D. Tenn. Nov. 5, 2015); *see also U.S. ex rel. Prather v. Brookdale Senior Living Cmtys.*, Inc.*, 2015 WL 1509211, at *14 (M.D. Tenn. Mar. 31, 2015 (dismissing original complaint); *U.S. ex rel. McFeeters v. N.W. Hosp.*, 2015 WL 328212, at *3-4 (Jan. 23, 2015 M.D. Tenn.); *U.S. ex rel.* Johnson v. E-Med Source of Fla., Inc. 2015 WL 6742059, at *3 (M.D. Fla. Nov. 3, 2015); *U.S. ex rel. Chorches v. Amer. Med. Response, Inc.*, 2015 WL 6870025, at *9-11 (D. Conn. Nov. 6, 2015).
84. 2015 WL 6870025, at *11; *see also U.S. ex rel. Hagerty v. Cyberonics*, 95 F. Supp. 3d 240, 266-70 (D. Mass. Mar. 31, 2015) (when defendant allegedly caused third parties to file false claims, factual and statistical evidence may be used to strengthen inference of fraud beyond a possibility); 2015 WL 328212*, at *4 (noting that relaxing the standard is appropriate when relator "cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that she cannot produce such allegations is not attributable to her own conduct").
85. *See, e.g.*, 2015 WL 328212, at *4 (M.D. Tenn. Jan. 23, 2015) (refusing to apply relaxed standard when patient pleaded first-hand knowledge of the allegedly fraudulent conduct, but did not show "any involvement with Defendants' billing or claims submission processes.").
86. 94 F. Supp. 3d 1250, 1258 (M.D. Fla. Feb. 6, 2015).
87. 2015 WL 4878456, at *4, 5 (M.D. Fla. Aug. 14, 2015).
88. 2015 WL 5025447, at *5 (3d Cir. Aug. 26, 2015).

tending to show that Lincare asked the Government to pay amounts it does not owe" because he "disclaimed any knowledge of [the defendant's] billing practices" and did not allege the "who," "what," "where," "when," and "how" of any fraudulent submissions.[89]

### *Pleading the Circumstances of Fraud*

A number of courts continued to scrutinize pleadings to determine whether they sufficiently pleaded the circumstances of a fraudulent scheme – the "who, what, when, where, and how" of the alleged fraud. While analyzing the circumstances of fraud is necessarily a case-by-case analysis, courts applied decidedly different approaches to examining certain components of a fraudulent scheme, including the "who" and "when" requirements.

Several cases demonstrated the nuances in pleading the appropriate "who" with particularity in FCA complaints against a corporation. In ***United States v. Sanford-Brown, Ltd.***, which involved claims against a college and its corporate parent, the Seventh Circuit held that allegations against the "Defendants" in general were insufficient to allow claims against the parent company to proceed.[90] With regard to the particularity required when identifying individuals who were involved in perpetuating a fraud alleged against a corporation, district courts reached different results. In ***U.S. ex rel. Modglin v. DJO Global Inc.***, a district court held it was insufficient to identify relevant actors as employees or "personnel" of the defendant company; rather, "[a]t a minimum, relators must identify the [relevant individuals] by their job titles and/or responsibilities."[91] In ***U.S. ex. rel. Cieszyksi v. LifeWatch Services, Inc.***, however, the district court held the complaint sufficiently identified "LifeWatch generally as the entity responsible" and did not need to "identify by name or position each person involved in submitting the alleged false claims."[92]

Several courts also drew distinctions with respect to the particularity required in pleading "when" a fraudulent scheme occurred. While one district court noted that a plaintiff can "plead a reasonable range of dates" to survive Rule 9(b),[93] another district court held that a relator did not sufficiently plead "when" the relevant claims were submitted even though he asserted "defendants submitted nearly $4 million of false invoices to the government between 2009 and 2011."[94]

Finally, courts also addressed the requirements for pleading the "what" and "how" components of FCA allegations based on a failure to comply with applicable regulations or guidelines. For example, the Fifth Circuit upheld the dismissal of claims against a defense contractor based on an implied certification theory when the relator alleged only that the defendant violated Federal Acquisition Regulation and Defense Federal Acquisition Regulation provisions but failed to specify which provisions were incorporated into the relevant contract.[95] Similarly, in ***U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.***, a district court upheld a dismissal of FCA claims based on allegations of off-label marketing when the "allegations only specify off-label uses which were medically accepted indications" during the relevant time periods.[96]

## Developments Concerning Falsity and Knowledge

Courts have continued to grapple with questions of falsity, materiality and knowledge with respect to the assertion of FCA claims. The resolution of these questions is often determinative of whether the relator can pursue FCA allegations against a healthcare provider. As discussed above, developments regarding falsity in particular should be closely watched in the coming year.

### *Use of Statistical Sampling to Establish Falsity*

Following the landmark ruling in ***U.S. ex rel. Martin v. Life Care Centers of***

89. 2015 WL 8526356, at *2-3 (11th Cir. Dec. 10, 2015).
90. 788 F.3d 696, 705-06 (7th Cir. 2015) ("By failing to allege specific facts beyond the single allegation that [the parent corporation] entered into a [Program Participation Agreement], the first amended complaint fails to plead sufficient facts to notify [the parent] of the circumstances of the alleged participation in the scheme."); *see also U.S. ex rel. Modglin v. DJO Global Inc.*, 2015 WL 4111709, at *18 (C.D. Cal. May 8, 2015) (rejecting allegation that "fails to distinguish between defendants").
91. 2015 WL 4111709, at *17 (C.D. Cal. May 8, 2015).
92. 2015 WL 6153937, at *11. Cf. *U.S. ex rel. Gates v. Austal, U.S.A. LLC*, 2015 WL 5782284, at *5 (S.D. Ala. Aug. 10, 2015) (complaint dismissed for failure to identify specific claim when relators did not identify who submitted relevant cost reports and invoices).
93. 2015 WL 4111709, at *18.
94. *U.S. ex rel. Gage v. Davis S.R. Aviation, LLC*, 2015 WL 4237682, at *4 (5th Cir. July 14, 2015).
95. *Id.* at *3.
96. *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 519 (E.D. Penn. 2015).

***America, Inc.***,[97] which we discussed at length last year, statistical sampling has become an increasingly important issue in FCA cases. This year, decisions by the district court in ***United States ex rel. Paradies v. AseraCare, Inc.***, reiterated this fact. AseraCare faces allegations that it falsely billed the government for hospice patients that failed to satisfy requirements that patients be terminally ill and have a life expectancy of six months or less. Anticipating lengthy trial testimony concerning the statistical sample of 233 claims, the district court bifurcated the trial for the FCA's falsity element from trial for all other elements. In arriving at its novel decision, the district court rejected the government's objections that bifurcation would result in juror confusion and duplicative evidence.

Later in the year—after the jury returned a verdict for the government on falsity—the district court granted AseraCare's motion for a new trial because the district court determined that it had erred in instructing the jury on the issue of falsity. The district court concluded that it should have instructed the jury that the FCA requires proof of an "objective" falsehood and that a difference in clinical judgment, without more, is insufficient to show that a Medicare hospice claim is false.[98] The district court also reopened summary judgment, noting that many key issues regarding the FCA are still developing, particularly in the hospice industry.[99] Given its clarified legal standard for falsity, the district court remarkably questioned whether the government had sufficient admissible evidence, beyond a difference of expert opinion, to show that the claims at issue are objectively false.

### *Express and Implied False Certification*

A particular trend this year has been the broadening circuit split regarding the implied certification theory of liability. In ***U.S. ex rel. Escobar v. Universal Health Services, Inc.***, the First Circuit embraced the implied certification theory of falsity under the FCA.[100] After a young woman died of a seizure at a mental health clinic operated by the defendant, her parents alleged that the clinic violated state regulations by employing unlicensed staff and failing to properly supervise its staff. The district court dismissed the relators' FCA claims, holding that compliance with the regulations was not a condition of payment. The First Circuit reversed the district court's decision, stating that "[a]lthough the record [was] silent as to whether [the clinic] explicitly represented that it was in compliance with conditions of payment . . . we have not required such 'express certification' in order to state a claim under the FCA."[101] The First Circuit held that the clinic implicitly communicated compliance with the regulations at issue whenever it submitted claims for reimbursement. Thus, the First Circuit held that a claim is legally false if it knowingly misrepresents compliance with a material precondition of payment contained in a statute, regulation, or contract, even if not expressly designated. As discussed above, the U.S. Supreme Court has granted the defendants' petition for writ of *certiorari* regarding the First Circuit's decision.

In ***U.S. ex rel. Badr v. Triple Canopy, Inc.***, the Fourth Circuit also adopted the implied certification theory of falsity under the FCA.[102] In ***Triple Canopy***, the defendant allegedly sought payment after hiring airbase security guards who did not satisfy the government contract's marksmanship requirement. The complaint also alleged that the defendant falsified marksmanship evaluations to hide the deficiencies. The district court dismissed the complaint for failing to allege a payment request that contained an objectively false statement. The Fourth Circuit reversed the district court and determined that an FCA violation was sufficiently pleaded. The court found that allegations suggesting a contractor sought payment while withholding information about its failure to satisfy material contract provisions are sufficient to state an FCA claim.

On the other hand, in ***United States v. Sanford-Brown, Ltd.***, the Seventh Circuit declined to adopt the implied certification theory as a basis for FCA liability.[103] The Seventh Circuit affirmed summary judgment for the defendant colleges on allegations that the colleges violated federal regulations regarding recruiting and retention practices in compliance with Title IV of the Higher Education Act. The Seventh Circuit found that the government's administrative mechanisms, not the FCA, are the proper forum for addressing the type of regulatory violations

97. 2014 U.S. Dist. LEXIS 142657 (E.D. Tenn. Sept. 29, 2014).
98. 2015 WL 8486874, at *7 (N.D. Ala. Nov. 3, 2015).
99. The district court previously denied AseraCare's motion for summary judgment, despite the government relying solely upon a sampling of claims and expert testimony concerning the sampling. *U.S. ex rel. Paradies v. AseraCare, Inc.*, 2014 WL 6879254, at *9 (N.D. Ala. Dec. 4, 2014).
100. 780 F.3d 504 (1st Cir. 2015).
101. *Id.* at 514 n.14.
102. 775 F.3d 628 (4th Cir. 2015).
103. 788 F.3d 696 (7th Cir. 2015).

> "The Government attempts to transmute evidence of Defendants' efforts to measure trends in its billing and to instruct its therapists on effective Medicare documentation into evidence of a nefarious plan to defraud the Government. However, this evidence merely establishes that Defendants employed prudent business practices, and does not create a material issue of fact as to whether Defendants' knew they or their therapists were submitting false claims to the Government."
>
> *U.S. ex rel. Lawson v. Aegis Therpaies, Inc.*

alleged. Notably, the court stated that it would be unreasonable to hold that compliance with thousands of pages of federal statutes and regulations, merely incorporated by reference, are conditions of payment under the FCA.

In ***U.S. ex rel. Hanna v. City of Chicago***, the district court dismissed the relator's allegations that the City of Chicago falsely certified that it would comply with federal fair housing laws in order to receive federal funds.[104] The relator alleged that the City violated its express certification when it did not comply with the housing laws, but did not allege that the City had no intention of complying with the housing laws at the time of the certification. The district court concluded that forward-looking commitments that an entity "shall" or "will" comply with statutes cannot give rise to express certification liability unless the entity was dishonest about its intent to comply at the time the certification is made.

Finally, in ***U.S. ex rel. Morsell v. Symantec Corp.***, the district court denied Symantec's motion to dismiss FCA allegations that Symantec failed to disclose more favorable pricing terms and misrepresented the discounts it offered on its software, a violation of its General Services Administration contract.[105] According to the district court, the allegations that Symantec violated contractual disclosure requirements sufficiently pleaded falsity under the implied certification theory.

### *Promissory Fraud Theory of Liability*

In ***U.S. ex. rel. Campie v. Gilead Sciences, Inc.***, the district court dismissed allegations that Gilead violated the FCA by selling products, including HIV medications, that lacked potency or were contaminated with filth, metal or microbes.[106] Relators alleged that Gilead made false certifications that it would comply with Good Manufacturing Practice regulations and withheld or falsified information to the FDA during the drug approval process. The district court, however, concluded that false certifications, statements or other fraudulent conduct directed at the FDA during the approval process would not render subsequent Medicare or Medicaid reimbursement requests "false" when there is no fraud directed toward the government payor itself.

### *Worthless Services as Establishing Falsity*

Last year, we reported on the Seventh Circuit's decision in ***U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc.***, which cast significant doubt on the "worthless services" theory of FCA liability.[107] Following the Seventh Circuit's ruling in ***Momence***, courts have reaffirmed the high hurdle that relators must surmount in order to plead a "worthless services" claim under the FCA.

In ***U.S. ex rel. Bellevue v. Universal Health Services of Hartgrove, Inc.***, the district court rejected the notion that requiring patients to sleep on cots in a dayroom results in services that are "worthless." The district court explained that, absent allegations that failure to provide a personal room destroyed the effectiveness of the rest of a patient's treatment, the relator could not state a claim for worthless services.[108] In a prior ruling dismissing the original complaint, the district court stated "[i]t is not plausible to believe that the room Hartgrove is supposed to provide to such patients is more essential than the therapy they also receive."[109] Therefore, the complaint lacked any allegations "explaining why the deprivation of a room is so detrimental to a patient's treatment that a claim for services provided to a patient should be considered false."

104. 2015 WL 5461664 (N.D. Ill. Sept. 16, 2015).
105. 2015 WL 5449795 (D.D.C. Sept. 10, 2015).
106. 2015 WL 106255 (E.D. Cal. Jan. 7, 2015).
107. 764 F.3d 699 (7th Cir. 2014).
108. 2015 WL 5873292 (N.D. Ill. Oct. 5, 2015).
109. 2015 WL 1915493 (N.D. Ill. Apr. 24, 2015).

In ***U.S. ex rel. McGee v. IBM Corp.,*** the district court dismissed a worthless services claim against Johnson Controls, Inc. ("JCI") that alleged JCI had installed non-functional and unreliable equipment on mobile platforms (interoperable voice, data and video systems for municipal emergency vehicles).[110] The district court concluded that "by alleging that some of the equipment was unreliable, [the relator] concede[d] that JCI provided something of value, even if unreliable."[111] The district court also concluded that JCI's work on a separate phase of the project did not implicate the worthless services theory, where JCI failed to fix equipment that the relator deemed unfixable. Nonetheless, the district court did hold that JCI's inability to "maintain" other equipment implicates the worthless services theory because the relator alleged that JCI had eliminated any value realized by the successfully installed equipment.

### *Knowledge/Scienter*

In ***U.S. ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.***, the district court granted Fresenius's motion for summary judgment, holding that no reasonable jury could find that Fresenius acted "knowingly."[112] The relator alleged that Fresenius violated the FCA by impermissibly billing Medicare for overfill in medication vials. The district court explained—in a 108-page opinion—that the relator could not prove that Fresenius knew its billing for overfills was impermissible or that it acted with deliberate ignorance or reckless disregard as to whether such billing was permissible. The district court focused on whether Fresenius had actual knowledge that it should not seek Medicare reimbursement for overfills. Key to this analysis were the facts that: (1) Fresenius relied on counsel in determining whether to bill Medicare and the law was silent on this issue during the relevant time period; (2) Fresenius and its counsel believed that many companies had billed for overfills and that the government knowingly reimbursed those companies for years; (3) Fresenius was very serious in its efforts to comply with Medicare rules and regulations; and (4) Fresenius had previously disclosed its overfill billing to the government, but was never warned that its actions were improper.

In ***U.S. ex rel. Fowler v. Evercare Hospice, Inc.***, the district court denied a motion to dismiss claims that Evercare knowingly made fraudulent claims for hospice patients for whom there was no documentation of terminal illness.[113] The district court found that the government sufficiently pleaded knowledge by alleging that Evercare pressured employees to admit patients, failed to train nurses to recognize when patients were terminally ill and threatened physicians who declined patient admissions. The district court considered Evercare's failure to ensure that physicians received adequate clinical information and its influence over physicians' judgment were sufficient allegations to plead, at a minimum, that Evercare acted in reckless disregard of the truth or falsity of its claims.

In ***U.S. ex rel. Estate of Donegan v. Anesthesia Associates of Kansas City, PC***, the district court granted the defendant's motion for summary judgment on allegations that it violated the FCA by submitting anesthesiology claims for which anesthesiologists did not participate in a patient's "emergence."[114] The district court found that the relator could not prove the defendant knowingly submitted a false claim because the meaning of "emergence" in Medicare regulations is ambiguous and the defendant's interpretation of the term was reasonable. Although the district court noted the defendant's interpretation was "opportunistic because it has a financial motive to interpret the regulation this way," it found that a defendant was not culpable simply for "taking advantage of a disputed legal question."[115]

Following more than a decade of litigation in ***U.S. ex rel. Kirk v. Schindler Elevator Corp.***, the district court granted summary judgment in favor of Schindler Elevator on the issue of knowledge.[116] The relator alleged that Schindler failed to comply with the Vietnam Era Veterans Readjustment Assistance Act and associated regulations by submitting false annual reports about the number of veterans employed by the company. The relator also alleged that Schindler's failure to have a mechanism for counting veterans amounted to

110. 81 F.Supp.3d 643 (N.D. Ill. 2015).
111. *Id.* at 665.
112. 2015 WL 7293156 (N.D. Ga. Oct. 30, 2015).
113. 2015 WL 5568614 (D. Colo. Sept. 21, 2015).
114. 2015 WL 3616640 (W.D. Mo. June 9, 2015).
115. *Id.* at *9.
116. 926 F.Supp.2d 510 (S.D.N.Y. 2015).

> "We ask simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment. Preconditions of payment, which may be found in sources such as statutes, regulations, and contracts, need not be expressly designated. Rather, the question whether a given requirement constitutes a precondition to payment is a fact-intensive and context-specific inquiry, involving a close reading of the foundational documents, or statutes and regulations, at issue."
>
> *United States ex rel. Escobar v. Universal Health Servs., Inc.*

reckless disregard. The district court found that failing to have a written policy for statutory or regulatory compliance—where none is required by statute or regulation—cannot establish scienter under the FCA by itself. Furthermore, because the district court determined that there was a legitimate disagreement regarding the interpretations of the regulations and that Schindler acted in good faith, the court found that Schindler did not knowingly submit a false claim. Finally, the district court found that allegations of an employee's identification of errors in a company's data collection or a recognized need for better quality control do not constitute reckless disregard within the meaning of the FCA.

**When Are False Statements Material?**

The materiality of a particular statement or action with respect to the government's decision to pay a claim remained an important issue in determining FCA liability last year. FCA claims should fail when the regulations allegedly violated are immaterial to the government's decision to pay a claim. Where the theory of FCA liability turns on compliance with statutes and regulations in the healthcare context, courts continue to distinguish between regulations that are conditions of participation in the federal healthcare program and regulations that are conditions of payment, holding only violations of the latter can underpin FCA liability. As the Sixth Circuit has explained, violations of condition of participation are best addressed through administrative sanctions, not the "extraordinary remedies" of the FCA.[117]

An example from this line of cases includes ***U.S. ex rel. Davis v. District of Columbia***, a case that involved allegations that the defendant violated regulations in seeking Medicaid reimbursement.[118] Explaining "[n]ot all failures to comply with a federal statute or regulation expose a provider to liability," *id.* at *125, the D.C. Circuit cited supporting cases from the Second, Third, Sixth and Tenth Circuits and held that "a defendant may be held liable under the [FCA] for falsely certifying it complied with a statute or regulation only if certification was a prerequisite to the government action sought."[119] The D.C. Circuit ultimately did not determine whether the regulations at issue were prerequisites to payment because the relator had failed to establish that the defendant was in knowing violation of any regulation.

In ***United States v. N. Am. Health Care, Inc.***, the district court dismissed allegations that a skilled nursing facility violated the FCA by manipulating its Star Ratings, a metric published on Medicare.gov and Nursing Home Compare websites to help consumers compare facilities.[120] These allegations were not tied to any specific false claims and did not satisfy the FCA's materiality standard. The district court reiterated for "Plaintiffs to state a claim based on the false certification theory, they must allege that Defendants violated a statute, regulation, or other law upon which the government conditions payment of Medicare or Medicaid claims."[121]

The district court in ***U.S. ex rel. Bierman v. Orthofix Intern, N.V.***, granted summary judgment, dismissing allegations that the defendant violated Medicare provider enrollment regulations by not creating a rental option for its DME.[122] Concluding that the regulations at issue were not conditions of payment, the district court noted that even if it were to assume they were, relator's claims

117. *U.S. ex rel. Hobbs v. MedQuest Assocs.*, 711 F.3d 707, 713 (6th Cir. 2013).
118. 793 F.3d 120 (D.C. Cir. Jul. 10, 2015).
119. *Id.* (quotation marks omitted).
120. 2015 WL 6871781 (N.D. Cal. Nov. 9, 2015).
121. *Id.* at *4.
122. 2015 WL 4197551 (D. Mass. July 1, 2015).

would fail because it did not satisfy the materiality requirement. The summary judgment record before the district court contained a CMS position letter that explicitly stated that a violation of the regulation at issue may lead to a revocation of billing privileges, but not a denial of a request for payment. As the district court explained, "[i]n light of this unequivocal statement about the consequences of non-compliance from the agency that administers Medicare, a reasonable jury could not conclude that defendants' allegedly false certifications were capable of influencing CMS's decision to pay their claims."[123]

Likewise, the district court granted summary judgment for the defendant in ***U.S. ex rel. Marshall v. Woodward, Inc.***, finding that relators had failed to establish materiality with regard to defendant's certifications of contractual compliance for helicopter parts manufactured for the U.S. Department of Defense ("DoD").[124] The district court acknowledged that materiality is judged objectively, but agreed with the defendant that "evidence that the fully-informed Government continues to purchase and pay for the product is legally dispositive evidence that any alleged fraud concerning the products quality is not capable of influencing the payment decision."[125] In the present case, "the record show[ed] that DoD understood Relators' allegations, conducted an extensive review, determined that there was no problem and that Relators' concerns were unfounded, and continued to purchase the parts from [Defendant]."[126]

In ***U.S. ex rel. Watkins v. KBR, Inc.***, the district court held that a government contractor's Truth In Negotiations Act ("TINA") certifications that cost and pricing data was accurate, complete and current were too remotely connected to payment to be considered material to the government's decision to pay.[127] The relator complained that the defendant submitted knowingly false "statement of allowable cost" reports with each invoice to the government. The district court ruled that such action, even if true, was not material to government payment, for two reasons. First, the regulations did not require the defendant to submit these allegedly false "statements of allowable costs" with invoices. "It can hardly be argued with a straight face that the Government deemed something it did not even require to be submitted to be influential to its decision-making process."[128] Second, the regulations that dictate the content that invoices must contain to be paid do not require an affirmative statement that the cost is allowable and reasonable.

In contrast to the above cases, certain courts avoided the distinction between conditions of payment and conditions of participation in favor of a less technical analysis of materiality. This trend was largely confined to cases outside of the healthcare industry. For example, the Eighth Circuit in ***U.S. ex rel. Miller v. Weston Educ'l, Inc.***, eschewed reliance on the dichotomy between conditions of participation and conditions of payment and instead opted for a more flexible view of materiality.[129] The relators alleged that Heritage College fraudulently induced Title IV funding by falsely stating it would maintain accurate records. The district court granted summary judgment for defendant, finding relator had not identified any conditions of payment. The Eighth Circuit reversed and remanded. Pointing to three places in the applicable regulations that conditioned participation on the maintenance of records, the Eighth Circuit reasoned that "Heritage could not have executed the [agreement with the government] without stating it would maintain adequate records....And without [this agreement], Heritage could not have received any Title IV funds. This forms a 'causal link' between the promise and the government's disbursement of funds."[130] Responding to the concern that "finding materiality here makes any regulatory violation actionable under the FCA," the Eighth Circuit responded that the FCA still requires violations to be ***knowing***, which would help cabin liability to appropriate cases.

***U.S. ex rel. Garbe v. Kmart Corp.*** involved allegations that Kmart artificially inflated its usual and customary ("U&C") prices for prescription drugs.[131] Kmart

123. *Id.* at *8.
124. 85 F.Supp.3d 973 (N.D. Ill. Mar. 27, 2015).
125. *Id.* at *982 (internal quotations omitted).
126. *Id.*
127. 2015 WL 2455533 (C.D. Ill. May 22, 2015).
128. *Id.* at *14.
129. 784 F.3d 1198 (8th Cir. 2010).
130. *Id.* at *1208-09.
131. 73 F.Supp.3d 1002 (S.D. Ill. Jan. 12, 2015).

Relators have filed more than 3,500 new *qui tam* lawsuits during the last five years.

argued the relator's claims failed for lack of materiality because relator could not establish that Kmart's U&C prices influenced government reimbursement. CMS pays Plan Sponsors flat-rate fixed reimbursement under contracts, only providing additional compensation in a few narrow situations. The district court rejected this defense, noting "materiality requires 'only that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is a result of indirect or intangible actions on the part of defendants.'"[132] The district court agreed that CMS would have paid the *Plan Sponsor* the same amount absent the alleged fraud, but noted "the government (acting through the PBMs and Plan Sponsors) would not have paid *Kmart* the same amount of money."[133] The false claim allegedly submitted was material "because it gave the 'particular impression' that Kmart was entitled to more money than it should have been entitled, thereby producing an 'effect,' *i.e.* Kmart receiving more Medicare Part D funds than it was entitled to receive."[134]

In ***U.S. ex rel. Simpson v. Bayer***, the relator alleged that the defendant had engaged in off-label marketing and argued that noncompliance with the Food, Drug and Cosmetic Act's ("FDCA") misbranding provisions were conditions of payment.[135] The district court dismissed the allegations for failure to establish materiality, noting that although the government "may eventually sue a drug manufacturer for failing to comply with the FDCA's misbranding provisions … [i]t does not follow [] that the Government conditions its payments for pharmaceuticals on a drug manufacturer's compliance with the FDCA's misbranding provisions[.]"[136]

In ***U.S. ex rel. Petratos v. Genentech, Inc.***, the district court dismissed allegations that the defendants withheld information regarding a popular cancer drug, reasoning that it was immaterial whether fewer doctors would have prescribed the drug if they had had more information.[137] Material to the government's decision to pay is whether or not the relevant agency, not any individual doctor, has deemed the drug medically reasonable and necessary.

## FCA STATUTE OF LIMITATIONS

In May 2015, the U.S. Supreme Court issued a unanimous decision in finding that the Wartime Suspension Limitations Act ("WSLA"), 18 U.S.C. § 3287, does not toll the statute of limitations in civil FCA actions, as it was only intended to apply to criminal actions. After lying dormant for more than 40 years, the WSLA had threatened to upend the FCA's limitations period and expose defendants to open-ended and extensive liability for otherwise stale FCA claims.

Amended in 2008, the WSLA provides that the statute of limitations applicable to "any offense" involving fraud against the United States during a time of war or when Congress has enacted a specific authorization for the use of military force is suspended until five years after the termination of hostilities. In a number of cases in the last several years, relators had begun relying on the WSLA as a means to avoid dismissal of claims brought outside of the FCA's limitations period by asserting that the United States' war in Iraq tolled the statute of limitations of civil FCA claims.

In ***Kellogg Brown & Root Service, Inc. v. U.S. ex rel. Carter***, the U.S. Supreme Court reversed an opinion by the Fourth Circuit, which had held that a relator could rely upon the WSLA to toll the FCA's limitations period.[138] The Supreme Court reasoned that the text, structure and history of the WSLA indicated that the Act was intended to apply only to criminal charges. In particular, the Court reasoned that inclusion of the term "offense" strongly demonstrated Congress's intent to limit the WSLA's applicability to criminal offenses,

132. *Id.* at 1028 (quoting *U.S. ex rel. Longhi v. United States*, 575 F.3d 458, 470 (5th Cir. 2009)).
133. *Id.*
134. *Id.*
135. 2015 WL 1190160 (D.N.J. Mar. 16, 2015).
136. *Id.* at *6.
137. 2015 WL 6561240 (D.N.J. Oct. 29, 2015).
138. *Kellogg Brown & Root Servs., Inc.* v. *U.S. ex rel. Carter*, 135 S. Ct. 1970 (2015).

particularly given that the Act was codified in Title 18, which uses the term to refer exclusively to criminal conduct.[139] Moreover, this interpretation of the Act's application is in line with the Court's historic position that the WSLA should be "narrowly construed."[140]

## REVERSE FALSE CLAIMS CASES

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

Prior to 2008, the reverse false claims provision required that a person or entity make or use a false record or statement to avoid, conceal or decrease an obligation to the United States (then codified at 31 U.S.C. § 3729(A)(7)). The Fraud Enforcement and Recovery Act of 2009 ("FERA"), however, eliminated that requirement and reduced the government and/or relator's burden because they no longer need to prove the affirmative use of a false record or statement in connection with avoiding repayment obligations. Despite this reduced burden, relators continued to struggle to satisfy Rule 9(b)'s heightened pleading requirements, and a number of reverse false claims complaints were dismissed for failing to state a claim.[141]

Twice last year, the relator in ***U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.***,* had claims dismissed for failing to satisfactorily plead a reverse false claim in accordance with Rule 9(b).[142] The relator alleged that the defendant engaged in four fraudulent schemes, including: (1) providing home health services without appropriate plans, order or certifications in place; (2) providing medically unnecessary services; (3) billing for improperly performed assessments; and (4) billing for skilled nursing visits when the underlying purpose was otherwise.[143] The relator also alleged that the defendant knowingly retained overpayments from Medicare associated with these schemes in violation of § 3729(a)(1)(G).[144] The district court dismissed the relator's claims because the Amended Complaint failed to allege what specific obligations the defendant owed to the government and what actions the defendants undertook to avoid repaying those obligations—"both of which are necessary to survive a motion to dismiss."[145]

In ***U.S. ex rel. Ibanez v. Bristol-Myers Squibb, Co.***, the plaintiff alleged that the defendants failed to refund overpayments they received as a result of alleged off-label promotion and a kickback scheme.[146] In opposition to the defendants' motion to dismiss the Second Amended Complaint, the relator alleged that the defendants failed to comply with their respective CIA and falsely certified compliance, which necessarily resulted in violations of the reverse false claims act.[147] The district court, however, dismissed the reverse false claims allegations because the Second Amended Complaint contained only ambiguous references to the defendants' obligations to pay under their respective CIA's, which were insufficient to meet Rule 9(b).[148]

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139. *Id.* at 1976-78.
140. *Id.* at 1978.
141. *See, e.g., U.S. ex rel. Rockey v. Ear Institute of Chicago, LLC*, 92 F. Supp 3d 804 (N.D. Ill 2015) (dismissing reverse false claim allegations because Defendant did not have an obligation to the government on certain claims in question and no statements, false or otherwise, can be "material to" a nonexistent obligation); *U.S. ex rel. Petratos v. Genentech, Inc.*, 2015 WL 6561240, (D.N.J. October 29, 2015) (dismissing relators § 3729(a)(1)(G) claims because they were a recasting of his § 3729(a)(2) claims and "[c]laims raised under the FCA's reverse false claims provision may not be redundant of FCA claims asserted under other provisions of the FCA"); Phipps v. Agape Counseling & Therapeutic Servs., Inc., 2015 WL 2452448, (E.D. Va. May 21, 2015) (dismissing reverse false claim allegations because relator failed to provide any specific allegations of what fraudulent record or statement Defendants made, who made the statement, when it was made, where it was made, or its content).
142. *See* 2015 WL 1509211 (M.D. Tenn. Mar. 31, 2015); 2015 WL 6812581 (M.D. Tenn. Nov. 5, 2015).
143. 2015 WL 1509211 at *10.
144. *Id.* at *16.
145. *Id.*
146. 2015 WL 1439054, *10 (S.D. Ohio Mar. 27, 2015).
147. *Id.*
148. Not all healthcare entities were able to successfully dismiss reverse false claims act allegations. *See, e.g., U.S. v. Mount Sinai Hosp.*, 2015 WL 7076092 (S.D.N.Y. Nov. 9, 2015) (finding that the relator met the 9(b) pleading requirements by (1) providing illustrative examples of how the defendant made false records and submitted fraudulent bills to the government and (2) unequivocally establishing that the defendant had an obligation to the government when the false statements were made); *Kane ex rel. U.S. v. Healthfirst, Inc.*, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015) (finding that owing money to the New York State Medicaid Program sufficiently establishes an obligation to the federal government, as required under 3729(a)(1)(G), because Medicaid is a joint federal and state program and Congress has repeatedly provided that claims submitted to Medicaid constitute false claims under the FCA).

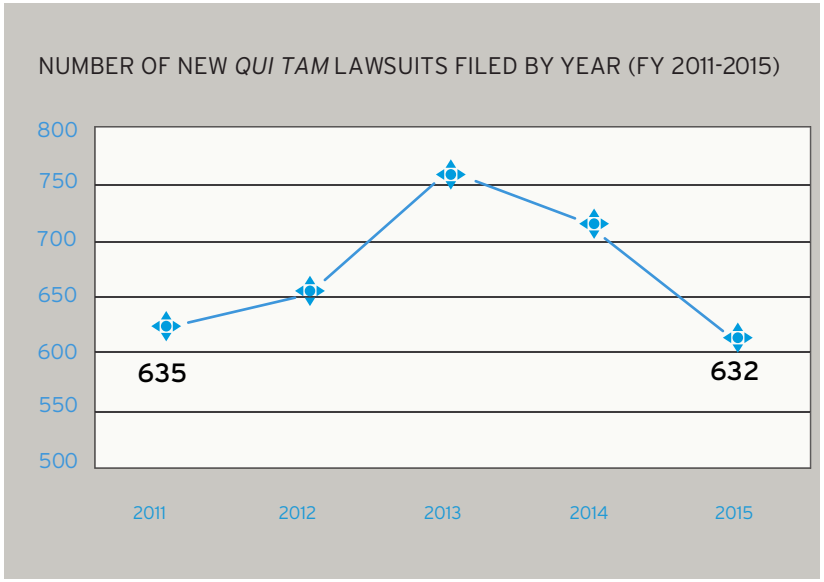
*Denotes matter handled by Bass, Berry & Sims attorneys.

## DEVELOPMENTS REGARDING DAMAGES AND PENALTIES

### Statistical Sampling and Damages

Parties continue to grapple with theories and arguments to obtain or limit damages recoverable in FCA cases. The continued use of extrapolation to identify claims as to both liability and damages no doubt will increase the possibility of higher recoveries, with even less direct evidence required to actually prove each claim comprising the damages amount. As we discussed earlier, the government and relators are seeking to use a limited sample size of claims to extrapolate across thousands of other claims in order to calculate the alleged loss to the government, especially in large cases such as ***Life Care*** and ***AseraCare***.[149]

Determining damages through extrapolation may be particularly useful to relators in declined cases where relators do not always have information necessary to establish liability or damages when filing suit. By requesting that the courts order data to be produced by defendants so that relators may pursue statistical sampling and extrapolation, the amount of potential damages may be dramatically increased. Relators' efforts have been recently supported by the government in declined cases in which the government has filed position statements (referred to as Statements of Interest), as the DOJ filed in ***Ruckh***. There, the government argued in favor of extrapolation because, if disallowed by the courts in cases involving large numbers of claims, it would have "the perverse effect of incentivizing fraud by making widespread fraudulent practices less enforceable."[150] The government also argued that sampling and extrapolation are both necessary and practical in FCA cases because "the use of statistical sampling evidence is not only routine but essential in False Claims Act cases where the defendants' conduct caused the submission of more false claims and records than could reasonably be tried before a court on a claim by claim basis."[151]




### Offsets and Reduction in Damages

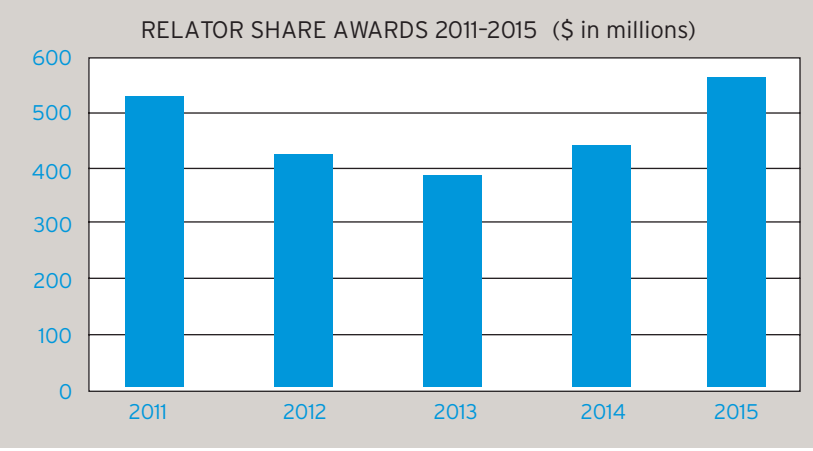
With inconsistent success, defendants have argued that they should be entitled to an offset or reduction in determining the amount of the value or benefit that the government ultimately received when calculating damages under the FCA. In response, the government typically has argued that it is entitled to recover the full amount of all payments, particularly where the government proves that it received no value from the product or service provided.[152] When applying any offset, the defendants and the government have disagreed on whether the offset should be applied against the recovery before or after trebling the damage award. The government has previously argued that an award should first be trebled, and then any offset should be applied, which is commonly referred to a "gross trebling."[153] Of course, gross trebling benefits the government by trebling the larger sum before the offset is applied. Defendants have argued that any offset amount should first be applied to the single damage calculation, and the remainder then trebled, which is referred to as "net trebling."

This issue was recently raised in ***U.S. ex rel. Purcell v. MWI Corp.***, but the parties advanced positions that were inconsistent with those typically urged by either the defendant or the government.[154] After a jury awarded the government

149. For example, in *Life Care*, the government seeks to analyze a sample of 400 admissions to extrapolate across approximately 54,000 admissions. In AseraCare, the government asserts that the $7 million damages identified in sample claims extrapolates to more than $67 million of single damages, and more than $200 million when trebled.
150. *U.S. ex rel. Ruckh v. Genoa Healthcare, LLC*, No. 8:11-cv-1303-T-23TBM (M.D. Fla. Apr. 7, 2015), United States' Statement of Interest.
151. *Id.*
152. *See U.S. ex rel. McLain v. Fluor Enterprises, Inc.*, 2015 WL 5321692 (E.D. Louisiana, September 10, 2015), (citing *U.S. v. Science Applications Intern.* Corp., 626 F.3d 1257, 1278-79 (D.C. Cir. 2010)).
153. *See U.S. v. Bornstein*, 423 U.S. 303, 314 (1976) (holding that an FCA defendant is entitled to an offset against treble damages by amounts paid to compensate the government for any harms caused by the false claims).
154. 2015 WL 7597536 (D.C. Cir. Nov. 24, 2015).

$7.5 million in damages under the FCA stemming from false certifications to secure loans from a bank in a government program, the district court trebled the damages to $22.5 million. The district court then reduced the government's recovery to zero after applying the amount of the loans repaid against the damages calculations, thereby subjecting the defendant only to civil penalties under the FCA for each of the 58 false certifications.[155] The government appealed, arguing this time that the amount of the loan repaid could only be offset against the amount of damages before trebling (the single damage award) and not against the trebled damages. Therefore, the government asserted that it was still entitled to the remaining $15 million in trebled damages. The district court disagreed and the case was appealed. The D.C. Circuit found that, notwithstanding the jury award, the government had failed to prove that the false claims were knowingly made, and reversed the judgment in favor of the defendant without reaching the government's damages argument.[156]

We anticipate that total awards of damages and penalties will increase in the coming year as a result of the increase in the amount of penalties to be awarded under the FCA. Currently, civil penalties may be imposed pursuant to the FCA from $5,500 to $11,000.[157] On November 2, 2015, President Obama signed the Bipartisan Budget Act of 2015, which requires the government to make inflation-based increases in civil penalties for FCA violations.[158] The amount of the increase was not specifically provided by the Act, but is to be determined by the appropriate governmental agency by August 1, 2016, and every year thereafter so that no further law is required for future increases.[159] Because the categories of civil penalties to be increased include those under the Social Security Act, Civil Monetary Penalties ("CMP"s) also will be increased for inflation pursuant to the Act by August 2016.




## DEVELOPMENTS REGARDING RELATORS

### First-to-File Bar

In addition to addressing the limitations of the WSLA, the Supreme Court's opinion in ***Carter*** clarified the FCA's first-to-file rule, which provides that "[w]hen a person brings an action . . . no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." In ***Carter***, the Supreme Court addressed a circuit court split regarding whether a dismissed action that is on appeal is "pending" for purposes of the first-to-file rule. The Court held that a *qui tam* suit under the FCA ceases to be "pending" once it is dismissed. Therefore, an earlier suit bars a later suit only until the earlier suit is dismissed. Although this ruling clarified that a previous action is not a perpetual bar to filing factually related claims, courts are still left to determine whether a dismissal lifts the bar for new actions and actions that were filed when the earlier, related action was pending or only for new FCA actions.

In ***U.S. ex rel. Carter v. Halliburton***, the district court interpreted the Supreme Court's ruling to allow new claims to be filed when related claims had been dismissed, but held that suits filed while a related suit was pending were still barred by the first-to-file-rule even when the related suit was later dismissed.[160] The district court further held that amending the complaint could not cure the first-to-file bar because a related action was pending when the relator brought his action.[161]

155. As the government has in the past, the court relied upon *Bornstein* when offsetting against the "gross treble." In *Purcell*, the bank had been repaid $108 million, well in excess of the jury's damages award.
156. *Id.* at *8.
157. This range was imposed by the Federal Civil Penalties Inflation Adjustment Act of 1990.
158. Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584.
159. While no increase is specifically provided by the Act, the increase is expressly capped at 150%.
160. 2015 WL 7012542 (E.D. Va. Nov. 12, 2015).
161. *See also U.S. ex rel. Shea v. Verizon Commnc'ns, Inc.*, 2015 WL 7769624, *9 (D.D.C. Oct. 6, 2015).

In ***U.S. ex rel. Gadbois v. PharMerica Corp.***, the First Circuit arrived at a different interpretation of the Supreme Court's holding in ***Carter***. The relator alleged that the defendants violated the FCA by making improper distributions of pharmaceuticals to long-term care facilities.[162] The district court granted the defendants' motion to dismiss the action as a result of the pendency of a previously filed action in Wisconsin. While on appeal, the Supreme Court issued its opinion in ***Carter*** and the pending Wisconsin action was dismissed. As a result, the relator moved to supplement his complaint.

The First Circuit held that, because of the Supreme Court's ruling in ***Carter***, the case should be remanded for the district court to consider the relator's motion to supplement his complaint. The First Circuit noted that while dismissal may have been proper when entered by the district court, the holding in ***Carter*** and the dismissal of the Wisconsin action removed the jurisdictional bar that otherwise prevented the relator from supplementing his complaint.[163]

In a number of cases, courts also have considered whether the first-to-file rule is jurisdictional or procedural in nature. In ***U.S. ex rel. Heath v. AT&T, Inc.***, the D.C. Circuit reversed the district court's dismissal of a relator's *qui tam* lawsuit under the FCA's first-to-file bar, finding that the relator's two *qui tam* lawsuits targeted factually distinct types of frauds.[164] The D.C. Circuit determined that the first-to-file rule was not jurisdictional in nature. The D.C. Circuit then determined that the relator's second *qui tam* lawsuit, which alleged that AT&T and 19 of its subsidiaries deprived schools and libraries of the lowest corresponding price for phone and internet services, was sufficiently different from the relator's first *qui tam* lawsuit in terms of its scope and description of the fraud scheme to avoid dismissal under the first-to-file rule.

In contrast, in ***U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.***, the Ninth Circuit determined that that the first-to-file rule is a jurisdictional bar.[165] Even so, it ruled that the relator in a later filed FCA complaint could proceed with her claims because the claims involved different underlying facts, and the first-to-file rule only bars related claims that are not factually distinct.

### FCA Seal Requirements

Under the procedural requirements of the FCA, relators must file a *qui tam* action under seal and provide the government with a written copy of the complaint and disclosure of all material evidence in the relator's possession that relates to the complaint. Relators are bound to abide by the seal until such time as the seal is lifted by the district court. Failure to do so may result in dismissal of the *qui tam* action or the imposition of other sanctions against the relator. Last year, a number of FCA cases considered seal breaches by relators and the consequences flowing from such breaches.

In ***U.S. ex rel. Rigsby v. State Farm Fire & Cas. Co.***, the relators filed an FCA action against State Farm for allegedly maximizing claims backed by the government and minimizing claims paid directly by the insurance company.[166] On appeal following a verdict in favor of relators on a single bellwether false claim under the FCA, the defendant argued that the case should be dismissed because the relators breached the FCA's seal requirement by disclosing the existence of the lawsuit and evidentiary disclosure to several news outlets. The Fifth Circuit held "that a seal violation does not automatically mandate dismissal" and relied on the test outlined by the Ninth Circuit in ***U.S. ex rel. Lujan v. Hughes Aircraft Co.***, which balanced the harm to the government, the nature of the violations, and whether the violations were made in bad faith, in determining that the relators' breach did not require dismissal.[167]

While the relator's motive for breaching the seal may be a factor considered by courts in determining the remedy for a breach of the FCA's seal requirement, a relator's bad faith still may not be enough for the court to dismiss a relator's

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162. 2015 WL 9093650 (1st Cir. 2015).
163. *See U.S. ex rel. Kurnik v. PharMerica Corp.*, 2015 WL 1524402 (D.S.C. Apr. 2, 2015). The relator was allowed to proceed with his amended complaint. While the amended complaint was filed after the earlier related action was dismissed, the original complaint was filed while the earlier related action was pending. The district court found that it would be futile to dismiss the relator's claims since the dismissal would be without prejudice and the relator could file a pleading identical to the amended complaint under a new case number.
164. 791 F.3d 112 (D.C. Cir. 2015).
165. 792 F. 3d 1121 (9th Cir. 2015).
166. 794 F.3d 457 (5th Cir. 2015).
167. *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 244 (9th Cir. 1995) (outlining three factors to consider when determining remedies for a breach of the seal requirement: (1) whether the government was harmed by the disclosure; (2) the nature of the violation; and (3) whether the relator acted in bad faith or willfully); *but see U.S. ex rel.* Summers v. LHC Grp., Inc., 623 F.3d 287, 291 (6th Cir. 2010) (rejecting Lujan and strictly construing the FCA's seal provision and determining that failure to follow those requirements resulted in disqualification of the relator).

complaint. In ***U.S. ex rel. Ruscher v. Omnicare***, the district court determined that the relator not only breached the seal requirement in bad faith, but also committed perjury during testimony about disclosures made during the seal period. Even so, the district court applied the factors outlined in ***Lujan*** and held that dismissing the complaint was an extreme remedy and denied the defendant's motion to disqualify the relator.[168]

Unlike the conclusions reached in ***Rigbsy*** and ***Ruscher***, the district court sanctioned the relators for violating the FCA's seal in ***U.S. ex rel. Bibby v. Wells Fargo Home Mortg. Inc.***[169] The relators alleged that certain lenders, including Wells Fargo, engaged in a fraudulent scheme to overcharge veterans on closing costs during the origination of VA loans. The government declined intervention after 18 extensions of the seal period, and the relators eventually succeeded in obtaining more than $161 million in settlements against six lenders. For their efforts, the relators received $43 million in their relators' share. After reaching those settlements, the relators' counsel notified the district court that the relators had breached the FCA's seal by engaging in long-running discussions with the media regarding their FCA lawsuit during the seal period. Wells Fargo immediately moved for dismissal of the relators. The district court denied Wells Fargo's motion, but required the relators to pay the government $1.61 million of their FCA awards as a sanction for their violation of the seal.

In ***Smith v. Clark/Smoot/Russell***, the relators' attorney breached the FCA seal by informing in-house counsel at the defendant company about the *qui tam* action in an attempt to stop retaliatory action against the relator.[170] After the seal was fully lifted, the defendant filed a motion to dismiss, which was granted. On appeal, the Fourth Circuit held that the district court erred in dismissing the action as a result of the seal breach, noting that the breach did not prevent the government from investigating the fraud and that the breach was between the parties, so there was no damage to the defendant's reputation.

**Relators' Conduct**

Courts have continued to scrutinize relators' conduct in *qui tam* actions. In ***U.S. ex rel. Schroeder v. CH2M Hill***, the Ninth Circuit affirmed the district court's dismissal of a complaint by a relator who pleaded guilty to a felony involving the same fraudulent conduct that gave rise to a *qui tam* suit.[171] Under § 3730(d)(3), a relator's *qui tam* action must be dismissed and the relator precluded from recovering if the relator is convicted of criminal conduct related to their role in violating the FCA. In ***Schroeder***, the Ninth Circuit concluded that this provision applied even to minor participants in the underlying alleged misconduct, who neither planned nor initiated the fraudulent scheme.

> "Distilled to its essence, each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary. Answering that question for each of the patients involved in this action is highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient. [S]ome cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages may be proved. This civil action, however, is not such a case."
>
> *U.S. ex rel. Michaels v. Agape Senior Community, Inc.*

In ***U.S. ex rel. Ortiz v. Mount Sinai Hosp.***,[172] the district court rejected the defendants' motion seeking dismissal of the complaint on the basis that the relators relied on patient records to support their allegations, which the relators allegedly had obtained without authorization following an internal investigation at the Hospital.

However, in ***Ruscher***, the district court allowed Omnicare to proceed with common law claims against the relator regarding the relator's alleged

168. 2015 WL 4389644 (S.D. Tex. July 15, 2015).
169. 76 F. Supp. 3d 1399 (N.D. Ga. 2015).
170. 796 F.3d 424 (4th Cir. 2015).
171. 793 F.3d 1080 (9th Cir. 2015).
172. 2015 WL 7076092 (S.D.N.Y. Nov. 9, 2015).

misappropriation of documents, which Omnicare claimed were subject to its confidentiality policies.[173] The district court's conclusion turned specifically on the allegation that the relator took more documents than were reasonably necessary to support her FCA claims.

### Retaliation

Courts continued to consider the type of conduct that constitutes protected activity in the post-FERA world. In ***Mikhaeil v. Walgreens, Inc.***, the district court denied Walgreen's motion for summary judgment related to retaliation claims filed by a former pharmacist who had raised a number of concerns to management about the hostile work environment created by her supervisor and concerns of Medicare fraud and was terminated shortly thereafter.[174] The district court held that the plaintiff had alleged a prima facie case of retaliation under the FCA because the plaintiff's internal reporting constituted protected activity as "other efforts" to stop an FCA violation. The temporal proximity between the reporting of the potential fraud and her termination and evidence that her work was more heavily scrutinized after she reported the potential fraud demonstrated that there was a causal connection between her protected activity and her termination.

In ***Arthurs v. Global TPA LLC***, the district court determined that internal reports of alleged violations of conditions of participation may be considered protected activity for the purpose of a retaliation claim under the FCA.[175] The district court rejected the defendant's motion to dismiss, and concluded that FERA expanded the type of activity proscribed by the FCA to reach "a regulatory violation . . . where there is a connection between the alleged violation and an entity's participation in a government-funded program."

While FERA's amendment of the FCA expanded the pool of relators who could claim a violation of the FCA's retaliation provision, courts continued to reject efforts by relators to assert individual liability for alleged violations of that provision. In ***U.S. ex rel. Sibley v. A Plus Physicians Billing Services, Inc.***, the district court rejected the relator's argument that FERA's removal of the phrase "by his or her employer" from § 3730(h) created individual liability.[176]

In ***Cestra v. Mylan***, the district court addressed the issue of whether § 3730(h) encompassed an employer who was not the target of the FCA investigation, but who fired the employee after learning that the employee was a whistleblower in an ongoing *qui tam* action.[177] Relying on the Eighth Circuit's opinion in ***Townsend v. Bayer Corp.***,[178] the district court determined that the prohibitions of the FCA's anti-retaliation provision reached an employer who retaliated against a whistleblowing employee, even when the employer was not the subject of the employee's whistleblowing activity.

## DISCOVERY DEVELOPMENTS IN FCA CASES

Defendants have had mixed results in a number of different types of discovery disputes this year, though they may find some relief from particularly high-cost discovery based on one court's decision that endorsed the "staged discovery" approach and limited the geographic or temporal scope of discovery.

### Rule 9(b) & Discovery

It is well accepted that a primary purpose of Rule 9(b)'s heightened pleading standard is to reduce "fishing expeditions." In ***U.S. ex rel. Robinson v. Indiana University Health Inc.***, however, the district court refused to stay discovery until it had resolved pending motions to dismiss, which challenged the adequacy of the pleadings under Rule 9(b).[179] The district court rejected the defendants' argument that proceeding with discovery while motions to dismiss remained unresolved would frustrate the purpose of Rule 9(b) and distinguished cases on which the defendants relied, in part, by noting the allegations before the district court were more detailed.[180] Furthermore, the district court determined that any burden claimed by the defendants was speculative because they had not provided specific estimates regarding the time or costs associated with discovery.[181] The district court's decision also appears to have been influenced by the parties' lack of diligence in pursuing the matter. In evaluating prejudice

173. 2015 WL 4389589 (S.D. Tex. July 15, 2015).
174. 2015 WL 778179 (E.D. Mich. Feb. 24, 2015).
175. 2015 WL 1349986 (M.D. Fla. 1349986) (M.D. Fla. Mar. 25, 2015).
176. 2015 WL 4978686 (N.D. Ill. Aug. 20, 2015).
177. 2015 WL 2455420 (W.D. Penn. May 22, 2015).
178. 774 F.3d 446,460 (8th Cir. Dec. 17, 2014).
179. 2015 WL 3961221, at *9 (S.D. Ind. June 30, 2015).
180. *Id.* at *2-3.
181. *Id.* at *5.

to the judicial system, the district court emphasized the fact that the parties had "accomplished very little" in the 18 months during which the suit had been pending.[182]

### Self-Help Discovery

Courts often have been asked to evaluate the rights of a relator to obtain and possess confidential corporate documents for use in FCA cases. Courts have recognized a broad policy interest in not discouraging whistleblowers from undertaking investigative efforts that might expose fraud against the government. Typically, the protections afforded "self-help" discovery only extend to the collection of materials that are reasonably related to the formation of the case and have not extended to privileged materials. Furthermore, when a relator's retention of documents is overbroad and unreasonable, courts have allowed defendants to seek relief against such relators in the form of counterclaims or other sanctions.[183]

In ***Shmushkovich v. Home Bound Healthcare, Inc.***, the district court denied the defendant's motion for return of property taken by the relator, which included original and electronic files that the relator maintained on his home computer and copies of those files that he had provided to his attorney.[184] The district court reviewed the range of responses by other courts in response to self-help by relators, including sanctions in the form of dismissal, requiring the relator to return the documents and refusing to order the return when documents would inevitably be recovered through discovery. The district court then rejected the defendants request for return of property, because it would "only serve to unnecessarily increase the expense and extend the length of the litigation." The district court ordered the relator to destroy any non-relevant documents and provide a list of remaining documents to the defendant, who could contest the relevance of those documents.[185] While this middle-of-the-road approach appears to further judicial efficiency, it fails to provide protection to defendants whose property has been misappropriated.

### Discoverability of Independent Review Organization Reports

In ***U.S. ex rel. Willis v. SouthernCare, Inc.***, a district court quashed many of the relators' document requests submitted to a third party, but required the production of Independent Review Organization ("IRO") reports generated pursuant to a CIA. The relator alleged violations of the FCA similar to those that were the subject of an FCA settlement into which the defendant entered several years before. As part of discovery, the relator sought various documents from the IRO that the defendant had engaged as part of its CIA. While the district court agreed with the IRO that many of the requests were overbroad, it ordered the IRO to produce the reports generated pursuant to the CIA and any documents mentioned in those reports.[186] The district court determined the protective order in place would provide sufficient protection for any trade secrets or confidential business information contained in the reports.[187] Providers that have resolved FCA issues should be mindful of the possibility of such discovery when engaging non-privileged consultants to assist with remediation.

### Protection of Relators' Disclosure Statements

In a trio of cases last year, defendants failed in efforts to obtain discovery of relators' disclosure statements provided to DOJ, as required by § 3730(b)(2). These cases each applied the same reasoning in concluding that the circumstances in which relators' disclosure statements are discoverable are extremely limited.

In each case, the district courts found that the relators' disclosure statements were protected from discovery under the attorney work product doctrine. The work product doctrine provides a qualified protection for documents and other tangible things prepared in anticipation of litigation. When materials constitute attorney work product, however, the party seeking discovery must establish: (1) a substantial need for the privileged materials; and (2) an inability to obtain the information through other means.

182. *Id.* at *6-7.
183. *See U.S. ex rel. Cafasso v. General Dynamics C4 Sys., Inc.*, 637 F.3d 1047 (9th Cir. 2011); *U.S. ex rel Wildhirt v. AARS Forever, Inc.*, 2013 WL 5304092 (N.D. Ill. Sept. 19, 2013).
184. 2015 WL 3896947, at *1, 3 (N.D. Ill. Nov. 17, 2015).
185. *Id.* at *2-3.
186. The court held that the defendant did not have standing to object to the subpoena on the grounds that it was overbroad because any burden would be borne by the IRO. *See* 2015 WL 5604367, at *2 (S.D. Ga. Sept. 23, 2015).
187. *Id.* at *3-6.

In these three cases, the district courts concluded the defendants had not established a substantial need for the documents or undue hardship in obtaining the information.[188] In particular, the courts rejected the defendants' arguments that compiling information through extensive discovery created a substantial need and undue burden because those means of discovery adequately provided access to any information contained in the disclosure statements.[189] Given the availability of other discovery mechanisms, particularly the ability to depose relators and "glean" information about allegations contained in the disclosure statement,[190] these recent decisions suggest the circumstances in which a relator's disclosure statement will be discoverable will be extremely limited.[191]

**Limiting the Temporal and Geographic Scope of Discovery**

Courts often are called upon to determine the scope of discovery in FCA cases in which relators allege wide-ranging fraud schemes.

In ***U.S. ex rel. Dalitz v. AmSurg Corp.***,* the district court rejected the relators' attempt to obtain nationwide discovery based on alleged misconduct occurring at the particular facility where the relators formerly worked.[192] The district court determined that the relators conclusory allegations of a national scheme did not plausibly suggest that the alleged conduct occurred outside of the facility at which the relators had worked. The district court found that the relators failed to demonstrate the relevance of the requested discovery and concluded that the discovery sought was disproportionate to the needs of the case.

In ***U.S. ex rel. Oughatiyan v. IPC The Hospitalist Company***, the district court applied initial geographic limitations in a "staged discovery" approach instead of approving DOJ's requests for "nationwide discovery" when it had pleaded a "nationwide scheme." The district court explained "[s]taged discovery" limits the burdens on both parties in discovery by "allow[ing] what is learned in the first stage to inform and refine any further discovery." In particular, the district court was sensitive to the burdens of producing electronically stored information, noting "the additional cost of accessing different systems in the different subsidiaries" in multiple states "is not justified." The district court agreed with the defendant's proposal to initially limit discovery to those seven states with regard to which the complaint made factual allegations, but left open the possibility for the government to seek additional discovery if the first stage of discovery suggested "an expanded geographic scope is appropriate."[193]

> "Because the false claim itself is a requirement of a FCA cause of action, it is not sufficient that the Amended Complaint alleges underlying fraudulent conduct with particularity; it must also allege the presentation of false claims for payment to the government with the same particularity."
>
> *U.S. ex rel. Prather v. Brookdale Sr. Living Communities, Inc.*

## JUDICIAL REVIEW OF SETTLEMENTS

In ***Rille v. PricewaterhouseCoopers, LLP***, the relator brought an FCA action against several government contractors based upon allegations of fraudulent disclosures made to the government and failure to implement contracted price reductions.[194] After investigating the allegations, the government intervened in the action and eventually settled with the defendants. The relators then moved

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

188. *See U.S. ex rel. Spletzer v. Allied Wire & Cable, Inc.*, 2015 WL 7014620, at *3 (E.D. Penn. Nov. 12, 2015); *U.S. ex rel. Fisher v. Oscwen Loan Servicing, LLC*, 2015 WL 4609742, at *4 (E.D. Tex. July 31, 2015); *U.S. ex rel. Fisher v. Homeward Residential, Inc.*, 2015 WL 4610284, at *4 (E.D. Tex. July 31, 2015).
189. 2015 WL 4609742, at *4 (noted relators had produced all the factual documents that accompanied the disclosure statement and the identities of any people named in the statement); 2015 WL 4610284, at *4 (same); 2015 WL 7014620, at *3 (deposition of the relator would "not only aid in narrowing down the amount of documents that Defendant would be required to examine but it also provides an additional avenue for Defendant to glean what information was included in the [disclosure statement].").
190. 2015 WL 7014620, at *3.
191. But see *U.S. ex rel. Cericola v. Ben Franklin Bank*, 2003 WL 22071484, at *3-4 (N.D. Ill. Sept. 4, 2003) (portions of disclosure are discoverable when defendants argued a substantial need existed because they needed to compare the disclosure to publicly available information previously disclosed by defendants to determine if relator was an original source).
192. 2015 WL 8717398 (E.D. Cal. Dec. 15, 2015).
193. 2015 WL 4249195, at *2-4 (N.D. Ill. July 14, 2015).
194. 803 F.3d 368 (8th Cir. 2015).

to recover a share of the proceeds. The government objected, arguing that the relators' complaint did not form the basis of the claims that the government had settled with the defendants. The district court awarded the relators 17% of the settlement amount, from which DOJ appealed.

On appeal the Eighth Circuit, citing the Sixth Circuit's opinion in ***U.S. ex rel. Bledsoe v. Community Health Systems, Inc.***,[195] held that relators are entitled to the proceeds of a settlement "where the conduct contemplated in the settlement agreement overlaps with the conduct alleged in the relator's complaint." Relators, however, are not entitled to proceeds of settlements that "resulted from the claim" or "were caused by the claim." The case was remanded to allow the district court to apply the correct legal standard.

In ***U.S. ex rel. Doghramji v. Community Health Systems, Inc.***, the district court considered requests for attorneys' fees by relators who were party to seven cases that were part of a $97 million global settlement with the United States by the defendants regarding FCA claims primarily focused on patient status issues.[196] After paying attorneys' fees in connection with two of the cases, the defendants objected to paying fees and expenses of other relators. The defendants argued that they had reserved the right to object to such fees and expenses under the FCA's attorneys' fee provision, § 3730(d), and that the FCA's first-to-file and/or the public disclosure provisions barred the award of fees and expenses sought by the relators. The district court concluded that neither the FCA's first-to-file bar, nor the FCA's public disclosure provisions were implicated by the defendants' reservation of rights regarding §3730(d).

195. 342 F.3d 634 (6th Cir. 2003).
196. 2015 WL 4662996 (M.D. Tenn. Aug. 6, 2015).

# STARK LAW/ANTI-KICKBACK STATUTE

**Last year saw increased pressure on establishing compliant physician employment arrangements following a number of large settlements based on alleged Stark Law and AKS violations for above FMV and commercially unreasonable arrangements.**

At the same time, DOJ sharpened its focus on these substantive aspects of physician arrangements, CMS provided relief from several of the technical aspects of the Stark Law.

**Physician Compensation Arrangements Garner Scrutiny**

In ***U.S. ex rel. Payne v. Adventist Health***, Adventist agreed to pay a record-setting $118.7 million to settle allegations that it violated the FCA by maintining improper physician compensation arrangements under the Stark Law and AKS.[197]

In two parallel *qui tam* actions, relators alleged that Adventist instituted a corporate policy of encouraging its hospitals to purchase physician practices or employ physicians to control patient referrals for both inpatient and outpatient services and boost the hospital's revenues. To convince the physicians to sell their practices or become hospital employees, Adventist allegedly provided the physicians and their employees with excessive compensation, perks and benefits. Adventist also allegedly ignored a prior FMV survey that flagged 50 physician compensation arrangements as potentially not being commercially reasonable.

The scheme to control referral revenue through employed and contracted physicians was allegedly demonstrated by a "pattern of economic trade-offs" where hospitals were willing to pay above FMV compensation to physicians and absorb persistent losses because the hospital captured the referral revenue generated by those physicians.

In its press release announcing this record-breaking settlement, DOJ warned "would be violators" to "take notice" that DOJ "will use the False Claims Act to prevent and pursue health care providers that threaten the integrity of our healthcare system and waste taxpayer dollars" by promising to "continue to investigate such wasteful business arrangements."[198]

In ***U.S. ex rel. Reilly v. North Broward Hospital District***, DOJ announced a $69.5 million settlement with North Broward Hospital District, a special taxing district of Florida that operates hospitals and healthcare facilities.[199] Similar to ***Adventist***, this case alleged that Broward was liable under the FCA for providing excessive compensation in violation of the Stark Law and AKS. Specifically, the complaint alleged that Broward deliberately recruited, employed and agreed to pay physicians excessive compensation based in part on anticipated profits from referrals from such physicians to Broward hospitals and clinics. Broward also actively monitored and tracked these referral profits in secretive "Contribution Margin Reports." If the value and volume of referrals did not offset the high compensation, Broward allegedly pressured physicians for increased referrals to Broward hospitals and clinics.

The complaint also alleged that the compensation paid to employed physicians exceeded the 90th percentile and that the compensation to collections ratio

> "The *sine qua non* of a FCA case is not the defendant's bad conduct, procedures, or policies, but the actual false claim."
>
> *U.S. ex rel. Paradies v. AseraCare Inc.*

197. *U.S. ex rel. Payne v. Adventist Health System/Sunbelt, Inc.*, No. 12-856 (W.D.N.C); *U.S. ex rel. Dorsey v. Adventist Health System Sunbelt Healthcare Corp.*, No. 13-217 (W.D.N.C).
198. http://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations.
199. *U.S. ex rel. Reilly v. North Broward Hospital District*, No. 10-60590 (S.D. Fla.).

(which exceeded a 1:1 ratio) was double that of the 90th percentile. In its press release announcing the settlement, DOJ highlighted its continued focus on physician compensation arrangements, noting that "our citizens deserve medical treatment uncorrupted by excessive salaries paid to physicians as a reward for the referral of business rather than the provision of the highest quality healthcare."[200]

In ***U.S. ex rel. Barker v. Columbus Regional Healthcare System Inc.***, DOJ reached a settlement with Columbus Regional Healthcare System and a medical oncologist employed by Columbus Regional's cancer center in which Columbus Regional agreed to pay $25 million and up to $10 million in contingency payments.[201] The settlement resolved alleged FCA violations based on Stark Law and AKS violations and allegations of up-coding.

The complaint alleged that Columbus Regional paid the physician more than twice the amount of the collections and revenue Columbus Regional received for the services he personally performed. DOJ explained that "the only way [this compensation arrangement] makes sense is if [Columbus Regional] determined his compensation by indirectly calculating the financial benefits to [Columbus Regional] of the designated health services [the physician] referred to the Defendant."[202] In addition to his clinical compensation, the physician also received a stipend of $300,000 for two medical directorships. Nearly half of the oncologists employed by the cancer center served as medical directors, calling into question the need for duplicative services and the commercial reasonableness and necessity of the directorship arrangements. And, despite getting multiple valuations indicating that the physician was being compensated above the 90th percentile, the parties continued under this arrangement.

In ***U.S. ex rel. Schaengold v. Meml. Health, Inc.,*** Memorial Health, a not for profit health system operating a Savannah, Georgia, hospital, agreed to pay almost $9.9 million to settle alleged Stark Law and AKS violations.[203] To address financial pressure due to declining patient volumes, Memorial discussed expanding its employed primary physician base to ensure that specialists received referrals. It then focused on acquiring Eisenhower Medical Associates

> "Because this case involves civil [FCA] claims, the WSLA does not suspend the applicable statute of limitations under either the 1948 or the 2008 version of the statute."
>
> *Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*

to shift patient admissions and referrals from a competing hospital. A pro forma projected that the acquisition would result in a financial loss of $650,000 for each of the five years after acquisition. Memorial continued with the transaction despite this fact and incurred a loss of roughly $3 million during a 30-month period. Conversely, the physicians received an estimated compensation of $1.5 million in compensation above FMV during the same 30-month period. Memorial's Board of Directors was eventually informed by the relator of the FMV issues and its consequences, but the Board allegedly rejected a plan to correct the overcompensation and voted to extend the contracts to avoid losing referral volume.

In ***U.S. ex rel. Dan Bisk v. Westchester County Health Care Corporation,*** Westchester County Health Care Corporation ("WMC") agreed to pay $18.8 million to settle claims that it violated the Stark Law and AKS.[204] From 2000 through 2007, WMC maintained an improper financial relationship with Cardiology Consultants of Westchester, P.C. ("CCW"), a cardiology practice formerly operating on WMC's Valhalla campus.[205] WMC allegedly advanced funds to CCW to open a practice for the express purpose of generating referrals to the hospital.[206] WMC received hundreds of referrals as a result, and CCW carefully tracked referrals and discussed the value of these referrals to WMC.[207] When CCW began making payments to WMC, purportedly repaying the advances, WMC entered into retroactive, no-work consulting agreements under which it

200. http://www.justice.gov/opa/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act.
201. *U.S. ex rel. Barker v. Columbus Regional Healthcare System*, No. 4:12-cv-108 (M.D. Ga.); *U.S. ex rel. Barker v. Columbus Regional Healthcare System*, No. 4:14-cv-304 (M.D. Ga.).
202. http://www.justice.gov/opa/pr/georgia-hospital-system-and-physician-pay-more-25-million-settle-alleged-false-claims-act-and.
203. *U.S. ex rel. Schaengold v. Meml. Health, Inc.*, No. 4:11-CV-00058 (S.D. Ga.); *see also* http://www.justice.gov/usao-sdga/pr/government-settles-alleged-false-claims-act-violations-memorial-health-inc.
204. *U.S. ex rel. Dan Bisk v. Westchester Medical Center, Westchester County Health Care Corporation*, No. 06-CV-15296 (S.D.N.Y.); *see also* http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-westchester-medical-center.
205. *U.S. ex rel. Dan Bisk Westchester Medical Center, Westchester County Health Care Corporation*, No. 06-CV-15296, Compl. in Intervention of the United States of America, at ¶¶ 39-61.
206. *Id.*
207. *Id.* at ¶¶ 49, 52.

paid CCW tens of thousands of dollars.[208] Additionally, WMC permitted CCW to use WMC's residents and fellows free of charge.[209]

In ***U.S. ex rel. Parikh v. Citizens Med. Ctr.***, Citizens Medical Center agreed to pay $21.75 million to settle alleged FCA violations tied to Stark Law and AKS allegations.[210] Citizens is a county-owned hospital in Texas which allegedly implemented a bonus and fee-sharing program for physicians that referred patients to Citizens and allegedly compensated employed physicians beyond FMV.[211]

### Final Chapter: Resolution of *Tuomey* Case

After roughly 10 years of litigation, ***U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.*** finally ended with a $72.4 million settlement before the sale of Tuomey Healthcare System to Palmetto Health. This settlement followed a ruling by the Fourth Circuit, which affirmed the district court's order for Tuomey to pay more than $237.5 million for Stark Law, AKS and FCA violations.[212]

The allegations involved Tuomey's attempt to regain lost revenue from physicians who began performing procedures at their own offices or off-site surgery centers by entering into part-time employment agreements.[213] These agreements provided compensation by combining a base salary and a bonus determined by the physician's collections.[214] Initially, the district court found that Tuomey had violated the Stark Law and the FCA by employing and compensating 19 part-time physicians in excess of FMV and in a manner that varied with the volume or value of their referrals.[215] Affirming the lower court's decision, the Fourth Circuit held that the physicians' base salaries and bonus payments could be viewed as varying with the "volume or value of referrals" to the hospital, even though the base salaries were based on the physicians' professional services collections and bonuses were tied solely to the collection of professional fees rather than hospital facility fees.[216]

### CMS Stark Law Changes Increase Flexibility and Reduce Technical Burdens

In October 2015, CMS implemented changes to the Stark Law promoting flexibility and easing technical burdens while reducing ambiguity in its Final Rule revising the Medicare Physician Fee Schedule.[217] These changes should ease the technical burdens associated with the Stark Law and reduce the number of technical violations, which helped create a wave of self-disclosures that has resulted in a Self-Disclosure Protocol backlog that can span years. Notable clarifications include the following:

- CMS clarified that the "in writing" requirement found in many of the Stark Law's exceptions can be met through a collection of documents, even in absence of a formal contract.[218] Specifically, a collection of documents may include "contemporaneous documents evidencing the course of conduct between the parties" and "the relevant inquiry is whether the available contemporaneous documents . . . would permit a reasonable person to verify compliance with the applicable exception at the time a referral is made."[219]
- CMS removed the distinction between inadvertent and advertent failures to obtain signatures by uniformly allowing for a 90-day grace period to obtain missing signatures.[220] At most, the new temporary noncompliance rule may be used only once every three years with respect to the same referring physician.
- CMS eased technical burdens to allow expired leasing and personal services arrangements to continue indefinitely on the same terms and conditions

208. *Id.* at ¶¶ 50-51.
209. *Id.* at ¶¶ 53-57.
210. *U.S. ex rel. Parikh v. Citizens Medical Center*, No. 6:10-CV-64 (S.D. Tex.); *see also* http://www.justice.gov/opa/pr/texas-based-citizens-medical-center-agrees-pay-united-states-2175-million-settle-alleged.
211. *U.S. ex rel. Parikh v. Citizens Med.* Ctr., 977 F. Supp. 2d 654 (S.D. Tex. 2013) aff'd sub nom. *U.S. ex rel.* Parikh v. Brown, 762 F.3d 461 (5th Cir. 2014), opinion withdrawn and superseded on reh'g 587 F. App'x 123 (5th Cir. 2014), withdrawn from bound volume (Oct. 1, 2014), and aff'd sub nom. *U.S. ex rel. Parikh v. Brown*, 587 F. App'x 123 (5th Cir. 2014).
212. *U.S. ex rel.* Drakeford v. Tuomey Healthcare Sys., 792 F.3d 364 (4th Cir. 2015).
213. *Id.* at 371-72.
214. *Id.*
215. *Id.* at 373; *U.S. ex rel. Drakeford v. Tuomey*, 976 F. Supp.2d 776 (2013).
216. *Id.* at 379-80.
217. 80 Fed. Reg. 70886 ( Nov. 16, 2015).
218. *See* 42 C.F.R. §§ 411.357 (requiring arrangements be set forth in writing to meet various exceptions to the Stark Law).
219. 80 Fed. Reg. 71315.
220. 42 C.F.R. § 411.353(g).

> "A manufacturer that leaves its sales force at liberty to converse unscripted with doctors about off-label use of an approved drug invites a misbranding action if false or misleading (e.g., one-sided or incomplete) representations result."
>
> *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*

as the immediately preceding arrangement, as long as the arrangement is otherwise compliant, including continuing to satisfy FMV.[221]

- CMS also promoted additional access for care by creating a new exception allowing for a hospital to assist in the recruitment of a non-physician practitioner for primary care and mental health services.

**Focus on Laboratory Arrangements Continues**

Two cardiovascular disease testing laboratories paid $48.5 million to resolve allegations that they paid remuneration to cardiologists in exchange for patient referrals.[222] The allegations involved the improper processing and handling fees, activities addressed by the HHS-OIG in a 2014 Special Fraud Alert.[223] In particular, the laboratories induced physicians to refer patients for blood tests by paying them processing and handling fees of between $10 and $17 per referral and by routinely waiving co-pays and deductibles.

221. 42 C.F.R. § 411.357; 80 Fed. Reg. 71320.
222. *U.S. ex rel. Mayes v. Berkeley HeartLab, Inc.*, No. 9:11-cv-01593-RMG (D.S.C.); *U.S. ex rel. Riedel v. Health Diagnostic Laboratory, Inc.*, No. 1:11-cv-02308 (D.D.C.); *U.S. ex rel. Lutz v. Health Diagnostic Laboratory, Inc.*, No. 9:14-cv-0230-RMG (D.S.C.); *see also* http://www.justice.gov/opa/pr/two-cardiovascular-disease-testing-laboratories-pay-485-million-settle-claims-paying.
223. http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.

# PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

**Last year, regulatory and enforcement agencies, including the DOJ, HHS-OIG, and the FDA continued to scrutinize the activities of pharmaceutical and medical device manufacturers, including their financial relationships with specialty pharmacies and insurance providers.**

In addition, the government continued to monitor the conduct of compound pharmacies. Further, and of particular note, the DOJ ramped up its efforts to hold executives criminally liable for corporate misconduct.

It was not all bad news for manufacturers, as the life sciences industry received a favorable judgment that may slow the FDA's ability to bring off-label promotion enforcement actions against pharmaceutical and medical device manufacturers.

### Rebate Agreements between Manufacturers and PBMs

DOJ resolved a number of cases involving allegedly inappropriate remuneration arrangements between pharmaceutical manufacturers and pharmacy benefit managers ("PBMs"). It is common for pharmaceutical companies to offer large purchasers of their products (including PBMs) rebates on their drugs. These arrangements can be problematic, if manufacturers are found to be improperly influencing what drugs are made available by the PBMs to consumers.

For example, AstraZeneca agreed to pay the government $7.9 million to resolve allegations that it paid kickbacks to Medco Health Solutions in exchange for Medco keeping Nexium at an elevated status on certain Medco formularies.[224] Medco allegedly received up to $40 million of remuneration through price concessions on three of AstraZeneca's other products. In the corresponding press release, DOJ signaled that it would pursue similar actions and noted that these types of "hidden financial relationships" between PBMs and manufacturers are problematic because they "can improperly influence which drugs are available to patients and price paid for drugs."

Novartis Pharmaceuticals Corp. agreed to pay $390 million to settle allegations that it gave kickbacks to induce pharmacies, including Accredo Health Group, Inc., Bioscrip, Inc., Curascript, Inc. and CVS Caremark Corporation, to recommend Novartis' specialty medications Exjade and Myfortic.[225] Novartis allegedly entered into rebate contracts with the pharmacies that specifically tied discounts on drugs to the pharmacy's ability to induce referrals; the higher the refill rates, the higher rebates offered. Prior to the agreement with Novartis, Bioscrip and Accredo reached settlements totaling approximately $75 million to resolve related federal and state claims.

### Compound Pharmacy Enforcement

In November 2013, Congress empowered the FDA with oversight authority over compound pharmacies that produce sterile drugs in batches for hospitals and physicians (referred to as "outsourcing facilities") and instituted requirements that such facilities meet the Current Good Manufacturing Practices ("CGMP") requirements.[226] As it did in 2014, the FDA continued to utilize its newly vested authority to closely inspect compound pharmacies. As a result, the FDA, for a second consecutive year, issued more than 25 warning letters to compound pharmacies in 2015.[227]

In addition to the FDA, the DOJ also turned its focus on compound pharmacies. In July 2015, the U.S. Attorney's Office for the Middle District of Florida stated publicly that compound pharmacies were likely to receive closer scrutiny, as coverage for prescription drugs expanded and the prices for various specialty medicines continue to increase in price.[228]

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224. *See* http://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations.
225. *See* http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis.
226. Drug Quality and Security Act, 113 P.L. 54, 127 Stat. 587.
227. *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm.
228. *See* http://www.law360.com/articles/680619/us-atty-sees-big-fca-hauls-looming-in-fla-.

Late last year, DOJ announced that six compound pharmacies in Florida, their owners and associated physicians agreed to pay approximately $30 million to resolve claims that they fraudulently billed TRICARE.[229] Jacksonville-based MedMatch took the largest hit, agreeing to pay $4.7 million to settle allegations that it paid kickbacks to marketers, filled prescriptions it knew or should have known were illegitimate, and disseminated prescription drugs to locations in which it did not have a valid license. While Florida appears to be leading the charge in enforcement, compound pharmacies in other jurisdictions should anticipate a similar crackdown in their region.

### Holding Individuals Accountable for Criminal Conduct

DOJ has expressed its continued willingness to rely on the Park Doctrine to prosecute executives responsible for corporate fraud. The doctrine, which received its name after the 1975 Supreme Court case ***United States v. Park***, permits the government to prosecute executives based on their position in the corporate structure if the official had responsibility over conduct that violated the FDCA.[230] For example, in April 2015, two top executives from Quality Egg, LLC received three-month prison sentences for their role in a 2010 salmonella outbreak that resulted in nearly 2,000 reported consumer illnesses.[231] The company's owner and chief operating officer claimed that they had no knowledge that their company's products were contaminated, but were still charged with violating § 333(a)(1) of the FDCA, a strict liability misdemeanor offense. In the government's press release regarding the sentencing, it made clear that claims of ignorance or delegation of responsibility would not protect someone from criminal responsibility.[232]

Although not specifically relying on the Park Doctrine, in June 2015, the former chief executive officer of OtisMed Corporation was sentenced to 24 months in prison, one year of supervised release, and a fine of $75,000 for his role in introducing adulterated devices into interstate commerce.[233] Between 2006 and 2009, OtisMed promoted and sold thousands of its OtisKnee cutting guide tools to surgeons despite failing to satisfy the FDA's pre-market requirements and possibly compromising patient safety.

Given the announcement of the Yates Memo and the DOJ's continued willingness to rely on the Park Doctrine to pursue individual wrongdoers, pharmaceutical and medical device manufacturers should be on high alert, as these initiatives strongly suggest that individual employees, particularly executives, will increasingly face criminal prosecution for corporate misconduct.

### Off-Label Enforcement Efforts

In previous years, we reported that state and federal enforcement agencies continued to target pharmaceutical companies promoting drugs for off-label purposes. While that enforcement priority remains, life science companies took a big step in reducing the FDA's ability to bring enforcement actions against companies for making non-misleading, truthful, but off-label, statements about its products.

In ***Amarin Pharma, Inc. v. U.S. Food & Drug Admin.,*** the district court granted Amarin Pharma's request for a preliminary injunction, preventing the FDA from bringing misbranding claims against the company for using truthful information to promote its product Vascepa for off-label purposes.[234] Amarin alleged that the threat of an FDA enforcement action chilled the company's right to free speech under the First Amendment and diminished its ability to provide physicians with accurate and non-harmful information. In reaching its conclusion, the district court relied heavily on the Second Circuit's decision in ***United States v. Caronia***, which vacated the conviction of a sales representative charged with promoting a product to a physician for an off-label purpose despite using truthful, non-misleading information.[235] The district court concluded that "where the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under ***Caronia,*** *cannot* be the act upon which an action for misbranding is based."[236]

While the court's thorough decision protects only a narrow type of speech, it is likely to have a significant impact on the industry and act as a gateway for additional challenges to the FDA's authority to bring misbranding claims.

229. *See* http://www.justice.gov/usao-mdfl/pr/united-states-announces-new-round-compound-pharmacy-settlements-expected-result-more-30.
230. *See* 421 U.S. 648 (1975).
231. *See* http://www.justice.gov/usao-ndia/pr/quality-egg-company-owner-and-top-executive-sentenced-connection-distribution.
232. This case is on appeal to the Eight Circuit, as the executives have questioned the government's ability to issue prison sentences for FDCA violations when the charged individuals were unaware of the underlying misconduct.
233. *See* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm452987.htm.
234. 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015).
235. *See United States v. Caronia*, 703 F.3d 149 (2d Cir.2012).
236. 2015 WL 4720039 at *25.

# APPENDIX

## APPENDIX A - 2015 NOTABLE SETTLEMENTS

# HOSPITALS AND HOSPITAL SYSTEMS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| January 9, 2015 | Medical College of Wisconsin | The Medical College of Wisconsin agreed to pay $840,000 to resolve FCA allegations that it improperly billed Medicare and Tricare for teaching physicians' services involving residents when those physicians were responsible for multiple overlapping surgeries and did not provide the requisite level of supervision for the surgeries.[1] | $840,000 |
| January 16, 2015 | South Shore Physicians Hospital Organization ("SSPHO"); South Shore Hospital, Inc.; Physicians Organization of the South Shore, Inc. | South Shore Physicians Hospital Organization and its affiliates agreed to pay nearly $1.8 million to the United States and Massachusetts to resolve FCA allegations that SSPHO approved 103 recruitment cash grants to 33 physician groups who agreed to refer patients to SSPHO affiliated providers. This action arose after SSPHO voluntarily reported the results of its own independent review to regulatory officials.[2] | $1.775 million |
| February 2, 2015 | Community Health Systems ("CHS") Professional Services Corporation; Eastern New Mexico Medical Center; Mimbres Memorial Hospital and Nursing Home; Alta Vista Regional Medical Center | CHS and three affiliated hospitals agreed to pay $75 million to resolve FCA allegations in a *qui tam* action styled ***U.S. ex rel. Baker v. Community Health Systems*** (D.N.M.) that CHS caused the state of New Mexico to submit false claims by making improper donations to various counties that were then impermissibly used to obtain federal matching payments under New Mexico's Sole Community Provider program. In connection with the settlement, the relator agreed to the dismissal of similar claims against two other hospitals in which the United States previously declined to intervene.[3] | $75 million |
| February 23, 2015 | Portage Hospital, LLC | Portage Hospital agreed to pay $4.44 million to resolve FCA allegations that one of its staff therapists had provided physical therapy services to Medicare home health patients that were medically unnecessary, inadequately documented and/or not qualified for reimbursement for other reasons. This investigation and settlement resulted from Portage's self-disclosure to HHS-OIG.[4] | $4.44 million |
| February 27, 2015 | Baptist Health Medical Center North Little Rock ("BHMC-NLR") | BHMC-NLR agreed to pay $2.7 million to resolve FCA allegations that it improperly billed Medicare for certain "short-stay" inpatient stays, defined as hospital stays lasting less than two nights, as a result of (1) improper orders converted from outpatient status to inpatient status; (2) improper inpatient standing orders for admission without proper physician involvement; and (3) improper orders for inpatient status following scheduled outpatient procedures. As part of the settlement, Baptist Health, BHMC-NLR and a sister hospital agreed to enter into a five-year CIA with HHS-OIG.[5] | $2.7 million |
| March 18, 2015 | Adventist Health System Sunbelt Healthcare Corporation | Adventist Health, a nonprofit health system and hospital operator, agreed to pay $5.41 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Montejo v. Adventist Health System Sunbelt Healthcare*** (M.D. Fla.) that several of its facilities wrongfully billed Medicare for radiation oncology services provided to beneficiaries without adequate supervision by radiation oncologists. After initially declining to intervene in the action, the government later partially intervened only as to certain claims against Adventist for settlement purposes.[6] | $5.41 million |

1. http://www.justice.gov/usao-edwi/pr/medical-college-wisconsin-inc-pays-840000-settle-alleged-false-claims-neurosurgeries.
2. http://www.justice.gov/usao-ma/pr/south-shore-physicians-hospital-organization-pay-1775-million-alleged-kickbacks-patient.
3. http://www.justice.gov/opa/pr/community-health-systems-professional-services-corporation-and-three-affiliated-new-mexico.
4. http://www.justice.gov/usao-wdmi/pr/2015_0323_PortageHospital.html.
5. http://www.justice.gov/usao-edar/pr/baptist-health-medical-center-north-little-rock-enters-settlement-agreement-under-false.
6. http://www.justice.gov/opa/pr/adventist-health-system-pay-54-million-resolve-false-claims-act-allegations.

| DATE | ENTITY | ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| March 31, 2015 | Robinson Health System, Inc. | Robinson Health System agreed to pay $10 million to resolve FCA allegations that it paid improper remuneration in exchange for referrals to more than 30 physicians during a 10-year period, in violation of the AKS and Stark Law. The remuneration allegedly took the form of management agreements with at least two physician groups when the payments were not justified by the good faith management services provided by the physicians, and lease and service agreements lacking adequate documentation. The investigation and settlement resulted from Robinson's self-disclosure of questionable financial relationships to HHS-OIG, following a due diligence review conducted while searching for a partner health system.[7] | $10 million |
| April 21, 2015 | Citizens Medical Center | Citizens Medical Center agreed to pay $21.75 million to resolve FCA allegations that it compensated several cardiologists in excess of the FMV for their services and paid bonuses to emergency room physicians that improperly took into account the value of their cardiology referrals, in violation of the Stark Law.[8] | $21.75 million |
| April 27, 2015 | The Medical Center of Central Georgia ("MCCG") | MCCG agreed to pay $20 million to resolve FCA allegations that it billed for medically unnecessary inpatient admissions when the care provided should have billed as outpatient or observation services. As part of the settlement, MCCG agreed to enter into a five-year CIA with HHS-OIG.[9] | $20 million |
| April 29, 2015 | Hospital Authority of Irwin County ("ICH") | ICH agreed to pay $520,000 to resolve FCA allegations of purported violations of the AKS and Stark Law related to the amount of compensation paid by ICH to one physician, ICH's leases with nine physicians, and the supervision of certain diagnostic imaging services at ICH.[10] | $520,000 |
| May 7, 2015 | Jackson-Madison County General Hospital | Jackson-Madison County General Hospital agreed to pay $1.32 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Deming, et al. v. Jackson-Madison County General Hospital, et al.*** (W.D. Tenn.) that the hospital billed Medicare and Medicaid in connection with unnecessary cardiac stent placements and other unnecessary cardiac procedures. The government declined to intervene in the action as to the allegations against the hospital, only intervening against a physician.[11] | $1.32 million |
| May 7, 2015 | Health Management Associates ("HMA"); Community Health Systems; Various Hospitals | HMA and 14 hospitals it formerly owned and operated, CHS and a subsidiary hospital, and the North Texas Medical Center agreed to pay collectively $15.69 million to resolve FCA allegations that they billed for intensive outpatient psychotherapy ("IOP") services in violation of certain Medicare rules and policies because, for example, the patient's condition did not qualify for IOP or the patient's progress was not being adequately tracked and documented. The IOP services at issue were typically performed on the providers' behalf by a separate post-acute healthcare management company.[12] | $15.69 million |

7. http://www.justice.gov/opa/pr/ohio-based-health-system-pays-united-states-10-million-settle-false-claims-act-allegations.
8. http://www.justice.gov/opa/pr/texas-based-citizens-medical-center-agrees-pay-united-states-2175-million-settle-alleged.
9. http://www.justice.gov/opa/pr/georgia-hospital-pay-20-million-resolve-false-claims-act-allegations.
10. http://www.justice.gov/usao-mdga/pr/hospital-authority-irwin-county-resolves-false-claims-act-investigation-520000.
11. http://www.justice.gov/usao-wdtn/pr/tennessee-hospital-pays-132-million-settle-allegations-improper-medicare-and-medicaid.
12. http://www.justice.gov/opa/pr/sixteen-hospitals-pay-1569-million-resolve-false-claims-act-allegations-involving-medically.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| May 8, 2015 | Baptist Health; Century Ambulance Service; Various Hospitals | Baptist Health, owner and operator of four Florida hospitals, Century Ambulance Service, and five other Florida hospitals agreed to pay collectively $7.5 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Pelletier v. Southern Baptist Hospital of Florida, Inc., et al.*** (M.D. Fla.). The hospitals allegedly provided Certificates of Medical Necessity that attested to the need for basic life support, non-emergency transports even when those transports were not medically necessary. Century Ambulance allegedly upcoded claims from Basic to Advanced life support, unnecessarily transported patients and unnecessarily transported patients to their homes in an "emergent" fashion. As part of the settlement, Century Ambulance agreed to enter into a five-year CIA with HHS-OIG. The government did not reach a settlement with one defendant in the *qui tam* action, Liberty Ambulance, and subsequently filed an intervening complaint against Liberty in August 2015, which is detailed in the next section.[13] | $7.5 million |
| May 14, 2015 | Westchester Medical Center ("WMC") | WMC agreed to pay $18.8 million to resolve FCA allegations that it violated the AKS and Stark Law through an improper financial relationship with a cardiology practice during a six-year period. The government contended that (1) WMC advanced monies to the cardiology practice to open a practice for the express purpose of generating referrals to WMC; (2) when the cardiology practice started repaying the advances, WMC entered into retroactive, no-work consulting agreements under which it paid the cardiology practice tens of thousands of dollars; and (3) WMC permitted the cardiology practice to use its fellows in the practice's office free of charge. The settlement also resolved related allegations that WMC obtained Medicare reimbursement for costs it did not occur.[14] | $18.8 million |
| June 4, 2015 | Health Management Associates; Clearview Regional Medical Center | HMA and Clearview Regional Medical Center agreed to pay $595,155 to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Williams v. Health Mgmt. Assocs. Inc., et al.*** (M.D. Ga.) that the hospital paid kickbacks to an obstetric clinic that primarily served undocumented Hispanic women, in exchange for referral of those patients to the hospital. Co-defendants Tenet Healthcare Corporation and several affiliated entities are still litigating this case, in which the government intervened in 2014.[15] | $595,155 |
| June 15, 2015 | Children's Hospital; Children's National Medical Center, Inc. | Children's Hospital, Children's National Medical Center and affiliated entities agreed to pay $12.9 million to resolve FCA allegations that they submitted false information regarding their available bed count used to calculate reimbursement in an HHS pediatric program application and filed cost reports misstating their overhead costs.[16] | $12.9 million |
| June 15, 2015 | Vanguard Health Systems, Inc.; Arizona Heart Institute ("AHI"); Vanguard Physician Services, LLC; Abrazo Health Systems; | Vanguard Health, AHI and affiliated entities agreed to pay $2.9 million to resolve FCA allegations that the Vanguard-owned AHI paid certain physicians salaries and bonuses that were above fair value and violated the Stark Law and AKS. The settlement also resolved allegations that AHI physicians upcoded evaluation & management ("E&M") patient visit codes and that AHI billed for cardiac rehabilitation therapy provided by a physician who was not properly supervising the therapists providing the services.[17] | $2.9 million |
| June 29, 2015 | John Muir Health | John Muir Health agreed to pay $550,000 to resolve FCA allegations that physicians who were contracted with John Muir Health to provide radiation therapy failed to properly supervise that treatment, which is a condition of payment for Medicare.[18] | $550,000 |

13. http://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-multiple-jacksonville.
14. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-westchester-medical-center.
15. http://www.justice.gov/opa/pr/united-states-settles-kickback-allegations-georgia-hospital.
16. http://www.justice.gov/opa/pr/childrens-hospital-pay-129-million-settle-false-claims-act-allegations.
17. http://www.justice.gov/usao-mdtn/pr/vanguard-health-systems-inc-agrees-pay-29-million-settle-false-claims-act-allegations.
18. http://www.justice.gov/usao-ndca/pr/john-muir-health-agrees-pay-550000-resolve-false-claims-allegations.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| June 30, 2015 | Community Health Network ("CHN") | CHN agreed to pay $20.32 million to resolve FCA allegations that it billed Medicare and Medicaid for outpatient surgeries performed in its hospitals when the surgeries were actually performed in free-standing ambulatory surgery centers ("ASCs"), not owned by CHN. CHN, which contracted with the ASCs to provide surgical services to CHN patients and then billed for the services, allegedly billed in this fashion for nearly two years after being specifically placed on notice by CMS that services provided in an ASC should only be billed at ASC rates. As part of the settlement, CHN agreed to enter into a five-year CIA with HHS-OIG.[19] | $20.32 million |
| August 12, 2015 | Oswego Hospital; Dr. Vilas Patil | Oswego Hospital agreed to pay $1.45 million to resolve FCA allegations related to billing improprieties that Oswego voluntarily disclosed to the government and, upon discovery, took corrective action to remedy. Specifically, Oswego identified claims during an internal review where supporting documentation: (1) was not created or could not be located; (2) contained incorrect service dates; (3) were simply verbatim treatment notes from prior appointments with patients; and/or (4) failed to include time-related information required for certain time-based billing codes. In a related investigation, Dr. Vilas Patil, a physician formerly working as an independent contractor with Oswego, agreed to pay $204,365 to resolve FCA liability.[20] | $1.65 million |
| August 13, 2015 | Mercy Health Springfield Communities; Mercy Clinic Springfield Communities | Mercy Health and Mercy Clinic, formerly known as St. John's Health System and St. John's Clinic, agreed to pay $5.5 million to resolve FCA allegations that they paid physician bonuses based on a formula that improperly took into account the value of the physicians' referrals to Adventist hospitals, in violation of the Stark Law.[21] | $5.5 million |
| August 24, 2015 | Benedictine Hospital; Columbia Memorial Hospital; St. Joseph's Medical Center; SpecialCare Hospital Management Corp.; Robert McNutt | Three New York hospitals agreed to pay collectively $2.13 million in connection with a long-running *qui tam* action related to the operation and marketing of inpatient drug and alcohol detoxification programs without having received licenses from the state. In late 2014, it was announced that SpecialCare Hospital Management and its CEO Robert McNutt had agreed to pay $6 million to resolve allegations regarding this action. As part of their settlement agreement, which was not made public until 2015, SpecialCare and McNutt agreed to be enjoined from doing business with any Medicaid or Medicare provider in New York for five years.[22] | $2.13 million |
| September 4, 2015 | Columbus Regional Healthcare System; Dr. Andrew Pippas | Columbus Regional agreed to pay up to $35 million ($25 million in fixed payments, up to $10 million in contingent payments), and Dr. Andrew Pippas agreed to pay $425,000, to resolve FCA allegations that during a 10-year period, Columbus Regional provided excessive salary and directorship payments to Dr. Pippas, in violation of the Stark Law, and that Columbus Regional billed for certain services at higher levels than was actually provided or supported by documentation. As part of the settlement, Columbus Regional agreed to enter into a five-year CIA with HHS-OIG.[23] | $25.425 million (fixed);<br>up to $10 million (contingent) |
| September 15, 2015 | North Broward Hospital District | North Broward Hospital District agreed to pay $69.5 million to resolve FCA allegations that it recruited, employed and agreed to pay nine physicians excessive compensation based in part on anticipated profits from referrals to Broward entities, in violation of the Stark Law. Broward purportedly monitored these referral profits in "Contribution Margin Reports" and pressured physicians to increase referrals if their value was not offsetting the physicians' compensation. As part of the settlement, North Broward agreed to enter into a five-year CIA with HHS-OIG.[24] | $69.5 million |

19. http://www.justice.gov/usao-sdin/pr/united-states-attorneys-office-recovers-over-twenty-million-dollars-case-against.
20. http://www.justice.gov/usao-ndny/pr/oswego-hospital-and-physician-combine-pay-over-15-million-resolve-billing-improprieties.
21. http://www.justice.gov/opa/pr/missouri-hospital-agrees-pay-united-states-55-million-settle-alleged-false-claims-act.
22. http://www.justice.gov/usao-edny/pr/five-defendants-pay-over-8-million-resolve-civil-fraud-allegations-they-billed-medicare.
23. http://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations.
24. http://www.justice.gov/usao-sdfl/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| September 21, 2015 | Adventist Health System | Adventist agreed to pay $115 million to the federal government and $3.5 million to the state of Florida (in a separate settlement) to resolve FCA allegations that it paid physician bonuses based on a formula that improperly took into account the value of the physicians' referrals to Adventist hospitals, in violation of the Stark Law, and billed Medicare for physicians' professional services with improper coding modifiers.[25] | $118.5 million |
| September 29, 2015 | St. Francis Hospital | St. Francis Hospital agreed to pay $4.28 million to resolve FCA allegations that it billed for patients admitted into its inpatient rehabilitation unit when the admission was not medically necessary and/or the services provided did not fully qualify for reimbursement. The settlement also resolved allegations that St. Francis employed an individual that was excluded from participating in federal healthcare programs. St. Francis voluntarily disclosed these issues to the government and took corrective action to address improper payment upon discovering these issues.[26] | $4.28 million |
| October 9, 2015 | West Chester Hospital; UC Health | West Chester Hospital and its parent company agreed to pay $4.1 million to resolve FCA allegations that the hospital billed Medicare and Medicaid for medically unnecessary spine surgeries performed by a surgeon who was previously arrested and charged with related healthcare fraud violations in 2013 and subsequently fled the United States.[27] | $4.1 million |
| October 16, 2015 | Tuomey Healthcare System | The United States and Tuomey reached a settlement to resolve a $237 million judgment entered in 2013 by the trial court in ***U.S. ex rel. Drakeford v. Tuomey Healthcare Systems*** (D.S.C.), involving FCA allegations that Tuomey employed and compensated 19 part-time physicians in excess of FMV and in a manner that varied with the volume or value of their referrals, in violation of the Stark Law. On July 2, 2015, the U.S. Court of Appeals for the Fourth Circuit affirmed the trial court's judgment. Tuomey subsequently agreed to pay $72.4 million to the United States and $2.5 million for the relator's attorneys' costs and fees. The settlement was conditioned on Tuomey being successfully acquired by Palmetto Health prior to December 31, 2015. In connection with the settlement, Tuomey agreed to enter into a five-year CIA with HHS-OIG.[28] | $74.9 million |
| October 30, 2015 | Various Hospitals | The government reached 70 settlements involving 457 hospitals in 43 states for more than $250 million to resolve FCA allegations related to implantable cardioverter defibrillators ("ICDs") being implanted in Medicare patients that recently had suffered a heart attack or had heart bypass surgery or angioplasty prior to certain waiting periods having passed, in violation of Medicare coverage requirements.[29] | $250 million |
| November 16, 2015 | HCA Holdings, Inc.; West Florida Hospital; Regional Medical Center Bayonet Point; Oak Hill Hospital; and Medical Center of Trinity | HCA and four of its Florida hospitals agreed to pay $2 million to resolve FCA allegations that they submitted laboratory claims for direct count low density lipids ("LDL") when the tests were not ordered and/or not medically necessary and improperly billed for fetal biophysical profiles with non-stress tests.[30] | $2 million |
| December 18, 2015 | Various Hospitals | Thirty-two hospitals in 15 states agreed to pay more than $28 million to settle FCA allegations that the hospitals improperly billed Medicare for kyphoplasty spinal fracture treatment by billing the procedure as an inpatient rather than an outpatient procedure. Currently, DOJ has settled FCA claims with more than 130 hospitals related to kyphoplasty treatment.[31] | $28 million |

25. http://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations.
26. http://www.justice.gov/usao-de/pr/hospital-agrees-4-million-settlement-voluntary-disclosures.
27. http://www.justice.gov/opa/pr/ohio-hospital-pay-41-million-resolve-false-claims-act-allegations.
28. http://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital.
29. http://www.justice.gov/opa/pr/nearly-500-hospitals-pay-united-states-more-250-million-resolve-false-claims-act-allegations.
30. http://www.justice.gov/usao-sc/pr/hca-settles-allegations-billing-unnecessary-lab-tests-and-double-billing-fetal-testing.
31. http://www.justice.gov/usao-wdny/pr/32-hospitals-pay-us-more-28-million-resolve-false-claims-act-allegations-related.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| December 21, 2015 | Regional Hospital of Jackson | Regional Hospital of Jackson agreed to pay an undisclosed amount to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Deming, et al. v. Jackson-Madison County General Hospital, et al.*** (W.D. Tenn.) that the hospital billed Medicare and Medicaid in connection with unnecessary cardiac stent placements and other unnecessary cardiac procedures. The government declined to intervene in the action as to the allegations against the hospital, only intervening against a physician.[32] | Undisclosed |
| December 23, 2015 | Aria Health Systems | Aria Health agreed to pay more than $3 million to resolve FCA and Stark Law violations that it self-disclosed to the government. Specifically, the allegations were that (1) Aria made a trademark payment to an orthopedic group during an acquisition in excess of FMV, based on an independent valuation performed during an internal investigation; (2) Aria paid a surgeon annual compensation in excess of fair market value; and (3) a cardiologist performed unnecessary invasive procedures, which Aria became aware of after complaints were raised and an independent review of claims was performed.[33] | $3.06 million |
| December 23, 2015 | Memorial Health, Inc.; Memorial Health University Medical Center; Provident Health Services, Inc.; Memorial Health University Physicians | Memorial Health and its related entities agreed to pay $9.895 million to resolve FCA allegations involving Stark Law violations. As part of the settlement, Memorial Health entered into a five-year CIA with HHS-OIG.[34] | $9.895 million |

# HOSPICE

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| January 30, 2015 | Compassionate Care Hospice of New York, LLC; Compassionate Care Hospice Group Ltd. ("CCH") | The Compassionate Care entities agreed to pay $4.9 million to the United States and $1.6 million to New York resolve FCA allegations that it sought payment from Medicare and Medicaid for hospice nursing services that were not delivered according to several regulatory guidelines governing the provision of reimbursable hospice services. Specifically, CCH New York failed to treat patients according to an individualized plan of care, meet the needs of certain patients, make nursing services available 24/7 as required and maintain adequate clinical records, while CCH Group failed to provide sufficient oversight of CCH New York through its compliance audits. As part of the settlement, CCH Group and CCH New York agreed to enter into five-year CIAs with HHS-OIG.[35] | $6.5 million |
| February 6, 2015 | Good Shepherd Hospice, Inc.; Good Shepherd Hospice of Mid America, Inc.; Good Shepherd Hospice, Wichita, L.L.C.; Good Shepherd Hospice, Springfield, L.L.C.; Good Shepherd Hospice-Dallas L.L.C. | Good Shepherd Hospice and several related entities agreed to pay $4 million to resolve FCA allegations they fraudulently certified patients as hospice-eligible even though the patients did not have a terminal prognosis of six months or less. As part of the settlement, each of the Good Shepherd entities agreed to enter into a five-year CIA with HHS-OIG.[36] | $4 million |

32. U.S. ex rel. Deming, et al. v. Jackson-Madison County General Hospital, et al., No. 07-1116 (W.D. Tenn.), Dkt. No. 166.
33. http://www.justice.gov/usao-edpa/pr/united-states-settles-aria-health-systems-over-unnecessary-invasive-procedures-and.
34. http://www.justice.gov/usao-sdga/pr/government-settles-alleged-false-claims-act-violations-memorial-health-inc.
35. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-compassionate-care-hospice.
36. http://www.justice.gov/opa/pr/united-states-settles-false-claims-act-suit-against-good-shepherd-hospice-inc-and-related.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| June 18, 2015 | Covenant Hospice Inc. | Covenant agreed to pay $10.1 million to resolve FCA allegations that it overbilled for hospice services by billing for general inpatient care when medical records supported only necessity of routine care.[37] | $10.1 million |
| September 3, 2015 | St. Joseph Hospice Entities; Patrick T. Mitchell | St. Joseph Hospice Entities and Patrick T. Mitchell, its majority owner and manager, agreed to pay $5.86 million to resolve FCA allegations that they submitted false claims for delivery of continuous home care hospice services to patients when there was no crisis. According to the government, the hospice was identified as an outlier in billing for these services, the rate for which is the highest daily rate a hospice can bill Medicare. As part of the settlement, St. Joseph Hospice Entities agreed to enter into a five-year CIA with HHS-OIG.[38] | $5.86 million |
| October 2, 2015 | Guardian Hospice of Georgia LLC; Guardian Home Care Holdings Inc.; AccentCare Inc. | Guardian and its affiliates agreed to pay $3 million to resolve FCA allegations that they billed Medicare for hospice patients who were not terminally ill. The government asserted that Guardian's business practices contributed to its submission of false claims, including failing to properly train staff and medical directors on the hospice eligibility criteria, establishing aggressive targets to recruit and enroll patients, and failing to adequately oversee the hospice.[39] | $3 million |
| October 7, 2015 | Serenity Hospice and Palliative Care; Ruth Siegel | Serenity and Ruth Siegel, its founder and former president, agreed to pay $2.2 million to resolve FCA allegations that it billed Medicare for hospice services for patients that were ineligible to receive such services. As part of the settlement, Serenity agreed to enter into a five-year CIA with HHS-OIG, and Siegel agreed to a five-year exclusion from federal healthcare programs.[40] | $2.2 million |
| November 19, 2015 | Hospice of Citrus County, Florida ("HOCC") | HOCC agreed to pay $3.02 million to resolve FCA allegations that it billed Medicare and Medicaid for medically unnecessary hospice care for at least 52 patients who had lengths of stay greater than 1,000 days. The government asserted that the documentation for these patients failed to support the length of hospice services, failed to document basic patient characteristics and included unsigned records or records signed with inconsistent practitioner information. Certain patients were allegedly admitted to HOCC because their spouse was in hospice care; other patients purportedly were approved to take multiple, lengthy, out-of-state trips during a five-year period.[41] | $3.02 million |
| December 18, 2015 | Iowa Hospice, LLC | Iowa Hospice agreed to pay $1.08 million to resolve FCA allegations that it improperly billed for hospice services because, during some or all of the period that certain patients were receiving hospice care, the patients did not have a medical prognosis of six months or less if their illnesses ran their normal course.[42] | $1.08 million |

37. http://www.justice.gov/opa/pr/covenant-hospice-inc-pay-101-million-overcharging-medicare-tricare-and-medicaid-hospice.
38. http://www.justice.gov/usao-sdms/pr/hospice-facility-and-its-managermajority-owner-pay-approximately-586-million-resolve.
39. http://www.justice.gov/opa/pr/united-states-settles-false-claims-act-suit-against-guardian-hospice-and-related-entities.
40. http://www.justice.gov/usao-az/pr/serenity-hospice-and-palliative-care-pay-22-million-resolve-false-claims-allegations.
41. http://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-hospice-citrus-county-more-3.
42. http://www.justice.gov/usao-ndia/pr/iowa-hospice-pay-more-1-million-resolve-false-claims-act-allegations.

# HOME HEALTH

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| February 10, 2015 | ResCare Iowa, Inc. | ResCare Iowa, a home health company, agreed to pay $5.63 million to resolve allegations that it billed Medicare and Medicaid for home health services without properly documenting the continued medical necessity of the services, the types of services necessary or the performance of the required face-to-face assessment of the patient by the certifying physician.[43] | $5.63 million |
| March 9, 2015 | Recovery Home Care, Inc.; Recovery Home Care Services, Inc.; National Home Care Holdings LLC | Recovery Home Care, Recovery Home Care Services and National Home Care Holdings agreed to pay $1.1 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Simony v. Recovery Home Care***. The Recovery Home Care entities allegedly paid several physicians to serve as medical directors for their office locations at rates substantially above the FMV of the actual services provided by the physicians, in violation of the AKS and Stark Law. After initially declining to intervene in the *qui tam* action in January 2014, the government partially intervened in June 2014, eventually leading to this settlement. National Home Care purchased the Recovery Care entities after the purported misconduct had occurred. [44] | $1.1 million |
| June 1, 2015 | Friendship Home Healthcare, Inc. (d/b/a Friendship HealthCare System); Friendship Home Health Inc./Angel Private Duty and Home Health (d/b/a Friendship Private Duty); Friendship Home Health Agency, LLC; Theophilus Egbujor | The Friendship entities and their owner Theophilus Egbujor agreed to pay $6.5 million to resolve FCA allegations that they improperly billed for home health services. Specifically, the government alleged Friendship provided nursing services that were furnished or provided by a woman who had been excluded from federal healthcare programs; submitted required forms to TennCare that contained the forged signature of Friendship's Director of Nursing; billed TennCare for services without the required forms and signatures; and failed to repay TennCare within 60 days of learning that Friendship had wrongly billed for care provided by a woman whose nursing license had lapsed. As part of the settlement, the Friendship entities and Egbujor agreed to enter into a five-year CIA with HHS-OIG.[45] | $6.5 million |
| June 16, 2015 | Advanced Homecare, Inc. | Advanced Homecare agreed to pay $1.29 million to resolve FCA allegations that it developed protocols to accept home health referrals from two neurologists through which it treated and billed for patients who were not actually homebound and did not have a valid physician certification of home health need. The settlement also resolved allegations that Advanced recklessly permitted its employees to aggressively market its services to this neurology practice and that those marketing employees obtained access to the practice's patient records to complete referral forms and used the doctors' signature stamps to sign orders to evade the physician certification requirement.[46] | $1.29 million |
| June 29, 2015 | United Home Healthcare, Inc.; B&L Personal Services, Inc. | United Home Healthcare and B&L Personal Services agreed to pay $1.5 million to resolve FCA allegations that they engaged in a pattern of overbilling for personal care and attendant services, as patient files and billing data purportedly showed many billed services were not documented; dates for which United was reimbursed where the patient file showed no service was received; and service hours were billed in excess of those actually provided.[47] | $1.5 million |

43. http://www.justice.gov/opa/pr/iowa-home-care-company-pay-563-million-settle-false-claims-act-allegations.
44. http://www.justice.gov/opa/pr/florida-home-health-care-company-agrees-pay-11-million-resolve-false-claims-act-allegations.
45. http://www.justice.gov/usao-mdtn/pr/nashville-based-friendship-home-healthcare-and-related-companies-pay-us-and-tennessee.
46. http://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-jacksonville-based-home.
47. http://www.justice.gov/usao-sdin/pr/united-states-attorneys-office-recovers-15-million-case-against-home-healthcare-company.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| July 7, 2015 | Vicki S. House | Vicki House, the Executive Director of Nurses' Registry and Home Health Corporation, agreed to pay $1.08 million to settle FCA allegations in the *qui tam* action styled ***U.S. ex rel. Robinson-Hill v. Nurses' Registry and Home Health Corp.*** (E.D. Ky.) that she provided unlawful compensation to physicians who referred patients to the agency, in violation of the Stark Law. The remaining defendants in the action settled at a later date (see below).[48] | $1.08 million |
| August 4, 2015 | Pediatric Services of America Healthcare ("PSA"); Pediatric Services of America, Inc.; Pediatric Healthcare, Inc.; Pediatric Home Nursing Services; Portfolio Logic, LLC | Pediatric Services of America and certain affiliated entities, along with Portfolio Logic, agreed to pay $6.88 million to resolve FCA allegations that PSA, a provider of home nursing services to medically fragile children, knowingly (1) failed to disclose and return overpayments that it received from Medicare and Medicaid; (2) submitted claims under the Georgia Pediatric Program for home nursing care without documenting the requisite monthly supervisory visits by a registered nurse, and (3) submitted claims to federal healthcare programs that overstated the length of time their staff had provided services, which resulted in PSA being overpaid. As part of the settlement, PSA agreed to enter into a five-year CIA with HHS-OIG. This FCA settlement is the first settlement based upon a healthcare provider's failure to identify potential overpayments.[49] | $6.88 million |
| October 1, 2015 | Nurses' Registry and Home Health Corporation;<br>Estate of Lennie House | Nurses' Registry and its former owner and CEO's estate agreed to an entry of a judgment of $16 million to resolve FCA allegations in the long-going *qui tam* action styled ***U.S. ex rel. Robinson-Hill v. Nurses' Registry and Home Health Corp.*** (E.D. Ky.) that Nurses' Registry, at House's direction, billed Medicare for medically unnecessary home health services and services tainted by kickbacks to referring physicians. Nurses' Registry allegedly falsified records to make it appear as if patients had a medical need for services and/or were homebound, and recertified ineligible patients for service. The settlement followed the district court's denial of the defendants' motion for summary judgment related to a Stark Law issue.[50] | $16 million |
| November 18, 2015 | Deaconess Home Health, Inc.; Lazarus Bonilla | Deaconess and its owner, Lazarus Bonilla, agreed to pay $3.72 million to resolve civil FCA allegations involving the false billing of personal care services to Medicaid that were not medically necessary or that Deaconess could not verify had ever been provided. In a related criminal case, Deaconess pleaded guilty, while Bonilla entered into a deferred prosecution agreement with the government and agreed to an exclusion from federal healthcare programs for a period of 15 years.[51] | $3.72 million |
| November 18, 2015 | Atlas Healthcare, Inc.; Deana Bajanan; Sheena Jones | Atlas Healthcare and its owners agreed to pay $435,000 to resolve FCA allegations that they billed Medicaid for personal care services for patients that did not need the services or did not need the level of services billed.[52] | $435,000 |

48. http://www.justice.gov/usao-edky/pr/home-health-agency-executive-director-pay-us-government-over-1-million-settle-civil.
49. http://www.justice.gov/usao-sdga/pr/pediatric-services-america-and-related-entities-pay-688-million-resolve-false-claims.
50. http://www.justice.gov/usao-edky/pr/lexington-home-health-agency-and-estate-deceased-owner-agree-judgment-16-million.
51. http://www.justice.gov/usao-edwi/pr/wisconsin-home-health-agency-and-owner-agree-criminal-and-civil-resolution-health-care.
52. http://www.justice.gov/usao-edwi/pr/wisconsin-home-health-agency-and-owner-agree-civil-resolution-health-care-fraud-charges.

# SKILLED NURSING FACILITIES AND NURSING HOMES

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| February 20, 2015 | Oceana County Medical Care Facility ("OCMCF"); Agility Health, LLC | OCMCF, which provides nursing home and rehabilitation care, and Agility Health, which managed OCMCF's therapy department and assisted with billing such services, agreed to pay collectively $1 million to resolve FCA allegations involving billing Medicare for inpatient skilled therapy services that were not provided, were upcoded and were medically unnecessary. The settlement also resolved allegations that Agility Health caused false claims for durable medical equipment to be submitted to Medicare after an Agility Health employee at OCMCF improperly disclosed protected health information to an outside vendor and that vendor used the information to bill Medicare for unnecessary medical equipment that some patients never received.[53] | $1 million |
| March 2, 2015 | Catholic Health Care System d/b/a ArchCare | ArchCare agreed to pay $3.5 million in an administrative agreement to resolve allegations that it billed Medicare for inflated therapy services provided by an affiliate of RehabCare Group East, Inc. and Kindred Healthcare. Specifically, three ArchCare facilities failed to take sufficient steps to prevent the subcontractor from engaging in a practice of ramping up the amount of therapy provided to patients during the assessment reference period; placing patients in the highest reimbursement level unless it was shown that the patients could not tolerate that amount of therapy; discouraging the provision of therapy in amounts lower than the minimum threshold required for the highest RUG level; arbitrarily shifting planned therapy minutes between therapy disciplines to meet RUG targets; recording rounded or estimated minutes instead of the actual amount of therapy provided; reporting time spent on initial evaluations as therapy time to avoid prohibition on counting initial evaluation time as reimbursable therapy time; and reporting time providing unskilled palliative care as time spent on reimbursable skilled therapy.[54] | $3.5 million |
| March 30, 2015 | Ross Manor | Ross Manor agreed to pay $1.2 million to resolve FCA allegations that it billed Medicare for inflated therapy services provided by RehabCare Group East, Inc. Specifically, Ross Manor failed to take sufficient steps to prevent RehabCare from engaging in a practice of ramping up the amount of therapy provided to patients during the assessment reference period; providing significantly more therapy on the final day of a period to reach the next RUG level; placing patients in the highest reimbursement level unless it was shown that the patients could not tolerate that amount of therapy; and discouraging the provision of therapy in amounts lower than the minimum threshold required for the highest RUG level.[55] | $1.2 million |
| April 15, 2015 | Asbury Health Center | Asbury Health Center, a continuing-care retirement community, agreed to pay $1.33 million to resolve FCA allegations it self-disclosed to the government concerning claims submitted for skilled nursing facility services that lacked the physician certifications and recertifications required by Medicare.[56] | $1.33 million |

53. http://www.justice.gov/usao-wdmi/pr/2015_0225_AgilityHealth.html.
54. http://www.justice.gov/usao-ma/pr/new-york-catholic-nursing-chain-pay-35-million-resolve-allegations-concerning-claims.
55. http://www.justice.gov/usao-ma/pr/maine-nursing-home-pay-12-million-resolve-allegations-concerning-rehabilitation-therapy.
56. http://www.justice.gov/usao-wdpa/pr/13m-settlement-asbury-health-center-resolves-false-claims-act-allegations.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| April 30, 2015 | Rousseau Management, Inc. | Rousseau Management, which owns a rehabilitation center and previously provided administrative management services to a skilled nursing facility, agreed to pay $300,000 to resolve FCA allegations that it submitted, or caused the submission, of false claims for the provision of unreasonable, unnecessary and/or unskilled rehabilitation therapy, or therapy that was not provided at all. The therapy at issue was provided by RehabCare Group East, Inc.[57] | $300,000 |
| May 21, 2015 | Country Villa Watsonville East Nursing Center; Country Villa Watsonville West Nursing and Rehabilitation Center; CF Watsonville East, LLC; CF Watsonville West, LLC; ARBA Group; Country Villa Health Service Corporation | Two California nursing homes and the owners, operators and manager of the nursing homes agreed to pay $3.8 million to resolve FCA allegations that they provided materially substandard and/or worthless services to residents of the nursing homes as a result of persistent and severe overmedication. As part of the settlement, the two nursing homes and the two for-profit entities that owned and operated the nursing homes agreed to enter into a five-year CIA with HHS-OIG.[58] | $3.8 million |
| June 16, 2015 | Hebrew Homes Health Network Inc.; Affiliated Entities; William Zubkoff | Hebrew Homes, its operating subsidiaries and affiliates, and its former president and executive director agreed to pay $17 million to resolve FCA allegations that Hebrew Homes operated a kickback scheme in which they hired numerous physicians ostensibly as contracted medical directors with specific job duties and hourly requirements, and yet most of the medical directors were required to perform few, if any, of their contracted duties. Instead, the government alleged they were paid for their patient referrals, in violation of the AKS. As part of the settlement, Hebrew Homes agreed to enter into a five-year CIA with HHS-OIG.[59] | $17 million |
| November 30, 2015 | Regent Management Services L.P. | Regent Management Services, which manages several nursing facilities, agreed to pay $3.19 million to resolve FCA allegations that it engaged in a "swapping" scheme whereby it received kickbacks from ambulance companies in exchange for rights to Regent's more lucrative Medicare and Medicaid transport referrals. This is believed to be the first settlement with a medical institution—as opposed to an ambulance company—regarding these kind of "swapping" arrangements. As part of the settlement, Regent agreed to enter into a five-year CIA with HHS-OIG.[60] | $3.19 million |
| December 23, 2015 | Genesis HealthCare LLC | Genesis HealthCare agreed to pay $600,000 to resolve FCA allegations that the employees at one of its skilled nursing facilities failed to provide patient care activities as recorded in the medical record and failed to provide certain care activities consistent with standing physician orders. As part of the settlement, Genesis agreed to pay for a one-year transition consultant to assist the new operator of the facility.[61] | $600,000 |

57. http://www.justice.gov/usao-ma/pr/maine-nursing-home-operator-pay-300000-resolve-allegations-concerning-claims.
58. http://www.justice.gov/usao-ndca/pr/watsonville-nursing-home-owners-operators-and-manager-agree-pay-38-million-settle.
59. http://www.justice.gov/opa/pr/florida-skilled-nursing-facility-agrees-pay-17-million-resolve-false-claims-act-allegations.
60. http://www.justice.gov/usao-sdtx/pr/skilled-nursing-facility-company-agrees-pay-more-3-million-resolve-kickback-allegations.
61. http://www.justice.gov/usao-edva/pr/arlington-nursing-home-agrees-pay-600000-settle-false-claim-act-violations.

# PHARMACEUTICAL AND MEDICAL DEVICE

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| January 7, 2015 | Ansun Biopharma, Inc. (f/k/a NexBio, Inc.) | Ansun Biopharma, a biotechnology company, agreed to pay a total of $2.149 million to settle civil FCA allegations and related criminal charges that it defrauded the government by fabricating, altering and/or manipulating the hours on timesheets used to track the amount of time spent on the development of an influenza drug under a $50 million National Institutes of Health research contract.[62] | $1.65 million (criminal)<br>$495,000 (civil) |
| January 8, 2015 | Daiichi Sankyo Inc. | Daiichi Sankyo, a global pharmaceutical company, agreed to pay $39.01 million to resolve FCA allegations that it paid improper kickbacks to induce physicians to prescribe its drugs. The allegedly improper kickbacks took the form of speaker's fees paid for duplicative speeches given at Daiichi dinners exceeding Daiichi's internal per person cost limitations, as well as payments for speeches made to the physician's own staff. As part of the settlement, Daiichi agreed to enter into a five-year CIA with HHS-OIG.[63] | $39.01 million |
| January 14, 2015 | Medtronic, Inc. | Medtronic agreed to pay $2.8 million to resolve FCA allegations that it induced several physicians to submit Medicare reimbursement claims for a non-reimbursable, investigational medical procedure known as SubQ stimulation.[64] | $2.8 million |
| January 26, 2015 | AstraZeneca LP | AstraZeneca agreed to pay $7.9 million to resolve FCA allegations that it provided remuneration to a PBM in order to induce the PBM to maintain its Nexium product as the "sole and exclusive" drug of its type on the PBM's formulary. The prohibited remunerations allegedly took the form of price concessions on certain drugs other than Nexium.[65] | $7.9 million |
| February 5, 2015 | ev3, Inc. (f/k/a Fox Hollow Technologies, Inc.) | ev3, Inc., a vascular device manufacturer, agreed to pay $1.25 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Cashi v. Fox Hollow Technologies*** that ev3 had inappropriately advised various hospitals to bill arthrectomy procedures using its technologies as inpatient claims as opposed to less expensive outpatient claims. The government intervened in the action only as to the claims against ev3 and declined to intervene as to similar claims against 135 hospitals, which were subsequently dismissed as part of this settlement.[66] | $1.25 million |
| March 16, 2015 | Medtronic, PLC; Medtronic, Inc.; Medtronic USA, Inc.; Medtronic Sofamor Danek USA Inc. | Medtronic and several affiliated entities agreed to pay $4.41 million to resolve FCA allegations that they sought payment from the Departments of Veterans Affairs and Defense for medical devices manufactured in China and Malaysia despite their contractual promise to provide goods manufactured in the United States or other countries specified in the Trade Agreements Act.[67] | $4.41 million |
| March 17, 2015 | Biotelemetry, Inc. | Biotelemetry, a cardiac monitoring company, agreed to pay $6.4 million to resolve FCA allegations that its subsidiary, CardioNet, overbilled Medicare for real-time Mobile Cardiac Outpatient Telemetry monitoring for patients whose symptoms could be adequately tracked with less expensive, periodic monitoring equipment.[68] | $6.4 million |

62. https://www.fbi.gov/sandiego/press-releases/2015/ansun-biopharma-to-pay-more-than-2-million-for-overbilling-the-u.s.
63. http://www.justice.gov/opa/pr/daiichi-sankyo-inc-agrees-pay-39-million-settle-kickback-allegations-under-false-claims-act.
64. http://www.justice.gov/opa/pr/medtronic-inc-pay-28-million-resolve-false-claims-act-allegations-related-subq-stimulation.
65. http://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations.
66. http://www.justice.gov/opa/pr/minnesota-based-ev3-pay-united-states-125-million-settle-false-claims-act-allegations.
67. http://www.justice.gov/opa/pr/medtronic-pay-441-million-resolve-allegations-it-unlawfully-sold-medical-devices-manufactured.
68. http://www.justice.gov/opa/pr/cardiac-monitoring-company-pay-64-million-alleged-overbilling-government-health-care-programs.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| April 8, 2015 | Glenmark Generics, Inc. | Glenmark, a generic drug manufacturer, agreed to pay $25 million to resolve a state of Texas investigation involving state FCA allegations that Glenmark reported inflated drug prices to the Medicaid program.[69] | $25 million |
| May 4, 2015 | American Rehab Equipment Company (f/k/a Patients First Medical Equipment Company) | American Rehab agreed to pay $300,000 to resolve FCA allegations that it overcharged Medicaid for custom power wheelchairs provided to nursing facilities residents by billing the "retail" price when it actually paid much less under wholesale and other special pricing agreements with vendors.[70] | $300,000 |
| May 27, 2015 | Orbit Medical Inc.; Rehab Medical Inc. | Orbit Medical and Rehab Medical agreed to pay $7.5 million to resolve FCA allegations in a *qui tam* action styled ***U.S. ex rel. Clyde, et al. v. Orbit Medical, et al.*** (D. Utah) that the companies falsely billed for power wheelchairs and accessories by falsifying or altering required prescriptions and medical documentation to make it appear as if the DME prescriptions and documentation met Medicare reimbursement criteria. This settlement does not resolve allegations against one of Orbit Medical's principals, Jake Kilgore, who is another defendant in the ongoing action, and who was indicted in 2013 in a parallel criminal proceeding. As part of the settlement, Orbit Medical and Rehab Medical each agreed to enter into a five-year CIA with HHS-OIG.[71] | $7.5 million |
| June 17, 2015 | Inspire Pharmaceuticals, Inc. | Inspire agreed to pay $5.9 million to resolve FCA allegations it misleadingly focused on purported anti-inflammatory properties of one of its eye drugs that were unsupported by substantial evidence or substantial clinical experience in order to cause doctors to prescribe the drug for uses not covered by federal healthcare programs, which resulted in those programs paying millions of dollars in false claims.[72] | $5.9 million |
| July 6, 2015 | AstraZeneca LP; Cephalon, Inc. | AstraZeneca and Cephalon agreed to pay $46.5 million and $7.6 million, respectively, to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Streck v. Allergan, Inc., et al.*** (E.D. Pa.) that they knowingly underpaid rebates owed under the Medicaid Drug Rebate Program by improperly reducing the reported average manufacturer prices for service fees it paid to wholesalers. The government initially declined to intervene in this action against AstraZeneca and Cephalon, but intervened in 2015 for purposes of settling. Several defendants remain in litigation against the relator.[73] | $54.1 million |

69. https://www.texasattorneygeneral.gov/oagnews/release.php?id=5012.
70. http://www.justice.gov/usao-dc/pr/durable-medical-equipment-supplier-pay-united-states-300000-resolve-false-claims.
71. http://www.justice.gov/opa/pr/durable-medical-equipment-suppliers-pay-75-million-resolve-false-claims-act-allegations.
72. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-inspire-pharmaceuticals-inc.
73. http://www.justice.gov/opa/pr/astrazeneca-and-cephalon-pay-465-million-and-75-million-respectively-allegedly-underpaying.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| July 30, 2015 | NuVasive Inc. | NuVasive agreed to pay $13.5 million to resolve FCA allegations that it caused healthcare providers to submit false claims for spine surgeries ineligible for reimbursement by marketing the company's CoRoent System for non-FDA approved surgical uses. The settlement also resolved allegations that NuVasive paid illegal remuneration to induce physicians to use its CoRoent System in spine fusion surgeries, in violation of AKS.[74] | $13.5 million |
| October 29, 2015 | Warner Chilcott PLC; Warner Chilcott U.S. Sales LLC | Warner Chilcott agreed to pay $102.06 million to resolve civil FCA allegations that it paid illegal remuneration to prescribing physicians in connection with so-called "Medical Education Events" and speaker programs, in violation of the AKS, and caused the submission of false prior authorization requests for two of its osteoporosis drugs in order to overcome formulary restrictions that favored less expensive drugs. A Warner Chillcott subsidiary pleaded guilty to a related criminal charge involving the illegal marketing of seven drugs and agreed to pay a criminal fine of $22.94 million. Several individuals have pleaded guilty or been charged in connection with this fraud scheme.[75] | $102.06 million (civil); $22.94 million (criminal) |
| November 20, 2015 | Novartis Pharmaceuticals Corp. | Novartis agreed to pay $390 million, including a $20 million forfeiture of proceeds, to settle FCA allegations in a *qui tam* action styled ***U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp., et al.*** (S.D.N.Y.) that Novartis paid kickbacks to specialty pharmacies in return for recommending two of its drugs. Accredo Health Group, another defendant in this action, settled earlier in the year (see below). As part of the settlement, Novartis agreed to bolster the terms of an existing CIA with HHS-OIG and extend the CIA by five years.[76] | $390 million |
| December 16, 2015 | Vintage Pharmaceuticals, LLC (d/b/a Qualitest Pharmaceuticals); Endo Pharmaceuticals, Inc. | Qualitest Pharmaceuticals, its parent corporation Endo, and seven subsidiaries or affiliates ("Qualitest") agreed to pay $39 million to resolve federal and state FCA allegations that Qualitest knowingly manufactured and sold chewable fluoride tablets that contained less than half the amount of fluoride ion indicated on the drug label and thus caused federal healthcare programs to be fraudulently billed for these tablets.[77] | $39 million |
| December 18, 2015 | Dynasplint Systems Inc.; George Hepburn | Dynasplint and its president agreed to pay approximately $10.3 million to resolve FCA allegations that they improperly billed Medicare for splints provided to SNF patients by misrepresenting that patients were in their homes or other places that were not SNFs in order to receive separate reimbursement, as these splints are among items covered in the bundled payment Medicare makes to SNFs.[78] | $10.3 million |
| December 22, 2015 | Coloplast Corporation; Liberator Medical Supply, Inc. | Coloplast and Liberator agreed to pay $3.16 million and $500,000, respectively, to resolve FCA allegations that Coloplast paid illegal kickbacks to several medical suppliers, including Liberator, to induce them to conduct promotional campaigns designed to refer individual users to Coloplast products.[79] | $3.66 million |

74. http://www.justice.gov/opa/pr/medical-device-manufacturer-nuvasive-inc-pay-135-million-settle-false-claims-act-allegations.
75. http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.
76. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis.
77. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-39-million-civil-fraud-settlement-against-qualitest.
78. http://www.justice.gov/usao-edla/pr/splint-supplier-and-its-president-pay-over-10-million-resolve-false-claims-act.
79. http://www.justice.gov/usao-ma/pr/coloplast-corp-and-liberator-medical-agree-pay-36-million-resolve-kickback-allegations.

# PHARMACY SERVICES AND PHARMACY BENEFIT MANAGERS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| May 1, 2015 | Accredo Health Group | Accredo agreed to pay $60 million to settle FCA allegations related to its role in a kickback scheme, detailed above, involving AstraZeneca (detailed further above). Novartis allegedly provided Accredo kickbacks in the form of patient referrals and related benefits in exchange for Accredo's recommending refills to Novartis drug Exjade patients without counseling patients on potentially life-threatening side effects.[80] | $60 million |
| May 6, 2015 | Physician Pharmacy Alliance, Inc. ("PPA") | PPA, a provider of home delivery pharmacy services, agreed to pay $5 million to settle FCA allegations that, under prior ownership, PPA provided gift cards to induce referrals or enrollments of Medicare or Medicaid patients and routinely waived co-payments for Medicare and Medicaid patients, in violation of the AKS.[81] | $5 million |
| May 14, 2015 | PharMerica Corporation | Long-term care pharmacy PharMerica agreed to pay $23.5 million to resolve FCA allegations that it caused the submission of false claims to Medicare Part D for improperly dispensed Schedule II drugs. PharMerica agreed to separately pay $8 million to resolve related allegations that it violated the Controlled Substances Act by enabling its staff to order, and pharmacists to dispense, Schedule II narcotics without confirming that a physician had deemed them medically necessary. As part of the settlement, PharMerica agreed to enter into a five-year CIA with HHS-OIG.[82] | $23.5 million |
| May 20, 2015 | Medco Health Solutions Inc. | Medco agreed to pay $7.9 million to resolve FCA allegations that it knowingly caused false claims to be submitted through its role in a kickback scheme whereby it solicited illegal remuneration from AstraZeneca in the form of price concessions on multiple drugs in exchange for Medco's maintenance of AstraZeneca's Nexium product as the "sole and exclusive" drug of its type on Medco's formulary.[83] | $7.9 million |
| June 26, 2015 | Trinity HomeCare, LLC; Walgreens Infusion Services, Inc. (f/k/a Option Care, Inc.); Option Care of New York, Inc.; Walgreen Co. | Trinity HomeCare, a former Walgreens subsidiary, and affiliated entities agreed to pay $2.5 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Cantor v. Option Care Inc.*** (S.D.N.Y.) that Trinity, a specialized pharmacy that dispenses and delivers prescription drugs to patient homes, billed Medicaid for costly anti-hemophilic medications that were unneeded or unused, as a result of its delivery policy. Notably, the federal government declined to intervene in the *qui tam* action, but the State of New York proceeded to investigate the case and obtain this settlement.[84] | $2.5 million |
| July 9, 2015 | Trinity HomeCare, LLC; Walgreens Infusion Services, Inc. (f/k/a Option Care, Inc.); Option Care of New York, Inc.; Walgreen Co. | Trinity HomeCare, a former Walgreens subsidiary, and affiliated entities agreed to pay $22.4 million to resolve FCA allegations arising out of a *qui tam* action styled ***U.S. ex rel. Vierczhalek v. Trinity HomeCare, LLC*** (S.D.N.Y.) and a subsequent investigation by the State of New York. Specifically, Trinity allegedly (1) submitted Medicaid claims for Synagis, an injectable drug for premature infants that can cost more than $2,000 per dose, without proper authorizations or prescriptions; (2) pushed families and physicians to use Synagis regardless of medical need; (3) used the names of pediatricians and physician assistants on Synagis prescriptions and Medicaid bills without authorization; and (4) billed for excess Synagis by overstating an infant's weight. As with the prior Trinity settlement, the federal government declined to intervene in the *qui tam* action, but the State of New York proceeded to investigate the case and obtain this settlement.[85] | $22.4 million |

80. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-60-million-civil-fraud-settlement-accredo-health-group.
81. http://www.justice.gov/usao-ednc/pr/pharmacy-company-agreed-pay-5-million-settle-claims-it-gave-gift-cards-and-waived.
82. http://www.justice.gov/opa/pr/long-term-care-pharmacy-pay-315-million-settle-lawsuit-alleging-violations-controlled.
83. http://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations.
84. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-25-million-settlement-nyc-pharmacy-improper-medicaid.
85. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-224-million-settlement-nyc-pharmacy-improper-medicaid.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| July 15, 2015 | Blanding Health Mart Pharmacy | Compounding pharmacy Blanding agreed to pay $8.4 million to resolve FCA allegations that for a two-month period in early 2015, it billed government payers for compounding pharmaceutical prescriptions that were not medically necessary and were written by physicians that had ever actually seen the patients.[86] | $8.4 million |
| September 1, 2015 | Kmart Corporation | Kmart agreed to pay $1.4 million to resolve FCA allegations that it improperly influenced the decisions of Medicare beneficiaries to use its in-store pharmacies by permitting them to use drug manufacturer coupons to reduce or eliminate co-pays that they otherwise would be obligated to pay, and by offering varying levels of discounts on gasoline purchases at participating gas stations based on the number of prescriptions they filled at Kmart.[87] | $1.4 million |
| October 7, 2015 | PharMerica Corporation | Long-term care pharmacy PharMerica agreed to pay $9.25 million to resolve FCA allegations from two *qui tam* actions that it solicited and received illegal remuneration from Abbott Laboratories in exchange for promoting an anti-epileptic drug for nursing home patients. The government initially declined to intervene as to the allegations against PharMerica in these two actions until this settlement.[88] | $9.25 million |
| November 25, 2015 | MedMatch Pharmacy; OHM Pharmacy; WELL Health Pharmacy; Topical Specialists; Durbin Pharmacy; North Beaches Pharmacy; Individual Owners and Physicians | Several compounding pharmacies, their owners and certain physicians agreed to pay in total more than $22 million in fixed payments, and certain pharmacies also agreed to pay 50% of their net profits during the next five years, to resolve FCA allegations that they fraudulently billed Tricare. Specifically, the allegations were that (1) MedMatch paid kickbacks to marketers, filled prescriptions it knew or should have known were not legitimate and sent prescriptions to states in which it did not have a valid license; (2) OHM knew, or should have known, it was filling prescriptions from a doctor who was writing them outside the ordinary course of practice, considering the sheer magnitude and volume of prescriptions written; (3) WELL Health Pharmacy and its owner knowingly filled prescriptions that were written by referral sources that had a financial interest in the prescriptions in the form of a sham research study the compensation for which exceeded FMV; (4) Topical Specialists submitted prescriptions tainted by the aforementioned "research study" fees; (5) Durbin submitted prescriptions tainted by kickbacks and knew, or should have known, that the prescriptions it was filling from certain physicians were not legitimate because there was no bona fide patient/physician relationship; and (6) North Beaches filled prescriptions tainted by illegal kickbacks.[89] | $22.1 million (fixed);<br><br>potentially more than $30 million |
| December 23, 2015 | PharMerica Corporation | PharMerica agreed to pay $2.5 million to resolve FCA allegations in the long-going *qui tam* action styled ***U.S. ex rel. Kurnik v. Amgen, et al.*** (D.S.C.) involving the illegal promotion of Aranesp, an anemia drug manufactured by Amgen. The government intervened in this action as to allegations against Amgen and Omnicare, and those defendants previously settled for $24.9 million and $4.19 million, respectively. The government declined to intervene as to the allegations against PharMerica.[90] | $2.5 million |

86. https://www.fbi.gov/tampa/press-releases/2015/united-states-settles-false-claims-act-allegations-against-jacksonville-based-compounding-pharmacy-for-more-than-8-million.
87. http://www.justice.gov/opa/pr/kmart-corporation-pays-14-million-resolve-false-claims-act-allegations-connection-drug.
88. http://www.justice.gov/opa/pr/nations-second-largest-nursing-home-pharmacy-pay-925-million-settle-kickback-allegations.
89. http://www.justice.gov/usao-mdfl/pr/united-states-announces-new-round-compound-pharmacy-settlements-expected-result-more-30.
90. http://www.justice.gov/usao-sc/pr/district-south-carolina-settles-long-term-care-pharmacy-whistle-blower-case-completing.

# LABORATORY, PATHOLOGY AND DIAGNOSTICS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| April 9, 2015 | Health Diagnostic Laboratory Inc. ("HDL"); Singulex Inc. | HDL agreed to pay $47 million, and Singulex agreed to pay $1.5 million, to resolve FCA allegations in three *qui tam* actions that the two cardiovascular testing disease laboratories (1) induced physicians to refer patients to them for blood tests by paying them processing and handling fees per referral and routinely waiving patient co-pays and deductibles; and (2) billed for medically unnecessary testing. The government also intervened in the three lawsuits as to similar allegations against another laboratory (Berkley HeartLab), a marketing company (BlueWave Healthcare Consultants) and its owners, and the former CEO of HDL, but these settlements did not resolve those allegations. As part of the settlements, HDL and Singulex agreed to enter into separate five-year CIAs with HHS-OIG.[91] | $48.5 million |
| April 21, 2015 | Family Dermatology, P.C. | Family Dermatology, which owns and operates a dermatopathology laboratory and dermatology practices, agreed to pay $3.24 million to settle FCA allegations that it routinely required its employed dermatologists to use its in-house pathology lab for their pathology services, in violation of the Stark Law, and billed for analyses on specimens sent to the lab by these employed physicians. As part of the settlement, Family Dermatology agreed to enter into a five-year CIA with HHS-OIG.[92] | $3.24 million |
| August 25, 2015 | Quest Diagnostics, Inc.; Quest Diagnostics Clinical Laboratories Inc. | Quest Diagnostics agreed to pay $1.79 million to settle FCA allegations that its facilities submitted duplicative claims to Medicare for certain venipuncture services and diagnostic tests and certain panel tests and select components of those panels.[93] | $1.79 million |
| October 1, 2015 | Strata Pathology Laboratory, Inc. (StrataDx) | Strata agreed to pay $558,793 to resolve FCA allegations that it induced physicians to refer Medicare and Medicaid patients to Strata by paying kickbacks in the form of sham consulting fees and providing unlawful discounts to physicians through "account billing" arrangements that facilitated fee-splitting between Strata and seven physicians, in violation of the AKS.[94] | $558,793 |
| October 19, 2015 | Millennium Health | Millennium agreed to pay $256 million to resolve FCA allegations that it billed for medically unnecessary urine drug and generic testing, in part through the promotion of "custom profiles" that were effectively standing orders that caused physicians to order a large number of tests without an individualized assessment of each patient's needs. The settlement also resolved allegations that Millennium provided free items to physicians who agreed to refer expensive laboratory testing business to the company, in violation of the Stark Law and AKS. As part of the settlement, Millennium agreed to enter into a five-year CIA with HHS-OIG.[95] | $256 million |
| November 30, 2015 | Piedmont Pathology Associates, Inc.; Piedmont Pathology, P.C. | Piedmont Pathology agreed to pay $500,000 to resolve allegations that it engaged in improper financial relationships with referring physicians in violation of the AKS by providing electronic medical record software licenses at little to no cost to nine physicians' practices close in time to when those practices entered contracts to refer specimens to their pathology lab.[96] | $500,000 |

91. http://www.justice.gov/opa/pr/two-cardiovascular-disease-testing-laboratories-pay-485-million-settle-claims-paying.
92. http://www.justice.gov/opa/pr/family-dermatology-pccagrees-pay-united-states-more-32-million-settle-alleged-false-claims.
93. http://www.justice.gov/usao-edca/pr/quest-diagnostics-pays-united-states-179-million-resolve-false-claims-act-allegations.
94. http://www.justice.gov/usao-ma/pr/strata-pathology-resolve-allegations-regarding-kickback-payments.
95. http://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic.
96. http://www.justice.gov/usao-sc/pr/piedmont-pathology-associates-inc-and-piedmont-pathology-pc-settle-false-claims-act-cases.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| December 1, 2015 | Pharmasan Labs, Inc.; NeuroScience, Inc.; Gottfried Kellerman; Mieke Kellerman | Pharmasan Labs, NeuroScience, a related company that bills for Pharmasan's services, and the companies' founders agreed to pay $8.5 million to resolve FCA allegations that Pharmasan billed Medicare for ineligible food sensitivity testing; submitted false information to disguise the type of test that Pharmasan was performing so Medicare would pay for the services; and billed for laboratory services referred from non-physician practitioners that were not eligible to refer Medicare paid services. As part of the settlement, the companies and their founders entered into a five-year CIA with HHS-OIG.[97] | $8.5 million |
| December 18, 2015 | 21st Century Oncology LLC | 21st Century Oncology agreed to pay $19.75 million to resolve FCA allegations that it billed for "FISH" tests performed at its laboratory and ordered by four of its urologists that were not medically necessary and, and that it encouraged these urologists to order unnecessary tests by offering bonuses based in part on the number of tests referred to its laboratory.[98] | $19.75 million |
| December 30, 2015 | Pathway Genomics Corporation | Pathway Genomics Corporation agreed to pay $4.03 million to resolve FCA allegations that it induced healthcare providers to refer Pathway genetic testing kits and services by offering physicians and medical groups reimbursements of up to $20 for each saliva kit they collected from patients and submitted to Pathway for genetic testing, in violation of the AKS. The government alleged that individual physicians received as much $13,534 in reimbursements and that prior to enrolling in Pathway's reimbursement programs, most of these physicians had not ordered these genetic tests.[99] | $4.03 million |

97. http://www.justice.gov/usao-wdwi/pr/osceola-laboratory-agrees-pay-85-million-resolve-false-billing-case.
98. http://www.justice.gov/opa/pr/21st-century-oncology-pay-1975-million-settle-alleged-false-claims-unnecessary-laboratory.
99. https://www.fbi.gov/sandiego/press-releases/2015/san-diego-genetics-laboratory-pays-4-million-to-settle-federal-kickback-allegations-in-connection-with-patient-referrals.

# SPECIALTY CARE AND OTHER PROVIDER ENTITIES

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| January 14, 2015 | Nason Medical Center; Baron S. Nason, M.D.; Robert T. Hamilton, M.D. | An urgent care center and its owners agreed to pay $1.02 million to settle FCA allegations that they billed the physician rate for services actually provided by physician assistants, billed for medically unnecessary imaging tests and billed for radiological services provided by a radiology technician who did not hold a current state license. As part of the settlement, Nason Medical agreed to enter into a five-year CIA with HHS-OIG.[100] | $1.02 million |
| January 16, 2015 | Sea Mar Community Health Centers | Sea Mar Community Health Centers agreed to pay $3.35 million to resolve state FCA allegations that it overbilled Medicaid for thousands of fluoride treatments and dental exams.[101] | $3.35 million |
| January 23, 2015 | Associates in Dermatology; Michael Steppie, M.D. | A dermatology practice and its owner agreed to pay $3 million to resolve FCA allegations arising from having an unlicensed medical assistant performing radiation therapy without proper supervision; performing unnecessary destructions of skin lesions; and failing to properly document these destructions.[102] | $3 million |
| January 26, 2015 | Lafferty Enterprises, LLC d/b/a Trans-Star Ambulance Services | Trans-Star Ambulance Services agreed to pay $948,000 to settle FCA allegations that it billed Medicare for medically unnecessary ambulance transportation to and from dialysis clinics. As part of the settlement, Trans-Star entered into a five-year CIA with HHS-OIG.[103] | $948,000 |
| February 4, 2015 | Ageless Men's Health, LLC | A national chain of testosterone replacement therapy clinics agreed to pay $1.6 million to resolve FCA allegations that it billed for medically unnecessary evaluation and management services each time a testosterone shot was administered. As part of the settlement, Ageless agreed to enter into a five-year CIA with HHS-OIG.[104] | $1.6 million |
| February 4, 2015 | Associates in Eye Care P.S.C. | An optometry practice agreed to pay $800,000 to settle FCA allegations that it billed for eye examinations performed by one of its optometrists, Dr. Phillip Robinson, that were purportedly worthless because Dr. Robinson performed so many examinations per day that it was not possible for all his patients to have received legitimate eye examinations.[105] Dr. Robinson did not settle related allegations and was later found liable in a jury trial (see below). | $800,000 |
| February 19, 2015 | Vision and Eye Care Medical Diagnostic and Laser Center, Inc.; Robert Charles Duke, O.D. | An optometrist and his business agreed to pay $150,000 to settle FCA allegations that the optometrist billed Medicare and Medicaid for services delivered in his office when they were actually delivered at nursing homes and billed for more than 12 hours per day, even more than 24 hours per day, on numerous occasions.[106] | $150,000 |
| February 23, 2015 | Dickson Medical Associates, P.C. | A physician-owned medical group agreed to pay $500,000 to resolve FCA allegations that, through the medical group, one of its physicians acquired, prescribed and billed for a foreign non-FDA approved version of an approved osteoporosis drug.[107] | $500,000 |

100. http://www.justice.gov/usao-sc/pr/charleston-doctors-and-medical-clinic-settle-allegations-fraud-0.
101. http://www.atg.wa.gov/news/news-releases/sea-mar-health-centers-pay-335-million-attorney-general-s-office-investigation.
102. https://www.fbi.gov/tampa/press-releases/2015/united-states-settles-false-claims-act-allegations-against-florida-based-dermatology-practice-for-3-million.
103. http://www.justice.gov/usao/kye/news/2015/2015-01-26-trans-star%20ambulance%20service.html.
104. http://www.justice.gov/usao/tnw/news/2015/02-04-2015.html.
105. http://www.justice.gov/usao/kye/news/2015/2015-02-04-aec.html.
106. http://www.justice.gov/usao-ndok/pr/settlement-reached-medicare-fraud-lawsuit-against-catoosa-doctor-and-owner-vision-and.
107. http://www.justice.gov/usao-mdtn/pr/dickson-tennessee-medical-practice-pay-more-half-million-dollars-settle-false-claims

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| February 24, 2015 | Acadiana Cardiology LLC; Acadiana Cardiovascular Center; Mehmood Patel, M.D. | The Acadiana entities and Mehmood Patel, M.D., agreed to pay $650,000 to resolve FCA allegations that Dr. Patel performed and billed Medicare and Medicaid for medically unnecessary procedures. In 2008, Dr. Patel was convicted in a parallel criminal proceeding of 94 counts of healthcare fraud.[108] | $650,000 |
| March 17, 2015 | Coastal Dermatology; Sanjiva Goyal, M.D. | A dermatology practice and its owner agreed to pay $787,814 to resolve FCA allegations that they billed Medicare for procedures that were cosmetic in nature and not medically necessary, for procedures lacking the necessary clinical documentation and for procedures billed at inappropriately high rates of reimbursement.[109] | $787,814 |
| April 10, 2015 | Jacksonville Center for Reproductive Medicine; Michael Fox, M.D. | A fertility clinic and its owner agreed to pay $98,838 to resolve FCA allegations that they (1) billed for work performed by a physicians' assistant or nurse practitioner that were not "incident to" a physician's course of treatment; (2) upcoded claims for payment; and (3) billed for services provided when Dr. Fox was out of the country.[110] | $98,838 |
| May 4, 2015 | DaVita HealthCare Partners | DaVita agreed to pay $450 million, plus reserve an additional $45 million to cover fees, to resolve FCA claims in a *qui tam* action styled ***U.S. ex rel. Vainer, et al. v. Davita, Inc., et al.*** (N.D. Ga.) in which the government declined to intervene. The whistleblowers alleged that Davita developed and utilized dosing grids and protocols to create and maximize reimbursable waste of the dialysis drugs Zemplar and Venofer, which are packaged in single-use vials. For example, a protocol allegedly required a patient to receive 25 mg of Venofer, which is packaged in 100 mg vials, per week, so 300 mg of waste was billed to the government per month, whereas if the patient received the entire vial once per month, there would have been no waste. This appears to be the largest non-intervened *qui tam* settlement ever.[111] | $450 million |
| May 4, 2015 | Balboa Ambulance Service, Inc.; E.R. Ambulance, Inc.; Pacific Ambulance, Inc.; Bowers Companies, Inc.; Care Ambulance Service, Inc. | Five ambulance companies agreed to pay a total of $11.5 million to settle FCA allegations that they engaged in so-called "swapping" kickback schemes by providing deeply discounted—and often below cost—ambulance services to hospitals and/or skilled nursing facilities in exchange for exclusive rights to the facilities' more lucrative Medicare patient referrals. As part of the settlement, Balboa agreed to enter into a five-year CIA with HHS-OIG.[112] | $11.5 million |
| May 6, 2015 | Mattoo & Bhat Medical Associates, P.C.; Feng Qin. M.D. | A surgical practice specializing in dialysis care and one of its doctors agreed to pay $1.15 million to settle allegations that they fraudulently billed for vascular surgical procedures not covered under Medicare. The practice and doctor entered into CIAs with HHS-OIG.[113] | $1.15 million |
| May 14, 2015 | EFK of Connecticut, Inc., d/b/a Nelson Ambulance Service; SKMP Enterprises, Inc., d/b/a Access Ambulance Service | Two ambulance providers agreed to pay $595,000 to resolve FCA allegations that during a five-year period they routinely billed Medicare and Medicaid for non-emergency, scheduled ambulance services for dialysis patients that were not medically necessary.[114] | $595,000 |

108. http://www.justice.gov/usao-wdla/pr/united-states-attorney-announces-650000-settlement-acadiana-cardiology-acadiana.
109. http://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-jacksonville-based.
110. http://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-jacksonville-based-fertility.
111. http://www.justice.gov/opa/pr/davita-pay-450-million-resolve-allegations-it-sought-reimbursement-unnecessary-drug-wastage.
112. https://www.fbi.gov/sandiego/press-releases/2015/five-southern-california-ambulance-companies-to-pay-more-than-11.5-million-to-resolve-kickback-allegations.
113. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-vascular-surgery-clinic-and.
114. http://www.justice.gov/usao-ct/pr/ambulance-companies-pay-595000-settle-allegations-medically-unnecessary-ambulance.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| May 27, 2015 | Hamilton Health Center, Inc. | A federally qualified health center agreed to pay $270,000 to resolve FCA allegations that it self-disclosed under the OIG's Provider Self-Disclosure Protocol related to its employing, during a seven-year period, an individual previously excluded from participation in Medicare and Medicaid.[115] | $270,000 |
| May 28, 2015 | Garden State Cardiovascular Specialists P.C. | A cardiology practice agreed to pay more than $3.6 million to resolve allegations that its facilities and its principals billed Medicare for various cardiology diagnostic tests and procedures which were not medically necessary.[116] | $3.6 million |
| June 17, 2015 | Grove Place Surgery Center, LLC; Donald Proctor, Jr., M.D.; | An ambulatory surgery center and its practice manager, Dr. Donald Proctor, agreed to pay $4 million to resolve FCA allegations that they billed Medicare for Mohs surgeries and other surgical procedures that Dr. Proctor either did not perform or were medically unnecessary. As part of the settlement, Dr. Proctor agreed to be excluded from federally funded healthcare programs for at least five years.[117] | $4 million |
| June 30, 2015 | Rolla Neurology Pain & Sleep Center, LLC; Mohammad Akhtar Choudhary, M.D. | A neurologist and his pain and sleep center agreed to pay $861,571 to resolve allegations of upcoding claims for payment for evaluation and management of patients and for nerve conduction studies.[118] | $861,571 |
| July 2, 2015 | American Access Care Holdings, LLC ("AAC") | AAC, which formerly operated a vascular access center in Miami, agreed to pay $1.2 million to resolve FCA allegations that it billed Medicare for medically unnecessary percutaneous transluminal angioplasties ("PTA") and thrombectomies performed at the center, and billed for more PTAs per patient encounter than permitted. The alleged conduct occurred prior to AAC's merger with Fresenius Vascular Care.[119] | $1.2 million |
| August 5, 2015 | Allied Dental Practices of New Jersey | A dental practice agreed to pay $420,000 to resolve FCA allegations in a declined *qui tam* action that the practice erased several accounts payable to Medicare and Medicaid.[120] | $420,000 |
| August 14, 2015 | East Central Family Health Center | A federally qualified health center ("FQHC") agreed to pay $825,000 to resolve allegations that it billed Medicaid for behavioral health and dental services for patients of non-FQHC healthcare providers and who were not East Central patients, leading Medicaid to pay a higher amount for these services under the FQHC rate. As part of the settlement, East Central entered into a CIA with HHS-OIG.[121] | $825,000 |
| August 28, 2015 | Jeffrey Sponseller, O.D.; Sponseller Eye Care One, P.C.; S&H Eye Care, LLC | An optometrist and the Eye Care One entities agreed to pay $275,000 to resolve FCA allegations that they billed for eye examinations on nursing home patients that were either much shorter than the type of eye examination billed for or never performed. In 2014, the optometrist was sentenced to 33 months in prison for a related criminal conviction.[122] | $275,000 |
| September 28, 2015 | American Access Care Holdings, LLC | AAC, which formerly operated a vascular access center in Providence, RI, agreed to pay $2.6 million to resolve FCA allegations arising from the center that it (1) billed Medicare for medically unnecessary PTAs; (2) billed for more PTAs per patient encounter than permitted; and (3) billed for medically unnecessary procedures during follow-up visits. The alleged conduct occurred prior to AAC's merger with Fresenius Vascular Care.[123] | $2.6 million |

115. http://www.justice.gov/usao-mdpa/pr/hamilton-health-center-agrees-settlement-federal-civil-matter.
116. http://www.justice.gov/usao-nj/pr/garden-state-cardiovascular-specialists-pc-agrees-pay-36-million-allegedly-submitting.
117. http://www.justice.gov/usao-sdfl/pr/florida-physician-agrees-pay-4-million-and-accept-5-year-exclusion-medicare-resolve-0.
118. http://www.justice.gov/usao-edmo/pr/united-states-reaches-civil-settlement-doctor-and-his-clinic-false-claims-submitted.
119. http://www.justice.gov/usao-sdfl/pr/government-settles-false-claims-act-allegations-against-american-access-care-holdings-0.
120. http://www.app.com/story/money/business/2015/08/05/allie-dental-whistle-blower/31155155.
121. http://www.justice.gov/usao-wdok/pr/oklahoma-federally-qualified-health-center-agrees-pay-825000-settle-allegations.
122. http://www.justice.gov/usao-sdga/pr/optometrist-jeffrey-sponseller-and-eye-care-one-settle-false-claims-act-case-275000.
123. http://www.justice.gov/usao-ri/pr/26-million-recovered-through-settlement-false-claims-act-allegations-against-american.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| September 28, 2015 | American Access Care Holdings, LLC | AAC, which formerly operated a vascular access center in Fairfield, CT, agreed to pay $3.59 million to resolve FCA allegations arising from the center that it billed Medicare for multiple PTAs performed during the same patient encounter and for medically unnecessary procedures during follow-up visits. The alleged conduct occurred prior to AAC's merger with Fresenius Vascular Care.[124] | $3.59 million |
| October 15, 2015 | Westwood Mental Health LLC; MedSouth LLC | A community mental health center and its parent company agreed to pay $3.5 million to resolve FCA and AKS allegations that Westwood falsified patient records, billed for services not medically necessary, billed for services that were not rendered, provided bribes to Medicare beneficiaries who did not qualify for partial hospitalization services and provided bribes and/or kickbacks to employees to further or to conceal the fraud. The investigation and settlement resulted from Westwood's self-disclosure to HHS-OIG.[125] | $3.5 million |
| October 27, 2015 | Maine Dermatology, LLC | A dermatology practice agreed to pay $629,816 to resolve FCA allegations that it billed Medicare for providing evaluation and management services to patients in violation of applicable Medicare billing guidelines.[126] | $629,816 |
| October 29, 2015 | Vericare Management Inc. | Vericare, which provides psychiatric and psychological services to geriatric patients in long-term care and skilled nursing facilities, agreed to pay $1 million to resolve FCA allegations that it sought and obtained standing orders or other agreements with 128 facilities under which Vericare's clinicians performed evaluations on all new admissions to the facility regardless of whether such an evaluation was medically necessary. The settlement also resolved FCA allegations that Vericare self-disclosed to the government regarding the submission of Medicare claims for certain nursing facility evaluation and management services which were not supported by the patient's medical record.[127] | $1 million |
| November 5, 2015 | Rhode Island Dermatology and Cosmetic Center, LLC; Rhode Island Dermatology OBS, LLC | A dermatology and cosmetic surgery provider agreed to pay $152,043 to resolve FCA allegations that it billed Medicare for surgical closure procedures at a higher rate of complexity than was supported by certain patients' condition or the circumstances of the closure.[128] | $152,043 |
| December 15, 2015 | Mobile Medical, Inc. d/b/a OnSight Health Care | Onsight agreed to pay $4.5 million to resolve FCA allegations that it billed Medicare for podiatrist services that were not provided or were medically unnecessary, and that it provided kickbacks to nursing homes in the form of paying nursing home employees for transportation services, providing diabetic shoes, providing "warranties" on certain DME that were not supplied by OnSight, and waiving copayments and deductibles on medical services. As part of the settlement, OnSight agreed to enter into a CIA with HHS-OIG.[129] | $4.5 million |

124. http://www.justice.gov/usao-ct/pr/government-settles-false-claims-act-allegations-against-american-access-care-holdings-llc.
125. http://www.justice.gov/usao-wdla/pr/us-attorney-announces-35-million-settlement-westwood-mental-health-llc.
126. http://www.justice.gov/usao-me/pr/lincolnville-medical-practice-settles-federal-health-care-billing-complaint.
127. http://www.justice.gov/usao-nj/pr/behavioral-health-services-provider-agrees-pay-1-million-allegedly-submitting-false.
128. http://www.justice.gov/usao-ri/pr/ri-dermatology-and-cosmetic-center-pays-more-150000-settle-allegations-upcoding-medicare.
129. http://www.cleveland.com/court-justice/index.ssf/2015/12/healthcare_company_with_office.html.

# INDIVIDUAL PROVIDERS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| December 31, 2014 | Alan Buhler, M.D.; Lynn Buhler | A physician and his wife agreed to pay $1.05 million to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Guthrie v. A Plus Home Care*** (S.D. Fla.) that they had been party to a scheme under which the wife was paid by A Plus Home Health Care under a sham marketing agreement in order to induce her husband to refer patients to A Plus. The government previously settled with A Plus, its owner and five other couples who accepted payments from A Plus. The government declined to intervene as to the allegations against the Buhlers.[130] | $1.05 million |
| January 21, 2015 | Benjamin Sabido, M.D. | A physician agreed to pay $700,545 to resolve civil FCA allegations that he billed for physical therapy services and nerve conduction studies that were either not medically necessary, not properly supervised or not actually provided. Dr. Sabido also pleaded guilty to a related criminal charge.[131] | $700,545 |
| January 29, 2015 | Mark Heinicke, M.D. | A physician agreed to pay $338,493 to resolve civil FCA allegations that he illegally purchased and used foreign, non-FDA approved drugs on patients without informing them about the drugs, and then billed for the administration of these drugs as if they were the FDA-approved versions. Dr. Heinicke also pleaded guilty to a related criminal charge.[132] | $338,493 |
| February 12, 2015 | Michael J. Reinstein, M.D. | A physician agreed to pay $3.79 million to resolve civil FCA allegations involving his acceptance of kickbacks, in the form of a consulting agreement and various all-expenses paid trips, from a pharmaceutical manufacturer in exchange for prescribing generic clozapine, an anti-psychotic drug, in violation of AKS. Dr. Reinstein also pleaded guilty to a related criminal charge.[133] | $3.79 million |
| February 23, 2015 | Craig Prokos, M.D.; Cynthia Prokos | A physician and his wife agreed to pay $90,000 to resolve FCA allegations in the *qui tam* action styled ***U.S. ex rel. Guthrie v. A Plus Home Care*** (S.D. Fla.) involving a marketing kickback scheme with A Plus Home Health Care previously detailed above. The government declined to intervene as to the allegations against the Prokoses.[134] | $90,000 |
| February 24, 2015 | Prabhjit S. Purewal, M.D. | An oncologist agreed to pay $550,000 to resolve FCA allegations that he wrongfully billed Medicare and Medicaid for non-FDA approved chemotherapy drugs that he purchased from a pharmaceutical distributor who was not licensed to distribute drugs in the United States.[135] | $550,000 |
| March 4, 2015 | Daniel P. Schecter, D.D.S. | A dentist agreed to pay $484,744 to resolve FCA allegations that he billed Medicaid for medically unnecessary tooth extractions and for narcotics prescribed without proper justification.[136] | $484,744 |

130. http://www.justice.gov/opa/pr/two-florida-couples-agree-pay-113-million-resolve-allegations-they-accepted-kickbacks.
131. http://www.justice.gov/usao-nj/pr/physician-admits-billing-medicare-and-medicaid-phantom-physical-therapy-services.
132. http://www.justice.gov/usao-wdky/pr/louisville-physician-pays-51540885-treating-patients-misbranded-drugs-and-fraudulently.
133. http://www.justice.gov/opa/pr/illinois-physician-pleads-guilty-taking-kickbacks-pharmaceutical-company-and-agrees-pay-379.
134. http://www.justice.gov/opa/pr/two-florida-couples-agree-pay-113-million-resolve-allegations-they-accepted-kickbacks.
135. http://www.justice.gov/usao-edca/pr/manteca-oncologist-agrees-pay-550000-resolve-false-claims-act-allegations.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| May 1, 2015 | Phillip Robinson, M.D. | In an FCA jury trial, an optometrist was found liable for FCA violations stemming from his providing eye examinations to the vast majority of his nursing home patients, once a month, regardless of the patient's condition or medical need. The jury found that Dr. Robinson billed for more than 11,000 unnecessary eye examinations. As a result of the jury verdict, Dr. Robinson was required to pay $1.257 million. Dr. Robinson's practice group, Associates in Eye Care, previously settled related allegations in January 2015 (see above).[137] | $1.25 million |
| May 20, 2015 | Sean Orr, M.D. | A neurologist agreed to pay $150,000—based on his ability to pay—to resolve FCA allegations that he knowingly misdiagnosed certain patients with various neurological disorders, such as multiple sclerosis, which caused federal healthcare programs to be billed for medical unnecessary services and drugs. In 2014, the government settled related allegations against Baptist Health System for $2.5 million.[138] | $150,000 |
| June 5, 2015 | Dennis Jaffe, D.M.D., P.C. | A dentist agreed to pay $324,327 to resolve FCA allegations that he fraudulently billed Medicaid for tooth extraction procedures and for services rendered by a dental assistant when Jaffe was not in the office. Dr. Jaffe also pleaded guilty to a related criminal charge and agreed to surrender his dental license as part of the plea.[139] | $324,327 |
| June 11, 2015 | Jerome Block, M.D.; Integrations Medical Clinic | A physician and his clinic agreed to pay $105,000 to resolve FCA allegations involving their permitting unlicensed personnel and staff to provide medical services to patients, in violation of Medicare regulations.[140] | $105,000 |
| June 18, 2015 | Edward Berman, M.D. | A physician agreed to pay $218,633 to resolve FCA allegations that he upcoded Medicare claims for skilled nursing facility services.[141] | $218,633 |
| July 13, 2015 | David Lester Johnston, M.D. | A physician agreed to pay $270,528 to resolve FCA allegations that he billed Medicare for office visits, osteopathic manipulative treatment and physical therapy services that were not performed. As part of the settlement, Dr. Johnston has been excluded from participation in federal healthcare programs for five years. In January 2015, Dr. Johnston pleaded guilty to a related criminal charge and subsequently was sentenced to three months in prison.[142] | $270,528 |
| July 24, 2015 | Haroutyoun Margossian, M.D. | An obstetrician and gynecologist agreed to pay $8.04 million to resolve allegations that he utilized unlicensed and often unsupervised staff to treat women suffering from urinary incontinence, in violation of Medicare and Medicaid regulations, and upcoded in billing for pelvic floor rehabilitation. To resolve a related criminal charge, Dr. Margossian entered into a deferred prosecution agreement that requires him to install an independent billing monitor of his practice.[143] | $8.04 million |
| July 24, 2015 | Neelesh Bangalore, M.D. | An oncologist agreed to pay $736,000 to resolve FCA allegations that he billed Medicare, Medicaid and Tricare for certain chemotherapy drugs purchased from an unlicensed foreign pharmaceutical manufacturer.[144] | $736,000 |

136. http://www.justice.gov/usao-me/pr/rockport-dentist-settles-federal-health-care-fraud-complaint.
137. http://www.justice.gov/usao-edky/pr/somerset-optometrist-found-liable-false-claims-act.
138. http://www.justice.gov/opa/pr/government-settles-false-claims-act-allegations-against-florida-neurologist-150000.
139. http://www.justice.gov/usao-ndga/pr/atlanta-dentist-pay-settlement-resolve-false-claims-act-allegations.
140. http://www.justice.gov/usao-ndok/pr/settlement-reached-medicare-fraud-lawsuit-against-tulsa-doctor-and-his-medical-clinic.
141. http://www.justice.gov/usao-ct/pr/ridgefield-doctor-pays-218633-settle-allegations-under-false-claims-act.
142. http://www.justice.gov/usao-ct/pr/ridgefield-physician-sentenced-prison-health-care-fraud-pays-270k-false-claims-act.
143. http://www.justice.gov/usao-edny/pr/board-certified-obstetrician-and-gynecologist-agrees-civil-fraud-settlement-conjunction.
144. http://www.justice.gov/usao-edca/pr/stockton-oncologist-pays-736000-resolve-false-claims-act-allegations.

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| August 12, 2015 | Vikas Desai, M.D.; Robert Maccone, M.D. | Two physicians agreed to pay collectively $1.12 million to resolve allegations that they submitted claims to Medicare for nerve conduction studies that were not medically necessary.[145] | $1.12 million |
| August 19, 2015 | Bashir Azher, M.D. | A physician agreed to pay $207,988 to resolve FCA allegations that he billed Medicare for prostate laser ablation procedures that were too short to generate a therapeutic benefit, failed to meet professional standards of care, were medical unnecessary and/or violated Medicare regulations.[146] | $207,988 |
| September 24, 2015 | Elizabeth Kressin, D.C. | A chiropractor agreed to pay $62,349 to resolve FCA allegations that she billed Medicaid for medically unnecessary procedures and for the treatment of conditions for which payment is not allowed.[147] | $62,349 |
| October 6, 2015 | Amira Mantoura, D.P.M. | A podiatrist agreed to pay $288,538 to resolve civil FCA allegations, and pleaded guilty to a related criminal charge, that she billed Medicare for nail avulsion procedures she knew she did not perform; instead, she typically was performing routine foot care.[148] | $288,538 |

# MISCELLANEOUS/NON-PROVIDERS

| DATE | ENTITY | FCA ALLEGATIONS | SETTLEMENT AMOUNT |
|---|---|---|---|
| February 27, 2015 | Charles Denham, M.D.; Health Care Concepts Inc.; Texas Medical Institute of Technology | A consulting company, research organization and the patient safety consultant who operates both entities, Charles Denham, M.D., agreed to pay $1 million to resolve FCA allegations that Dr. Denham solicited and received kickbacks from CareFusion, a medical technology company, in exchange for influencing the recommendations of the National Quality Forum and for promoting the purchase of one of CareFusion's products, in violation of the AKS. The prohibited payments allegedly took the form of monthly payments to Dr. Denham while he sat on the forum's Safe Practices Committee. As part of the settlement, Dr. Denham and his two businesses have been excluded from participating in federal healthcare programs.[149] | $1 million |
| November 20, 2015 | University of Florida | The University of Florida agreed to pay $19.87 million to resolve FCA allegations that the university improperly charged HHS for salary and administrative costs on hundreds of federal grants awarded to the university between 2005 and 2010. The government alleged that the university overcharged for the salary costs of its employees without proper supporting documentation, and charged certain grants for administrative costs for equipment and supplies in contravention of federal regulations.[150] | $19.87 million |

145. http://www.justice.gov/usao-edny/pr/long-island-physicians-pay-11-million-resolve-civil-fraud-allegations-they-provided-and.
146. http://www.justice.gov/usao-az/pr/bullhead-city-physician-pay-207000-resolve-false-claims-allegations.
147. http://www.justice.gov/usao-ndia/pr/spencer-chiropractor-pay-62349-resolve-false-claims-act-allegations.
148. http://www.justice.gov/usao-ct/pr/stamford-podiatrist-pleads-guilty-submitting-false-medicare-claims-also-pays-288k-civil.
149. http://www.justice.gov/opa/pr/united-states-settles-false-claims-act-allegations-against-patient-safety-consultant-and-his.
150. http://www.justice.gov/opa/pr/university-florida-agrees-pay-19875-million-settle-false-claims-act-allegations.

## APPENDIX B - INTERVENED CASES

| DATE OF INTERVENTION/ FILING | CASE STYLE | FCA ALLEGATIONS | STATUS |
|---|---|---|---|
| March 31, 2015 | ***U.S. ex rel. Lutz, et al. v. Health Diagnostic Laboratory, Inc., et al.***, No. 14-230 (D.S.C.)<br><br>***U.S. ex rel. Mayes v. Berkeley HeartLab Inc., et al.***, No. 11-1593 (D.S.C.)<br><br>***U.S. ex rel. Riedel v. Health Diagnostic Lab. Inc., et al.***, No. 11-2308 (D.D.C.) | ***Laboratory, Marketing Company, Owners & CEO.*** The government intervened in part in three *qui tam* actions filed in 2011 and 2014 and filed a consolidated complaint-in-intervention against Berkeley Heartlab, Inc., BlueWave Healthcare Consultants, Inc., the companies' owners, and the former CEO of Health Diagnostic Laboratory, alleging that the defendants paid kickbacks, primarily in the form of $80 million in "processing and handling" fees, to induce physicians to refer blood samples to specialty pharmacies for large panels of tests, and that certain defendants entered into illegal contracts for commission-based payments in exchange for arranging for and recommending that physicians refer laboratory tests. At the time of intervention, two other defendants, Health Diagnostic Laboratory, Inc. and Singulex, agreed to settle similar allegations with the government (see prior section).[1] | Pending MTDs Complaint in Intervention and relators' complaints |
| April 20, 2015 | ***U.S. ex rel. Ribik v. ManorCare, Inc., et al.***, 09-13 (E.D. Va.)<br><br>***U.S. ex rel. Carson v. HCR ManorCare, et al.***, 11-1054 (E.D. Va.)<br><br>***U.S. ex rel. Slough v. HCR ManorCare, et al.***, 14-1228 (E.D. Va.) | ***Skilled Nursing Facilities Operator.*** The United States intervened in whole or part in three *qui tam* actions, initially filed in 2009, 2011 and 2014, and filed a consolidated complaint-in-intervention against HCR ManorCare and affiliated entities alleging that ManorCare knowingly and routinely submitted false claims to Medicare and Tricare for rehabilitation therapy services that were medically unreasonable and unnecessary. The government contends that ManorCare used corporate-wide financial pressure to significantly increase revenues without regard to patients' actual clinical needs; threatened to terminate SNF managers and therapists if they did not administer the additional treatments necessary to qualify for the highest Medicare payments; and kept patients in SNFs past the time they were medically ready to be discharged.[2] | MTD Complaint in Intervention denied September 2015<br><br>MTD relator's complaint in ***Carson*** case granted on first-to-file grounds; relator filed notice of appeal |
| May 11, 2015 | ***U.S. v. Hastings, et al.***, 15-2557 (E.D. Pa.) | ***Medical Supply Company & Owners.*** The United States filed a civil FCA action alleging that John and Sarah Hastings knowingly sought to bypass John Hastings' exclusion from Medicare for healthcare-related criminal charges by submitting claims to Medicare for supplies through their medical supply company, Diabetic Care Solutions, Inc., and attempting to conceal John Hastings' role in the company. On the same day the complaint was filed, the parties filed a stipulated order and consent judgment whereby the defendants will pay the United States $200,000 in phases to settle the underlying claims.[3] | Discovery regarding defendants' financial status ongoing |

1. http://www.justice.gov/opa/pr/two-cardiovascular-disease-testing-laboratories-pay-485-million-settle-claims-paying.
2. http://www.justice.gov/opa/pr/government-sues-skilled-nursing-chain-hcr-manorcare-allegedly-providing-medically-unnecessary.
3. http://www.justice.gov/usao-edpa/pr/united-states-sues-supply-company-and-delaware-county-couple-healthcare-fraud.

| DATE OF INTERVENTION/ FILING | CASE STYLE | FCA ALLEGATIONS | STATUS |
|---|---|---|---|
| May 11, 2015 | ***U.S. ex rel. Dresser v. Qualium Corp, et al.***, 12-1745 (N.D. Cal.) | ***Sleep Clinic Operator & Durable Medical Equipment Distributor.*** The United States intervened and filed a complaint in intervention in a *qui tam* suit filed in 2012 alleging that two companies and their individual owners fraudulently billed Medicare for diagnostic sleep tests that were conducted at unapproved locations and performed by technicians lacking the licenses or certifications required by Medicare. The government also alleges that defendants fraudulently billed Medicare for medical devices in violation of Medicare rules and regulations that prohibited providers of diagnostic sleep tests from supplying medical devices and from sharing a sleep laboratory location with a durable medical equipment supplier. The government declined to intervene as to claims against a third-party billing company and claims regarding alleged improper payments made by the defendants to medical providers.[4] | Pending MTDs Complaint in Intervention and Relator's First Amended Complaint |
| May 15, 2015 | ***U.S. ex rel. Smith v. Carolina Community Mental Health Ctrs., Inc., et al.***, 11-2756 (E.D. Pa.) | ***Mental Health Clinics & Owners.*** The United States intervened in a *qui tam* FCA suit alleging that Melchor Martinez and his wife operated mental health clinics despite Martinez's exclusion from federal healthcare programs in 2000. The government alleges that during Martinez's exclusion, the clinics fraudulently billed government programs for (1) psychiatrist visits that were shorter in duration than actually billed; (2) services of "therapists" who were not qualified to provide mental health services; and (3) therapy services provided without the requisite supervision.[5] | Defendants have until February 19, 2016 to answer all complaints |
| June 1, 2015 | ***U.S. ex rel. Sorensen v. Outreach Diagnostic Clinic, et al.***, No. 12-428 (S.D. Tex.) | ***Diagnostic and Eye Care Clinics, Medical Director & Owner.*** The United States intervened in a *qui tam* action, initially filed in 2012, and filed a complaint-in-intervention alleging that Outreach Diagnostic Clinic and Outreach Eyecare billed Medicare for special eye pressure tests that were not performed, as the clinics did not even have the necessary equipment to perform the tests. Notably, in March 2015, the district court stated in an order that the government had been given three years to decide whether to intervene, had not decided, and thus, by abdication, had declined to intervene. Two weeks later though the court granted the government's unopposed motion to intervene.[6] | Pending MTD |
| June 12, 2015 | ***U.S. ex rel. Pelletier v. Liberty Ambulance Services, Inc.***, 11-587 (M.D. Fla.) | ***Ambulance Company.*** The United States filed a complaint in intervention as to Liberty Ambulance Services, Inc. after settling with all other defendants in the underlying *qui tam* suit in May 2015 (see prior section). The government alleges that Liberty trained its employees to submit false statements to justify medically unnecessary ambulance transports and engaged in a systematic kickback scheme whereby it offered commercially unreasonable rates to private payors (and not the government), in order to induce private payors to provide Liberty with exclusive access to their federal government subsidized patient population.[7] | MTD Complaint in Intervention granted as to FCA claims on Rule 9(b) grounds<br><br>Government ordered to file an amended complaint by February 1, 2016 |

4. http://www.justice.gov/usao-ndca/pr/united-states-joins-lawsuit-against-bay-area-sleep-clinics.
5. http://www.justice.gov/usao-edpa/pr/civil-complaint-alleges-fraud-operators-community-mental-health-clinics.
6. http://www.justice.gov/usao-sdtx/pr/united-states-files-suit-against-outreach-diagnostic-clinic-and-outreach-eyecare.
7. http://www.justice.gov/usao-mdfl/pr/united-states-files-lawsuit-against-jacksonville-based-ambulance-company.

| DATE OF INTERVENTION/ FILING | CASE STYLE | FCA ALLEGATIONS | STATUS |
|---|---|---|---|
| September 18, 2015 | ***U.S. ex rel. Aldridge v. Cain, et al.***, 07-309 (S.D. Miss.) | ***Hospital, Management Co., & Individuals.*** The United States intervened in a *qui tam* action and filed a complaint-in-intervention against rural acute care hospital Stone County Hospital; its management company, H. Ted Cain; who owned and controlled the hospital and management company; and related individuals for billing Medicare for excessive and ineligible expenses through their abuse of the special Medicare rules exempting rural hospitals from the prospective payment system. Specifically, the allegations include billing Medicare for managerial and directorship services that were either not provided or were duplicative of jobs performed by other employees; including personal luxury automobiles on the hospital's cost reports; and wrongfully charging to the hospital work that Ted Cain did at his other businesses.[8] | Pending MTD, Transfer Venue, and/or For More Definite Statement of Claims |
| October 28, 2015 | ***U.S. ex rel. Hayward v. SavaSeniorCare, LLC, et al.***, No. 11-0821 (M.D. Tenn.)<br><br>***U.S. ex rel. Scott v. SavaSeniorCare Administrative Servs., LLC***, No. 15-0404 (M.D. Tenn.)<br><br>***U.S. ex rel. Kukoyi v. Sava Senior Care, L.L.C., et al.***, No. 15-1102 (M.D. Tenn.) | ***Skilled Nursing Facilities Operator.*** The United States intervened in part in three separate *qui tam* lawsuits, initiated in 2011 and 2015, and filed a consolidated complaint-in-intervention alleging that SavaSeniorCare LLC and related entities ("Sava") knowingly and routinely submitted false claims to Medicare for rehabilitation services that were medically unreasonable, unnecessary and/or not skilled in nature. The government's complaint alleges that Sava set aggressive corporate targets for high Medicare reimbursement rates and pressured employees to hit those targets, without regard for the patients' clinical needs, and also allegedly delayed discharging patients from its facilities to increase reimbursement. The United States declined to intervene in many other allegations, including AKS violations, improper SNF billing to Medicaid and FCA conspiracy claims. The 13 states involved declined intervention in full.[9] | Defendants have until January 28, 2016 to answer all complaints except for complaint in ***Scott***, where relator has moved for leave to amend his complaint |
| October 29, 2015 | ***U.S. v. Jakacki et al.***, 15-cv-8512 (S.D.N.Y.) | ***Pharmacies, Pharmacist & Two Individuals.*** The United States filed a criminal indictment and civil complaint against two pharmacies, European Apothecary, Inc. and MW&W Global Enterprises, Inc., and three individuals, Lilian and Marcin Jakacki and Robert Cybulski, alleging illegal distribution of oxycodone with a street value between $10 and $15 million, money laundering and healthcare fraud. This alleged pill mill operated under the guise of "mom and pop" pharmacies in Brooklyn and Queens.[10] | Motion to stay pending completion of parallel criminal proceedings |
| November 18, 2015 | ***U.S. ex rel. Jane Doe v. Heart Solution, PC, et al.***, No. 14-3644 (D.N.J.) | ***Diagnostic Testing Companies & Owner/Operators.*** The United States intervened in relator's litigation, initiated in June 2014, alleging that defendants (1) created fraudulent diagnostic test reports, forged physician signatures on the same, and then billed Medicare for the reports and underlying tests used to fabricate the reports; and (2) improperly billed for neurological tests conducted without physician supervision.[11] | Complaint in Intervention filed |

8. http://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-mississippi-hospital-two.
9. http://www.justice.gov/opa/pr/government-intervenes-lawsuits-alleging-skilled-nursing-chain-savaseniorcare-provided.
10. http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-criminal-and-civil-charges-against-pharmacist-two.
11. http://www.justice.gov/usao-nj/pr/us-attorney-s-office-files-civil-lawsuit-against-new-jersey-couple-and-two-diagnostic.

# ABOUT BASS, BERRY & SIMS PLC

**The Bass, Berry & Sims Healthcare Fraud Task Force** represents healthcare providers in connection with fraud and abuse matters, including responding to governmental inquiries by the U.S. DOJ and U.S. Attorneys' Offices, the Office of Inspector General of the U.S. Department of Health and Human Services, federal program safeguard contractors, and various states' Attorneys General offices. We have a track record of successfully representing providers in related FCA litigation, including multiple declinations and dismissals in FCA qui tam cases in 2015 alone. We routinely counsel healthcare providers on implementing state-of-the-art compliance programs and assist clients in navigating self-disclosure and other compliance-related projects.

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


## Matthew M. Curley

*Member*

**615.742.7790 TEL**

**mcurley@bassberry.com**



## Wallace W. Dietz

*Member*

**615.742.6276 TEL**

**wdietz@bassberry.com**



## Anna M. Grizzle

*Member*

**615.742.7732 TEL**

**agrizzle@bassberry.com**



## John E. Kelly

*Member*

**202.827.2953 TEL**

**jkelly@bassberry.com**



## Lisa S. Rivera

*Member*

**615.742.7707 TEL**

**lrivera@bassberry.com**



## Brian D. Roark

*Member*

**615.742.7753 TEL**

**broark@bassberry.com**

**Bob Cooper** advises clients on matters related to compliance and enforcement issues and assists clients in responding to internal investigations from federal, state or local governments. Bob rejoined the firm in 2015 after 12 years of public service, serving as legal counsel to Tennessee Governor Phil Bredesen from 2003-2006 and Attorney General from 2006-2014. While Tennessee Attorney General, Bob formed a division within the Attorney General's Office devoted to pursuing provider Medicaid fraud and recovered more than $150 million for the state.

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

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

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

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

**Eli Richardson** helps businesses respond to government investigations involving alleged white-collar crime or quasi-criminal civil violations. He conducts internal investigations, advises on compliance policies, provides compliance training and helps clients in self-disclosure to government authorities. Eli previously held positions with the DOJ, including serving as Criminal Chief at the U.S. Attorney's Office and with the FBI.

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

**Brian Roark** leads the firm's Healthcare Fraud Task Force and concentrates his practice on representing healthcare clients in responding to governmental investigations and defending False Claims Act lawsuits. He is an adjunct professor at Vanderbilt School of Law, teaching Healthcare Fraud and Abuse.

**Danielle Sloane** helps life science and healthcare clients navigate federal and state healthcare laws and regulations. She frequently advises clients on compliance, fraud and abuse, and operational matters, including self-disclosures, voluntary repayments, overpayments, compliance plans and audits, and internal investigations.

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

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

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

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

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

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

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

**Rob Laser** represents clients in compliance investigations and related civil and criminal litigation involving the DOJ, FDA, HHS-OIG, CMS and the SEC. Rob previously was a law clerk for the Hon. Judge David J. Hale of the U.S. District Court for the Western District of Kentucky.

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

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

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

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

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

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