



HEALTHCARE FRAUD & ABUSE REVIEW 2019

BASS
BERRY 
SIMS

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A LOOK BACK ... A LOOK AHEAD

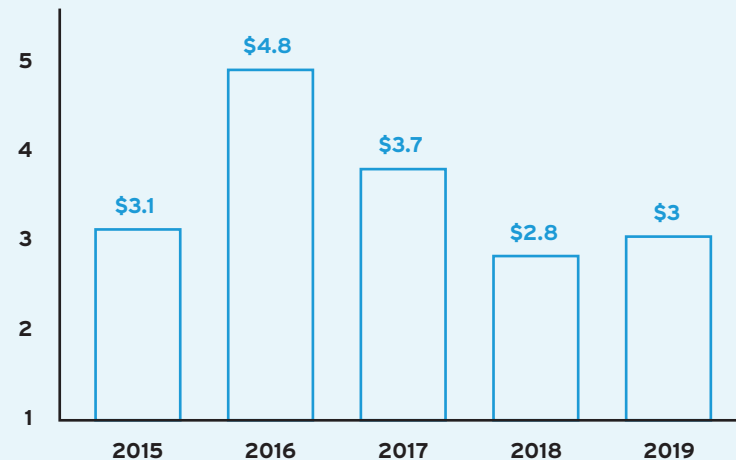
Turmoil at the highest levels of government served as the backdrop for civil and criminal healthcare fraud enforcement efforts again last year. At the beginning of the year, this took the form of leadership changes at the U.S. Department of Justice (DOJ) and within the U.S. Department of Health and Human Services (HHS). U.S. Attorney General Robert Barr was confirmed on February 14, 2019, and long-serving HHS Inspector General Daniel Levinson stepped down from his position after serving for more than a decade to be replaced by Acting Inspector General Joanne Chiedi. Notwithstanding these leadership changes, government enforcement efforts remained consistently focused on previously-announced priorities with significant success.

DOJ's announced results reflect that the government's healthcare fraud enforcement efforts have continued unabated. Civil fraud recoveries by DOJ rose to more than \$3 billion in the fiscal year ending September 30, 2019 (FY 2019) as compared to \$2.8 billion in FY 2018, and recoveries attributable to the healthcare industry were \$2.6 billion in FY 2019 - up slightly from \$2.5 billion in FY 2018.¹

Whistleblowers filed 633 new *qui tam* lawsuits under the False Claims Act (FCA) in FY 2019, which represented a slight drop-off compared with prior years, but brought the total number of FCA *qui tam* lawsuits filed since 2010 to more than 6,600. For their efforts, whistleblowers recovered more than \$265 million in relator share awards in FY 2019, bringing the total awards to relators to more than \$2.1 billion in the last five years.

Throughout the year, DOJ and HHS announced a number of healthcare fraud takedowns - many of which focused on enforcement actions involving opioid distribution. In September, DOJ announced a coordinated healthcare fraud enforcement action across seven federal districts in the Northeastern United States, involving more than \$800 million in losses and

CIVIL FRAUD RECOVERIES FY 2015-2019 (\$BILLIONS)



¹ <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>.

Recoveries attributable to the healthcare industry were \$2.6 billion in FY 2019 - up slightly from \$2.5 billion in FY 2018.

the distribution of more than 3.25 million pills in connection with “pill mill” clinics.² The announced takedown also involved the disclosure of guilty pleas by executives of numerous telemedicine and durable medical equipment (DME) companies for their roles in the submission of more than \$600 million in fraudulent Medicare claims. Earlier in the year, DOJ announced that the Appalachian Regional Prescription Opioid Strike Force filed charges in 11 federal districts against

60 individuals, including 31 physicians, seven pharmacists, eight nurse practitioners, and seven other licensed medical professionals stemming from 350,000 prescriptions for opioids and other narcotics.³

DOJ also made two key announcements in 2019. The first concerned how prosecutors will evaluate corporate compliance programs, which followed the 2017 guidance by DOJ on this same topic. The second announcement concerned how DOJ will evaluate a party’s cooperation in connection with resolution of civil FCA claims. Both of these DOJ pronouncements provide practical guidance for healthcare providers to consider in evaluating civil and criminal enforcement risks. For its part, the Centers for Medicare & Medicaid Services (CMS) provided further explanation of its approach to considering sub-regulatory guidance in connection with enforcement actions following the Supreme Court’s opinion in *Azar v. Allina Health Services*, which determined that substantive changes to regulations need to follow notice-and-comment rulemaking procedures.

HEALTHCARE FRAUD TAKEDOWN IN NORTHEASTERN UNITED STATES BY THE NUMBERS



² <https://www.justice.gov/opa/pr/federal-health-care-fraud-takedown-northeastern-us-results-charges-against-48-individuals>.

³ <https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against>.

Finally, the year ended in December with a panel of the U.S. Court of Appeals for the Fifth Circuit striking down the individual mandate of the Patient Protection and Affordable Care Act (PPACA), which imposes minimal essential coverage requirements under which certain individuals are obligated to purchase and maintain health insurance coverage, as unconstitutional in a 2-1 decision in *Texas v. United States*.⁴ The Fifth Circuit remanded the case back to the district court for consideration of whether the individual mandate is severable from the balance of PPACA. While the implications of the Fifth Circuit’s ruling could have a far-reaching impact on healthcare broadly speaking, PPACA also included key amendments to the FCA that could hang in the balance with respect to any result that imperiled PPACA.

Our firm’s annual **Healthcare Fraud & Abuse Review** is intended to assist healthcare providers in developing a greater understanding of the civil and criminal enforcement risks they face during a time of great uncertainty for the healthcare industry. Without question, understanding the key developments during the prior year is an important step in implementing necessary safeguards designed to minimize enforcement risks for healthcare providers.

For their efforts, whistleblowers recovered more than \$265 million in relator share awards in FY 2019, bringing the total awards to relators to more than \$2.1 billion in the last five years.

⁴ 945 F.3d 355 (5th Cir. 2019).

NOTEWORTHY SETTLEMENTS

As in recent years, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2019. Of the \$3 billion in settlements and judgments, recoveries from matters involving the healthcare industry amounted to \$2.6 billion (87%). This is the tenth consecutive year that recoveries in federal civil healthcare fraud matters have exceeded \$2 billion.⁵

As has been typical in recent years, newly-filed *qui tam* complaints accounted for the vast majority of the new civil fraud matters initiated in FY 2019. Whistleblowers filed 633 *qui tam* lawsuits in FY 2019 and recoveries from these and earlier filed lawsuits accounted for \$2.1 billion of the \$3 billion recovered. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than \$1.9 billion of the recoveries from healthcare companies during FY 2019.

The **Appendix** to our Healthcare Fraud & Abuse Review contains a detailed breakdown of key settlements from the past year, many of which are referenced within this section of the Review.

5 <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>.

HOSPITALS AND HEALTH SYSTEMS

There were several notable settlements involving hospitals and health systems resolving FCA allegations, many of which related to alleged violations of the Stark Law or the Anti-Kickback Statute (AKS). Improper compensation arrangements with physician referral sources remained a key area of scrutiny with inappropriate remuneration taking on various forms, such as compensation either exceeding fair market value (FMV) or accounting for the volume or value of physician referrals,⁶ kickbacks disguised as professional services agreements,⁷ and loans without repayment expectations.⁸

In the year's largest series of settlements involving hospitals and health systems, Sutter Health, several of its affiliated hospitals, and a group of cardiovascular surgeons agreed to pay more than \$46.1 million to resolve a number of alleged Stark Law violations, including allegations that physicians were paid in excess of FMV, space was leased at below-market rates, and physicians were reimbursed for recruiting expenses in excess of the expenses incurred. Approximately one-third of the settlement amount (\$15.1 million) was attributable to the resolution of self-disclosed Stark Law violations, as well as allegations that several of Sutter's ambulatory surgical centers double-billed Medicare.⁹

Hospitals and health systems also resolved several cases related to medical necessity issues, including allegations of inappropriately billing or coding claims or treating patients in an inpatient setting when an outpatient or observation setting was sufficient.¹⁰ And, a number of settlements involved general failures to adhere to reimbursement or coverage requirements.¹¹

LONG-TERM CARE PROVIDERS

The medical necessity of services provided continued to be the dominant focus of settlements involving home health, hospice, skilled nursing, and nursing home providers.¹² Several settlements resolving FCA allegations related to Stark Law and AKS violations involved improper remuneration in the form of sham medical director agreements allegedly used to induce referrals.¹³ Long-term care providers settled alleged violations of both federal

6 See, e.g., <https://www.justice.gov/usao-ndga/pr/union-general-hospital-pay-5-million-resolve-alleged-false-claims-act-violations>; <https://www.justice.gov/usao-md/pr/medstar-health-pay-us-35-million-resolve-allegations-it-paid-kickbacks-cardiology-group>.

7 <https://www.justice.gov/usao-md/pr/medstar-health-pay-us-35-million-resolve-allegations-it-paid-kickbacks-cardiology-group>.

8 <https://www.justice.gov/opa/pr/rialto-capital-management-and-current-owner-indiana-hospital-pay-36-million-resolve-false>.

9 <https://www.justice.gov/opa/pr/california-health-system-and-surgical-group-agree-settle-claims-arising-improper-compensation>.

10 See, e.g., <https://www.justice.gov/usao-md/pr/anne-arundel-medical-center-pay-more-3-million-settle-federal-false-claims-act>; <https://www.justice.gov/usao-edpa/pr/prime-healthcare-services-and-ceo-dr-prem-reddy-pay-125-million-settle-false-claims-act>; <https://www.justice.gov/usao-wdtk/pr/oklahoma-city-hospitals-agree-pay-28-million-settle-allegations-submitting-false-claims>.

11 See, e.g., <https://www.justice.gov/usao-wdla/pr/qui-tam-lawsuit-and-federal-investigation-results-half-million-dollar-settlement>; <https://www.justice.gov/usao-wdtx/pr/justice-department-reaches-settlement-agreement-vibra-healthcare-and-el-paso>; <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-123-million-settlement-lenox-hill-hospital-submitting>.

12 See, e.g., <https://www.mass.gov/news/ag-healey-announces-10-million-in-recoveries-from-home-health-care-companies-for-falsely>; <https://www.justice.gov/usao-edva/pr/capital-caring-pays-31-million-resolve-medicare-billing-claims>; <https://www.justice.gov/usao-mdtn/pr/skilled-nursing-facility-management-company-agrees-settle-false-claims-act-allegations>.

13 <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-cases-against-home-health-agency>; <https://www.justice.gov/usao-mdfl/pr/orlando-skilled-nursing-facility-physician-and-related-providers-agree-pay-15-million>.

COMPARISON OF TOTAL RECOVERIES: INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (2015-2019)¹⁴

YEAR	INTERVENED CASES	DECLINED CASES
2015	\$1.89 billion	\$516.38 million
2016	\$2.92 billion	\$108.29 million
2017	\$2.54 billion	\$601.70 million
2018	\$2.00 billion	\$135.22 million
2019	\$1.91 billion	\$293.17 million

and state fraud and abuse laws, including one settlement with Vanguard Healthcare LLC that marked the state of Tennessee's highest settlement in history for worthless nursing home services.¹⁵

In the year's largest settlement involving a long-term care provider, Encompass Health Corporation f/k/a HealthSouth Corporation, the nation's largest operator of inpatient rehabilitation facilities (IRFs), agreed to pay \$48 million to resolve FCA allegations that some of its facilities: (1) submitted inaccurate information to Medicare to maintain IRF status and earn a higher rate of reimbursement; and (2) billed Medicare for medically unnecessary admissions. To ensure compliance with Medicare IRF requirements, Encompass allegedly falsely diagnosed patients with conditions unsupported by clinical evidence and admitted patients who were ineligible for treatment in an IRF.¹⁶

And, a South Florida nursing facility owner was convicted for his role in a wide-ranging fraud scheme involving alleged kickbacks paid to physicians in exchange for patient admissions, described by DOJ as "the largest healthcare fraud scheme ever charged."¹⁷ At trial, DOJ's evidence showed that the owner bribed physicians to admit patients to his

¹⁴ <https://www.justice.gov/opa/press-release/file/1233201/download>.

¹⁵ See, e.g., <https://www.justice.gov/opa/pr/vanguard-healthcare-agrees-resolve-federal-and-state-false-claims-act-liability>; <https://www.mass.gov/news/ag-healey-announces-10-million-in-recoveries-from-home-health-care-companies-for-falsely>.

¹⁶ <https://www.justice.gov/opa/pr/encompass-health-agrees-pay-48-million-resolve-false-claims-act-allegations-relating-its>.

¹⁷ <https://www.justice.gov/opa/pr/south-florida-health-care-facility-owner-convicted-role-largest-health-care-fraud-scheme-ever>.

facilities, and then, cycled the patients through those facilities without providing appropriate medical care or by providing medically unnecessary services, which were then billed to government healthcare programs. The owner was sentenced to 20 years in prison for his role in the kickback scheme.¹⁸

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

In FY 2019, the pharmaceutical and medical device industry continued to account for some of the largest recoveries within the healthcare industry. These settlements typically involved allegations of AKS violations and fraudulent drug pricing, among others.

Settlements related to the government's efforts to address the opioid crisis resulted in some of the largest settlements to date. The highly-publicized charges against Insys Therapeutics, Inc., ended in a \$225 million settlement to globally resolve criminal and civil FCA allegations in June 2019.¹⁹ The settlement resolved allegations that Insys violated the AKS by paying illegal kickbacks to healthcare practitioners to induce prescriptions of its highly addictive fentanyl spray, Subsys, in the form of sham speaker program fees, jobs for prescribers' relatives and friends, and lavish meals and entertainment. The settlement also resolved allegations that Insys encouraged physicians to prescribe Subsys to patients for whom it was not clinically indicated and to falsify diagnoses to obtain additional reimbursement from Medicare and Tricare.

A number of settlements involved the improper utilization of patient assistance programs (PAPs) by pharmaceutical companies as conduits to pay kickbacks to patients in order to induce prescriptions. Astellas Pharma US, Inc., paid \$100 million in April 2019 to resolve allegations that it worked with two nonprofit foundations to establish a charitable foundation to assist patients with certain types of prostate cancer, but then implemented certain qualifying restrictions so that, in practice, only Astellas' own drugs qualified for co-pay assistance. Similarly, Jazz Pharmaceuticals plc (\$57 million), Lundbeck LLC (\$52.6 million), Amgen, Inc. (\$24.75 million), Alexion Pharmaceuticals, Inc. (\$13 million), and US WorldMeds LLC (\$17.5 million) also settled allegations related to their agreements with purportedly independent foundations in 2019.²⁰

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¹⁸ <https://www.justice.gov/opa/pr/south-florida-health-care-facility-owner-sentenced-20-years-prison-role-largest-health-care>.

¹⁹ <https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal>.

²⁰ <https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid>; <https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid>; <https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients>.

FY 2019 also saw an uptick in state and federal government actions against pharmaceutical companies for their role in increasing drug prices. Teva Pharmaceuticals USA Inc. agreed to pay \$135 million to the state of Illinois in January 2019 to resolve allegations that it inflated its reported average wholesale price (AWP). Medicaid programs rely on reported AWP's to set reimbursement rates, and thus, it has been alleged that inflated AWP's result in artificially increased drug costs and overpayments by the state.²¹

Teva's settlement is the result of a 2005 lawsuit filed by the state of Illinois against 47 pharmaceutical drug makers that alleged the companies fraudulently published inflated AWP's. The lawsuit was fully resolved in October 2019, and in total, the Illinois Attorney General's office recovered more than \$678 million in settlements in connection with the lawsuit.²² Finally, in November 2019, Fagron Holding USA LLC agreed to pay \$22.05 million to resolve similar allegations made by the federal government.

OTHER PROVIDERS AND INDIVIDUALS

Settlements in FY 2019 underscored the federal government's continued focus on individual actors and their roles in healthcare fraud schemes. In one notable case, an orthopedic surgeon became the twelfth party to settle kickback allegations stemming from the same investigation into a compounding pharmacy. The government alleged that the individuals received payments disguised as medical director fees in exchange for prescribing the pharmacy's compounded pain creams.²³ In another case, a former CEO of a hospital chain agreed to pay \$3.46 million to resolve FCA allegations that he pressured emergency department physicians to recommend medically unnecessary hospital admissions and caused the hospital chain to make unlawful payments to physicians and its emergency department staffing company. The hospital chain and the staffing company had previously resolved related allegations in 2018 and 2017, respectively.²⁴

Other providers, including individuals, settled allegations involving drug and lab tests. A behavioral health clinic and its psychiatrist owner agreed to pay more than \$3.38 million to resolve state and federal FCA allegations that they: (1) billed Medicare for multiple units of urine drug screening tests when they should have known only one unit of service per patient encounter could be billed; and (2) billed separately for certain tests that they should have known were encompassed in other tests that they billed, among other allegations related to improper urine drug test billing.²⁵ In another case, an operator of drug treatment centers agreed to pay \$17 million and enter into a five-year corporate integrity agreement (CIA) to resolve FCA allegations that its centers submitted claims to Medicaid for urine and blood tests they were not certified to perform and, in some cases, had not performed.²⁶

This year also saw several notable settlements related to electronic health record (EHR) software. In one case, an EHR software developer agreed to pay \$57.25 million and enter into a five-year CIA to resolve FCA allegations that it caused its users to submit false claims for EHR incentive payments by misrepresenting the capabilities of one of its products and by providing unlawful remuneration to users to induce them to recommend the product, in violation of the AKS.²⁷ In another, a pathology laboratory agreed to pay \$63.5 million to resolve FCA allegations that it violated the AKS and Stark Law by providing physicians with subsidies for EHR systems and free or discounted technology consulting services in exchange for patient referrals.²⁸

21 http://www.illinoisattorneygeneral.gov/pressroom/2019_01/20190110.html.

22 http://www.illinoisattorneygeneral.gov/pressroom/2019_10/20191028.html.

23 <https://www.justice.gov/usao-ndok/pr/texas-orthopedic-surgeon-pay-300000-settle-false-claims-act-allegations>.

24 <https://www.justice.gov/opa/pr/former-ceo-hospital-chain-pay-346-million-resolve-false-billing-and-kickback-allegations>.

25 <https://www.justice.gov/usao-ct/pr/new-london-psychiatrist-and-mental-health-clinic-pay-over-33-million-settle-false-claims>.

26 <https://www.justice.gov/usao-sdvw/pr/united-states-attorney-announces-17-million-healthcare-fraud-settlement>.

27 <https://www.justice.gov/usao-vt/pr/electronic-health-records-developer-pay-second-largest-recovery-history-district-vermont>.

28 <https://www.justice.gov/opa/pr/pathology-laboratory-agrees-pay-635-million-providing-illegal-inducements-referring>.

ISSUES TO WATCH

There are a number of key issues that will have a significant impact on how healthcare fraud matters are prosecuted and defended in the coming year.

ALLINA AND ITS AFTERMATH

Last year, we covered two internal DOJ memoranda released in 2018 that we believed constituted significant shifts in the government's approach to analyzing and pursuing allegations of healthcare fraud. One of these memos, referred to as the Brand Memo, prohibits DOJ litigators from using noncompliance with agency guidance documents in affirmative civil enforcement cases to establish violations of applicable laws, including the FCA.²⁹ During 2019, there were key developments that should further curb efforts by the government and relators to rely on sub-regulatory guidance to establish FCA violations.

In June 2019, the Supreme Court issued its opinion in *Azar v. Allina Health Services*.³⁰ At issue in that case was a challenge by affected hospitals with respect to changes made by HHS to the Medicare formula for calculating disproportionate share hospital payments. The change had the effect of significantly and retroactively lowering Medicare payments

During 2019, there were key developments that should further curb efforts by the government and relators to rely on sub-regulatory guidance to establish FCA violations.

to hospitals serving low-income patients. In striking down the announced policy, the Court affirmed that the public received no warning of the change and no chance to comment on the change, which resulted in a violation of the agency's notice-and-comment obligations. In essence, the Court determined that Medicare issuances that established or changed a "substantive legal standard" governing the scope of benefits or eligibility to furnish services must go through notice-and-comment rulemaking.

Following the Supreme Court's opinion in *Allina*, Kelly Cleary, Deputy General Counsel and CMS Chief Legal Officer, issued a memorandum entitled "Impact of *Allina* on Medicare Payment Rules" (Cleary Memo).³¹ The Cleary Memo recognizes the impact of the Supreme Court's decision in *Allina* as requiring notice-and-comment rulemaking with respect to any CMS issuances that established or changed a "substantive legal standard" concerning the scope of benefits, payment for services, or eligibility to receive or provide Medicare benefits. The Cleary Memo acknowledges that announced CMS payment rules often form the basis of enforcement actions and stresses the importance of CMS conforming its guidance documents to the rulemaking obligations set forth in *Allina*. The Cleary Memo specifically states that to the extent guidance sets forth "payment rules not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because in *Allina*, it was not validly issued." With respect to local coverage determinations (LCDs), the Cleary Memo explains that "as a result of *Allina*, government enforcement actions based solely on LCDs are generally unenforceable."

Notably, the Cleary Memo acknowledges the Supreme Court's decision in *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, and recognizes that continued payment of claims by CMS with knowledge of a party's noncompliance with laws or regulations is strong evidence of a lack of materiality, noting that "[a]lthough *Escobar* left open the possibility that a violation may be material even if the government continued to pay with full knowledge of that violation,

When considered in conjunction with the Brand Memo, the Cleary Memo should have a significant impact on curtailing enforcement actions - including overpayment collections - premised on violations of regulatory guidance and sub-regulatory documents.

²⁹ <https://www.justice.gov/file/1028756/download>.
³⁰ 139 S. Ct. 1804 (2019).

³¹ <https://www.law360.com/articles/i222453/attachments/0>.

such cases are exceedingly rare” (emphasis supplied). The Cleary Memo’s recognition of this principle reaffirms the importance of providers facing FCA enforcement actions to seek discovery from CMS regarding its knowledge of the alleged violations at issue.

When considered in conjunction with the Brand Memo, the Cleary Memo should have a significant impact on curtailing enforcement actions – including overpayment collections – premised on violations of regulatory guidance and sub-regulatory documents. Under the Cleary Memo, “the critical question is whether the enforcement action could be brought absent the guidance document.”

RISE OF THE PROFESSIONAL RELATOR

A number of recent *qui tam* lawsuits have been filed by corporate data-analytic relators seeking to pursue FCA allegations against healthcare providers by mining Medicare claims data or other publicly available data sources. Lawsuits pursued by such relators are not characterized by personal knowledge of factual information associated with the alleged wrongdoing, which is the typical hallmark of well-pleaded FCA allegations. Rather, these professional relators are opportunistic, drawing inferences of fraud based on their own data analysis.

Late in 2018, DOJ sought to dismiss 10 lawsuits brought by 10 different limited liability companies created by the National Health Care Analysis Group (NHCA) for the sole purpose of serving as the relator in *qui tam* lawsuits filed against a number of pharmaceutical companies throughout the country.³² NHCA’s lawsuits alleged that the defendant pharmaceutical companies were engaged in massive schemes to violate the AKS. In an interview, NHCA’s managing agent laid bare the purpose of the creation of NHCA and the filing of the *qui tam* lawsuits at issue, explaining that CMS’s decision to make Medicare claims data available to the public was “a massive business opportunity” for such organizations to file *qui tam* lawsuits.³³

Similar FCA cases based solely on data analysis have been brought by Austin, Texas-based Integra Med Analytics, LLC, which is led by a University of Texas Professor of Finance and holds itself out as an analytics firm that researches and investigates fraud, waste, and abuse in healthcare. Integra has filed FCA lawsuits throughout the United States against various types of providers alleging that these providers submitted false claims, including allegations that a hospital system inflated Medicare reimbursement through the use of secondary diagnosis codes³⁴ and that skilled nursing facilities provided medically unnecessary therapy services to Medicare beneficiaries.³⁵ The United States has declined to intervene in each

case brought by Integra, but providers have had only mixed results in seeking dismissal of these cases at the pleading stage under the FCA’s public disclosure bar and Rule 9(b).³⁶

As claims data and similar information become increasingly available to analytics firms, providers should expect to see more opportunistic FCA cases brought based on data analytics and for traditional relators (such as employees or former employees) to seek to bolster their cases through publicly-available reimbursement data. These cases serve as an important reminder to providers to understand their own data because the government and relators certainly are endeavoring to do so.

DOJ ISSUES GUIDANCE ON COMPLIANCE AND COOPERATION

In 2019, DOJ issued two significant pronouncements with respect to civil and criminal enforcement actions concerning compliance and cooperation. These pronouncements will help shape how providers consider responding to civil and criminal investigations, as well as provide key considerations for resolution of such matters.

Evaluation of Corporate Compliance Programs. In April 2019, DOJ’s Criminal Division issued its Evaluation of Corporate Compliance Programs, which followed and built upon DOJ’s Criminal Fraud Section guidance issued in 2017 on the same topic. This follow-up guidance by DOJ clarified and supplemented its previous announcement and makes the guidance applicable to DOJ’s entire Criminal Division.

Under the new guidance, in evaluating a company’s compliance program, DOJ prosecutors should consider the following three questions:

- (1) Is the company’s compliance program well designed?
- (2) Has the compliance program been effectively implemented?
- (3) Does the compliance program work in practice?

With respect to the design of the company’s compliance program, DOJ stressed the notion that compliance programs should convey a clear message of zero tolerance with respect to misconduct and that compliance policies and procedures should be designed to ensure that the compliance program is well-integrated into the company’s operations and workforce. DOJ expects that compliance programs will be tailored to the company’s particular line of business and will be risk-based with adequate attention to high-risk areas based on the relevant regulatory landscape. Prosecutors are directed to pay particular attention to whether a company has made revisions to its compliance program “in light of lessons learned.”

32 See United States’ Motion to Dismiss Relator’s Second Amended Complaint at 1-2, *U.S. ex rel. Health Choice Grp., LLC v. Bayer Corp.*, No. 5:17-cv-00126-RWS-CMC (E.D. Tex. Dec. 17, 2018), ECF No. 116 (U.S. Bayer Motion).

33 J.C. Herz, Medicare Scammers Steal \$60 Billion a Year. This Man is Hunting Them, *Wired* (Mar. 7, 2016, 6:45 AM).

34 *U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White Health*, No. 5:17-cv-886 (W.D. Tex.); *U.S. ex rel. Integra Med Analytics, LLC v. Providence Health and Servs.*, No. 17-cv-1694 (C.D. Cal.); *U.S. ex rel. Integra Med Analytics, LLC v. Charlotte-Mecklenburg Hospital Authority, Inc.*, No. 17-cv-00553 (W.D.N.C.).

35 *U.S. ex rel. Integra Med Analytics, LLC v. Creative Solutions in Healthcare, Inc.*, No. 17-cv-1249 (W.D. Tex.); *U.S. ex rel. Integra Med Analytics, LLC v. Mariner Health Care, Inc.*, No. 18-cv-00653 (C.D. Cal.).

36 See, e.g., *U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White Health*, 2019 WL 3713756 (W.D. Tex. Aug. 5, 2019) (dismissing FCA claims as relator failed to plead that its statistical analysis of hospital’s coding of comorbidities constituted evidence of a fraud scheme); *U.S. ex rel. Integra Med Analytics, LLC v. Creative Solutions in Healthcare, Inc.*, 2019 WL 5970283 (W.D. Tex. Nov. 13, 2019) (denying skilled nursing facility operators’ motion to dismiss under the FCA’s public disclosure bar and for failure to plead particularity under Rule 9(b)); *U.S. ex rel. Integra Med Analytics, LLC v. Providence Health and Servs.*, 2019 WL 3282619 (C.D. Cal. July 16, 2019) (denying defendants’ motion to dismiss based on public disclosure bar and granting motion to dismiss, in part, for failure to plead with particularity under Rule 9(b)).

DOJ stressed the importance of risk-based training and the availability of guidance for employees, as well as senior management's effective communication regarding the company's position on misconduct. And, DOJ prosecutors should consider whether a

In 2019, DOJ issued two significant pronouncements with respect to civil and criminal enforcement actions concerning compliance and cooperation.

company has applied risk-based due diligence to its third-party partners, including agents, consultants, and distributors.

Whether a company's compliance program has been implemented effectively focuses on an objective analysis rather than a subjective assessment of the company's purposes and intent in implementing the program. DOJ prosecutors should consider the commitment of senior leaders in

encouraging compliance and whether the board and external auditors have adequate oversight authority. It also is critical that those leading the company's compliance program act with adequate authority and autonomy and are equipped with adequate resources and experience. Finally, DOJ will consider whether a company has established adequate incentives for compliance and disincentives for noncompliance, as well as whether disciplinary actions for noncompliance are applied consistently.

In evaluating whether the company's compliance program works in practice, DOJ has stressed the need to evaluate whether the compliance program has evolved and improved based on experience and changing risks, including assessing the frequency and effectiveness of internal audits, whether the compliance program has been control tested, and whether the company has facilitated a culture of compliance. DOJ prosecutors will consider whether the company has timely and thoroughly investigated allegations of misconduct, as well as the response to any findings of misconduct, including whether a root cause analysis was performed and remediation undertaken in response to any issues identified by the compliance program.

Cooperation Credit. In May 2019, DOJ issued guidance intended to explain the manner in which DOJ will award credit to defendants who cooperate with the government during an FCA investigation.³⁷ This guidance was incorporated into the Justice Manual upon announcement. Cooperation credit in connection with civil FCA investigations most often manifests itself in reducing the FCA's damages multiplier in connection with the resolution of FCA claims. DOJ also has indicated a willingness to notify relevant agencies regarding a company's cooperation in connection with the agency's consideration of any administrative remedies and to consider publicly acknowledging the company's cooperation.

Under the new guidance, DOJ has indicated that "maximum" cooperation credit may be earned by voluntarily disclosing misconduct unknown to the government, explaining that maximum credit can mean reducing liability to the government's single damages amount.

In evaluating voluntary disclosures, DOJ indicated that it will consider the following: (1) the timeliness and voluntariness of the assistance; (2) the truthfulness, completeness, and reliability of the information and/or testimony provided; (3) the nature and extent of the assistance provided; and (4) the usefulness and significance of the cooperation provided to the government.

DOJ also stated that "partial" cooperation credit may be earned by cooperating in an ongoing investigation or by undertaking remedial measures in response to a violation that has been identified. Examples of conduct that may earn such credit include: (1) preserving, collecting, and disclosing documents and information beyond existing business practices or legal requirements; (2) identifying individuals responsible for or aware of the misconduct; (3) disclosing relevant facts learned during the company's independent investigation; and (4) facilitating the review of data or information that requires access to special or proprietary technologies. DOJ indicated that a company's undertaking a root cause analysis and implementing remedial measures, improving its compliance program to prevent a recurrence of wrongdoing, and removing those responsible for the misconduct may be considered as part of DOJ's cooperation assessment.

The guidance issued by DOJ regarding both evaluation of compliance programs and cooperation credit offers valuable roadmaps for healthcare providers facing possible civil or criminal investigations. Proactively evaluating the considerations outlined in both pronouncements can provide a head start for providers in ensuring they are in the best possible posture relative to potential enforcement actions or in responding to a compliance issue when one arises.

DOJ DISMISSALS OF QUI TAM ACTIONS

In January 2018, DOJ Civil Fraud Director Michael Granston issued an internal guidance memorandum, now known as the Granston Memo, setting forth considerations for DOJ attorneys to evaluate when deciding whether to seek dismissal of declined *qui tam* lawsuits under 31 U.S.C. § 3730(c)(2)(A).³⁸ The Granston Memo, which has since been formally incorporated into DOJ's Justice Manual, summarizes these considerations by describing DOJ's dismissal authority as "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent."³⁹

Since January 2018, DOJ has sought (c)(2)(A) dismissal in at least 45 cases, including 11 *qui tam* lawsuits related to PAPs filed by NHCA, as discussed previously; 12 cases where the relator was not represented by counsel, and two cases where the relator had shorted the stock of the defendant. In a December 19, 2019 letter to Senator Charles Grassley responding to concerns regarding use of its dismissal authority, DOJ noted that "[w]hile *qui tam* cases serve an important role in identifying fraud against taxpayer-funded programs, not every

37 <https://www.justice.gov/opa/pr/departments-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual>.

38 <https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf>.

39 See Justice Manual § 4-4.111, available at <https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.111>.

“While *qui tam* cases serve an important role in identifying fraud against taxpayer-funded programs, not every *qui tam* case advances this objective” -DOJ

qui tam case advances this objective” and that DOJ was exercising its dismissal authority “judiciously” and only when it had “determined that the relator’s pursuit of the case would adversely affect the government’s interests.”⁴⁰

One of the earlier invocations of the Granston Memo’s guidance occurred in **Gilead Sciences, Inc. v. U.S. ex rel. Campie**, a closely watched case that then was pending before the Supreme Court.⁴¹ In late 2018, the government surprised many observers by urging the Supreme Court to deny the defendant’s petition for a writ of certiorari because it planned to seek dismissal of the case in the event that it were remanded

to the district court. True to its word, after the Supreme Court denied certiorari in early 2019, the government sought dismissal of the case in the district court, citing the case’s lack of merit and the cost of burdensome discovery obligations that the litigation would impose on government agencies - both of which were factors cited in the Granston Memo.⁴² Relying on those justifications, the district court granted the government’s motion and dismissed the case.

Another significant application of the government’s dismissal authority occurred in **U.S. ex rel. Polansky v. Executive Health Resources, Inc.**, a long-running *qui tam* action alleging that the defendant had helped various hospitals overcharge federal healthcare programs by billing for inappropriate inpatient admissions.⁴³ The government sought dismissal of the complaint more than five years after originally declining to intervene, citing the need to avoid further costs associated with monitoring the litigation and the importance of preserving government evidentiary privileges. Notably, although the district court granted the government’s motion to dismiss, it went on also to grant the defendant’s pending motion for partial summary judgment, reasoning that it was “imperative to memorialize conclusions and findings on issues additional to the government’s ... motion, given the extensive history and briefing” on those issues. The relator has appealed the district court’s order dismissing the case to the Third Circuit.

The increasing frequency of the government’s requests to dismiss *qui tam* actions also has brought renewed attention to a long-existing circuit split concerning the appropriate standard that courts should apply when deciding whether to grant such a request. This split centers on whether DOJ’s dismissal authority under the FCA is “unfettered” and thus not subject to judicial review, as the D.C. Circuit held in **Swift v. United States**,⁴⁴ or

instead is contingent on the government demonstrating that its dismissal request bears a “rational relationship” to a valid government interest, as the Ninth Circuit held in **U.S. ex rel. Sequoia Orange v. Baird-Neece Packing Corp.**⁴⁵

In **U.S. ex rel. Kammarayil v. Sterling Operations, Inc.**, the district court applied the more permissive **Swift** standard, explaining that although the government must file a motion with the court to obtain dismissal of an FCA action, it “has what amounts to an ‘unfettered right to dismiss’” such an action as long as it provides the relator with notice of its motion and an opportunity for a hearing.⁴⁶ Because the government, in that case, had provided the requisite notice prior to filing its motion to dismiss, the court granted the dismissal.

By contrast, application of the “rational relationship” test has been well illustrated by the various court decisions to date stemming from DOJ’s December 2018 motions to dismiss the patient-assistance cases filed by NHCA. For instance, applying that test in **U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc.**, the district court denied DOJ’s motion to dismiss based on the district court’s conclusion that its “proffered reasons” for dismissal were “pretextual” and that its “true motivation [was] animus towards the relator,” an entity that appeared to exist solely to file *qui tam* actions.⁴⁷ In support of this conclusion, the district court cited the government’s cursory investigation of NHCA’s allegations, its failure to conduct an adequate cost-benefit analysis, and the lack of any “rational relationship between the government’s expressed policy interest in the enforcement prerogatives of its healthcare programs and the dismissal of th[e] case.” The government has appealed the district court’s decision.

In many cases, however, the difference between the two standards may prove to have little practical impact. For example, in **U.S. ex rel. Harris v. EMD Serono, Inc.**, the district court adopted the more stringent “rational relationship” test, but still granted the government’s motion to dismiss, holding that its stated interests in avoiding litigation costs and protecting government healthcare policies and enforcement discretion were valid government interests rationally related to dismissal.⁴⁸ And, in another of the NHCA actions, the district court found it unnecessary to choose between the two standards at all, similarly reasoning that DOJ’s stated interests would suffice even if the more searching **Sequoia Orange** inquiry were to apply.⁴⁹

With DOJ more frequently moving to dismiss *qui tam* actions it views as meritless or unnecessarily burdensome ... the Granston Memo has been a beneficial development for healthcare providers facing FCA claims.

40 Letter from Stephen E. Boyd, Assistant Attorney General for Legislative Affairs, to The Honorable Charles E. Grassley, United States Senate (Dec. 19, 2019), available at <https://aboutblaw.com/NTC>.

41 Case No. 17-936 (U.S.).

42 *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, No. C-11-941 (N.D. Cal.).

43 2019 WL 5790061 (E.D. Pa. Nov. 5, 2019).

44 318 F.3d 250 (D.C. Cir. 2003).

45 151 F.3d 1139 (9th Cir. 1998).

46 2019 WL 464820 (D.D.C. Feb. 6, 2019).

47 2019 WL 1598109 (S.D. Ill. Apr. 15, 2019).

48 370 F. Supp. 3d 483 (E.D. Pa. 2019).

49 2019 WL 4727422 (E.D. Tex. Sept. 27, 2019).

With DOJ more frequently moving to dismiss *qui tam* actions it views as meritless or unnecessarily burdensome – and courts deferring to DOJ’s requests in virtually every instance – the Granston Memo has been a beneficial development for healthcare providers facing FCA claims.

PRIVATE EQUITY

In February 2018, DOJ filed a complaint-in-intervention in ***Medrano v. Diabetic Care Rx, LLC***, which asserted FCA claims against not only a compounding pharmacy, but also its private equity controlling owner, underscoring the potential risks private equity firms face when operating in the highly regulated healthcare space.⁵⁰ DOJ’s complaint alleged that the compounding pharmacy, Patient Care America (PCA), paid illegal kickbacks to marketing firms who targeted military members and their families for prescriptions for compounded drugs the pharmacy then created not to meet individual patient needs, but rather to maximize reimbursement from Tricare, the federal military healthcare program. DOJ also named the private equity company Riordan, Lewis & Haden Inc. (RLH), which manages and controls PCA through a general partner, as a defendant in its complaint.

The government alleged that RLH did not act as a passive investor in PCA, but that RLH knew about and approved the marketing activities that the government alleged violated the AKS. In March 2019, DOJ filed an amended complaint in intervention, and the defendants moved to dismiss. While the defendants’ motions to dismiss were pending, the parties reached a settlement, under which PCA and RLH agreed to pay \$21.05 million. In its September 2019 press release announcing the settlement, DOJ highlighted that the prosecution and resolution of the case demonstrate the government’s “continuing commitment to hold all responsible parties to account” for the submission of false claims to the government.

It is likely too early to tell whether this case represents something of an outlier in pursuing FCA claims against private equity firms or more of a harbinger of things to come. Private equity’s interest and investment in the healthcare industry has grown rapidly and consistently over the past decade, and that trend shows no signs of slowing. Private equity firms investing in healthcare – particularly those that are actively engaged in the management and control of healthcare companies in which they invest – should ensure those companies employ vigilant and robust compliance efforts.

TRAVEL ACT

Federal prosecutors increasingly invoked the federal Travel Act, as a new tool not traditionally employed by the government in its healthcare fraud and abuse enforcement efforts. Originally passed in 1961 to combat organized crime activities, the Travel Act makes it illegal to travel in or use mail “or any facility” in interstate commerce with the intent to promote or facilitate any “unlawful activity,” which includes bribery as defined by state law. The government’s use of the Travel Act typically involves matters for which the AKS is not implicated because there is no government healthcare program involved. In

other words, the government is using the Travel Act to prosecute alleged misconduct that might otherwise be pursued under the AKS, but lacks the required government healthcare program element under the AKS.

Last year, federal prosecutors used the Travel Act to prosecute healthcare providers through state bribery laws based on the providers’ referral arrangements. In ***United States v. Beauchamp***, the government alleged that Forest Park Medical Center, a physician-owned surgical hospital, paid more than \$40 million in bribes and kickbacks to induce surgeons to use the hospital to provide their services.⁵¹ The improper payments were concealed as purported consulting fees and marketing funds. The government indicted 21 individuals, including the hospital’s founders and investors, hospital executives, physicians, and hospital staff. Two of the defendants were convicted under the Travel Act based on their use of email and a bank’s online computer network to carry out the conspiracy and to transmit improper payments. Notably, although the allegedly fraudulent consulting and marketing arrangements arguably qualified for safe harbor protection under the federal AKS, the district court ruled that the conduct nonetheless could be prosecuted under a state bribery law.

In ***United States v. Savino***, the Third Circuit upheld a physician’s conviction under the Travel Act for accepting bribes in exchange for referrals to a blood testing lab.⁵² The Third Circuit rejected the defendant’s argument that the payments he received constituted rent in exchange for allowing the lab to use space in his medical office, holding that the established facts more than sufficed to sustain the jury’s verdict. The Third Circuit also rejected the defendant’s challenge to his Travel Act convictions, noting that the bribery law at issue “criminalizes the acceptance of any benefit as consideration for knowingly violating or agreeing to violate a duty of fidelity to which he is subject as ... [a] physician.”

Using the Travel Act to prosecute allegations of healthcare fraud and abuse expands the government’s reach with respect to the types of conduct it may pursue. Both ***Beauchamp*** and ***Savino*** involved referrals of patients of private commercial health plans. In light of those Travel Act prosecutions, providers cannot rely solely on compliance with federal fraud and abuse laws such as the AKS and Stark Law. Similarly, arrangements that either do not involve government healthcare reimbursement or rely on safe harbor protection by “carving out” remuneration only for government business should not be considered beyond the government’s reach. Providers also should consider whether their arrangements comport with applicable state laws, particularly state bribery statutes.

The government is using the Travel Act to prosecute alleged misconduct that might otherwise be pursued under the AKS, but lacks the required government healthcare program element under the AKS.

50 No. 15-62617-CIV-BLOOM (S.D. Fla.).

51 No. 3:16-cr-00516-JJZ-3 (N.D. Tex.).

52 2019 WL 4665765 (3d Cir. 2019).

FALSE CLAIMS ACT UPDATE

The FCA continues to be the federal government's primary civil enforcement tool for imposing liability on healthcare providers that defraud 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 and the manner in which relators pursue FCA claims.

ESCOBAR'S "RIGOROUS" MATERIALITY REQUIREMENT

The Supreme Court's 2016 decision in *Escobar* continues to play a significant role in courts' analysis of FCA claims, particularly when it comes to considering the FCA's materiality element. In *Escobar*, the Supreme Court described the materiality element as "rigorous" and "demanding" and set forth a number of non-exclusive considerations to guide the inquiry, which primarily focus on the government's actual conduct with respect to payment of purportedly false claims. Courts have continued to grapple with specific applications of *Escobar*'s directives, with some courts appearing to apply its materiality requirement less "rigorously" than others.

Appellate Court Developments. As we discussed in last year's Review, the seemingly irreconcilable decisions issued by the nation's circuit courts about how *Escobar*'s non-exclusive factors should apply in particular cases led parties in at least three such cases to seek further clarity from the Supreme Court.⁵³ The Supreme Court, however, denied review in each of these three cases, perhaps signaling that - at least for now - it is content to allow the various issues raised by its *Escobar* decision to continue to percolate in the lower courts.

Meanwhile, appellate court decisions have continued to apply *Escobar*'s materiality guidance in a manner that is arguably less "rigorous" than how it has been applied often times by district courts. For example, in *U.S. ex rel. Lemon v. Nurses to Go, Inc.*, the Fifth Circuit reversed a district court's order that had dismissed an FCA action on materiality grounds, holding that the relators had plausibly alleged that the hospice regulations at issue were material requirements.⁵⁴ In rejecting the district court's conclusion to the contrary, the Fifth Circuit emphasized that Congress and Medicare had expressly designated the regulations as conditions of payment and credited the relators' allegation that the government had sought to enforce the regulations in the past both civilly and criminally. Notably, the Fifth Circuit cited the Sixth Circuit's 2018 decision in *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.* (a decision we covered in detail in last year's Review) as "persuasive" authority for the proposition that "*Escobar* does not require the relator to allege in the complaint specific prior government actions prosecuting similar claims."⁵⁵

In *Godecke v. Kinetic Concepts, Inc.*, the Ninth Circuit likewise reversed a district court decision holding that relators had failed to adequately plead the materiality of the alleged false representations.⁵⁶ In that case, the relator alleged that the defendant, a DME supplier, violated applicable LCDs by supplying the relevant equipment to patients before receiving an order from a physician. In finding that the "prior order" requirement was material, the Ninth Circuit stressed that not only did the LCDs explicitly identify the requirement as a condition of payment, but the LCDs also were themselves the product of "extensive negotiation" between the specific defendant and Medicare representatives. In addition, the Ninth Circuit pointed to the lack of any evidence that the government had paid any claims in full with actual knowledge that the prior order requirement had not been followed.

Government Knowledge and Payment. Consistent with *Escobar*'s guidance, the government's decisions about whether to pay particular claims allegedly tainted by regulatory violations have continued to be a significant focus of the materiality analysis under the FCA. In particular, several courts this year found the materiality element satisfied based on evidence that the government would not have paid particular claims had it known about the alleged misrepresentations. In *U.S. ex rel. Doe v. Heart Solution, PC*, the Third Circuit affirmed the district court's grant of summary judgment based on un rebutted evidence submitted by the government that it would not pay claims for diagnostic neurological testing "in the absence of a certification from a supervising neurologist."⁵⁷ Similarly, in *U.S. ex rel. Park v. Legacy Heart Care, LLC*, the district court held that the relator

53 See *Gilead Sciences, Inc. v. U.S. ex rel. Campie*, No. 17-936 (U.S.); *U.S. ex rel. Harman v. Trinity Indus., Inc.*, No. 17-1149 (U.S.); *Brookdale Senior Living Communities, Inc. v. U.S. ex rel. Prather*, No. 18-699 (U.S.).

54 924 F.3d 155 (5th Cir. 2019).

55 See 892 F.3d 822 (6th Cir. 2018).

56 937 F.3d 1201 (9th Cir. 2019).

57 923 F.3d 308 (3d Cir. 2019).

Courts have continued to grapple with specific applications of *Escobar's* directives, with some courts appearing to apply its materiality requirement less “rigorously” than others.

had plausibly alleged the materiality of the defendants’ purported violations of a Medicare National Coverage Determination (NCD) in part because the complaint “state[d] that the government recoups payment for procedures performed in violation of the NCD.”⁵⁸

Conversely, when a defendant can show that the government continued to pay claims despite actual knowledge of the alleged false representations, courts have found the materiality element lacking. For example, in *U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.*, the relator

alleged that a DME supplier violated the FCA by submitting claims to Medicare that were not compliant with an applicable LCD.⁵⁹ As the district court explained, however, the relevant Medicare administrative contractor had long been aware of the defendant’s noncompliant billing practices, including through repeated discussions with the defendant and the results of various pre- and post-payment audits. Despite that knowledge, the government never took any steps to deny or recoup payment, which the court concluded meant that the relevant requirements could not have been material.⁶⁰

As we reported last year, however, courts have split as to whether a relator bears the burden to plead facts regarding the government’s past payment decisions in order to survive a motion to dismiss. In *U.S. ex rel. Thornton v. Pfizer Inc.*, the district court dismissed the relator’s claims because the relator “fail[ed] to allege any change to Government reimbursement” or “any regulatory action taken by the FDA” in response to his lawsuit, nor had he alleged that the government consistently refused to pay claims based on noncompliance with the relevant regulations.⁶¹ By contrast, the district court in *U.S. ex rel. Wollman v. The General Hospital Corp.* declined to dismiss a relator’s FCA claims related to billing for overlapping surgeries – despite the defendants’ protestations that the government pays for at least some overlapping surgeries – because the regulations at issue were sufficiently “central to the payment scheme” and the defendants had not offered sufficient evidence that the violations were *not* material.⁶²

Notably, in analyzing *Escobar's* government-knowledge factor, several courts have distinguished between the government’s mere awareness of *allegations* of misconduct and knowledge of actual regulatory noncompliance. For example, in *U.S. ex rel. Clarke v. Aegerion Pharmaceuticals, Inc.*, the district court observed that although the government learned about the relators’ off-label marketing allegations when they filed their *qui tam* lawsuit, the government’s continued payment was not relevant to the materiality analysis because there was “no indication that the government had ‘actual knowledge’ of ‘actual noncompliance’” with FDA regulations.⁶³

Likewise, in *U.S. ex rel. Rahimi v. Rite Aid Corp.*, the district court rejected the defendant pharmacy’s argument that alleged regulatory violations were not material because the government continued paying its claims after learning about allegations related to certain pricing regulations.⁶⁴ The district court explained that the pharmacy’s argument wrongly “assume[d] that the Government *knows* that [the pharmacy] *violated*” the regulatory requirements, despite the pharmacy’s own argument that it had not committed any such violations. In the district court’s view, the pharmacy’s argument “conflate[d] ‘actual knowledge that certain requirements were violated’ with actual knowledge of *allegations* that certain requirements were violated.”⁶⁵ Justifying this distinction, another district court has aptly explained that industry “would [not] warmly welcome a rule that required the Government to cut off ... funding whenever a *qui tam* action is filed or forfeit its right to seek reimbursement.”⁶⁶

Significance of Intervention Decisions.

In assessing the FCA’s materiality element, courts have increasingly taken divergent approaches regarding the significance of the government’s decision about whether to intervene in a *qui tam* action. In several decisions, district courts held that the government’s decision to intervene in a *qui tam* action was relevant – even if not dispositive – to the materiality analysis under *Escobar*. In *U.S. ex rel. Longo v. Wheeling Hospital, Inc.*, for instance, the district court found that the government’s decision to intervene in the very *qui tam* action before it “strongly militate[d] in favor of materiality.”⁶⁷ And, in *U.S. ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc.*, the district court explained that

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58 2019 WL 4450371 (N.D. Tex. Sept. 17, 2019); see also *U.S. ex rel. Integra Med Analytics, LLC v. Creative Solutions in Healthcare, Inc.*, 2019 WL 5970283 (W.D. Tex. Nov. 13, 2019) (citing statements in a government press release related to a past FCA settlement involving similar allegations as evidence of materiality).

59 2019 WL 3291582 (C.D. Cal. June 14, 2019).

60 Government audits also factored into several other courts’ conclusions that alleged regulatory noncompliance was not material. See *U.S. ex rel. Zissa v. Santa Barbara Cty. Alcohol, Drug, & Mental Health Servs.*, 2019 WL 3291579 (C.D. Cal. Mar. 12, 2019) (no materiality where the government knew of the alleged regulatory violations “through audit data” but “opted to stay the course” and continue making payments); *U.S. ex rel. Nedza v. Am. Imaging Mgmt., Inc.*, 2019 WL 1426013 (N.D. Ill. Mar. 29, 2019) (finding alleged regulatory violations immaterial where the government had audited the defendant Medicare Advantage plans, yet the relator did “not allege that CMS ceased payment” or terminated its contracts with the plans).

61 2019 WL 1200753 (N.D. Ill. Mar. 14, 2019); see also *U.S. ex rel. Prose v. Molina Healthcare of Ill., Inc.*, 2019 WL 3555336 (N.D. Ill. July 31, 2019) (finding relator’s “conclusory allegations that the government would have ceased payments if it knew” about the alleged regulatory violations insufficient to plausibly plead materiality).

62 394 F. Supp. 3d 174 (D. Mass. 2019).

63 2019 WL 1437914 (D. Mass. Mar. 31, 2019).

64 2019 WL 1426333 (E.D. Mich. Mar. 30, 2019).

65 See also, e.g., *U.S. ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc.*, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019) (holding that the government’s continued payment of claims after learning about allegations of misconduct was not relevant to materiality because there was “no evidence that any investigation into [the alleged misconduct] took place, let alone its scope or any findings”); *U.S. ex rel. Campbell v. KIC Dev., LLC*, 2019 WL 6884485 (W.D. Tex. Dec. 10, 2019) (“[T]he Government’s actual knowledge that it has been defrauded is not necessarily imputed from its awareness that allegations of fraud have been brought by a relator.”).

66 2019 WL 4478843 (N.D. W. Va. Sept. 18, 2019).

67 2019 WL 4478843 (N.D. W. Va. Sept. 18, 2019).

the government's decision to intervene in "a factually similar case" in the same district "provide[d] strong evidence that AKS violations were material to the Government's payment decisions," even though the government had not intervened in the case before the court.⁶⁸

Other courts have similarly held that the government's decision *not* to intervene is relevant to the materiality analysis. In *U.S. ex rel. MacDowell v. Synnex Corp.*, the district court stated that, although not dispositive, the government's decision not to intervene "weigh[ed] toward finding a lack of materiality."⁶⁹ And, in *U.S. ex rel. Polansky v. Executive Health Resources, Inc.*, the district court noted that the government's actions in the litigation, namely, "declining to intervene and moving for dismissal," were "probative of the lack of materiality of [the relator's] claims."⁷⁰ On the opposite side of the ledger, however, the district court in *Rahimi* refused to consider the government's decision not to intervene in the litigation, somewhat confusingly explaining that "to infer a lack of materiality from the Government's non-intervention would make the Government's non-intervention dispositive of the materiality analysis."⁷¹

Essence of the Bargain. As we have discussed in prior years, certain courts continue to focus their materiality analysis on whether the alleged violations went to the "essence of the bargain" between the government and the defendant. For example, the district court in *Brown v. Okmulgee Terrace, Inc.*, cited that factor to support finding a lack of materiality.⁷² In that case, the relator alleged that a mental health facility had employed a convicted felon in its housekeeping department in violation of applicable state regulations. Granting

summary judgment for the defendant, the district court explained that any regulatory violation was "minor or insubstantial" – and not material – because "[h]ousekeeping duties, while certainly necessary and proper for the residents, are not central to Medicare/Medicaid cost reports" and thus were not "misleading" as to the "goods and services" provided by the facility to its residents and for which the government was billed.

Adopting a similar approach, in *U.S. ex rel. Buth v. Walmart Inc.*, the district court found a lack of materiality where

Several courts reaffirmed that the materiality element usually will be satisfied in FCA actions that are premised on underlying alleged AKS violations.

the relator alleged that a Walmart pharmacy had dispensed and billed the government for 90-day supplies of medication when only a 30-day supply was required.⁷³ Because the government was billed for exactly what the patients received, the district court explained, the alleged "conversion" to 90-day supplies was not material to the government's decision to pay the claims.

68 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019).
69 2019 WL 4345951 (N.D. Cal. Sept. 12, 2019).
70 2019 WL 5790061 (E.D. Pa. Nov. 5, 2019) (appeal pending).
71 2019 WL 1426333 (E.D. Mich. Mar. 30, 2019).
72 2019 WL 845269 (E.D. Okla. Jan. 14, 2019).
73 2019 WL 3802651 (E.D. Wisc. Aug. 13, 2019).

By contrast, in *U.S. ex rel. Strauser v. Stephen L. LaFrance Holdings, Inc.*, the district court relied on the "essence of the bargain" analysis to conclude that the alleged regulatory violations were material to the government's payment decision.⁷⁴ There, the relator alleged that pharmacies overcharged government healthcare programs by reporting that their usual and customary (U&C) prices to the public were higher than their actual U&C prices. The district court held that the complaint adequately pleaded materiality because the "alleged misrepresentations go to an essential element of the bargain" – namely, the price the government paid for drugs.

Despite these courts' reliance on the "essence of the bargain" analysis, such a framework may nevertheless be subject to criticism on the basis that it largely ignores the specific materiality factors outlined in *Escobar* and would appear to be somewhat question-begging. Indeed, in *Arnstein*, the district court criticized the "essence of the bargain" test as "circular" and inconsistent with *Escobar*, finding it unhelpful in part because "[w]henver a contractor violates any contractual or regulatory provision, the Government does not get what it bargained for."⁷⁵

Materiality of AKS Violations. Finally, several courts reaffirmed that the materiality element usually will be satisfied in FCA actions that are premised on underlying alleged AKS violations. As the district court explained in *Arnstein*, Congress amended the AKS in 2010 to provide that a claim resulting from an AKS violation "constitutes a false or fraudulent claim for purposes of [the FCA]," thereby making post-amendment AKS violations "per se material" and leaving "no need for an independent assessment of materiality."⁷⁶ Even pre-2010 AKS violations, however, will usually suffice to establish the materiality element of an FCA claim based on the government's extensive history of enforcing the AKS, among other factors.

For instance, in *Thornton v. National Compounding Co.*, the district court cited the government's record of excluding and suspending AKS violators from participation in government healthcare programs as strong evidence that AKS violations are material to claims for payment.⁷⁷ Indeed, the district court described the materiality of AKS violations as a "common sense" proposition. Reaching the same conclusion, the district court in *Longo* held that AKS violations satisfy the materiality requirement because the AKS "is a felony statute requiring specific intent," goes to the "essence of Medicare's bargain with participating healthcare providers," and has been the subject of numerous settlements and government enforcement actions.⁷⁸

Nevertheless, while most courts have concluded that AKS violations are clearly material, the district court in *Arnstein* notably declined to find pre-2010 AKS violations material as a matter of law, instead concluding that their materiality was a disputed issue of fact that could not be resolved at the summary judgment stage.⁷⁹ In support of this holding, the district court cited the "rigorous" nature of the materiality requirement and the fact that *Escobar* "contemplate[d] that a defendant will have an opportunity to provide evidence of a lack of

74 2019 WL 1086363 (N.D. Okla. Mar. 7, 2019).
75 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019).
76 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019).
77 2019 WL 2744623 (M.D. Fla. July 1, 2019).
78 2019 WL 4478843 (N.D. W. Va. Sept. 18, 2019).
79 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019).

materiality – specifically by demonstrating that the Government ‘pays a particular claim in full despite its actual knowledge that certain requirements were violated.’” Although the government had offered a wealth of evidence that the AKS violations at issue were material, the court concluded that the defendants had presented enough countervailing evidence – including continued payment by the government after disclosure of the allegations – to at least preclude summary judgment.

DEVELOPMENTS IN PLEADING STANDARDS

Defendants continued to seek dismissal of FCA complaints based on the argument that a relator failed to plead the circumstances of fraud with the particularity demanded by Rule 9(b) of the Federal Rules of Civil Procedure. For FCA claims, Rule 9(b) requires detailed allegations of a fraud “scheme” carried out by the defendant *and* detailed allegations tying that scheme to some request for reimbursement from the government.

Pleading the Details of a Fraudulent Scheme

Generally speaking, courts agree that a complaint asserting FCA claims must identify the “who, what, when, where and how” of a fraud scheme to survive a motion to dismiss.

For example, in *U.S. ex rel. Aryai v. Skanska*, the district court dismissed a relator’s allegations that several construction firms performing government-contracted work had engaged in a fraudulent payroll scheme to pay union foremen extra overtime pay, although they did not perform any overtime work.⁸⁰ One firm was dismissed because the complaint made no specific allegations regarding its conduct, referring only to “the Defendants” as a group. Two more were dismissed because the only allegations specific to them were from a time period not contemplated by the complaint, and the relator merely speculated that their conduct continued into the relevant period. A fourth firm was dismissed even though the complaint included specific allegations that it was engaged in this practice because the allegations failed to specify which construction projects were implicated, where and when the overtime was submitted, which government entities were billed for the overtime, and what amount was paid.

By contrast, in *U.S. ex rel. Wollman v. The General Hospital Corp.*, the district court held that the relator’s second amended complaint satisfied Rule 9(b) because his allegations of inappropriately-billed surgeries included 11 example procedures for which he identified the surgery type, start time, duration, services billed, physician name, billing provider, amount billed, and amount paid by the government.⁸¹

It is not enough, though, to plead the details of only the fraud scheme. To state an FCA claim, a complaint must allege that the scheme caused the presentment of a “false” claim to the government. For example, in *U.S. ex rel. Strubbe v. Crawford City Memorial Hospital*, the Eighth Circuit held that the relators adequately described the fraud scheme by providing the names of the individuals involved, the relevant time period, and by quoting specific

statements by supervisors relating to the alleged scheme.⁸² But, because the complaint failed to allege how the scheme led to claims being submitted to the government, the Eighth Circuit affirmed the dismissal.

Pleading the Submission of False Claims

Though courts generally agree on the details required to adequately describe a fraud scheme, they have split over the required level of particularity with respect to “presentment” or “submission” of those claims to the government. Recent cases have brought no real clarity to that question. Some circuits, like the Sixth and Eleventh Circuits, demand that relators provide a representative example or have personal, first-hand knowledge of a defendant’s billing practices to survive a motion to dismiss. Others, like the Ninth Circuit, require only that a relator provide “reliable indicia” leading to a “strong inference” that claims were actually submitted.

Pleading Actual Claims. Two district court cases illustrated the Sixth Circuit’s application of Rule 9(b). In *U.S. ex rel. Holloway v. Heartland Hospice, Inc.*, a former employee alleged that the defendants implemented a corporate-wide scheme to falsely certify non-terminally ill patients as hospice eligible.⁸³ The relator’s complaint included a list of patients that she believed were ineligible for hospice, including the patients’ names, places of service, core clinical diagnoses, and start-of-care dates, but the district court concluded the patients were not “representative examples” as required by the Sixth Circuit because they lacked key information about the claims and the reasons why the patients were not qualified for hospice. The district court explained that even in cases where the Sixth Circuit has applied a “relaxed” standard for relators who had personal knowledge of billing practices, the allegations required more detail than what was included in this relator’s complaint.

Likewise, in *U.S. ex rel. Petkovic v. Found. Health Sol.*, the district court dismissed a *qui tam* complaint filed by a podiatrist and podiatry tech against a company that provided operational management services to several nursing

homes where the podiatrist provided care.⁸⁴ The relators alleged that the management company accepted kickbacks from its former employer because the homes would bill the management company directly for each pair of diabetic shoes they ordered, and the management company in turn would bill Medicare for the shoes at a higher rate, pocketing the profit. In dismissing the complaint, the district court explained that in the Sixth Circuit, a relator must provide a representative claim that was actually presented to

Courts agree that a complaint asserting FCA claims must identify the “who, what, when, where and how” of a fraud scheme to survive a motion to dismiss.

80 2019 WL 1258938 (S.D.N.Y. 2019).

81 394 F. Supp. 3d 174 (D. Mass 2019).

82 915 F.3d 1158 (8th Cir. 2019).

83 386 F. Supp. 3d 884 (N.D. Ohio 2019).

84 2019 WL 251556 (N.D. Ohio Jan. 17, 2019).

the government for payment, and only in rare occasions will courts apply the “relaxed” standard that allows a relator to rely on “personal knowledge” in lieu of a representative claim. Because the district court found that the relators’ personal knowledge related only to the alleged scheme, not to the submission of claims to the government, they did not fit into the “extremely narrow” exception.

The Eleventh Circuit traditionally has employed a similar standard. In **U.S. ex rel. Fernandez v. Miami Cancer Inst.**, the district court dismissed a *qui tam* complaint filed by a former pharmacy technician and inventory manager, who alleged the hospital’s pharmacy was using leftover amounts of cancer drugs to fill compound prescriptions, but was billing the government as if new vials were used.⁸⁵ The relators alleged that the orders were entered

into the pharmacy’s electronic record system, which was used by the accounting department to create bills sent to insurers. Representative claims, however, were not provided. Instead, the relators asked for the district court to apply a more “relaxed” Rule 9(b) standard based on their participation in and knowledge of the fraud scheme. The district court held that although their positions allowed them first-hand knowledge of the scheme, they did not have first-hand knowledge of the defendant’s billing practices, so they could not state a claim.

Alternatives to Pleading Actual Claims.

Other circuits have taken a more lenient view of what satisfies Rule 9(b). For instance, in

U.S. ex rel. Streck v. Takeda Pharm. Am., Inc., the district court denied a motion to dismiss, holding that although the relators had not provided any of the specific false reports at issue, it was enough that they described the fraud scheme and cited regulatory requirements that those reports be filed every 30 days.⁸⁶

Similarly, the Ninth Circuit reversed the dismissal of a complaint in **Godecke**.⁸⁷ As discussed previously, the relator alleged that a manufacturer had delivered DME to Medicare patients before obtaining a written order from a physician, but the relator did not identify any actually-submitted claims. In reversing the district court’s dismissal, the Ninth Circuit explained that a relator is not required to identify actual examples of submitted false claims to state a claim under the FCA. Instead, it found reliable indicia leading to a strong inference that false claims had been submitted. This conclusion was based on the relator’s allegations that sales representatives told her that: (1) the defendant often delivered devices without the requisite order; (2) the defendant set up a system to hide this fact; (3)

the relator’s review of data pinpointed claims that were paid without the order; and (4) a former colleague told the relator she had personally reviewed claims that were submitted despite lacking the appropriate documentation.

In contrast, the Eighth Circuit held in **Strubbe** that although relators provided all the necessary details of the fraud scheme and had first-hand knowledge of the scheme, the alleged statements made by the relators’ supervisors that the fraudulent practices were “for billing and reimbursement purposes” showed only the *possibility* that claims were actually submitted, which fell short of creating the *strong inference* required in the Eighth Circuit.

DEVELOPMENTS REGARDING FALSITY

Objective Falsity in Medical Necessity Cases

In recent years, healthcare providers have increasingly faced civil and criminal enforcement actions premised on the allegation that services billed to government healthcare programs were not medically necessary in violation of the FCA and/or various criminal statutes. These actions – whether brought by the government in civil or criminal proceedings or *qui tam* relators in civil FCA cases – pose significant issues for providers.

In the face of such allegations, providers have made headway in prior years in challenging the underlying fraud theory by arguing that claims for reimbursement for medical procedures or services cannot be false or fraudulent if the theory of wrongdoing is based on nothing more than a difference of opinion as to the propriety of the clinical judgment exercised by the provider. Last year, we summarized two appellate decisions – **United States v. Paulus**⁸⁸ and **U.S. ex rel. Polukoff v. St. Mark’s Hospital**⁸⁹ – that blunted defendants’ argument that a difference of clinical judgment, without more, could not form the basis for a fraud claim. In the wake of these appellate court decisions, certain district courts have indicated they are not inclined to side with defendants on arguments concerning the failure to plead objective falsity.⁹⁰

The tides in medical necessity cases may be shifting again, however, in the wake of the Eleventh Circuit’s opinion in **U.S. ex rel. Paradies v. AseraCare, Inc.**, in which the appellate court upheld the district court’s post-trial finding that the government could not establish falsity of hospice claims merely through expert testimony that presented only a reasonable difference of opinion as to medical necessity. As background, AseraCare operates a network of hospice facilities that bill Medicare for end-of-life care for elderly patients. The Medicare hospice benefit requires that the patient’s attending physician, if there is one, and the medical director of the hospice provider each certify, in writing, at the beginning of each hospice stay period that the individual is terminally ill. According to the government, the

85 2019 WL 1993513 (S.D. Fla. May 6, 2019).

86 381 F. Supp. 3d 932 (N.D. Ill. 2019).

87 937 F.3d 1201 (9th Cir. 2019).

88 894 F.3d 267 (6th Cir. 2018).

89 895 F.3d 730 (10th Cir. 2018).

90 See, e.g., *U.S. ex rel. Dildine v. Pandya*, 389 F. Supp. 3d 1214 (N.D. Ga. 2019) (holding in an intervened case that, at the pleading stage, the government’s allegations that the defendant physician had made “objectively false” diagnoses had to be accepted as true, concluding that “[a] physician’s latitude in medical judgment does not nullify the Complaint’s falsity allegations”); see also *U.S. v. Adams*, 371 F. Supp. 3d 1195 (N.D. Ga. 2019) (denying motion to dismiss, rejecting defendants’ argument on objective falsity and holding that the court “agrees with those courts that have concluded that a physician’s subjective medical opinions or judgments can be false for purposes of the FCA”).

defendants admitted patients who were not terminally ill, pressured staff to meet aggressive monthly quotas for patient intake, and had physicians who rubber-stamped terminal illness certifications without thoroughly examining patient medical records.

In the district court, AseraCare maintained that the government's evidence of falsity - which was based solely on medical-opinion testimony - was inadequate. After the district court denied AseraCare's motion for summary judgment, AseraCare moved to bifurcate trial into two phases: one phase on the falsity element of the FCA and the second on the FCA's remaining elements. The district court granted the motion, and the case proceeded to an eight-week jury trial on the issue of falsity, with the parties each putting forward expert testimony as to how to determine life expectancy and terminal illness. From a universe of 2,180 hospice patients who had been on hospice for more than one year, the government drew a sample of 223 patients. At trial, the government's expert identified 123 of the 223 patients who the expert testified were not terminal at the time of diagnosis. However, on cross examination, the government's expert conceded that he could not say AseraCare's expert was wrong in testifying that the patients were eligible for hospice services. That is, he did not testify that no reasonable doctor could have concluded that the identified patients were terminally ill at the time of certification. At the close of the proof, the jury found that AseraCare had submitted false claims on 104 of 123 patients identified by the government.

Following the verdict, the district court set aside the verdict, holding that the jury should have been instructed that the "FCA's falsity element requires proof of an objective falsehood" and "that a mere difference of opinion between physicians, *without more*, is not enough to show falsity." The district court concluded that the failure to properly instruct the jury constituted reversible error and ordered a new trial. In addition, the district court *sua sponte* granted summary judgment in favor of AseraCare, holding that the government failed to present evidence of objective falsehood as required to establish falsity.

On appeal, the Eleventh Circuit largely adopted the falsity standard articulated by the district court, holding that the government's claims were "narrowly construed" to challenge only whether AseraCare's certifications that patients were terminally ill satisfied Medicare's statutory and regulatory reimbursement requirements. On review of these requirements, the Eleventh Circuit rejected the government's argument that the supporting documentation submitted with the eligibility certification must objectively support the certification of terminal illness, holding that the government's position "would read more into the legal framework than its language allows" and reiterating that "CMS's rulemaking commentary signals that well-founded clinical judgments should be granted deference." As a result, the Eleventh Circuit affirmed the district court's holding that a reasonable difference of opinion "among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments - or any claims based on them - are false under

the FCA."⁹¹ Rather, the court held that a hospice claim is not false unless the underlying clinical judgment reflected an objective falsehood, such as, the certifying physician failed to review the patient's medical record or did not subjectively believe that the patient was terminally ill, or if no reasonable physician could have concluded that the patient was terminally ill given the medical records. The Court of Appeals did set aside the district court's grant of summary judgment in favor of AseraCare because the district court had limited the review of evidence supporting falsity to only the testimony of the government's expert. The Court of Appeals held that the government could put forth other evidence that AseraCare's certification process was flawed, but only so long as the government could link evidence of improper certification practices to the specific claims at issue.

The Eleventh Circuit affirmed the district court's holding that a reasonable difference of opinion "among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments - or any claims based on them - are false under the FCA."

In addition to the important holding in **AseraCare**, the Eleventh Circuit's opinion provides a notable discussion distinguishing **Paulus** and **Polukoff**. In **Paulus**, the Sixth Circuit reversed the district court's decision setting aside a guilty verdict against a cardiologist, who was charged with committing healthcare fraud and making false statements by exaggerating the extent of artery blockages so that he could perform and bill for unnecessary procedures. The Eleventh Circuit concluded in **AseraCare** that the government's reliance on **Paulus** was misplaced because "coronary artery blockage actually exists as an aspect of reality," meaning that an assertion about the degree of blockage can be objectively true or false. Moreover, in **Paulus**, the government's experts indicated that no reasonable doctor would have interpreted the scan in the same manner as the defendant, whereas the government's expert in **AseraCare** declined to conclude that AseraCare's physicians lied about their clinical judgment, or even that the judgments were unreasonable.

The distinction between **AseraCare** and **Polukoff** is a bit murkier. The Eleventh Circuit conceded that the Tenth Circuit held in **Polukoff** that, "regardless of the physician's opinion to the contrary, he will be deemed to have made a false statement when claiming reimbursement if the medical procedure is determined to have not been reasonable or necessary." The Eleventh Circuit, however, went on to explain that the text of the "hospice-benefit provision at issue here, by design, looks to whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion as to a patient's likely longevity."

91 The Eleventh Circuit reversed the grant of summary judgment in favor of AseraCare and remanded the case to the district court for further proceedings on the question of whether a triable issue of fact existed as to falsity. The government argued on appeal that it had produced evidence in discovery and was prepared to show in phase two of the trial that the opinions forming the basis for the certification were not reasonably held.

AseraCare will no doubt be cited favorably by defendants as a counter to **Paulus** and **Polukoff** in pending and future healthcare fraud cases challenging the medical necessity of procedures billed to federal healthcare programs. Given **AseraCare**'s apparent tension with **Polukoff**, it remains to be seen whether **AseraCare** will be cabined to hospice benefit cases or will be adopted by courts outside the hospice context considering medical necessity issues.

Statistical Sampling

In cases alleging lack of medical necessity as a basis for false claims, the government or relators have attempted to rely increasingly on statistical sampling to establish civil liability and/or damages across a vast universe of claims. Requiring objective proof of a false claim or claims, however, is a potential defense to the use of statistical sampling when sampling would be used to prove falsity.

For example, in **U.S. ex rel. Dolan v. Long Grove Manor, Inc.**, the district court granted the defendants' motion for summary judgment on the grounds that the relator could not rely on statistical sampling to prove falsity absent evidence of any actual false claims.⁹² The relator alleged that defendants, which provide therapists to skilled nursing facilities around the country, participated in a scheme to improperly assign Medicare patients into the highest therapy (and reimbursement) category regardless of the patients' actual therapy needs.

To demonstrate falsity at summary judgment, the relator relied on his expert, who opined that defendants provided excessive therapy to patients, which the relator claimed could be extrapolated to prove that defendants provided patients with medically unnecessary treatment. The district court rejected this view, holding that a relator must present evidence of at least one false claim before relying on statistical and probabilistic evidence. The district court also rejected the relator's argument that an exhibit that included a list of six patients receiving purportedly unnecessary therapy satisfied this requirement, as the exhibit itself was not tied to the submission of any claims, nor did the relator make any attempt to show that the therapy these patients received was medically unnecessary. A separate exhibit showing billed claims, without more, was similarly held to be insufficient.

Express and Implied Certification

In the three years since *Escobar*, courts' views on the FCA's falsity requirement continue to evolve. While courts appear to be coalescing around *Escobar*'s implied certification liability standard, the parameters of that standard, along with the express certification liability standard, remain an open question. This past year brought a few notable opinions in which courts sided with relators to find that relators had adequately pleaded or established falsity in relying on either express or implied certification theories.

In **U.S. ex rel. Lemon v. Nurses to Go, Inc.**, the Fifth Circuit reversed a district court's dismissal of relators' allegations against several hospice organizations.⁹³ The relators, former Nurses to Go employees, alleged that the defendants: (1) failed to complete and maintain certifications and recertifications for hospice patients; (2) failed to complete and maintain physician narratives in support of certifications; (3) allowed non-medical personnel

to complete certifications and physician narratives; and (4) completed certifications after the time period required for completion. The district court dismissed the case on materiality grounds, but the Fifth Circuit reversed, holding in pertinent part that relators' claims were based on defendants' allegedly fraudulent certifications of compliance with CMS's conditions of payment.

In **U.S. ex rel. Simpson v. Bayer Corp.**, the district court denied cross-motions for summary judgment, holding that the relator had shown adequate evidence of falsity under theories of both express and implied false certification related to its claims against Bayer for off-label

marketing and illegal kickbacks to hospital providers related to the drug Trasyolol. First, the district court found that express false certification applied even though the relevant CMS hospital certification form only requires certification that the "services identified" were provided in compliance with legal requirements. The district court focused on the certification language that "payment of a claim by Medicare is conditioned on the claim *and the underlying transaction* complying with" applicable laws and regulations, including AKS. According to the district court, the "'underlying transaction' includes the bundle of items and services provided to a Medicare beneficiary during a claimed procedure." Furthermore, the

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district court held that AKS itself confirms that certifications of compliance with AKS are expressly false where claims are submitted for payment covering items or services resulting from a kickback. Separately, as to implied false certification, the district court held that *Escobar* did not require specific false representations about Trasyolol in order for liability to attach. Instead, the district court held that, under *Escobar*, such specific representations were sufficient, but not necessary, to render a claim false under a theory of implied false certification. In support of its holding, the district court cited to cases in which the Third Circuit has taken an "especially expansive view of FCA liability in the context of noncompliance with the AKS."

Lastly, in **U.S. ex rel. Streck v. Bristol-Myers Squibb Co.**, the district court held that relators had properly pleaded falsity in a case alleging that the defendant pharmaceutical manufacturer, Bristol-Meyers Squibb Co. (BMS), improperly counted price appreciation credits given to existing customers as "bona fide service fees."⁹⁴ The relator alleged BMS engaged in this scheme in order to suppress the reported average manufacturer price (AMP) for its drugs, resulting in a lower rebate owed by BMS to state Medicaid programs. In response, BMS argued that the relator did not identify any statute or regulation that prohibited treating price appreciation credits as bona fide service fees, aside from a 2012

92 2019 WL 2774149 (N.D. Ill. July 2, 2019).

93 924 F.3d 155 (5th Cir. 2019).

94 370 F. Supp. 3d 491 (E.D. Pa. 2019).

proposed CMS rule, which could not form the basis for a false claim. The district court disagreed, holding that, in issuing the proposed rule, CMS also declared that “price appreciate credits do not meet the definition of bona fide service fees as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer.” Following this announcement, BMS continued to treat price appreciation credits as excludable bona fide service fees, lowering the AMP reported to CMS. Thus, the district court found that the AMP certified to CMS was false, as were BMS’s rebate claims.

Pleading and Proving Falsity

In addition to the foregoing, other courts issued notable opinions addressing the general requirements for pleading and proving falsity under the FCA.

In an unpublished opinion, the Tenth Circuit in **Pack v. Hickey** affirmed a district court’s grant of summary judgment and award of attorneys’ fees in favor of defendant Cloud Peak Initiatives, Inc., a corporation that operates mental health services facilities, and its president.⁹⁵ The relator, the terminated CEO of the corporation, alleged that the defendant fraudulently and repeatedly billed a skills group as a therapy group, despite the fact that it was not led by a licensed therapist, in violation of CMS rules. The district court granted summary judgment to the defendant, finding that the relator failed to adduce evidence of either the falsity or scienter elements of an FCA claim, and the Tenth Circuit agreed. With respect to falsity, the Tenth Circuit explained that the relator failed to provide actual evidence that a licensed therapist did not attend the group meetings, nor did the relator identify a single false claim that was submitted. The Tenth Circuit, therefore, rejected relator’s theory of falsity, which it held was based merely on “supposition and conjecture,” which is “insufficient to demonstrate a false claim,” especially since the relator failed to identify “a single false bill.” The Tenth Circuit also upheld the district court’s award of attorneys’ fees, which was based in pertinent part on the relator’s admitted inability to identify a single fraudulent bill, and on relator’s failure to depose or obtain sworn testimony from any key individuals in the case.

Conversely, in **U.S. ex rel. Wollman v. The General Hospital Corp.**, the district court denied defendants’ motion to dismiss, holding that the relator adequately alleged falsity by alleging that various surgeries were carried out at least in part by medical residents without adequate supervision in violation of Medicare rules.⁹⁶ Medicare regulations prohibit teaching hospitals, like defendant Massachusetts General Hospital, from billing for surgery performed by medical residents without proper supervision. At the pleading stage, the relator pointed to at least 11 specific surgeries in which the attending surgeons at Massachusetts General Hospital, a teaching hospital, failed to designate a qualified teaching physician to oversee medical residents when the primary doctor was unavailable, allegedly resulting in false claims. In denying the motion to dismiss, the district court also relied on allegations relating to the defendants’ purported conduct to conceal the alleged scheme and defendants’ certifications of compliance in submitting claims to Medicare.

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

To establish a defendant’s liability under the FCA, a relator or the government must prove that the defendant acted with actual knowledge, deliberate indifference, or reckless disregard of the underlying conduct that allegedly caused the submission of false claims. The Supreme Court has described the scienter requirement as “rigorous.”⁹⁷ At the same time, Rule 9(b) allows plaintiffs to allege knowledge generally. As a result, the particularity requirement that applies to pleading other elements of an FCA claim does not apply to the scienter element. Defendants, therefore, often have difficulty asserting a failure to plead scienter as a basis for dismissal at the pleading stage.

Continuing that trend, a number of courts denied motions to dismiss FCA complaints for purported lack of scienter. These cases leave open the possibility that FCA plaintiffs can establish scienter at the pleading stage in numerous ways. In **United States v. Adams**, for instance, the district court found that the government’s complaint sufficiently pleaded scienter where the government alleged that the defendant physician billed the government for administering treatment to patients not suffering from lead poisoning, despite knowing of NCDs and Medicare policies restricting that treatment to lead-poisoning patients.⁹⁸

In **U.S. ex rel. Dildine v. Pandya**, the district court similarly denied a defendant ophthalmologist’s motion to dismiss allegations of inflated Medicare billing. The district court found scienter supported by allegations that Medicare billings “skyrocketed” when the defendant took over the practice and that the defendant diagnosed glaucoma at 10 times the state average.⁹⁹

Likewise, in **U.S. ex rel. Wollman v. General Hospital Corp.**, the district court found that the relator sufficiently pleaded scienter as to allegations that the defendant hospital knowingly billed the government for physicians’ overlapping and concurrent surgeries. According to the district court, scienter was “supported by active concealment of concurrent surgeries from patients and intentionally restrict[ing] record-keeping practices designed to avoid government detection.”¹⁰⁰

In **U.S. ex rel. Alt v. Anesthesia Services Associates, PLLC**, the district court denied a motion to dismiss by an individual defendant who claimed not to have played a direct role in the alleged billing of medically unnecessary urine drug tests. The district court held that the complaint sufficiently pleaded scienter by alleging the defendant personally set the company’s policies as to the subject testing and was aware of internal overutilization of urine drug testing.¹⁰¹

Defendants historically have had more success in challenging scienter in cases involving ambiguous regulations. Courts have held that a defendant cannot be held liable under the

95 776 F. App’x 549 (10th Cir. 2019).

96 394 F. Supp. 3d 174 (D. Mass. 2019).

97 *Escobar*, 136 S. Ct. at 2002.

98 371 F. Supp. 3d 1195 (N.D. Ga. 2019).

99 389 F. Supp. 3d 1214 (N.D. Ga. 2019).

100 394 F. Supp. 3d 174 (D. Mass. 2019).

101 2019 WL 7372510 (M.D. Tenn. Dec. 31, 2019).

FCA where it adopts a reasonable interpretation of an ambiguous legal requirement.¹⁰² Last year, several courts addressed whether ambiguity was dispositive in FCA cases.

In **Pack v. Hickey**, for example, the Tenth Circuit upheld the district court's grant of summary judgment in favor of a mental health services facility because the relator failed to present any direct evidence supporting allegations of scienter. In addition, it reasoned that the relator's claims should be dismissed because the Medicaid Fraud Unit of the Wyoming Attorney General's Office had released a report observing possible ambiguity in the applicable rules. The Tenth Circuit was unwilling to impose liability where the state recognized that the provider's legal obligations were unclear.¹⁰³

In **U.S. ex rel. Krawitt v. Infosys Tech. Ltd.**, the district court granted the motion to dismiss filed by Infosys Technologies, Ltd. and Apple, Inc., on similar grounds. The relator alleged that defendants violated immigration laws by improperly using B-1 visas instead of the more-expensive H1-B visas to bring contractors to the United States to provide training at Apple. The district court held that these allegations did not support liability "because there is simply no exhaustive list or case law of all permissible activities under a B-1 visa. Moreover, there is no case law or regulatory guidance that providing training is impermissible under a B-1 visa."¹⁰⁴

The district court likewise found the defendant's lack of knowledge dispositive in **U.S. ex rel. Patt v. Greer Labs., Inc.**, granting summary judgment as to allegations that the defendant improperly sold immunotherapy allergy products without obtaining a separate license. The district court found that the defendant had no reason to believe that it needed a separate license and, as a result, the defendant lacked scienter because its conduct was "industry practice" that had openly occurred for decades and had been disclosed to the FDA and because there was otherwise no evidence the defendant knew its practices were wrong.¹⁰⁵

Not all cases resolved questions of ambiguity in favor of defendants. In **U.S. ex rel. Streck v. Takeda Pharm. Am., Inc.**, the district court rejected the defendant pharmaceutical companies' bids to dismiss the complaint based on apparent regulatory ambiguity in a case where the relator accused the defendants of improperly calculating rebates owed under the Medicaid Drug Rebate Program. The district court examined the disputed regulations and found them sufficiently clear "to have warned defendants away" from the alleged misconduct. That said, the district court acknowledged the issue "of scienter can be revisited at the summary judgment stage when the Court will have a more complete record."¹⁰⁶

In the related case of **U.S. ex rel. Streck v. Bristol-Myers Squibb Co.**, the district court similarly rejected the defendant's scienter argument at the motion to dismiss stage. The district court found that factual issues remained as to whether a proposed CMS rule and judicial opinion had warned the pharmaceutical company away from its interpretation of applicable regulations.¹⁰⁷

102 See, e.g., *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (9th Cir. 2015); see also *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007) (addressing similar knowledge requirement under Fair Credit Reporting Act).

103 776 F. App'x 549 (10th Cir. 2019).

104 372 F. Supp. 3d 1078 (N.D. Cal. 2019).

105 2019 WL 3987762 (W.D.N.C. Aug. 22, 2019).

106 381 F. Supp. 3d 932 (N.D. Ill. 2019).

107 370 F. Supp. 3d 491 (E.D. Pa. 2019).

REVERSE FALSE CLAIMS

Under the "reverse false claim" provision of the FCA, 31 U.S.C. § 3729(a)(1)(G), liability may arise when a defendant: (1) "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government;" or (2) "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." Under either prong, there must exist an "obligation" to pay money to the government, which includes the retention of an overpayment.

Contingent Payment Obligations and the Right to Information as an Obligation

As noted previously, courts have emphasized that "obligation[s]" that are *contingent* on future acts or events do not support liability under the FCA's reverse false claims provision, which requires there be an "established duty" before reverse false claims liability may arise.

In **U.S. ex rel. Kasowitz Benson Torres LLP v. BASF Corp.**, the relator alleged that the defendants' failure to inform the Environmental Protection Agency (EPA) of substantial risk information as required by statute created reverse false claim liability. The relator also alleged that the defendant's failure to pay civil penalties owed under the Toxic Substances Control Act (TSCA) supported reverse false claim liability.¹⁰⁸ The D.C. Circuit affirmed dismissal by the district court on the grounds that the defendants had no obligation that they could have concealed or avoided for purposes of a reverse false claim. Although the relator argued that the TSCA automatically imposes an obligation to pay a penalty when a violation occurs, the D.C. Circuit rejected that argument because the EPA has discretion as to whether to impose a civil penalty.

In the same case, the D.C. Circuit also addressed whether a duty to inform can constitute an obligation to transmit property. The D.C. Circuit rejected that theory and held that the requirement to inform the EPA was not an obligation to transmit property and therefore did not constitute an obligation for purposes of the FCA's reverse false claims provisions. The D.C. Circuit also reiterated the Supreme Court's statement from *Escobar* that "the FCA is not 'a vehicle for punishing garden-variety ... regulatory violations.'"

Relationship to Traditional FCA Violations

Courts also continued to emphasize that a defendant's failure to report or return money obtained through violations of (a)(1)(A) or (a)(1)(B) of the FCA will not support liability for "reverse" false claims.

In **U.S. ex rel. Lutz v. Laboratory Corporation of America Holdings**, the relators alleged that the defendant received payments that were tainted by violations of the AKS and that those payments constituted improperly retained overpayments.¹⁰⁹ The district court dismissed the relators' cause of action based on reverse false claims because it was based on the same conduct as the relators' traditional false claims.

108 929 F.3d 721 (3d Cir. 2019).

109 2019 WL 236799 (D.S.C. Jan. 16, 2019).

Retention of Overpayments

Finally, of particular importance to healthcare providers is the potential for reverse false claims liability when an overpayment is retained for more than 60 days after it is identified or for more than 60 days after it should have been identified through the exercise of reasonable diligence.¹¹⁰ To hold a defendant liable for retention of overpayments, however, a relator must tie specific claimed overpayments to the allegation of retention.

In ***U.S. ex rel. Holloway v. Heartland Hospice, Inc.***, the district court dismissed the relator's reverse false claim allegations because the relator failed to plead facts showing that the defendant had received an overpayment.¹¹¹ The relator alleged that the defendant violated the FCA by "refusing to review patients' previous billings beyond the most recent billing cycle to determine whether it owed funds," and that the defendant directed her to provide an unduly limited audit response to prevent further inquiry by the auditor. The district court held that those factual allegations were not sufficiently tied to a claimed overpayment or to the defendant's retention of any such overpayment to survive a motion to dismiss.

PUBLIC DISCLOSURE BAR

The FCA's public disclosure bar prevents a relator from maintaining a *qui tam* complaint that alleges substantially the same information previously disclosed to the public, thus precluding parasitic lawsuits based on publicly available information.¹¹² PPACA amendments to the FCA in 2010 continue to affect courts' analysis of the public disclosure bar, with those amendments sometimes conclusively establishing whether allegations are barred on public disclosure grounds. In applying the public disclosure bar, courts must determine: (1) whether a public disclosure has occurred; (2) whether that disclosure was substantially similar to the relevant FCA allegations; and (3) if a substantially similar public disclosure has occurred, whether the relator is nevertheless an "original source" of the FCA allegations.

Which Version of the Public Disclosure Bar Applies?

While the PPACA amendments to the FCA's public disclosure bar occurred in March 2010, cases involving conduct happening both before and after the PPACA amendments continue to arise. When faced with alleged conduct occurring pre- and post-PPACA, courts often divide their public disclosure bar analysis between pre-PPACA conduct under the older version of the FCA and post-PPACA conduct under the current version. Whether conduct occurred before or after the PPACA can sometimes be dispositive. For example, in ***U.S. ex rel. Aryai v. Skanska***, the district court applied the public disclosure bar to only pre-PPACA conduct.¹¹³ The district court concluded that the public disclosure bar precluded the relator from alleging pre-PPACA conduct, but, without explanation, declined to apply the public disclosure bar to alleged conduct occurring after the PPACA amendments. Instead, the district court dismissed the relator's remaining claims relying on post-PPACA conduct on grounds other than the public disclosure bar.

Quite often, though, whether the conduct occurred before or after the PPACA amendments is immaterial to the public disclosure bar's application. In ***U.S. ex rel. Fadlalla v. DynCorp. Int'l LLC***, the district court concluded that the relators' claims survived "[u]nder either version of the public disclosure bar" because of the original source exception.¹¹⁴ The relators alleged conduct from 2007 to 2012, thus overlapping the PPACA amendments. The district court held that, because the relevant time period straddled the PPACA amendments, both versions of the public disclosure bar applied. Nonetheless, while the pre- and post-PPACA versions of the public disclosure bar have different requirements to meet the "original source" exception, the relators alleged "personal, firsthand experiences" of the fraud scheme satisfying either version of the exception. Therefore, whether the conduct alleged by relators occurred before or after the PPACA's enactment, the public disclosure bar did not apply.

What Qualifies as a Public Disclosure?

As an initial step to the public disclosure bar analysis, the district court must examine what sources of information constitute a "public disclosure" under the FCA. The public disclosure bar applies to public information "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation," and "from the news media."

In many circumstances, the determination as to whether information qualifies as a public disclosure under the FCA is straightforward. For example, in ***U.S. ex rel. Graziosi v. R1 RCM, Inc.***, the district court held that the audits performed by HHS-OIG and a CMS contractor qualified as public disclosures under the FCA as those audits were clearly "federal audits" per the public disclosure bar's plain language.¹¹⁵

Over the past year, however, courts have faced difficult questions regarding the application of the public disclosure bar based on the source of public information. One question continuing to challenge courts is whether the government must intervene in a prior *qui tam* lawsuit for that lawsuit to be one in which "the Government or its agent is a party" and thus a public disclosure. The district court in ***U.S. ex rel. Holloway v. Heartland Hospice, Inc.***, joined a growing majority of courts holding that a non-intervened *qui tam* lawsuit can constitute a public disclosure.¹¹⁶ The district court reasoned that "a relator acts as the government's agent despite its declination to intervene because it 'is the real party in interest and the relator is the assignee of the Government's damages claim.'"¹¹⁷ In doing so, the district court rejected the argument that a relator is not the government's agent because the government relinquishes control to the relator in a non-intervened case and does not "authorize" the relator to take its place in a *qui tam*. Instead, because the government retains "a fair amount of control" and authority over a non-intervened *qui tam*, the district court reasoned that a relator acts as an agent for the government in the *qui tam*. According to the district court, "[w]ho, if not the private relator, is the government's agent?"

110 See 42 U.S.C. 1320a-7k(d); 42 C.F.R. § 401.305.

111 386 F. Supp. 3d 884 (N.D. Ohio 2019).

112 31 U.S.C. § 3730(e)(4).

113 2019 WL 1258938 (S.D.N.Y. Mar. 19, 2019).

114 402 F. Supp. 3d 162 (D. Md. 2019).

115 2019 WL 861368 (N.D. Ill. Feb. 22, 2019).

116 386 F. Supp. 3d 884 (N.D. Ohio 2019).

117 *Id.* (quoting *U.S. ex rel. Gilbert v. Virginia College, LLC*, 305 F. Supp. 3d 1315, 1323-24 (N.D. Ala. 2018)).

Another issue arising with increasing frequency is whether information publicly available on the internet constitutes “news media” under the FCA. In *U.S. ex rel. Integra Med Analytics LLC v. Providence Health & Servs.*, the district court held that the FCA’s reference to “news media ... cannot encompass all online information.”¹¹⁸ According to the district court, the term “news media” could not refer to the internet generally because the internet “is designed to be able to convey essentially anything.” Instead, the district court created the following five “guideposts” to determine whether an internet source constitutes “news media” under the FCA, which included whether: (1) the internet source conveys information commonly found in a newspaper or similar news source; (2) the source reflects some editorial judgment or independence; (3) the source intends “to disseminate information widely, as opposed to only to a few individuals;” (4) the internet source functions like a “traditional” outlet such as a newspaper or television station; and (5) the source falls within the “broad ordinary meaning” of the term “news media” as “at least some people [use] that term in everyday speech.”

Applying these guideposts, the district court held that a fact issue existed as to whether several internet sources qualified as “news media” because some of those internet sources were potentially inaccessible to the general public and other sources were “not easily accessible,” as they could “only be accessed ‘by typing in a precise URL.’”

A final recurring issue in determining whether information qualifies as a “public disclosure” under the FCA is whether the information revealed only to the government is “public.” The district court in *U.S. ex rel. Chiba v. Guntersville Breathables, Inc.*, concluded that information must be disclosed outside of the government to be considered public for purposes of the FCA’s public disclosure bar.¹¹⁹ The defendant had previously made a disclosure to U.S. Customs and Border Protection revealing that the defendant’s misclassification of an import had resulted in significant unpaid duties. The district court, however, held that the disclosure to U.S. Customs was not public as the information disclosed was simply “reported to a government agency and filed away in a bureaucrat’s office.” Because U.S. Customs did not publicly disclose the defendant’s prior disclosure, that disclosure was not sufficiently “public” for the public disclosure bar to apply.

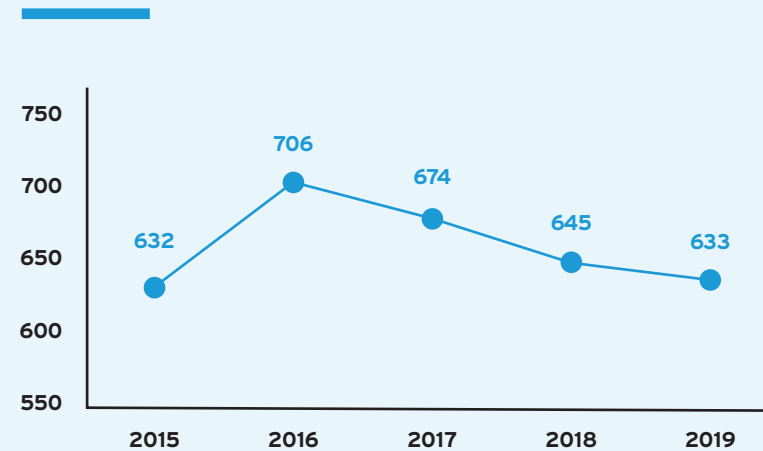
When Are Disclosures Sufficient to Bar FCA Allegations?

Following the identification of a public disclosure, courts must then determine whether the public disclosure is “substantially similar” to the relevant FCA allegations to put the government on notice of potential fraud. Recently, the determination as to whether a public disclosure is “substantially similar” to FCA allegations has led to more varied and inconsistent outcomes than in years past.

One frequent issue is whether the public disclosure needs to have revealed an allegation of fraud for the disclosure to be substantially similar to a relator’s FCA allegations. Courts have taken divergent approaches to that issue. In *U.S. ex rel. Clarke v. Aegerion Pharmaceuticals, Inc.*, the district court held that the public disclosure was not substantially similar to a relator’s FCA allegations as the disclosure contained “no allegation of fraud.”¹²⁰ Aegerion

118 2019 WL 3282619 (C.D. Cal. July 16, 2019).
 119 2019 WL 5067733 (N.D. Ala. Oct. 9, 2019).
 120 2019 WL 1437914 (D. Mass. Mar. 31, 2019).

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had previously issued public misstatements regarding the size of the patient population for a newly developed drug. The relator claimed that Aegerion’s misstatements allowed Aegerion to improperly off-label market the underlying drug, causing the submission of false claims. Aegerion argued that its misstatements about its patient population size publicly disclosed the same allegations as alleged by the relator. The district court disagreed, reasoning that Aegerion’s public misstatements about population size contained only “essential background information” without any allegation of fraud, namely the improper off-label marketing, and therefore failed to trigger the public disclosure bar.

By contrast, the district court in *U.S. ex rel. Kromenaker v. Kimberly Clark Corp.* concluded that a public disclosure need not “contain an allegation of wrongdoing.”¹²¹ The relator alleged that Kimberly Clark sold defective products to the government. Kimberly Clark, however, had previously issued numerous public recalls of its allegedly defective products. Although the relator argued that those recalls did “not report any allegations of fraud,” the district court held that the public disclosure bar “requires only disclosures of allegations of transactions,” and that “allegations of wrongdoing are not required” in public disclosure. Therefore, by disclosing the defective nature of its products, Kimberly Clark’s public recalls sufficiently revealed information substantially similar to the relator’s allegations of fraud.

Another issue receiving varying treatment among courts is the extent to which the identification of a defendant in a public disclosure affects whether that disclosure is “substantially similar” to a relator’s FCA allegations against that defendant. As some

121 2019 WL 2564579 (N.D. Ga. Mar. 27, 2019).

courts have held, the fact that a public disclosure names only one defendant does not mean that disclosure is distinct from a relator's allegations against another defendant. In **Schweizer v. Canon Inc.**, the district court held that public disclosure of fraud as to one defendant was still sufficiently similar to the relator's allegations against another defendant.¹²² Prior to the filing of the relator's lawsuit, Océ North America, Inc., had settled a *qui tam* lawsuit in which it was alleged to have overcharged the government for copiers and services. Canon acquired Océ shortly after Océ settled the *qui tam* lawsuit against it, and the relator alleged that Canon had adopted and expanded Océ's fraudulent scheme. The district court, however, held that the filings in the *qui tam* lawsuit against Océ publicly disclosed substantially the same information as that in the relator's allegations against Canon. While the relator argued that his *qui tam* was against Canon, not Océ, the district court observed that "[a] defendant undergoing a mere change in corporate ownership does not provide a license for a *qui tam* [relator] to renew allegations against that defendant based upon prior public disclosures."

Other courts, though, have held that, even if a public disclosure identifies a defendant later named in a relator's *qui tam*, the disclosure is not necessarily "substantially similar" to the relator's allegations. For example, the district court in **U.S. ex rel. Barrett v. Allergan, Inc.**, held that public disclosure about Allergan did not reveal substantially the same information as alleged by the relator because the relator's allegations were "different in kind and in degree from the previously disclosed information" about Allergan.¹²³ The relator claimed that Allergan failed to report accurate prices to the government for the prescription drug Botox, causing the government to overpay for the drug. Allergan, however, had already faced a *qui tam* lawsuit regarding its sale of Botox. Even though Allergan was now named in a second *qui tam* lawsuit regarding Botox, the district court concluded that the new *qui tam* lawsuit was not substantially similar to the earlier *qui tam*. Expressing caution about "reading *qui tam* complaints at only the highest level of generality," the district court held that the two lawsuits were not substantially the same because the new *qui tam* offered "a higher level of detail" and "more precise" allegations than its predecessor, allowing for the new *qui tam* to go forward against Allergan.

When is a Relator an Original Source?

If a public disclosure is substantially the same as a relator's FCA allegations, a relator may still qualify as an "original source" of the allegations, preventing the application of the FCA's public disclosure bar. The pre-PPACA version of the original source exception defines an original source as one who has "direct" and "independent" knowledge of the information upon which the FCA allegations are based and voluntarily disclosed that information before filing an FCA action. The post-PPACA version of the exception requires that an original source either: (1) voluntarily disclose the information upon which an FCA claim is based to the government before a public disclosure; or (2) have knowledge that is independent of and materially adds to public information and voluntarily disclose that knowledge to the government before filing an FCA action. Over the past year, courts have continued to apply the pre-PPACA version of the original source exception much more narrowly than the exception's post-PPACA counterpart.

In **U.S. ex rel. Denis v. Medco Health Solutions, Inc.**, the Third Circuit concluded that a relator did not qualify as an original source under the pre-PPACA version of the FCA.¹²⁴ The relator alleged that Medco received improper rebates, discounts, and other benefits from the manufacturer AstraZeneca. Applying the pre-PPACA version of the FCA requiring that an original source have "direct" knowledge, the Third Circuit held that the relator's knowledge of improper benefits was "second-hand." The relator made no allegation that he was involved in the negotiation of the agreements between Medco and AstraZeneca resulting in improper benefits. Instead, the relator relied "exclusively" on the information he learned from Medco employees and a review of the agreements. The district court held that knowledge gained from third parties and gathered from a review of documents was not "direct" knowledge of the alleged fraud to be considered an original source under the pre-PPACA version of the exception.

Similarly applying the pre-PPACA version of the FCA, the district court in **Aryai** held that a relator failed to satisfy the "direct" and "independent" knowledge requirements of the original source exception.¹²⁵ The relator alleged a longstanding fraudulent payroll practice through which defendants' construction workers routinely recorded two hours of overtime per day for time that was not worked while on government-funded projects. The relator, however, learned of this practice through one defendant's non-prosecution agreement and conversations with executives at a non-defendant construction firm. Because the relator's knowledge underlying his allegations relied on third-party sources, the district court concluded the relator's knowledge was neither "direct" nor "independent," and the relator failed to qualify as an "original source" of his allegations.

Applying the post-PPACA version of the exception, the district court in **U.S. ex rel. Maharaj v. Estate of Zimmerman**, found that the relator satisfied the post-PPACA version of the original source exception.¹²⁶ The relator claimed that defendants enrolled farmland in a conservation program under which the property owners received payments for dedicating land for preservation. According to the relator, however, the defendants did not actually own the land they enrolled in the conservation program. Prior to filing her *qui tam* lawsuit, the relator filed complaints with the Farm Service Agency (FSA) regarding the defendants' fraudulent enrollment of the relevant land in the conservation program. She subsequently requested the results of the FSA's investigation into her complaints under the Freedom of Information Act (FOIA), and the FSA's FOIA response detailed the relator's complaints and the FSA's decision not to further pursue those complaints. Defendants argued that the FSA's FOIA response was a public disclosure barring the relator's *qui tam*. The district court agreed that the FOIA response was a public disclosure, but held that the relator was nonetheless an original source of her allegations. More specifically, the relator was an original source under the post-PPACA version of the FCA because she had independent knowledge of defendants' fraud, having reported the alleged fraud to FSA, and materially added to FSA's investigation, providing documentation showing that defendants in fact did not own the relevant land.

122 2019 WL 5061097 (S.D. Tex. Oct. 9, 2019).

123 2019 WL 4675756 (C.D. Cal. Sept. 24, 2019).

124 777 F. App'x 30 (3d Cir. 2019).

125 2019 WL 1258938 (S.D.N.Y. Mar. 19, 2019).

126 2019 WL 6790645 (D. Md. Dec. 12, 2019).

Signaling a potential growing trend, two courts recently allowed a relator's claims to go forward despite the relator's reliance on quantitative analysis of claims data and lack of "first-hand knowledge of" the fraud that it alleged against defendants.

Trade Agreements Act, alleging the sale of non-compliant office products. While the district court held that those previous actions were qualifying public disclosures, it concluded that the relator was nevertheless an original source under both the pre- and post-PPACA versions of the original source exception. Under the pre-PPACA exception, the relator had both direct and independent knowledge of the information on which his allegations were based because he learned the information while employed at Synnex. The district court likewise held that the relator was an original source under the post-PPACA version of the exception. In addition to having independent knowledge of the fraud as a Synnex employee, the relator materially added to the prior *qui tam* actions by alleging "more serious conduct than what" was previously alleged, namely that the non-compliant office products had significant security vulnerabilities.

Qui Tam Cases Built from Data Mining

Signaling a potential growing trend, two courts recently allowed a relator's claims to go forward despite the relator's reliance on quantitative analysis of claims data and lack of "first-hand knowledge of" the fraud that it alleged against defendants.

In the first case, ***U.S. ex rel. Integra Med Analytics LLC v. Providence Health & Servs.***, the district court rejected the defendants' argument that the public disclosure bar precluded the claims raised by data analytics firm Integra Med Analytics.¹²⁷ The defendants argued that Integra's allegations pieced together information from multiple public sources, including: (1) CMS data; (2) publicly available OIG reports; and (3) information on certain websites and YouTube. The district court held that the public disclosure bar did not prevent Integra from bringing FCA claims against the defendants for several reasons. First, while the CMS data and OIG reports were public disclosures, the district court ruled that the public information revealed by the CMS data and OIG reports did not disclose "substantially the same" information as alleged by Integra. According to the district court, the CMS data did not indicate "the true state of facts" to reveal the alleged fraud, and the OIG reports

Applying both the pre- or post-PPACA version of the original source exception, the district court in ***U.S. ex rel. MacDowell v. Synnex Corp.*** held that a relator was an original source under both versions of the exception.¹²⁷ According to the relator, Synnex knowingly sold office products to the government that were non-compliant with the Trade Agreements Act before and after the enactment of the PPACA. Previous relators, though, had also filed *qui tam* actions against Synnex for the violation of the

merely described industry-wide conduct that was not sufficiently specific to the defendants. Second, as noted earlier in this section, the district court concluded that a fact issue existed as to whether information on certain websites and YouTube could be considered "news media" for purposes of the FCA. As a result, although "not a prototypical False Claims Act relator," the outside relator, Integra, was allowed to proceed with its claims despite the defendants' public disclosure bar challenge.

In a case brought by the same relator in a different district, the court in ***U.S. ex rel. Integra Med Analytics, LLC v. Creative Sols. in Healthcare, Inc.***, likewise rejected the defendant's argument that the public disclosure bar prevented Integra from bringing FCA claims.¹²⁹ The defendant argued that CMS data, upon which Integra's claims were based, publicly disclosed the allegations brought by Integra. The district court disagreed, reasoning that the CMS data only revealed "the misrepresented state of facts" without revealing the "true state of facts." That is, while the CMS data revealed that claims were submitted, the data did not disclose that the facts underlying the claims were untrue. The district court further observed that, if CMS data were alone sufficient to invoke the public disclosure bar, then the "submission of CMS data itself would effectively shield [a defendant] from FCA liability," which "cannot be the correct result."

STATUTE OF LIMITATIONS

Determining whether and how the FCA's statute of limitations applies to bar either a relator's or the government's FCA claims can have a significant impact on the scope of liability and damages for a defendant.

The FCA's statute of limitations provision, found at 31 U.S.C. § 3731(b), provides that an FCA lawsuit cannot be brought:

- (1) more than 6 years after the date on which the violation of section 3729 is committed, or
- (2) more than 3 years after the date when facts material to the right of action are known or should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

Until this year, federal courts were deeply divided about whether the tolling provision in § 3731(b)(2) should apply to claims brought by a relator when the government had declined to intervene. In a landmark decision, the Supreme Court provided much-needed clarity on that issue and ruled in ***Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*** that the limitations period begins to run when the government official responsible for acting in the circumstances - and not the relator - knew or should have known the relevant facts supporting an alleged FCA violation.¹³⁰ As a result, the Supreme Court's ruling effectively provides for a 10-year statute of limitations for a *qui tam* action as long as the relator files suit within three years of the responsible government official learning of the alleged fraud.

127 2019 WL 4345951 (N.D. Cal. Sept. 12, 2019).

128 2019 WL 3282619 (C.D. Cal. July 16, 2019).

129 2019 WL 5970283 (W.D. Tex. Nov. 13, 2019).

130 139 S. Ct. 1507 (2019).

The limitations period begins to run when the government official responsible for acting in the circumstances - and not the relator - knew or should have known the relevant facts supporting an alleged FCA violation.

In a unanimous opinion, the Supreme Court affirmed the Eleventh Circuit's application of the limitations period based on a plain reading of the FCA's statutory language. The Supreme Court held that limiting the phrase "civil action under section 3730" to only those FCA actions in which the government is a party "is at odds with fundamental rules of statutory interpretation." For this reason, the three-year knowledge-based limitations period of § 3731(b)(2) should be applied in non-intervened *qui tam* actions, as well.

The Supreme Court also rejected the argument that the relator in a declined case should be considered "the official of the United States charged with responsibility to act in the circumstances" for purposes of triggering §

3731(b)(2)'s limitations period. The Supreme Court noted that a relator is neither appointed as an officer of the United States nor employed by the United States and that the provision authorizing *qui tam* suits is entitled "Actions by Private Persons." In addition, private relators are not "charged with responsibility to act" because they are not required to investigate or prosecute an FCA action.

Although an expanded limitations period could increase FCA defendants' exposure to treble damages and statutory penalties in future cases, the Supreme Court's ruling in *Hunt* ensures that the limitations provision will be applied consistently. Moving forward, FCA defendants should be prepared to seek discovery about the substance and timing of the government's knowledge to determine when the applicable limitations period should begin to run.

DEVELOPMENTS REGARDING RELATORS

First-to-File Bar and Government Action

The FCA's first-to-file bar prohibits any person other than the government from "bring[ing] a related action based on the facts underlying" an already pending FCA action.¹³¹ Recent cases have focused on whether the bar is jurisdictional in nature and its application in related cases.

In particular, a decision of the First Circuit in *U.S. ex rel. McGuire v. Millennium Labs* deepened a circuit split by holding that the FCA's first-to-file bar should not be considered jurisdictional.¹³² The First Circuit relied heavily on the Supreme Court's 2015 decision in *Kellogg Brown & Root Services, Inc. v. U.S. ex rel. Carter*, finding that the Supreme Court addressed the operation of the first-to-file bar in "decidedly nonjurisdictional terms."¹³³ In reversing earlier circuit precedent, the First Circuit joined both the D.C. Circuit and the

Second Circuit and found that applying the "bright line rule" that Congress must "clearly state" that a provision is jurisdictional to the FCA could lead only to the conclusion that the first-to-file bar is not jurisdictional.¹³⁴

The First Circuit more narrowly analyzed what constitutes a "related action" in applying the bar, determining that the district court erred when it found that the first complaint provided the government with "sufficient notice" to initiate an investigation into the defendant. "Mere notice" or "some evidence from which an astute government official could arguably have been put on notice" is insufficient to bar a subsequent claim. Instead, the First Circuit required that the first complaint contains "all the essential facts" of the alleged fraud.¹³⁵

This appears to be a more stringent articulation of the standard applied in other jurisdictions. The majority of courts, like in *U.S. ex rel. Omni Healthcare Inc. v. McKesson Corp.*, have continued to analyze a related action and apply the first-to-file bar where the subsequent action alleges the "same material elements of fraud" that sufficiently puts the government "on notice" to investigate.¹³⁶ There, the district court held that a second complaint that mirrored the same fraudulent scheme, but named entirely unrelated defendants could survive a first-to-file challenge, explaining that a *qui tam* complaint alleging a particular fraudulent scheme does not bar "all other cases in which other unrelated defendants commit an entirely independent fraud involving the same elements." To be "equipped" to investigate fraud, the government must know whom to investigate.¹³⁷ In *U.S. ex rel. Ferrara v. Novo Nordisk Inc.*, the district court determined that the government is "equipped" to investigate the fraud where it has the material elements of the scheme, even if a later complaint articulates an alternative legal theory or more complete motive.¹³⁸

Finally, in *U.S. ex rel. Lazo v. Vratsinas Construction Co.*, the district court concluded that the first-to-file bar did not apply where the relator was substituted for a "John Doe" relator in the same case. The newly named relator, who was also the attorney in the case, claimed that he was the John Doe relator for the entirety of the case and so should not be barred under the first-to-file doctrine.¹³⁹ The district court agreed and allowed the relator to proceed while noting that generally a newly-named relator normally would be barred and over objections from defendants that the relator-attorney likely made misrepresentations to the court regarding his identity.

Seal Breach

Courts continue to apply severe consequences with respect to relators who fail to respect the requirement that FCA actions be brought and maintained under seal.¹⁴⁰ Courts have

131 31 U.S.C. § 3730(b)(5).
132 923 F.3d 240 (1st Cir. 2019).
133 135 S. Ct. 1970 (2015).

134 In contrast, district courts in the Ninth and Third Circuits treated the first-to-file bar as jurisdictional, following precedent in those jurisdictions. See *U.S. ex rel. Barrett v. Allergan, Inc.*, 2019 WL 4675756 (C.D. Cal. Sept. 24, 2019); *U.S. ex rel. LaFauci v. Abbvie Inc.*, 2019 WL 1450791 (D.N.J. Apr. 2, 2019) (rejecting transfer of venue in part because the first-to-file bar would be inappropriate where the court would not have jurisdiction over the claim).
135 923 F.3d at 254.
136 2019 WL 438357 (E.D.N.Y. Feb. 4, 2019).
137 The district court in *U.S. ex rel. LaFauci v. Abbvie Inc.*, determined that simply adding a new ancillary defendant is insufficient to escape the first-to-file bar as the government had "enough information to discover" the related frauds.
138 2019 WL 4305503 (D.D.C. Sept. 11, 2019). The district court there also rejected an "equitable exception" to the first-to-file bar, finding that it clearly "does not contain exceptions." *Id.* at *12.
139 2019 WL 4452967 (C.D. Cal. July 16, 2019).
140 31 U.S.C. § 3730(b)(2).

emphasized that the purpose of the FCA's seal requirement is to protect the government and its interests and not to protect relators.

In *U.S. ex rel. Brooks v. Stevens-Henager College*, the district court prohibited relators from maintaining new claims alleged in amended complaints where the relators had failed to file the new claims under seal.¹⁴¹ The district court determined that such a sanction was appropriate because it encouraged compliance with the seal requirement while also preserving the government's ability to pursue the claims.

In *U.S. ex rel. Graves v. Internet Corp. for Assigned Names and Numbers, Inc.*, the district court held that a matter could not remain under seal for the purpose of maintaining the secrecy of a relator's identity.¹⁴² Despite alleged fears of retaliation, the district court determined that the FCA provides the government time to investigate before unsealing, but after the intervention decision "fears of employment-related retaliation do not outweigh the strong presumption in favor of public access to judicial records in cases involving fraud against the government."

SETTLEMENT

In *U.S. ex rel. Allen v. Alere Home Monitoring, Inc.*, the district court denied the relator's motion to enforce a purported settlement with defendant Tamba Investments, holding that there was no meeting of the minds as to the scope of the government's release, and granted Tamba's cross motion to dismiss for failure to state a claim.¹⁴³ The relator argued that, through the parties' exchange of various versions of a settlement agreement, Tamba had entered into an enforceable settlement agreement and therefore was not entitled to dismissal. On review of the various agreements and email exchanges between the parties, the district court disagreed, holding that the purported agreement was contingent on the government agreeing to release Tamba's corporate officers from liability, a proposal which the government ultimately refused. Because the release was a material settlement term, the district court held that the purported settlement was not enforceable, ultimately granting Tamba's motion to dismiss.

ATTORNEYS' FEES

In *U.S. ex rel. Bliss v. Biocompatibles Int'l*, the district court rejected a defendant's argument that it should not be liable for time spent by relator's counsel pursuing claims against a separate co-defendant.¹⁴⁴ There, the relator sued Biocompatibles, a British medical technology firm, and Angiodynamics, Inc., its American distributor, for fraud in connection with off-label medical procedures. Following the government's investigation, Biocompatibles agreed to pay a \$25 million civil settlement and \$11 million in criminal fines; Angiodynamics subsequently agreed to pay a \$12.5 million civil settlement.

When the relator sought fees from Angiodynamics, the distributor argued that it should not be responsible for fees charged by relator's counsel to aid the government's criminal prosecution against Biocompatibles, since the government had not pursued criminal liability against Angiodynamics. But the district court disagreed, reasoning that relator's counsel's "time was devoted to the litigation as a whole." The district court was persuaded that Angiodynamics should be liable for the disputed time because the government's strategy was to use the criminal prosecution against Biocompatibles to leverage the civil settlement against Angiodynamics.

Another district court found that a fee reduction was appropriate where the relator sought recovery "for hours expended negotiating the relator's share of the government's recovery and preparing the fee agreement." Surveying the case law, the district court in *U.S. ex rel. Schiff v. Norman* found the "weight of authority persuasively reasons that because a defendant has no right to participate in a negotiation between the relator and the government, a relator cannot recover for the time expended by counsel to negotiate the relator's share."¹⁴⁵

In *U.S. ex rel. Doghramji v. Community Health Systems, Inc.*, the district court considered whether an FCA settlement agreement barred the defendant from challenging the relators' entitlement to a fees award. The relators accused the defendant hospital system of improper admission and billing practices. Following a government investigation, the defendant agreed to a \$92 million settlement. As part of the settlement agreement, the defendant agreed to release all claims against the relators, except that it reserved all challenges or objections to relators' claims for attorneys' fees. When the relators subsequently sought a fees award from the court, the defendant asserted that the first-to-file and public disclosure bars prevented relators' from recovering fees.

The relators challenged whether the defendant had preserved these objections in the settlement agreement. Following a prior district court decision finding in the relators' favor, the Sixth Circuit remanded to the district court to consider extrinsic evidence of the parties' understanding of the settlement agreement. Considering the issue in light of this evidence, the district court sided with the defendant the second time around. The district court reasoned that the "parties' outward manifestations when negotiating the Settlement Agreement reveal that Relators either shared, knew of, or had reason to know of [defendant's] understanding of [the carve-out], while [defendant] neither knew nor had reason to know of Relators' asserted interpretation." The district court's opinion resolved only questions about the scope of the settlement agreement. Further proceedings will follow to resolve the merits of the defendant's first-to-file and public disclosure bar arguments.¹⁴⁶

A defendant in an FCA action may be entitled to its "reasonable attorney's fees" against the relator in a non-intervened case if it "prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." 31 U.S.C. § 3730(d)(4).¹⁴⁷ Defendants, however, may find this standard hard to meet.

141 359 F. Supp. 3d 1088 (D. Utah Jan. 14, 2019).

142 398 F. Supp. 3d 1307 (N.D. Ga. Aug. 16, 2019).

143 355 F. Supp. 3d 18 (D. Mass. 2019).

144 2019 WL 79488 (W.D. Tex. Jan. 1, 2019).

145 2019 WL 2552254 (M.D. Fla. Feb. 26, 2019).

146 2019 WL 4887190 (M.D. Tenn. Oct. 2, 2019).

147 A prevailing defendant in an FCA case brought by the United States may have a right to seek attorneys' fees under the Equal Access to Justice Act, which is incorporated into the FCA. See 31 U.S.C. § 3730(g).

In ***Druding v. Care Alternatives***, the district court rejected the defendant's request for nearly \$2 million in attorneys' fees following the defendant's win in a decade-long FCA suit.¹⁴⁸ The relator accused the defendant hospice provider of inappropriate patient admissions and recertifications for hospice care. The defendant endured a seven-year government investigation before receiving a declination by the government. Following three additional years of litigation, the defendant prevailed at summary judgment, persuasively arguing that the district court should adopt the analyses in ***AseraCare*** and ***U.S. ex rel. Wall v. Vista Hospice Care, Inc. (Vista Hospice)***¹⁴⁹, with respect to the evidence required to prove "objective falsity" under the FCA.

Following the grant of summary judgment in its favor, the defendant sought to recover its attorneys' fees on the ground that the relator's theory of liability was "legally frivolous" under ***AseraCare II*** and ***Vista Hospice***. The district court disagreed. Although the district court was "sympathetic to the fact that Defendant has expended almost \$2 million in counsel fees and costs to successfully overcome Plaintiff-Relators' allegations," and recognized that the matter had taken a decade to resolve, it nonetheless found "the underlying circumstances do not rise to the level of egregiousness" the FCA requires. According to the district court, the relators were "within their rights to attempt to advance the law or to overturn precedent, particularly in areas of the law that are not well-trodden."

The Tenth Circuit reached a different conclusion in ***Pack v. Hickey***, though the circumstances in that case may demonstrate the exceptional nature of the defendants' recovery against a relator. The relator and one of the defendants had been in a romantic relationship when they incorporated a mental health services facility in Wyoming. The relationship continued until 2013, when the relator's employment with the facility was terminated, as well as their romantic relationship. While the relator and one of the defendants "traded volleys in state court, including in a child custody action," the relator raised concerns to state regulatory authorities and later initiated a *qui tam* action alleging improper billing.

Following the government's declination, the district court granted summary judgment in favor of the defendants and awarded attorneys' fees. The Tenth Circuit upheld both decisions on appeal. As to the award of attorneys' fees, the Tenth Circuit found no error in the district court's decision because the relator: (1) failed to adduce evidence of false billing; (2) failed to adduce evidence of scienter; (3) could not identify a single document to support his claim; (4) changed his claims throughout the litigation; and (5) had proposed a settlement offer "which tended to show he brought the action for an improper purpose."¹⁵⁰

RETALIATION CLAIMS

The FCA protects whistleblowers who report potential FCA violations from retaliation by their employer.¹⁵¹ To establish a retaliation claim, an employee must show that: (1) the employee engaged in protected activity; (2) the employer knew that the employee engaged in protected activity; and (3) the employer took an adverse employment action against the employee as a result.

148 2019 WL 337580 (D.N.J. Jan. 28, 2019).
149 2016 WL 3449833 (N.D. Tex. June 20, 2016).
150 776 F. App'x 549 (10th Cir. 2019).
151 See 31 U.S.C. § 3730(h).

Protected Activity and Underlying Fraud

The FCA defines protected activity as an employee's lawful actions "in furtherance of" an FCA action or "other efforts to stop 1 or more violations" of the FCA.¹⁵² Courts have continued to reason that in order to be a qualifying protected activity, the employee's actions must relate to a fraud against the government and not merely general compliance or regulatory concerns.

Though courts agree that protected activity must pertain to a reasonable belief of fraud on the government, they have generally not required employees to plead an underlying fraud in definite terms. In ***Guilfoile v. Shields***, the plaintiff complained that he was fired as president of a specialty pharmacy company for accusing the owner of the company of violating the AKS.¹⁵³ The plaintiff alleged that the owner had agreed to pay a consultant \$35,000 per quarter for each hospital contract for specialty pharmacy services that the consultant referred to the company and that he believed the referral fees to the consultant had improperly induced the consultant to steer hospital contracts to the company. The district court dismissed the complaint on the grounds that the AKS prohibits only payments made to induce providers or individuals to refer patients for services. As such, the plaintiff had not alleged conduct that could reasonably lead to an FCA action. The First Circuit reversed, holding that the standard in a retaliation case was not whether the plaintiff had adequately pleaded an underlying violation of the AKS or the FCA, but whether the plaintiff had reported concerns that the employer's conduct "reasonably could lead to an FCA action." The First Circuit found it reasonable to infer that the payments to the consultant enabled the company to obtain the hospital contract possibly in violation of the AKS and that it was plausible that the company would end up billing the government for services provided under the contract.

Likewise, in ***Singletery v. Howard University***, the D.C. Circuit reversed the district court's dismissal of an FCA retaliation claim even though the whistleblower's reports of her concerns about false certifications as to compliance with animal welfare laws "did not accuse the University of fraud in terms."¹⁵⁴ The D.C. Circuit reasoned that she nonetheless plausibly alleged actions taken that were sufficient under the second opposition clause of the FCA's anti-retaliation provision. Notably, the D.C. Circuit also held that the district court erred in requiring the plaintiff to allege protected activities outside the scope of her responsibilities as the attending veterinarian, who was charged with ensuring adequate veterinary care and other aspects of animal use.

Similarly, in ***Bacewicz v. Molecular Neuroimaging, LLC***, the district court refused to dismiss a retaliation lawsuit despite the employer's arguments that the research misconduct the plaintiff investigated and reported was not fraud, but merely violations of internal protocol.¹⁵⁵ The district court disagreed, finding that the plaintiff specifically alleged the falsification of data for monetary gain, supporting the element of fraud necessary for an FCA retaliation claim.

152 31 U.S.C. § 3730(h)(1).
153 913 F.3d 178 (1st Cir. 2019).
154 939 F.3d 287 (D.C. Cir. 2019).
155 2019 WL 4600227 (D. Conn. Sept. 23, 2019).

In contrast, other courts have held in favor of employers where employees raised compliance issues, but failed to come forth with evidence that their employers defrauded the government. In **U.S. ex rel. Strubbe v. Crawford County Memorial Hospital**, the Eighth Circuit upheld the dismissal of FCA retaliation claims where hospital employees failed to allege that they were taking action in furtherance of an FCA action or taking some action to stop an FCA violation.¹⁵⁶ The plaintiffs' complaints to hospital management and board members that the hospital's finances "were not adding up," that there "was something wrong" with changes made to breathing treatments, and that one of the hospital's paramedics was not properly licensed did not amount to notice of fraudulent conduct or conduct that would subject the hospital to FCA liability. Because they did not connect the alleged misconduct to "fraudulent or illegal activity or the FCA," the employees failed to plead that they were engaging in a protected activity under the FCA.

District courts have reached similar conclusions. In **U.S. ex rel. Johnson v. Raytheon Company**, the district court dismissed the relator's retaliation claim where the relator merely alleged that he expressed concerns about misrepresentations to the Navy under a government contract.¹⁵⁷ The court held that his internal complaints did not plausibly allege that he was attempting to expose illegality or fraud under the FCA. And, in **Wittenbrock v. Sunovion Pharmaceuticals Inc.**, the district court held that the plaintiff failed to allege that the defendant defrauded the government by submitting a false claim, or even that he suspected the defendant did so.¹⁵⁸ Rather, the plaintiff merely alleged that the defendant violated its own compliance program in support of an inference that the defendant *may* attempt to defraud the government in the future.

Likewise, the district court held that the relator's internal complaint about an improper admission to a geriatric behavioral health unit was insufficient to plead protected activity under the FCA in **U.S. ex rel. Kagebein v. Allegiance Health Management, Inc.**¹⁵⁹ The district court explained that "a plaintiff does not engage in protected activity when she complains of regulatory noncompliance without alleging fraud on the government." Finally, in **Hickman v. Spirit of Athens Alabama, Inc.**, the district court held that plaintiffs could not *reasonably* believe the defendant engaged in conduct that violated the FCA where their employer merely received some federal funding distributed by the state without submitting any claim.¹⁶⁰ The district court granted summary judgment for the defendant, explaining that "a plaintiff's protected activity necessarily must address conduct that could constitute an FCA violation."¹⁶¹

Employer Notice

While the Sixth Circuit had previously held that a heightened notice standard can apply for employees for whom typical protected activities fall within their employment obligations, requiring such plaintiffs to make clear their intention of bringing or participating in an FCA

action, in **Bourne v. Provider Services Holdings, LLC**, the district court cited multiple cases that have held this heightened pleading standard did not survive the FCA's 2009 amendment in light of the opposition clause of the FCA's anti-retaliation provision.¹⁶² The district court held that the plaintiffs' allegations that they repeatedly alerted supervisors of irregular billing practices were certainly sufficient absent a heightened notice standard, but that the plaintiffs also satisfied any heightened notice requirement, if such a standard were applied.

Adverse Employment Action Because of Protected Activity and Pretext

Courts have continued to address the need for employees to show a causal connection between an adverse employment action and protected activity - in other words, that their employers retaliated *because of* the protected activity. In **Garcia v. Professional Contract Services Inc.**, the Fifth Circuit reversed the district court's grant of summary judgment to the employer, who provided custodial services at government properties, holding that factual issues remained regarding whether the company had a pretextual reason for firing the employee.¹⁶³ The company argued that it terminated the plaintiff for failing to properly service two contracts for which he was responsible; the plaintiff argued this was a pretext, and that his employer fired him for whistleblowing. Acknowledging a circuit split, the Fifth Circuit first reiterated that it applied the heightened but-for causation standard only at the pretext stage of a retaliation analysis, and not at the prima facie stage. The Fifth Circuit then held that taken together, the plaintiff put forth enough evidence to create a genuine issue of material fact as to pretext: (1) temporal proximity; (2) disputes of facts leading up to his termination; (3) another employee who was not terminated for similar job performance; (4) supervisor harassment after the company knew about his reporting; (5) the reason the company stated for termination had been known for years; and (6) the company stood to lose millions of dollars if its conduct was discovered.

The district court reached the same conclusion in **Erickson v. Biogen, Inc.**, first holding that temporal proximity was sufficient to establish the plaintiff's prima facie case.¹⁶⁴ While her employer argued that her termination was simply part of a reduction in workforce, the district court held that plaintiff's evidence that the primary person responsible for her termination was aware of her repeated complaints and that she stated in an ethics complaint that she feared retaliation was sufficient to raise a material question of fact as to causation.

Other courts declined to apply the but-for causation standard at the pleading stage. In **Emekauwa v. Shaw University**, the district court allowed the plaintiff's retaliation claim to proceed against his former employer.¹⁶⁵ Distinguishing the case before it from other courts' analyses at summary judgment, the district court held that a plaintiff is not required to plead pretext. Citing Fourth Circuit precedent, the district court reasoned that the timeline of events plaintiff pleaded was sufficient to support a reasonable inference that he was terminated because he engaged in protected activity.

¹⁵⁶ 915 F.3d 1158 (8th Cir. 2019).

¹⁵⁷ 395 F. Supp. 3d 791 (N.D. Tex. 2019).

¹⁵⁸ 2019 WL 4453719 (C.D. Cal. May 20, 2019).

¹⁵⁹ 2019 WL 1848560 (W.D. La. Apr. 23, 2019).

¹⁶⁰ 2019 WL 861131 (N.D. Ala. Feb. 2, 2019).

¹⁶¹ See also *Sherman v. Berkadia Commercial Mortgage, LLC*, 2019 WL 195125 (D. Mo. Jan. 15, 2019) (holding email complaints about possible false certifications constituted protected activity, but that general complaints about the substance and timing of various disclosures in multiple projects did not).

¹⁶² 2019 WL 2010596 (S.D. Ohio May 7, 2019).

¹⁶³ 938 F.3d 236 (5th Cir. 2019).

¹⁶⁴ 2019 WL 5212807 (W.D. Wash. Oct. 16, 2019).

¹⁶⁵ 2019 WL 2500332 (E.D.N.C. June 14, 2019).

Arbitration of Retaliation Claims

At least one court addressed ancillary arbitration issues in connection with an alleged adverse employment action. In *Schreiber v. Tenet Healthcare Corp.*, the plaintiff was employed as president of Detroit Medical Center's Cardiovascular Institute (DMC).¹⁶⁶ After Tenet Healthcare acquired DMC, the plaintiff alleged that Tenet sacrificed patient care for profit-making and engaged in various forms of misconduct. The plaintiff contended that he had complained about these practices and, as a result, was demoted to executive director of the Cardiology Service Line and program director for Interventional Cardiology Fellowship. The plaintiff executed new contracts in connection with these two positions, which contained arbitration provisions. After he was later terminated from his leadership positions, the plaintiff filed suit alleging that defendants retaliated against him in violation of the FCA. Tenet moved to compel arbitration based on the provisions of the two directorship agreements. Although the plaintiff argued that his 14-year relationship with DMC was vastly more expansive and complicated than the duties and responsibilities of the two directorship agreements, the district court compelled arbitration, concluding that the retaliation at the heart of his FCA claim arose directly from the creation and termination of those agreements.

In *Kaki v. Tenet Healthcare Corp.*, the same district court compelled arbitration in a related case brought by two other cardiologists at DMC who alleged they were terminated after they complained about unsafe and illegal medical practices following Tenet's acquisition of the hospital.¹⁶⁷ The physicians had entered into medical directorship contracts with the hospital that contained arbitration provisions. The physicians argued that their directorship agreements did not need to be referenced to resolve the case because they were irrelevant to their employment relationship with the hospital. The district court disagreed, holding that the physicians' claims could not be resolved without reference to the directorship agreements.

DISCOVERY DEVELOPMENTS

As we noted in last year's Review, discovery disputes resulting from *Escobar's* materiality discussion continue to be litigated in both intervened and declined cases. Because of *Escobar*, the government cannot escape discovery requests directed at its past payment and enforcement practices. Indeed, the scope and burden associated with discovery requests upon the government have become a significant factor in the government's exercise of its discretion to dismiss cases following declination, a consideration outlined in the Granston Memo. Other issues such as the scope of the government's investigative authority likewise continue to be considered.

Civil Investigative Demands

The FCA affords the government broad discretion in issuing Civil Investigative Demands (CID) for documents to parties under investigation. And, courts are often deferential to DOJ when it comes to the exercise of this authority. In April 2019, DOJ sought to compel enforcement of a CID against an orthopedic surgeon who refused to comply with the

government's request for documents, interrogatories, and oral testimony.¹⁶⁸ The surgeon argued that settlement discussions between the government and another party under investigation should relieve him of his obligation to respond to the CID and that the government should be limited to pursuing discovery following the filing of a complaint.

While the district court acknowledged that "pre-litigation government investigations, whether civil or criminal, are indeed unilateral and do reflect an imbalance of power," there was no legal basis resulting from the government's settlement discussions for finding the CID unenforceable. Instead, the district court held that the scope of judicial inquiry concerning the enforcement of a CID is limited to: (1) whether Congress granted the authority to investigate; (2) whether procedural requirements were met; and (3) whether the evidence is relevant and material to the investigation.

Unlike discovery sought in litigation, the government's CID enforcement authority during an investigation is quite broad, and a district court's review of that authority is likely to be limited.

Government's Deliberative Process Privilege

In light of *Escobar*, parties often seek discovery from the government concerning its agencies' prior and current payment and enforcement practices. In the intervened case of *U.S. ex rel. Drennen v. Fresenius Medical Care Holdings, Inc.*, the government alleged that Fresenius improperly billed for excessive and medically unnecessary hepatitis B tests.¹⁶⁹ Fresenius sought discovery from the government for documents and deposition testimony related to an earlier government audit of Fresenius. The government refused to produce certain responsive documents, citing the deliberative process privilege and attorney-client privilege, both frequent assertions in litigation with the government.

In response to Fresenius's motion to compel, the district court noted that the assertion of the deliberate process privilege is a qualified privilege. Protection of the deliberative process must be balanced against a party's need for the information in the litigation, and a litigant can generally overcome the privilege by "showing that the information sought is relevant, helpful, and unavailable from other sources, or essential to a fair determination of a cause ..."

The district court held that the government failed to demonstrate the prerequisites for the deliberative process in its privilege log or otherwise. The district court also questioned the government's "generally stated interest" in protecting the particular records which

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¹⁶⁶ 2019 WL 5068473 (E.D. Mich. Oct. 9, 2019).

¹⁶⁷ 2019 WL 5068456 (E.D. Mich. Oct. 9, 2019).

¹⁶⁸ *U.S. v. Picetti*, No. 2:19-cv-00049 (E.D. Cal., Apr. 26, 2019).

¹⁶⁹ 2019 WL 1254554 (D. Mass. Mar. 19, 2019).

were 10 years old and concerned regulations long since amended, which weighed little against Fresenius's need for such documents in its defense. Consequently, all documents or testimony withheld by the government solely based on the deliberative process privilege were ordered produced by the district court. The district court reserved its ruling on documents the government asserted were also protected by the attorney-client privilege pending its *ex parte* review of requested examples of those documents.

Government's Investigation Documents

In *U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, the government intervened in an FCA case following a four-year investigation.¹⁷⁰ The government alleged that physicians paid below FMV for allegedly expensive trips arranged by defendants. In discovery, the defendants sought: (1) the basis for the government's claim of "below market value;" (2) the identification of the specific false claims alleged; and (3) the memoranda of interviews the government conducted pre-suit.

The government claimed that requests for its estimated fair value determination and corresponding basis were burdensome because it was "in fact Defendants' burden, and Defendants are in a position at this point in discovery to know more about various details than the United States." The magistrate judge held, however, that because the government made specific allegations in the complaint regarding FMV, it must have had some basis for doing so. Therefore, defendants were entitled to that information even at that arguably early stage of the litigation, and even if it was not the full and complete "universe of facts" that the government would ultimately offer in support of its allegations at trial. The information could be supplemented as appropriate.

The magistrate judge also ordered the identification and requested details of any known false claim - as alleged in the complaint - and held the government would not be prejudiced by answering to the extent of its knowledge. The magistrate judge noted that because parties are not "hemmed in" to a theory by virtue of early discovery information where responses are appropriately and timely supplemented, interrogatories - including contention interrogatories - may relate to any matter that may be explored under Rule 26. "Here, identification of the specific claims allegedly tainted by kickbacks is relevant to damages calculations at trial. And, frankly, it is relevant to Defendants' valuation of the case, a fact which favors providing such information sooner rather than later."

Defendants also sought the identity of the persons interviewed during the investigation, as well as all reports of interviews and notes. The government refused based on the work product doctrine, the informant's privilege, and the investigatory files privilege. The magistrate judge rejected each of these arguments. The FCA civil suit began after a criminal investigation of related conduct had been undertaken, which began a year before the civil *qui tam* was filed. As a result, the defendants' discovery request included interviews conducted by the FBI independently of the U.S. Attorney's Office, those in conjunction with or directed by the U.S. Attorney's Office, and those conducted solely by the AUSAs themselves.

Because the magistrate judge did not have sufficient information to distinguish when the work product doctrine might apply to any particular interview - which was the government's burden to demonstrate - the magistrate judge held that the work product doctrine would not apply to protect those documents created in advance of the civil government attorney's involvement, nor with respect to fact attorney work product information for which there is a "showing of substantial need and an inability to secure the substantial equivalent of the materials by alternative means without undue hardship." The magistrate judge was satisfied that the defendants had demonstrated a substantial need for all of the government's documents viewed as fact work product, particularly in light of the "passage of time" which prejudiced the defense's ability to obtain the same information by conducting those witness interviews at present. The magistrate judge also cited the government's four-year investigation with 11 requests for extension kept the matter under seal and enabled the government to maintain the information in its sole possession. The government appealed the magistrate's decision to the district court, which affirmed the magistrate judge's order and ordered the records produced.

In a subsequent hearing, the magistrate judge ruled on a discovery dispute between the same parties over the assertion of a common interest privilege by the government and the relator. Both argued that the privilege should preclude the discovery of communications between them by the defense.¹⁷¹ While acknowledging the possibility of the common interest between those parties, the magistrate judge found that they had failed to establish the existence of any common interest protection with respect to communications prior to the civil AUSA's involvement in the case. The magistrate judge refused to adopt the government's broad view that the common interest privilege is consistent with the purposes of the FCA, and noted instead that the interests of the relator and the government are "not always and necessarily aligned," such as when the government exercises its power to "sideline" a relator when useful in litigation and as it sees fit. The magistrate judge ordered the production of all materials and testimony between the relator and members of the government team that occurred before the date on which the civil AUSA became involved in the investigation.

Information Provided to the Government in Settlement Presentations

It is common for both the government and defendants to present confidential, relevant information shared pursuant to the provisions of Rule 408 in settlement discussions during the course of an FCA investigation. Should the government decline to intervene and a relator proceed with litigating the FCA claims, a relator may attempt to discover the information that the defense and the government shared during confidential settlement or resolution negotiations.

In *U.S. ex rel. Higgins v. Boston Science Corp.*, the relator sought all presentations that the defendant had made to the federal or state governments during the investigation.¹⁷² The defendant argued that the presentations should not be disclosed because: (1) they were produced pursuant to Rule 408; (2) that such communications are protected by public

170 No. 13-cv-3003 (D. Minn. Apr. 2, 2019).

171 2019 WL 6875354 (D. Minn. Dec. 17, 2019).

172 No. 11-cv-2453 (D. Minn. Aug. 28, 2019).

policy because they are necessary for the government to properly evaluate an FCA case; and (3) that the disclosures were protected under the attorney work product doctrine. The district court rejected each argument, finding that Rule 408 is limited to evidentiary considerations and does not govern the discoverability of information. The district court also explained that the disclosure prohibitions in the FCA's CID provisions applied to the government and not to private parties' own information. Finally, the district court reasoned that any attorney work product protections were waived upon the intentional disclosure to the government. The district court did note, however, that while some courts have applied a more heightened standard for discovery of confidential settlement communications, the Eighth Circuit had not done so.

Contrary conclusions also have been reached. In ***Strauser***, the relator made a discovery request for all documents exchanged between the defendants and the government during the investigation.¹⁷³ The defendants argued the documents were protected from disclosure by Rule 408 and by a public policy which favors the resolution of disputes and attending confidentiality. The defendants indicated that each withheld document had been designated: "Confidential - Subject to FRE 408." While agreeing with the relator that FRE 408 does not create a settlement or negotiation privilege, the magistrate judge noted that it nevertheless has the "wide discretion" to evaluate discovery requests pursuant to Fed. R. Civ. P. 26(b)(1) regarding relevance to the raised claims and defenses. The magistrate judge compared discovery considerations in its evaluation of the needs and importance of requested discovery to those when exchanging information in alternate dispute resolutions: (1) whether there is a special need for the materials; (2) whether there is unfairness if withheld; and (3) whether the need for the information outweighs the interest in maintaining its confidentiality. The magistrate judge found that the relator had failed to demonstrate any special need for the information or unfairness without access to defendants' discussions with the government, or that the information sought was only available from the settlement discussions and denied relator's motion to compel in the context of "the particular factual situation presented."

Scope of Discovery

Another discovery issue litigated in ***Strauser*** was the temporal proper scope and extent of discovery requests. FCA litigation frequently includes requests for discovery over broad time periods given the nature of the allegations at issue. In ***Strauser***, the relator's allegations pertained to conduct that allegedly ended in May 2013, yet the relator requested documents from January 2006 "to the present." The defendants objected to the temporal scope of the request, arguing that the relator had alleged that the conduct at issue that allegedly would have resulted in false claims ended in May 2013, and therefore claims and related documentation submitted after that date would be irrelevant. The magistrate judge found that relator's requests subsequent to May 2013 were not proportional to the needs of the case, as there was no dispute that the relator had alleged that the conduct at issue ended in May 2013, and relator failed to demonstrate the necessity of a more extensive time period for discovery of information compared to the burden of the production.

173 No. 18-cv-673-GKF-FHM (N.D. Okla. Nov. 14, 2019).

Waiver of Attorney-Client Privilege

In ***U.S. ex rel. Derrick v. Roche Diagnostics Corp.***, relator sought documents withheld by the defendants as protected by the attorney-client privilege.¹⁷⁴ Relator argued that the privilege had been waived when the defendant had pleaded the affirmative defense of good faith and reliance on applicable law and industry practice, and when producing documents that reflected consultation with counsel in connection with certain agreements relevant to the allegations. The relator argued that in doing so, the defendant "injected its state of mind and, implicitly, its reliance on advice of counsel, into the case."

The district court rejected the relator's argument that the privilege had been waived, noting that the "at issue" doctrine was limited and should not be used to "eviscerate" the attorney-client privilege. The district court explained that the privilege is not waived by merely asserting the defense of good faith and reliance on applicable law, but rather by reliance upon specific privileged attorney communications to prove a defense. The relator failed to present evidence that the defendant had intended to rely on any specific privileged communication to prove its defense, and the district court noted that there was available evidence other than the privileged communications which could be used by the defense.

174 2019 WL 1789883 (N.D. Ill. Apr. 24, 2019).

STARK LAW/ ANTI-KICKBACK STATUTE

Several notable developments involving the Stark Law and AKS occurred last year, including multiple cases that addressed a range of key concepts related to these statutes in the context of the expansive scope of potential liability.

Physician compensation remained a significant focus of enforcement in several cases. These cases demonstrate the importance of establishing compensation formulas within FMV and supported by a business justification for the arrangement. In *U.S. ex rel. D'Anna v. Lee Memorial Health System*, the relator, a former employee of Lee Memorial Health responsible for overseeing physician compensation, filed a complaint alleging her former employer violated the FCA and Stark Law by paying physicians referral fees under compensation arrangements that were above FMV and commercially unreasonable.¹⁷⁵ From 2005 to 2014, Lee Memorial Health allegedly paid neurosurgeons, cardiologists, pulmonologists, and a medical director: (1) compensation that increased with total annual work relative value units (wRVUs) performed; (2) compensation for services performed by non-physician extenders, including bonus pools accounting for extender wRVUs; (3) call coverage compensation in addition to payments for professional services rendered while on-call; and (4) excessive and duplicative medical directorship fees. The district

court denied the defendant's second motion to dismiss, in part, with respect to claims against the neurosurgeons after the relator provided sample false claims submitted for the neurosurgeons, outlined the neurosurgeons' excessive pay, and described the ways compensation exceeded FMV.¹⁷⁶ The district court also found the second amended complaint demonstrated Lee Memorial Health's awareness of the Stark Law compliance issues and its decision to proceed with submitting false claims and certifications.

In *U.S. ex rel. Longo v. Wheeling Hospital, Inc.*, the relator, a former executive of Wheeling Hospital, alleged that the hospital's CEO and the hospital's management company caused Wheeling Hospital to routinely employ and contract with physicians at inflated salaries to capture revenues from those doctors' patient referrals in violation of the Stark Law, AKS, and FCA.¹⁷⁷ The district court denied the defendants' motions to dismiss, noting that the complaint provided numerous examples of improper compensation arrangements with physicians who made Department of Human Services (DHS) referrals to the hospital and detailed examples of Medicare claims for such services. Moreover, the defendants allegedly ignored concerns raised internally about the legality of the hospital's physician compensation arrangements and continued to compensate physicians in a manner that accounted for the value of referrals and exceeded FMV of the services rendered.

In *U.S. ex rel. Bookwalter v. UPMC*, the relators alleged that the University of Pittsburgh Medical Center's (UPMC's) compensation for employed neurosurgeons amounted to prohibited indirect compensation under the Stark Law.¹⁷⁸ The compensation structure, commonly utilized among hospitals and health systems, included a productivity bonus for physicians who surpassed a certain number of wRVUs and potential reductions in base salary for physicians who did not achieve threshold wRVU levels. Applying the controversial reasoning adopted by the Fourth Circuit in *U.S. ex rel. Drakeford v. Tuomey*, the Third Circuit initially concluded the relators plausibly pleaded that the arrangements both varied with *and* took into account the volume or value of the physicians' ancillary service referrals to UPMC's hospitals.¹⁷⁹

Following UPMC's petition for rehearing, the Third Circuit reversed its conclusion that the structure of the surgeons' contracts satisfied the "varies with" prong simply because every time the surgeons personally performed a procedure at a UPMC hospital through which wRVUs were generated, they arguably made a referral for associated hospital claims. Nevertheless, the Third Circuit found that the relators adequately pleaded that the surgeons' compensation "takes referrals into account" through various allegations - which the court characterized as "smoke; and where there is smoke, there might be fire" - suggesting that the surgeons' pay exceeded FMV. These included allegations that: (1) some surgeons' pay exceeded their collections; (2) many surgeons' compensation and productivity exceeded the 90th percentile; and (3) surgeons engaged in abusive practices to fraudulently inflate their wRVUs, which in fact had been the subject of a prior FCA settlement with the government. In reversing dismissal of the relators' FCA claims, the Third Circuit also held that "[i]t is [] the defendants' burden to plead a Stark Act exception, not the relators' burden to plead that none exists."

¹⁷⁶ Opinion and Order, Case No.: 2:14-cv-437-FtM-38NPM (M.D. Fla. July 30, 2019).

¹⁷⁷ 2019 WL 4478843 (N.D. W. Va. Sept. 18, 2019).

¹⁷⁸ 2019 WL 7019394 (3d Cir. Dec. 20, 2019).

¹⁷⁹ 792 F.3d 364 (4th Cir. 2015).

¹⁷⁵ 2019 WL 1061113 (M.D. Fla. Mar. 6, 2019).

Courts did show a willingness to dismiss actions where the defendants could support the FMV of an arrangement. In **Bingham v. HCA, Inc.**, the relator - a real estate appraiser who worked for a large medical office management firm of which HCA was a client - alleged that HCA had violated the AKS and the Stark Law by providing “sweetheart deals” to certain physicians who leased space in medical office buildings developed by HCA in exchange for their referrals to two HCA hospitals.¹⁸⁰ The Eleventh Circuit emphasized that “[i]n a business transaction like those at issue in this case, the value of a benefit can only be quantified by reference to its fair market value.” The relator conceded that the rental rates paid by physician tenants were within the range of “market rates” for new construction, and the Eleventh Circuit found no other evidence of benefits conferred in excess of FMV. As such, the Eleventh Circuit concluded the relator had not met his burden of showing that HCA conveyed any remuneration to physician tenants for purposes of an AKS claim. In affirming dismissal of the relator’s Stark Law claims, the Eleventh Circuit held that an indirect compensation arrangement between the physician tenants and one of the HCA hospitals “plainly” did not exist where there was “no real basis in the record” beyond the relator’s “conclusory statements” from which to conclude the rental rates or other benefits given by HCA to physician tenants varied with or took into account the volume or value of their referrals.

As in past years, the marketing practices of pharmaceutical companies also continued to be a focus. In **U.S. ex rel. Arnstein v. Teva Pharmaceuticals USA, Inc.**, the relators, two former Teva sales representatives, filed a *qui tam* action alleging Teva paid kickbacks to physicians to participate in “sham” educational speaker programs in exchange for prescribing two of Teva’s prescription drugs.¹⁸¹ Denying the defendants’ motion for summary judgment, the district court held that the relators raised genuine issues of material fact as to Teva’s violation of the AKS and, for purposes of associated FCA liability, successfully linked the purported AKS violations to claims for prescriptions. Relators established an issue of material fact as to whether at least one purpose of Teva’s speaker program was to induce referrals in violation of the AKS.

Rejecting defendants’ argument that a quid pro quo arrangement was required to demonstrate the requisite unlawful intent required for an AKS violation, the district court highlighted several other indicia of an unlawful relationship between Teva and its speakers, including evidence that: (1) Teva closely tracked speakers’ prescription volumes; (2) speaker nominations were performed by sales instead of medical affairs or compliance personnel; (3) programs lacked legitimate educational value and were not modified to account for the given audience; (4) audiences often included sales representatives and presenters’ spouses; and (5) Teva provided “expensive dinners and alcohol” in addition to speaker honoraria. The district court disagreed with defendants’ arguments around FMV, referred to the relators’ contention that any payments to speakers in connection with sham speaker programs would be above FMV, and concluded that a reasonable jury could find Teva’s speaker program was a sham.¹⁸²

¹⁸⁰ 783 F. Appx. 868 (11th Cir. 2019).

¹⁸¹ 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019).

¹⁸² At year’s end, it was announced that Teva had reached an agreement to pay \$54 million to end the FCA litigation. See <https://www.law360.com/articles/1231587/teva-to-pay-54m-to-end-fca-suit-alleging-bribes-to-doctors>.

Courts also continued to examine compensation arrangements outside of the traditional physician-hospital context, which emphasizes the importance of considering the regulatory implications of any arrangement where federal healthcare reimbursement is in play. For example, in **U.S. ex rel. Headen v. Abundant Life Therapeutic Services Texas, LLC**, the relator alleged that Abundant Life, a medical-services provider, offered kickbacks to several Texas schools to induce Medicaid referrals in violation of both the AKS and FCA.¹⁸³ The complaint asserted that Abundant Life’s former manager used a nonprofit organization that he directed as a conduit to give free items to the principals of local schools, including free uniforms, computers, and other educational supplies. Abundant Life allegedly directed one of its independent contractors to provide free skills-building services at the schools receiving the donations, which resulted in referrals to Abundant Life for mental health services and assessments that were billed to Medicaid. Granting defendants’ motion to dismiss for a second time, the district court held that the second amended complaint failed to satisfy the FCA’s particularity requirements, “‘never link[ing] the alleged carrots to the’ alleged referral of students to Abundant Life.” Although the relator offered some facts about the purported kickback scheme, he failed to establish that Abundant Life’s donations induced the school principals or other school personnel to send patients to Abundant Life.

These cases demonstrate the importance of establishing compensation formulas within FMV and supported by a business justification for the arrangement.

The relator in **Stop Illinois Health Care Fraud, LLC v. Sayeed** alleged that a healthcare management company, its owner, a home health agency, and a physician practice paid a community care organization, Healthcare Consortium of Illinois (HCI), to give them information on low-income elderly patients so the defendants could market Medicare-reimbursed in-home healthcare services to those individuals.¹⁸⁴ The purported remuneration took the form of \$5,000 monthly payments pursuant to a management services agreement between the healthcare management company and HCI, as well as \$5 or \$10 Dunkin’ Donuts gift cards and Target gift cards provided to employees of HCI. Granting the defendants’ motion for a directed finding on all claims, the district court concluded the evidence “points to no connection between the gift cards or management services agreement and any illegal conduct.” Rather, the district court relied on testimony from several witnesses that the management services agreement - which had been approved by counsel for HCI - “did not indicate any expectations of referrals or other kickbacks.” In addition, the district court found persuasive a home health agency employee’s testimony that the gift cards were only given to a few HCI employees on special occasions (e.g., birthdays or showers), but “never ... with the expectation of receiving a referral” from HCI.

¹⁸³ 2019 WL 1930274 (S.D. Tex. Apr. 30, 2019).

¹⁸⁴ 2019 WL 3386964 (N.D. Ill. July 26, 2019).

In *U.S. ex rel. Suarez v. AbbVie, Inc.*, AbbVie successfully used past OIG guidance to obtain dismissal in a whistleblower action alleging AKS violations. In this action, the relator alleged that AbbVie, a pharmaceutical company, paid kickbacks to doctors in the form of product support services for AbbVie's prescription drug, Humira. AbbVie provided these support services through its "Ambassador Program."¹⁸⁵ The complaint specifically alleged that AbbVie was providing kickbacks to doctors by performing these product support functions for them at no cost and by providing doctors with free materials, such as Humira travel kits, instructional pens, pre-printed insurance benefit forms, and dedicated Humira terminals that print insurance-related documents.

AbbVie argued that previous OIG guidance expressly permitted these actions. Citing to OIG guidance, the district court determined that AbbVie's services were "integrally related" to Humira and not provided in tandem with another service or program that would confer a benefit on the referring provider. The district court dismissed the relator's claims, but without prejudice to all but two claims.

OIG Advisory Opinions. There also have been a number of noteworthy advisory opinions that likely will have an impact in the coming year, particularly as the regulatory agencies focus on the importance of quality of and access to healthcare as reimbursement shifts from fee-for-service to quality of care.

Adv. Op. 19-01 (Jan. 9, 2019): Advisory Opinion 19-01 is a positive opinion regarding a charitable pediatric clinic's arrangement under which the clinic waives cost-sharing

amounts in certain circumstances. As outlined in Opinion 19-01, the clinic provides medical, psychiatric, and dental care to children in a health professional shortage area. Most of the clinic's patients meet the financial need criteria (*i.e.*, qualify for Medicaid, state programs or family income below 200% of the federal poverty level). The clinic does not attempt to collect cost-sharing amounts because very few patients have them (because the vast majority of patients also participate in State Insurance Programs). Although the waivers do not meet the civil monetary

The district court disagreed with defendants' arguments around FMV ... and concluded that a reasonable jury could find Teva's speaker program was a sham.

penalty (CMP) cost-sharing waiver exception because the clinic's waivers are routine and it does not verify the financial need for all patients, the OIG concluded the arrangement presents minimal risk of fraud and abuse. The OIG pointed to following: (1) the likely small number of waivers each year; (2) the fact that the clinic does not advertise the waivers; (3) that no practitioners or staff receive compensation that varies based on the volume or value of services provided or referrals made; and (4) that the clinic is located in an area where a large number of children live in poverty.

Adv. Op. 19-02 (Jan. 24, 2019): Advisory Opinion 19-02 is a positive opinion regarding a pharmaceutical manufacturer's proposal to lend, on a temporary basis, a limited-functionality smartphone to financially needy patients who do not have the technology necessary to receive adherence data from a sensor embedded in prescribed antipsychotic medication. As outlined in Opinion 19-02, the smartphones would only be offered to financially needy patients who have a prescription for the drug, but who do not have a smartphone capable of running the application. The OIG saw the proposal as low risk, given that: (1) the program would not be advertised to patients; (2) the program would be unlikely to skew prescribing decisions; (3) the patients would not be permitted to keep the smartphones beyond a set time; and (4) the smartphones had limited functionality (*i.e.*, disabled except for the ability to make domestic phone calls and access the relevant application). The OIG noted that if the smartphones had increased functionality, like internet service or camera, the conclusion might be different.

Adv. Op. 19-03 (Mar. 1, 2019): Advisory Opinion 19-03 is a positive opinion regarding a program offered by a nonprofit medical center that provides free, in-home follow-up care to eligible individuals with congestive heart failure and the proposed expansion of the program to include certain chronic obstructive pulmonary disease (COPD) patients. As outlined in Opinion 19-03, under this arrangement, community paramedics provide follow-up care to chronically ill patients at higher risk of admission or readmission to the hospital. The OIG concluded that the arrangement did not meet the CMP exception for promoting access to care, but that sanctions would not be imposed. Factors influencing the OIG's conclusion include that the program was not advertised and that patients are required to select the medical center or clinic for follow-up care before even learning about the program. Further, patients are directed to follow-up with their established providers and are informed that they may obtain care from the provider of their choice. With numerous safeguards in place, the program poses a low risk of harm to patients, and may actually result in better adherence to treatment plans and cost savings by reducing the number of hospital admissions and readmissions. Additionally, the OIG noted that the arrangement was unlikely to increase costs to federal healthcare programs or patients through overutilization or inappropriate utilization and the risk of skewing clinical decision making was low.

Adv. Op. 19-05 (Sept. 6, 2019): Advisory Opinion 19-05 is a positive opinion regarding the purchase of real property by an operator of community health centers that receive Health Resources and Services Administration (HRSA) grant funding from a company co-owned by an individual excluded from participation in all federal healthcare programs. In rendering this opinion, the OIG determined the arrangement would not implicate the CMP because: (1) there would be no claim submitted to federal healthcare programs for payment; (2) there would be no federal grant funds used to purchase the property nor would any financing be received from the excluded person or his company; and (3) there would be no ongoing relationship with excluded person and his company.

185 2019 WL 4749967 (N.D. Ill. Sept. 30, 2019).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

Regulatory and enforcement agencies continued to scrutinize the activities of pharmaceutical and medical device manufacturers.

CRIMINAL ENFORCEMENT PRIORITIES

Insys Therapeutics agreed to pay \$225 million total to settle criminal and civil claims that it engaged in illegal marketing tactics and paid kickbacks to healthcare providers in an effort to promote its fentanyl painkiller spray Subsys.¹⁸⁶ As part of that resolution, Insys agreed to pay \$2 million in penalties and \$28 million in forfeiture and agreed to enter into a five-year deferred prosecution agreement. Its operating subsidiary also agreed to plead guilty to five counts of mail fraud for use of sham speaker programs as a vehicle to pay kickbacks to healthcare providers willing to prescribe Subsys.

As part of the overall settlement, Insys agreed to pay \$195 million as part of an FCA settlement based on alleged AKS violations. That settlement came just a month after the founder of Insys and four other high-level executives were charged under the Racketeer

186 DOJ, *Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations* (June 5, 2019), <https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal>.

Influenced and Corrupt Organizations Act for their involvement in a bribery scheme.¹⁸⁷ DOJ is seeking sentences ranging from six to 15 years with respect to those the executives.

Pharmaceutical distributor Rochester Drug Co-Operative, Inc. (RDC) and its former chief executive and chief compliance officers were charged with the unlawful distribution of oxycodone and fentanyl and for conspiring to defraud the Drug Enforcement Agency (DEA).¹⁸⁸ These charges reflected a theory of liability based on the pharmaceutical distributor as the “gatekeepers of prescription medication” for failing to satisfy their respective oversight obligations. In part, RDC allegedly supplied large quantities of pharmaceuticals to pharmacy customers while ignoring multiple “red flags” of diversion. RDC has entered into a deferred prosecution under which it would accept responsibility, pay \$20 million, implement changes to its compliance program, and submit to an independent monitorship.

DOJ has also scrutinized pharmaceutical companies’ marketing of drugs used to treat drug dependence. Reckitt Benckiser Group PLC (RB) agreed to pay \$1.4 billion to resolve alleged criminal and civil liability related to allegations that it misrepresented facts relating to the safety and diversion risk of Suboxone film.¹⁸⁹ RB also agreed not to make, market, or sell controlled substances in the United States for three years. In April 2019, a federal grand jury returned a 28-count indictment against Indivior, Inc., which RB spun off in late 2014, in connection with the same allegations. The indictment seeks forfeiture of \$3 billion along with several bank accounts, subsidiary corporations, and IP assets.

INCREASED FOCUS ON DRUG PRICING

As drug pricing became a key political issue this year, there were also a number of civil actions brought against pharmaceutical and medical device companies under the FCA alleging price-fixing in violation of the Sherman Act.

Generic drug manufacturer Heritage Pharmaceuticals agreed to pay \$7 million to resolve allegations that it paid and accepted remuneration from other generic drug manufacturers in an effort to fix prices for certain generics supplied to several federal programs. Rising Pharmaceuticals Inc. was charged with conspiring to fix prices and allocate customers for its hypertension drug Benazepril HCTZ. Rising agreed to pay \$1.1 million in civil damages for its related FCA violations.¹⁹⁰

MARKETING AND PATIENT ASSISTANCE

Despite new trends in enforcement, DOJ continued to scrutinize pharmaceutical company marketing practices and charitable foundations. As demonstrated by several of the

187 DOJ, *Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy* (May 2, 2019), <https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy>.

188 DOJ, *Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances* (Apr. 23, 2019), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and>.

189 DOJ, *Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History* (July 11, 2019), <https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case>.

190 DOJ, *Second Pharmaceutical Company Admits to Price Fixing, Resolves Related False Claims Act Violations* (Dec. 3, 2019), <https://www.justice.gov/opa/pr/second-pharmaceutical-company-admits-price-fixing-resolves-related-false-claims-act>.

settlements detailed in the Review's **Appendix** setting forth settlements within the pharmaceutical and device industry, off-label marketing continues to be a significant area of focus.

There also was continued scrutiny of pharmaceutical companies' use of charitable foundations to create PAPs. While PAPs are intended to assist financially needy patients to obtain necessary prescription medications and supplies, OIG has remained vigilant in scrutinizing their potential to function as conduits for pharmaceutical companies to pass kickbacks on to patients taking their drugs.

Jazz Pharmaceuticals PLC, Lundbeck LLC, and Alexion Pharmaceuticals agreed to pay \$122.6 million to resolve allegations that each entity worked with different charitable foundations to establish patient assistance funds for patients within a broader disease group and that those foundations only assisted patients using the respective companies' own drugs.¹⁹¹

And, pharmaceutical manufacturer US WorldMeds LLC agreed to pay \$17.5 million to resolve allegations that it, too, illegally paid Medicare co-pays for patients using its drugs through a third-party foundation for which it was the sole donor.¹⁹² Jazz, Lundbeck, and US WorldMeds also agreed to enter into five-year CIAs with HHS-OIG to ensure, in part, the independence of any charitable foundations to which the companies donate going forward.

DOJ continued to scrutinize pharmaceutical company marketing practices and charitable foundations.

¹⁹¹ DOJ, *Three Pharmaceutical Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations* (Apr. 4, 2019), <https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid>.

¹⁹² DOJ, *Pharmaceutical Company Agrees to Pay \$17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians* (Apr. 30, 2019), <https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients>.

**APPENDIX
2019 NOTABLE
SETTLEMENTS**

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/6/2019	Union General Hospital	Hospital agreed to pay \$5 million to resolve FCA allegations that from 2012-2016 it paid physicians amounts that were above or inconsistent with FMV or in a manner that accounted for the volume or value of physicians' referrals, in violation of the Stark Law. ¹	\$5 million
2/14/2019	Prime Healthcare Services, Inc.; Dr. Prem Reddy; two affiliated hospitals	Hospital system, its founder and CEO, and two affiliated hospitals in Pennsylvania agreed to pay \$1.25 million to resolve FCA allegations that the hospitals improperly billed Medicare for medically unnecessary inpatient admissions that should have been treated in a less costly outpatient or observation setting and for upcoded inpatient diagnoses. Prime, Dr. Reddy, and several affiliated hospitals in California settled similar allegations in 2018 for \$65 million. Prime entered into a five-year CIA with HHS-OIG in connection with the 2018 settlement. ²	\$1.25 million
3/21/2019	MedStar Health, Inc.; The Union Memorial Hospital d/b/a MedStar Union Memorial Hospital; Franklin Square Hospital Center, Inc. d/b/a MedStar Franklin Square Medical Center	Healthcare system and two of its hospitals agreed to pay \$35 million to resolve FCA allegations that they: (1) violated the AKS and Stark Law by paying kickbacks disguised as professional services agreements to a cardiology group in exchange for referrals to the hospitals for cardiac procedures; and (2) submitted false claims to Medicare for medically unnecessary cardiac stent procedures. The government alleged that the improper remuneration paid to the cardiology practice group physicians exceeded FMV and, in some instances, compensated physicians for services that were not provided. ³	\$35 million
5/3/2019	Decatur Hospital Authority d/b/a Wise Health System	Healthcare system agreed to pay \$431,182.96 to resolve FCA allegations that it billed Medicare for medically unnecessary genetic testing panels for surgical patients. ⁴	\$431,182
5/31/2019	Coffey Health System (CHS)	Healthcare system operating a critical access hospital agreed to pay \$250,000 to resolve FCA allegations that it received incentive payments under CMS's EHR Incentive Program based on false attestations of compliance with program requirements. Specifically, the government alleged CHS submitted false claims to Medicare and Medicaid, improperly attesting that it had conducted and/or reviewed security risk analyses in accordance with EHR Incentive Program objectives and measures. ⁵	\$250,000
5/31/2019	Oklahoma Heart Hospital, LLC; Oklahoma Heart Hospital South, LLC	Two hospitals agreed to pay \$2.8 million to resolve FCA allegations that they submitted claims to Oklahoma Medicaid for non-emergency, prescheduled cardiac stent procedures as inpatient services when they should have been billed and reimbursed as outpatient services. ⁶	\$2.8 million

1 <https://www.justice.gov/usao-ndga/pr/union-general-hospital-pay-5-million-resolve-alleged-false-claims-act-violations>.

2 <https://www.justice.gov/usao-edpa/pr/prime-healthcare-services-and-ceo-dr-prem-reddy-pay-125-million-settle-false-claims-act>.

3 <https://www.justice.gov/usao-md/pr/medstar-health-pay-us-35-million-resolve-allegations-it-paid-kickbacks-cardiology-group>.

4 <https://www.justice.gov/usao-wdtn/pr/decatur-hospital-authority-dba-wise-health-system-decatur-texas-will-pay-43118296>.

5 <https://www.justice.gov/usao-ks/pr/kansas-hospital-agrees-pay-250000-settle-false-claims-act-allegations>.

6 <https://www.justice.gov/usao-wdtk/pr/oklahoma-city-hospitals-agree-pay-28-million-settle-allegations-submitting-false-claims>.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/3/2019	Rialto Capital Management LLC (RCM); RL BB-IN KRE LLC (RL BB)	RCM and its former affiliate RL BB agreed to pay \$3.6 million to resolve FCA allegations that an RL BB-owned hospital entered into financial arrangements with physician referral sources in violation of the AKS and Stark Law. The government alleged that RCM approved personal loans to two of the hospital's key physician referral sources, then failed to require repayment, even after the loans matured and became due in full. ⁷	\$3.6 million
6/26/2019	Trustees of the University of Pennsylvania Health System	Health system agreed to pay \$275,000 to resolve FCA allegations that one of its hospitals submitted claims to Medicaid for obstetric ultrasounds that lacked timely professional reports interpreting the ultrasound studies, which were required for reimbursement. ⁸	\$275,000
6/27/2019	Anne Arundel Medical Center	Regional hospital agreed to pay \$3.154 million to resolve FCA allegations that one of its clinics submitted claims for medically unnecessary services to Medicare, Tricare, and the Federal Employees Health Benefit Program (FEHBP). The government alleged the hospital's Anticoagulation Clinic incorrectly coded and billed separately for outpatients' anticoagulation therapy, including submitting claims for unnecessary blood tests and Evaluation and Management (E&M) services. As part of the settlement, the hospital entered into a five-year CIA with HHS-OIG. ⁹	\$3.154 million
7/15/2019	Millcreek Community Hospital	Hospital agreed to pay \$2.451 million to resolve FCA allegations that it billed Medicare and Medicaid for inpatient rehabilitation services when patients did not qualify for such services and when patients' medical records lacked adequate documentation of medical necessity. As part of the settlement, the hospital entered into a five-year CIA with HHS-OIG. ¹⁰	\$2.451 million
7/24/2019	Eagleview Hospital	Hospital agreed to pay \$2.85 million to resolve FCA allegations that it submitted claims to Medicare, Medicaid, and FEHBP for hospital-level detox treatment services that failed to satisfy medical necessity requirements. In some cases, patients should have been treated using less intensive residential-level treatment, and, in other cases, patients' medical records lacked documentation to support the need for hospital-level detox treatment. As part of the settlement, Eagleview entered into a five-year CIA with HHS-OIG. ¹¹	\$2.85 million

7 <https://www.justice.gov/opa/pr/rialto-capital-management-and-current-owner-indiana-hospital-pay-36-million-resolve-false>.

8 <https://www.justice.gov/usao-edpa/pr/penn-medicine-agrees-pay-275000-settle-false-claims-act-allegations>.

9 <https://www.justice.gov/usao-md/pr/anne-arundel-medical-center-pay-more-3-million-settle-federal-false-claims-act>.

10 <https://www.justice.gov/usao-wdpa/pr/millcreek-community-hospital-will-pay-2451000-settle-claims-medically-unnecessary>.

11 <https://www.justice.gov/usao-edpa/pr/eagleview-hospital-pays-285-million-resolve-allegations-improper-billing-detox>.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/19/2019	Vaughan Regional Medical Center; Integrity Emergency Care, Inc. (IEC); Dr. Phillip Alan Hicks; Dr. Sai S. Namburu	Hospital, two ER physicians, and IEC, a physician staffing company owned by Dr. Hicks, agreed to pay \$1.45 million to resolve FCA allegations that they submitted claims to Medicare for outpatient hospital services performed outside the course and scope of inadequately licensed residents' residency program. In addition to the hospital submitting claims as if licensed physicians had provided the services, the government alleged the two physicians falsified medical records to make it appear as if licensed physicians had performed the services and received \$50 per hour to co-sign residents' charts. ¹²	\$1.45 million
9/26/2019	Biomedical Research Foundation of Northwest Louisiana; Board of Supervisors of Louisiana State University and Agricultural and Mechanical College; various companies related to Biomedical Research Foundation	Hospital owner/operators agreed to pay \$531,241.74 to resolve allegations that they violated the FCA and other laws by submitting claims for Medicare payment for procedures involving implantable automatic defibrillators despite failing to report requisite data to a qualified registry. ¹³	\$531,241
10/28/2019	Sanford Health; Sanford Medical Center; Sanford Clinic	Health system agreed to pay \$20.25 million to resolve FCA allegations that claims submitted by hospital to federal healthcare programs were false as a result of alleged violations of the AKS stemming from neurosurgeon's use of medical devices distributed through his medical device company and as a result of neurosurgeon performing alleged medically unnecessary services. As part of the settlement, defendants entered into a five-year CIA with HHS-OIG. ¹⁴	\$20.25 million
10/29/2019	Encompass Health Corporation f/k/a HealthSouth Corporation	Healthcare system agreed to pay \$4 million to resolve FCA allegations that one of its IRFs submitted claims to Medicare based on inaccurate and artificially low patient functionality assessments in order to obtain higher reimbursement than was warranted. ¹⁵	\$4 million
11/8/2019	Lenox Hill Hospital; Northwell Health, Inc.	Healthcare system and one of its hospitals agreed to pay \$12.3 million to resolve FCA allegations involving claims submitted to Medicare for: (1) endoscopic procedures performed, at least partially, by insufficiently supervised medical residents; (2) robotic surgeries where patients were left unattended to permit the attending physician to perform two surgeries simultaneously; (3) medically unnecessary operating room services for minor diagnostic procedures; and (4) designated health services referred to the hospital pursuant to an improper compensation arrangement with a physician, in violation of the Stark Law. ¹⁶	\$12.3 million

¹² <https://www.justice.gov/usao-sdal/pr/qui-tam-lawsuit-and-federal-investigation-result-145-million-settlement-vaughan>.

¹³ <https://www.justice.gov/usao-wdla/pr/qui-tam-lawsuit-and-federal-investigation-results-half-million-dollar-settlement>.

¹⁴ <https://www.justice.gov/opa/pr/sanford-health-entities-pay-2025-million-settle-false-claims-act-allegations-regarding>.

¹⁵ <https://www.justice.gov/usao-nv/pr/encompass-health-corporation-agrees-pay-4-million-resolve-allegations-improperly-billing>.

¹⁶ <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-123-million-settlement-lenox-hill-hospital-submitting>.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/13/2019	Vibra Healthcare, LLC; Vibra Healthcare II, LLC; Vibra Rehab Holdings, LP; Vibra Rehabilitation Hospital of El Paso, LLC d/b/a Highlands Rehabilitation Hospital; Vibra IRFM Company, LLC	Long-term care and acute rehabilitation hospital system agreed to pay \$6.25 million to resolve FCA allegations that it knowingly submitted claims to Medicare that failed to satisfy payment requirements for IRFs related to the intensity level of services provided, including the requirement that the patient be examined by a qualified physician at least three times per week throughout a patient's stay. ¹⁷	\$6.25 million
11/15/2019	Sutter Health; Sutter Memorial Center Sacramento; Sacramento Cardiovascular Surgeons Medical Group Inc. (Sac Cardio)	In a series of settlements, a health system, several of its affiliated hospitals, and a group of three cardiovascular surgeons agreed to pay \$46,123,516 to resolve FCA allegations involving the submission of claims to Medicare for services provided in violation of the Stark Law. One hospital agreed to pay \$30.5 million to resolve allegations that its compensation arrangements with Sac Cardio, a referral source, exceeded the FMV of the services provided. These improper compensation arrangements were also the basis of Sac Cardio's \$506,000 settlement, which involved allegations that Sac Cardio submitted duplicative bills to Medicare for the services of physician assistants that the group leased to the hospital through the compensation arrangements. The health system also agreed to pay \$15,117,516 for various self-disclosed Stark violations, including: (1) compensating physicians in excess of FMV under personal services arrangements; (2) leasing office space at below-market rates; and (3) reimbursing physicians for recruiting expenses in excess of the expenses incurred. The health system's \$15.1 million settlement also resolved allegations that several of its Ambulatory Surgery Centers (ASCs) double billed Medicare for services Medicare separately paid another entity for performing. ¹⁸	\$46.123 million
11/20/2019	Jewish Hospital & St. Mary's Healthcare Inc. d/b/a Pharmacy Plus and Pharmacy Plus Specialty	Hospital agreed to pay \$10,101,132 to resolve FCA allegations involving the submission of prescription drug claims to Medicare that failed to meet coverage requirements and that were based on improper remuneration to Medicare beneficiaries in violation of the AKS. The alleged improper remuneration included free blood glucose testing supplies and waiver of co-payments and deductibles for insulin. ¹⁹	\$10.101 million

¹⁷ <https://www.justice.gov/usao-wdtx/pr/justice-department-reaches-settlement-agreement-vibra-healthcare-and-el-paso>.

¹⁸ <https://www.justice.gov/opa/pr/california-health-system-and-surgical-group-agree-settle-claims-arising-improper-compensation>.

¹⁹ <https://www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations>.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/26/2019	Accurate Home Care, LLC	Home health provider agreed to pay \$726,957.59 to resolve self-disclosed FCA allegations that it submitted claims for the same services to both Minnesota Medicaid and private insurers and retained full payments from Minnesota Medicaid, even when Medicaid was not the primary insurer. ²⁰	\$726,957
4/30/2019	Amigos Homecare, LLC of Lawrence	Home health provider agreed to pay \$2.13 million to resolve allegations that it billed Massachusetts Medicaid (MassHealth) for unauthorized home health services, including claims that lacked the requisite physician-signed plan of care and claims submitted on behalf of hospitalized patients who were not receiving home health services. In order to continue to participate in MassHealth, Amigos is required to implement a multi-year, independent compliance program through an independent compliance monitor. ²¹	\$2.13 million
4/30/2019	Avenue Homecare Services, Inc. of Dracut	Home health provider agreed to pay \$8,305,300 to resolve allegations that it billed Massachusetts Medicaid (MassHealth) for unauthorized home health services, including claims that lacked the requisite physician-signed plan of care and claims submitted on behalf of hospitalized patients who were not receiving home health services. In order to continue to participate in MassHealth, Avenue is required to implement a multi-year, independent compliance program through an independent compliance monitor. ²²	\$8.305 million
6/7/2019	Nurse on Call	Home health provider agreed to pay an undisclosed amount to the federal government to resolve FCA allegations that it submitted claims to Medicare that were tainted by improper compensation arrangements and referral relationships, in violation of the AKS and Stark Law. The alleged improper financial relationships included: (1) a sham medical director agreement, compensating the physician for little, if any, work in order to induce patient referrals; (2) payments to referring physicians' spouses; and (3) employee compensation that accounted for the volume of physician-spouse referrals. In addition, the home health provider submitted claims to Medicare based on plans of care approved by a medical director who never evaluated the patient face-to-face. Because both cases involved a party in bankruptcy, the final settlement agreement is subject to potential bankruptcy proceedings. ²³	Undisclosed

²⁰ <https://www.justice.gov/usao-mn/pr/otsego-home-health-care-company-pay-more-700000-resolve-false-claims-act-liability>.

²¹ <https://www.mass.gov/news/ag-healey-announces-10-million-in-recoveries-from-home-health-care-companies-for-falsely>.

²² <https://www.mass.gov/news/ag-healey-announces-10-million-in-recoveries-from-home-health-care-companies-for-falsely>.

²³ <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-cases-against-home-health-agency>.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/15/2019	Guardian Healthcare, LLC	Home health provider agreed to pay \$1.95 million to resolve allegations that it billed Massachusetts Medicaid for home health services that lacked appropriate physician authorization of medical necessity. Allegations included both the failure to obtain and the failure to maintain physician-signed plans of care. In addition to the settlement, Guardian agreed to implement a multi-year, independent compliance program. ²⁴	\$1.95 million
9/9/2019	Capital Caring	Hospice and palliative care provider agreed to pay \$3.1 million to resolve FCA allegations that it billed Medicare for hospice services for patients who failed to meet hospice eligibility requirements or whose medical records failed to evidence the need for hospice care. ²⁵	\$3.1 million
11/5/2019	Health Care Options, Inc.; Health Care Options of Lafayette, Inc.; Home Care Options Houston, Inc.; Howard D. Austin, II	Home health providers agreed to pay \$2.5 million to resolve FCA allegations that they submitted claims to Medicare and Louisiana Medicaid that lacked requisite physician-patient face-to-face encounters. ²⁶	\$2.5 million

²⁴ <https://www.mass.gov/news/boston-home-health-company-to-pay-195-million-to-resolve-allegations-of-billing-medicare-for>.

²⁵ <https://www.justice.gov/usao-edva/pr/capital-caring-pays-31-million-resolve-medicare-billing-claims>.

²⁶ <https://www.justice.gov/usao-mdla/pr/home-health-companies-pay-25-million-settle-federal-false-claims-act-lawsuit>.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/9/2019	Conway Lakes NC, LLC; Matthew File; Clear Choice Health Care, LLC; Jeffrey Cleveland; Geoffrey Fraser; Kenneth Krumins, M.D.	SNF, its former administrator, its management company, and several management company executives agreed to pay \$1 million, and SNF's orthopedic surgeon medical director agreed to pay \$500,000, to resolve FCA allegations that they engaged in an illicit kickback scheme to pay sham medical director payments to the physician to induce referrals of Medicare and Tricare patients to the SNF for rehabilitation services, in violation of the AKS and Stark Law. The physician's settlement also resolved allegations that he engaged in a similar kickback scheme with a related home health agency. ²⁷	\$1.5 million
2/5/2019	Tennessee Health Management, Inc. (THM)	SNF management company agreed to pay \$9,764,107.98 to resolve FCA allegations that it submitted claims to Tennessee Medicaid with pre-admission evaluations that lacked appropriate physician signatures and instead contained photocopied or pre-signed physician signatures. As part of the settlement, THM entered into a five-year CIA with HHS-OIG. ²⁸	\$9.764 million
2/27/2019	Vanguard Healthcare LLC; various affiliated companies; William Orand; Mark Miller	Holding company of a SNF chain and several affiliated companies agreed to pay \$18.6 million, and their majority owner and CEO and former director of operations agreed to pay \$250,000, to resolve state and federal FCA allegations that they caused five Vanguard SNF facilities to improperly bill Medicare and Medicaid for worthless nursing home services. The allegations included the failure to: (1) properly administer prescribed medications; (2) provide standard infection control and wound care; (3) initiate measures to prevent pressure ulcers; (4) properly use physical restraints; and (5) meet basic nutrition and hygiene requirements. The settlement also resolved allegations that Vanguard submitted hundreds of pre-admission forms with forged nurse or physician signatures. As part of the settlement, Vanguard entered into a chain-wide five-year CIA with HHS-OIG. Although bankruptcy proceedings involving the Vanguard entities may reduce ultimate recoveries, this settlement was the largest worthless services resolution in Tennessee history. ²⁹	\$18.85 million
6/11/2019	The Carlton at the Lake Inc.; Ridgeview Rehab and Nursing Center; Lake Shore Healthcare and Rehabilitation Centre LLC; Balmoral Home Inc.	Four SNFs agreed to pay a total of \$8.53 million to resolve FCA allegations that they submitted claims to Medicare for unnecessary services and upcoded Resource Utilization Group (RUG) scores to maximize Medicare reimbursement. The government also settled with physical therapy provider, Quality Therapy & Consultation Inc., and its owner for their role in the allegations. ³⁰	\$8.53 million

²⁷ <https://www.justice.gov/usao-mdfl/pr/orlando-skilled-nursing-facility-physician-and-related-providers-agree-pay-15-million>.

²⁸ <https://www.justice.gov/usao-mdtn/pr/skilled-nursing-facility-management-company-agrees-settle-false-claims-act-allegations>.

²⁹ <https://www.justice.gov/opa/pr/vanguard-healthcare-agrees-resolve-federal-and-state-false-claims-act-liability>.

³⁰ <https://www.justice.gov/usao-ndil/pr/chicago-area-physical-therapy-center-and-4-nursing-facilities-pay-97-million-resolve>.

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/28/2019	Encompass Health Corporation f/k/a HealthSouth Corporation	Encompass, the nation's largest operator of IRFs, agreed to pay \$48 million to resolve FCA allegations that: (1) some of its facilities submitted inaccurate information to Medicare to maintain IRF status and earn a higher rate of reimbursement; and (2) billed Medicare for medically unnecessary admissions. To ensure compliance with Medicare IRF requirements, Encompass allegedly falsely diagnosed patients with conditions unsupported by clinical evidence and admitted patients who were ineligible for treatment in an IRF. ³¹	\$48 million

31 <https://www.justice.gov/opa/pr/encompass-health-agrees-pay-48-million-resolve-false-claims-act-allegations-relating-its>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/10/2019	Teva Pharmaceuticals USA Inc.	Drug manufacturer agreed to pay \$135 million to the state of Illinois to resolve FCA allegations that it inflated drug prices used to set Medicaid reimbursement rates. The settlement stems from a 2005 lawsuit filed by the state of Illinois alleging that 47 drug makers fraudulently published inflated AWP's, resulting in increased drug costs and overpayments by the state. ³²	\$135 million
2/22/2019	Lehigh Valley Technologies, Inc.	Pharmaceutical company agreed to pay \$4 million to resolve allegations that it violated the FCA by agreeing to pay two companies to submit new drug applications for a drug it had developed and for which it had previously received a fee waiver. The company allegedly conspired to pay two other companies for their submissions of new drug applications if these companies received the desired fee waiver related to their own drug because Lehigh Valley was ineligible to receive another fee waiver. ³³	\$4 million
3/4/2019	Novartis	Pharmaceutical company agreed to pay \$23 million to resolve FCA allegations that it donated money to a patient-assistance charity, which then used the money to cover the cost of beneficiary co-payments exclusively for Novartis's drugs. ³⁴	\$23 million
3/7/2019	Med Tech, LLC; Thomas Macre, Sr.	Medical equipment supplier and its owner agreed to pay \$467,090 to resolve federal and state FCA allegations that it billed Connecticut Medicaid for back braces and electrical stimulation equipment that was either never provided or was not medically necessary. ³⁵	\$467,090
3/11/2019	Covidien LP	Device manufacturer agreed to pay \$17,477,947 to resolve allegations that it violated the FCA by providing practice development and market development support to healthcare providers in an effort to get those providers to purchase its radiofrequency ablation catheters. Specifically, the government alleged the company: (1) provided customized marketing plans; (2) scheduled and conducted "lunch and learn" meetings and dinners with physicians; and (3) provided substantial assistance with planning, promoting, and conducting vein screening events, all in order to cultivate new patients for its products and induce referrals. ³⁶	\$17.477 million

32 http://illinoisattorneygeneral.gov/pressroom/2019_01/20190110.html.

33 <https://www.justice.gov/usao-edpa/pr/lehigh-valley-technologies-inc-pay-4-million-resolve-false-claims-act-liability-schem-0>.

34 <https://www.beckershospitalreview.com/pharmacy/novartis-to-pay-23m-to-settle-claims-it-used-charity-payments-as-kickbacks.html>.

35 <https://www.justice.gov/usao-ct/pr/connecticut-medical-equipment-supplier-pays-467k-settle-allegations-under-false-claims>.

36 <https://www.justice.gov/opa/pr/covidien-pay-over-17-million-united-states-allegedly-providing-illegal-remuneration-form>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/4/2019	Jazz Pharmaceuticals plc	Pharmaceutical company agreed to pay \$57 million to resolve allegations that it violated the FCA by paying kickbacks to patients through a purportedly independent charitable foundation. Jazz allegedly donated millions of dollars to a foundation's fund intended to cover co-payments for Medicare beneficiaries taking any narcolepsy or chronic pain drug, but that in practice, the funds were used exclusively to cover the co-payments of patients taking the company's own drugs. The government also alleged that Jazz raised the price of its narcolepsy drug over 24 times the rate of overall inflation during the period of the alleged misconduct. As part of the settlement, the pharmaceutical company entered into a five-year CIA with HHS-OIG. ³⁷	\$57 million
4/4/2019	Lundbeck LLC	Pharmaceutical company agreed to pay \$52.6 million to resolve allegations that it violated the FCA by paying kickbacks to patients through a purportedly independent charitable foundation. Lundbeck allegedly donated millions of dollars to a foundation's fund intended to cover co-payments for patients with Huntington's Disease, but in practice, the funds covered co-payments for any patient taking the company's own drug, regardless of the patient's diagnosis. The government also alleged that the company raised the price of its drug over 22 times the rate of overall inflation during the period of the alleged misconduct. As part of the settlement, the pharmaceutical company entered into a five-year CIA with HHS-OIG. ³⁸	\$52.6 million
4/4/2019	Alexion Pharmaceuticals, Inc.	Pharmaceutical company agreed to pay \$13 million to resolve allegations under the FCA that it worked with a foundation to create a Complement-Mediated Disease fund for which it was the sole donor, and that, in practice, the fund made financial assistance to beneficiaries contingent on taking the pharmaceutical company's own drug. HHS-OIG chose not to require a CIA as part of the settlement due to the fundamental organizational changes the company made following its alleged misconduct, such as hiring a new executive leadership team, changing half of its board of directors, and relocating 40% of its employees to its headquarters. ³⁹	\$13 million
4/25/2019	Astellas Pharma US, Inc.	Pharmaceutical company agreed to pay \$100 million to resolve allegations that it violated the FCA by working with two nonprofit foundations to provide funds that covered beneficiary co-payments for metastatic castration resistant prostate cancer drugs, then put restrictions on the funds such that almost all of the funds went to cover only the company's own drug. As part of the settlement, the pharmaceutical company entered into a five-year CIA with HHS-OIG. ⁴⁰	\$100 million

37 <https://www.justice.gov/usao-ma/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they>.

38 <https://www.justice.gov/usao-ma/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they>.

39 <https://www.justice.gov/usao-ma/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they>.

40 <https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/25/2019	Amgen, Inc. f/k/a Onyx Pharmaceuticals Inc.	Pharmaceutical company agreed to pay \$24.75 million to resolve FCA allegations that it set up a fund through a foundation with the intention that the fund would only cover Medicare patients' co-payments for its own drug. The company raised the price of its drug over four times the rate of overall inflation during the period the fund covered the drug. The settlement also resolved allegations that the company's predecessor set up a fund through a different foundation intended to cover healthcare-related travel expenses for patients taking any multiple myeloma drug, but that in practice, made financial assistance to beneficiaries contingent on taking the company's own drug. As part of the settlement, the pharmaceutical company entered into a five-year CIA with HHS-OIG. ⁴¹	\$24.75 million
4/30/2019	US WorldMeds LLC	Pharmaceutical company agreed to pay \$17.5 million to resolve FCA allegations that it set up a fund through a foundation with the intention that the fund would only cover Medicare patients' co-payments for its own drug. The settlement also resolved allegations that the company compensated two physicians with entertainment, speaking, and consulting fees to induce prescriptions, in violation of the AKS. As part of the settlement, the pharmaceutical company entered into a five-year CIA with HHS-OIG. ⁴²	\$17.5 million
5/13/2019	CareFusion Corporation	Medical device distributor agreed to pay \$3.3 million to resolve FCA allegations that it sold devices that were not yet cleared by the FDA and for which the "pre-amendment" exception for devices legally in commerce prior to 1976 did not apply. ⁴³	\$3.3 million
5/29/2019	Almirall, LLC f/k/a Aqua Pharmaceuticals, LLC	Pharmaceutical company agreed to pay \$3.5 million to resolve FCA allegations that it provided dermatology providers meals, trips, entertainment, and other forms of compensation, as well as providing speaking and consulting opportunities in an attempt to induce the physicians to prescribe their drugs. ⁴⁴	\$3.5 million
5/31/2019	Heritage Pharmaceuticals, Inc.	Drug manufacturer agreed to pay more than \$7 million to resolve FCA allegations that it participated in a scheme to inflate and fix prices for a number of generic drugs in return for remuneration from other drug manufacturers. The drug manufacturer separately entered into a three-year deferred prosecution agreement with the DOJ Antitrust division related to criminal charges under the Sherman Act. ⁴⁵	\$7 million+

⁴¹ <https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid>.

⁴² <https://www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients>.

⁴³ <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-medical-device-distributor>.

⁴⁴ <https://www.justice.gov/usao-edpa/pr/pharmaceutical-company-pay-35m-resolve-allegations-paying-kickbacks-doctors>.

⁴⁵ <https://www.justice.gov/usao-edpa/pr/heritage-pharmaceuticals-pays-over-7-million-resolve-civil-false-claims-act-allegations>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/5/2019	Insys Therapeutics, Inc.	Opioid manufacturer agreed to pay \$225 million to globally resolve criminal charges and civil FCA allegations. The settlement resolves allegations that Insys paid illegal kickbacks to practitioners in the form of sham speaker program fees, jobs for prescribers' relatives and friends, and lavish meals and entertainment, in order to induce prescriptions of its drug, Subsys. The settlement also resolved allegations that the company improperly encouraged physicians to prescribe its drug for inappropriate patients and falsify diagnoses in order to obtain reimbursement from Medicare and Tricare. As part of the criminal resolution, Insys entered into a deferred prosecution agreement and its operating subsidiary will plead guilty to five counts of mail fraud. As part of the settlement, Insys entered into a five-year CIA and Conditional Exclusion Release agreement with HHS-OIG. HHS-OIG elected not to pursue exclusion of Insys at the time of the settlement due to the company's extensive ongoing cooperation in the prosecution of culpable individuals. ⁴⁶	<p>\$195 million (civil)</p> <p>\$30 million (criminal)</p>
6/11/2019	ACell, Inc.	Medical device manufacturer agreed to pay \$15 million to resolve FCA allegations that: (1) its sales representatives made claims regarding the safety and effectiveness of its wound dressing product, which were unsupported by clinical data; (2) the company provided incorrect coding information for its devices, resulting in over-reimbursements from Medicare; and (3) the company paid kickbacks in the form of entertainment, payments and free products for physicians in an attempt to increase the number of prescriptions for its products. As part of the settlement, the company entered into a five-year CIA with HHS-OIG and pleaded guilty to related criminal charges. ⁴⁷	\$15 million
9/13/2019	Avalign Technologies, Inc.; Instrumed International, Inc.	Medical device manufacturer and its subsidiary agreed to pay \$9.5 million to resolve FCA allegations that it sold devices that were not yet cleared by the FDA and for which the "pre-amendment" exception for devices legally in commerce prior to 1976 did not apply. ⁴⁸	\$9.5 million
10/25/2019	Chronic Disease Fund, Inc. d/b/a Good Days from CDF (CDF)	Nonprofit foundation agreed to pay \$2 million to resolve allegations that it violated the FCA by operating funds that enabled various pharmaceutical companies to pay kickbacks to patients taking their drugs in the form of co-payment waivers. As part of the settlement, CDF entered a three-year integrity agreement (IA) with HHS-OIG. ⁴⁹	\$2 million

⁴⁶ <https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal>.

⁴⁷ <https://www.justice.gov/usao-md/pr/medical-device-maker-acell-inc-pleads-guilty-and-will-pay-15-million-resolve-criminal>.

⁴⁸ <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-claims-against-medical-device-manufacturer>.

⁴⁹ <https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/25/2019	Patient Access Network Foundation (PANF)	Nonprofit foundation agreed to pay \$4 million to resolve allegations that it violated the FCA by operating funds that enabled various pharmaceutical companies to pay kickbacks to patients taking their drugs in the form of co-payment waivers. As part of the settlement, PANF entered a three-year IA with HHS-OIG. ⁵⁰	\$4 million
10/28/2019	Abbott Laboratories, Inc.; Aventis Pharmaceuticals Inc.; Aventis Behring LLC n/k/a ZLB Behring; B. Braun Medical Inc.; Forest Laboratories, Inc.; GlaxoSmithKline LLC; Johnson & Johnson, Inc.; Janssen Pharmaceutical Products, LP; McNeil-PPC, Inc.; Orth Biotech Products, LP; Orth-McNeil Pharmaceutical, Inc.; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Pharmacia Corporation; TAP Pharmaceutical Products, Inc.	Drug manufacturers agreed to pay a collective total of \$242 million to the state of Illinois in relation to a 2005 lawsuit filed by the state of Illinois alleging that they inflated their reported AWP in violation of the FCA, resulting in increased drug costs and overpayments by the state. ⁵¹	\$242 million
11/7/2019	Fagron Holding USA LLC	Compounding ingredient supplier agreed to pay \$22.05 million to resolve FCA allegations that its subsidiary, Freedom Pharmaceutical Inc., reported false and inflated AWP for active pharmaceutical ingredients used in compound prescriptions. The government alleged Freedom promoted the high AWP and the resulting profit potential from the reimbursement of compound prescriptions as an inducement to pharmacies to purchase its ingredients, resulting in false claims to Tricare. The settlement also resolved allegations that a second pharmacy subsidiary: (1) submitted fraudulent compound prescription claims to federal healthcare programs; (2) used sham insurance programs to manipulate pricing; (3) paid kickbacks to physicians for bogus consulting agreements; and (4) illegally waived co-payments, as well as allegations that a third subsidiary set an inflated AWP for its drug, Gabapentin. ⁵²	\$22.05 million

⁵⁰ <https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare>.

⁵¹ http://www.illinoisattorneygeneral.gov/pressroom/2019_10/20191028.html.

⁵² <https://www.justice.gov/opa/pr/compound-ingredient-supplier-fagron-holding-usa-llc-pay-2205-million-resolve-allegations>.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/7/2019	Life Spine Inc.; Michael Butler; Richard Greiber	Device manufacturer agreed to pay \$5.5 million, company president agreed to pay \$375,000, and CEO agreed to pay \$115,000 to resolve FCA allegations that Life Spine entered into a variety of illicit agreements to increase usage of its products. Specifically, the government alleged that Life Spine recruited surgeons who had the potential to use a high volume of its product and entered into sham consulting agreements and/or agreements to buy out the surgeons' patents in exchange for purported support from the company and royalty payments, but the agreements were all ultimately tied to the surgeons' use of Life Spine's product. ⁵³	\$5.99 million
11/20/2019	The Assistance Foundation (TAF)	Nonprofit foundation agreed to pay \$4 million to resolve FCA allegations that it conspired with three drug manufacturers to function as a conduit to pass kickbacks on to patients taking their multiple sclerosis drugs under the guise of receiving funds from a charity. As part of the settlement, TAF entered into a three-year IA with HHS-OIG. ⁵⁴	\$4 million
12/3/2019	Rising Pharmaceuticals Inc.	Pharmaceutical company agreed to pay \$1.1 million to resolve FCA allegations that it paid and received remuneration in exchange for arrangements with another pharmaceutical company regarding price, supply, and customer allocation of certain generic drugs. The civil settlement is accompanied by a deferred prosecution agreement in a related criminal case against the company. ⁵⁵	\$1.1 million

53 <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-settlement-lawsuit-against-spinal-implant-company-its>.

54 <https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay-kickbacks>.

55 <https://www.justice.gov/usao-edpa/pr/second-nj-based-pharmaceutical-company-admits-price-fixing-resolves-related-false>.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/22/2019	Walgreens Boots Alliance, Inc. (Walgreens)	Pharmaceutical company agreed to pay a total of \$269.2 million to resolve FCA allegations arising from two separate lawsuits. Walgreens agreed to pay \$209.2 million to resolve allegations that it improperly billed Medicare, Medicaid, and other federal healthcare programs for hundreds of thousands of insulin pens it knowingly dispensed to program beneficiaries who did not need them. Walgreens separately agreed to pay \$60 million to resolve allegations that it overbilled Medicaid by failing to disclose to and charge Medicaid the lower prices that Walgreens offered the public through a discount program. In connection with these settlements, Walgreens entered into a five-year CIA with HHS-OIG. ⁵⁶	\$269.2 million
1/23/2019	Walgreen Co.	Pharmaceutical company agreed to pay \$3.5 million to resolve FCA allegations that its pharmacies dispensed stimulant medications to Wisconsin Medicaid beneficiaries without verifying that the medications were prescribed for medically appropriate treatment. ⁵⁷	\$3.5 million
2/4/2019	Pentec Health, Inc.	Provider of pharmacy compounding services agreed to pay \$17 million to resolve FCA allegations that it: (1) billed federal healthcare programs for excessive amounts of product wasted during the compounding of its drug, Proplete; (2) waived co-payments and deductibles to induce prescription and use of Proplete; and (3) submitted improperly coded or duplicate claims to FEHBP. As part of the settlement, the company entered into a five-year CIA with HHS-OIG. ⁵⁸	\$17 million
2/14/2019	Vital Life Institute LLC f/k/a AgeVital Pharmacy LLC; Jenny Wilkins; William Wilkins	Compounding pharmacy and its owners agreed to pay \$775,000 to resolve FCA allegations that they paid kickbacks to a third-party marketing company to solicit prospective patients for compounded drug prescriptions regardless of patient need. ⁵⁹	\$775,000
6/12/2019	Lake Country Pharmacy and Compounding Center; Chris Vaughan; Carey Vaughan	Compounding pharmacy and its two principals agreed to pay \$365,000 to resolve FCA allegations that they improperly billed Medicaid, Medicare, and Tricare for compounded medicines made from reimbursable tablets, when in reality they were made with non-reimbursable powders. As part of the settlement, the compounding pharmacy entered into a three-year CIA with HHS-OIG. ⁶⁰	\$365,000
7/23/2019	Darshan Bapa Inc. d/b/a E-Z Pharmacy II; Natverbhai Patel	Pharmacy owners agreed to pay \$400,000 to resolve allegations that they violated Medicare by submitting claims for prescription medicines that were never actually dispensed. ⁶¹	\$400,000

56 <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-2692-million-recovery-walgreens-two-civil-healthcare>.

57 <https://www.justice.gov/usao-edwi/pr/walgreen-co-agrees-pay-35-million-settle-allegations-under-false-claims-act>.

58 <https://www.justice.gov/usao-edpa/pr/pentec-health-inc-pay-17-million-settle-false-claims-act-allegations>.

59 <https://www.justice.gov/opa/pr/florida-compounding-pharmacy-and-its-owners-pay-least-775000-resolve-false-claims-act>.

60 <https://www.justice.gov/usao-mdga/pr/middle-georgia-compounding-pharmacy-agrees-pay-365000-resolve-fraud-claims>.

61 <https://www.justice.gov/usao-edpa/pr/philadelphia-based-pharmacy-owners-agree-pay-400000-resolve-false-claims-act-liability>.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/18/2019	Diabetic Care Rx LLC a/k/a Patient Care America (PCA); Riordan, Lewis & Haden Inc. (RLH); Patrick Smith; Mathew Smith	Compounding pharmacy PCA and private equity firm RLH agreed to pay \$21.05 million, PCA's CEO agreed to pay \$300,000, and PCA's former VPO agreed to pay \$12,788 to resolve FCA allegations related to their respective involvement in an alleged kickback scheme wherein PCA paid marketers to generate referrals of prescriptions for expensive pain creams, scar creams, and vitamins, regardless of patient need. The prescriptions were then reimbursed by Tricare. ⁶²	\$21.362 million
9/25/2019	Dhanyabapa LLC d/b/a E-Z Pharmacy; Shardaben Patel	Pharmacy owners agreed to pay \$1.1 million to resolve allegations that they violated the FCA by billing Medicare for multiple prescription medications that were never dispensed to beneficiaries. As part of the settlement, defendants are excluded from federal healthcare programs for 10 years. ⁶³	\$1.1 million
11/15/2019	Midwest Compounders, Inc.; Troy DeLong	Compounding pharmacy and its owner agreed to pay \$205,000 to resolve FCA allegations that it submitted claims to Tricare for medications that were the result of illegal kickback arrangements between the pharmacy and the prescribers and medications that had redundant active ingredients or that were not prescribed in medically necessary dosages. ⁶⁴	\$205,000

⁶² <https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million>.

⁶³ <https://www.justice.gov/usao-edpa/pr/pharmacy-owners-agree-pay-11-million-and-abide-10-year-federal-healthcare-exclusion>.

⁶⁴ <https://www.justice.gov/usao-ndia/pr/compounding-pharmacy-and-its-owner-pay-more-200000-resolve-false-claims-act-allegations>.

LABORATORY, PATHOLOGY, RADIOLOGY, AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/30/2019	Inform Diagnostics f/k/a Miraca Life Sciences Inc.	Pathology laboratory agreed to pay \$63.5 million to resolve FCA allegations that it violated the AKS and Stark Law by providing physicians with subsidies for EHR systems and free or discounted technology consulting services in exchange for patient referrals. ⁶⁵	\$63.5 million
2/11/2019	GenomeDx Biosciences Corp.	Genetic testing laboratory agreed to pay \$1.99 million to resolve FCA allegations that it billed Medicare for medically unnecessary genetic tests for prostate cancer patients. ⁶⁶	\$1.99 million
6/27/2019	Clinical Science Laboratory, Inc.; Stanley Elfbaum; Louis Amoruso	Laboratory testing provider and its owners agreed to pay \$1,508,106 to resolve federal and state FCA allegations that they billed Connecticut Medicaid for urine drug testing services at higher rates than they billed third parties for the same services. ⁶⁷	\$1.508 million
9/25/2019	MobilexUSA a/k/a Trident USA Health Services, LLC (Trident)	Mobile diagnostic services provider agreed to pay \$8.5 million to resolve FCA allegations that it engaged in a kickback scheme with SNFs to provide x-ray services at prices below FMV in exchange for patient referrals. Trident declared bankruptcy in February 2019. ⁶⁸	\$8.5 million
10/9/2019	UTC Laboratories, Inc. (RenRX); Tarun Jolly, M.D.; Patrick Ridgeway; Barry Griffith	Genetic testing laboratory agreed to pay \$41.6 million, and its three principals agreed to pay \$1 million, to resolve allegations that they violated the FCA by: (1) paying kickbacks to physicians in exchange for laboratory referrals for pharmacogenetic testing; and (2) furnishing and billing tests that were not medically necessary. As part of the settlement, RenRX is excluded from federal healthcare program participation for 25 years. ⁶⁹	\$42.6 million
11/19/2019	LabTox, LLC	Clinical laboratory agreed to pay \$2,101,335 to resolve FCA allegations that it billed Medicare and Kentucky Medicaid for higher complexity urine drug testing than was actually performed and improperly billed specimen validity testing separately from other tests in contravention of explicit Medicare guidance. As part of the settlement, LabTox entered into a three-year IA with HHS-OIG. ⁷⁰	\$2.101 million

65 <https://www.justice.gov/opa/pr/pathology-laboratory-agrees-pay-635-million-providing-illegal-inducements-referring>.

66 <https://www.justice.gov/opa/pr/genetic-testing-company-agrees-pay-199-million-resolve-allegations-false-claims-medicare>.

67 <https://www.justice.gov/usao-ct/pr/massachusetts-laboratory-and-its-owners-pay-over-15-million-settle-false-claims-act>.

68 <https://www.justice.gov/usao-edpa/pr/trident-usa-health-services-llc-pay-85-million-resolve-false-claims-act-liability>.

69 <https://www.justice.gov/usao-edla/pr/genetic-testing-company-and-three-principals-agree-pay-426-million-resolve-kickback-and>.

70 <https://www.justice.gov/usao-edky/pr/lexington-laboratory-agrees-pay-21-million-resolve-allegations-false-claims-urine-drug>.

LABORATORY, PATHOLOGY, RADIOLOGY, AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/26/2019	Boston Heart Diagnostics Corporation	Laboratory agreed to pay \$26.67 million to resolve FCA allegations that, in violation of the Stark Law and AKS, it: (1) conspired with third parties to pay physicians kickbacks disguised as investment returns from management services organizations in exchange for patient referrals; and (2) paid processing and handling fees, waived patient co-payments and deductibles, and provided physician practices with in-office dietitians in exchange for referrals for laboratory testing. The settlement also resolved allegations that Boston Heart conspired with hospitals to submit claims for outpatient laboratory testing for individuals who were not actually outpatient. ⁷¹	\$26.67 million

⁷¹ <https://www.justice.gov/opa/pr/laboratory-pay-2667-million-settle-false-claims-act-allegations-illegal-inducements-referring>.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/17/2019	Davis Group, LLC d/b/a Caring Family Solutions; Lamaara Davis	Behavioral health group and its owner agreed to pay \$100,000 to resolve FCA allegations that they submitted claims to Connecticut Medicaid for psychotherapy services that were provided by unlicensed individuals, services that were never provided, and services that did not qualify as psychotherapy services. As part of the settlement, the defendants are excluded from the Connecticut Medicaid program for 10 years. ⁷²	\$100,000
2/6/2019	Families United Services, Inc.; Pamela McKenzie	Behavioral health services provider and its owner agreed to pay \$645,000 to resolve FCA allegations that they billed Georgia Medicaid for behavioral healthcare services that were never provided. As part of the settlement, the defendants are excluded from federal healthcare programs for five years. ⁷³	\$645,000
3/15/2019	Connecticut Behavioral Health Associates, P.C.; Bassam Awwa, M.D.	Behavioral health and addiction clinic and its psychiatrist owner agreed to pay \$3,382,004 to resolve state and federal FCA allegations that they billed Medicare for multiple units of urine drug screening tests when they should have known only one unit of service per patient encounter could be billed and billed separately for certain tests that they should have known were encompassed in other tests that they billed. The settlement also resolved allegations that the defendants billed Medicaid for quantitative urine drug tests that were not performed and for improper specimen validity testing of urine samples. As part of the settlement, the defendants entered into a three-year billing IA with HHS-OIG. ⁷⁴	\$3.382 million
3/29/2019	Acacia Mental Health Clinic, LLC; Abraham Freund; Isaac Freund	Mental health and drug dependency clinic and its owner, Abraham Freund, agreed to pay \$4.1 million to resolve FCA allegations that they billed Wisconsin Medicaid for: (1) more complex urine drug tests than were actually performed; (2) medically unnecessary and duplicative urine drug tests; and (3) telemedicine services which were improperly provided by psychiatrists outside the United States. As part of the settlement, the clinic and Abraham Freund are excluded from participating in federal healthcare programs for 25 years. Abraham Freund's son, Isaac Freund, who was involved in the clinic's operations, is excluded for five years. ⁷⁵	\$4.1 million
5/6/2019	Acadia Healthcare Company, Inc. d/b/a CRC Health, L.L.C.	Operator of drug treatment centers agreed to pay \$17 million to resolve FCA allegations that its centers submitted claims to West Virginia Medicaid for urine and blood tests that they were not certified to perform and, in some cases, had not performed. As part of the settlement, CRC Health and Acadia Healthcare entered into a five-year CIA with HHS-OIG. ⁷⁶	\$17 million

⁷² <https://portal.ct.gov/AG/Press-Releases/2019-Press-Releases/New-Haven-Behavioral-Health-Provider-Agrees-to-Settlement-to-Resolve-False-Claims-Act-Allegations>.

⁷³ <https://www.justice.gov/usao-ndga/pr/families-united-services-and-pamela-mckenzie-pay-64500000-and-agree-exclusion-order>.

⁷⁴ <https://www.justice.gov/usao-ct/pr/new-london-psychiatrist-and-mental-health-clinic-pay-over-33-million-settle-false-claims>.

⁷⁵ <https://www.justice.gov/usao-edwi/pr/acacia-mental-health-clinic-llc-and-its-owner-abraham-freund-agree-pay-over-4-million>.

⁷⁶ <https://www.justice.gov/usao-sdww/pr/united-states-attorney-announces-17-million-healthcare-fraud-settlement>.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/16/2019	Ultimate Care Medical Services, LLC d/b/a Ultimate Treatment Center; Rose O. Uradu, M.D.	Substance abuse treatment center and its owner agreed to pay \$1.4 million to resolve FCA allegations that they billed Medicare and Kentucky Medicaid for: (1) E&M services for patients receiving daily methadone doses when in fact the services were not actually provided; and (2) complex urine drug testing that their equipment was incapable of performing. The settlement also resolved allegations that Dr. Uradu issued prescriptions for opioid addiction medication to more patients than permitted for a three-month period in 2014, thereby violating the Controlled Substances Act with each prescription over the limit. ⁷⁷	\$1.4 million
8/16/2019	2nd Chance, PLLC	Substance abuse treatment center agreed to pay \$200,494 to resolve FCA allegations arising from an alleged kickback scheme wherein 2nd Chance referred complex drug testing to CAL Lab in exchange for the rent-free use of a chemistry analyzer from CAL Lab, enabling 2nd Chance to submit tainted claims for payment for services performed on the analyzer to Kentucky Medicaid. This settlement is part of a broader criminal and civil investigation of CAL Lab and affiliated individuals and entities. In June 2018, CAL Lab settled unrelated FCA allegations related to overpayments for specimen validity testing. ⁷⁸	\$200,494
10/31/2019	Pondville Medical Associates LLC; Riad Mortada, M.D.; Ahmed Basheer, M.D.; Rezene Berhane, M.D.	Physician practice and three affiliated physicians agreed to pay \$150,000 to resolve FCA allegations that they charged Massachusetts Medicaid patients cash out-of-pocket for a covered substance use disorder treatment instead of billing the treatments to Massachusetts Medicaid. ⁷⁹	\$150,000

⁷⁷ <https://www.justice.gov/usao-edky/pr/ashland-physician-and-substance-abuse-treatment-center-agree-pay-14-million-resolve>.

⁷⁸ <https://www.justice.gov/usao-edky/pr/substance-abuse-clinic-agrees-pay-federal-government-200494-settle-civil-claims>.

⁷⁹ <https://www.mass.gov/news/norfolk-medical-practice-settles-claims-of-illegally-charging-cash-for-suboxone>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/15/2019	Diamond Braces; Oleg Drut, DDS	Chain of dental offices and its owner agreed to pay \$9 million to resolve FCA allegations that they improperly billed New York Medicaid for orthodontic procedures that were performed by uncertified individuals. As part of the settlement, the defendants agreed to enter into a CIA or retain an independent monitor. ⁸⁰	\$9 million
1/28/2019	East Coast Stepping Stones, Inc. (ECSS)	Provider of autism therapy services agreed to pay \$360,000 to resolve FCA allegations that it submitted claims to Tricare that misrepresented what services were provided and who had provided them. The settlement also resolved allegations that services were not documented as required and that ECSS fabricated and altered medical records. ⁸¹	\$360,000
1/29/2019	WellBound of Memphis	Dialysis facility agreed to pay \$3.246 million to resolve FCA allegations that it paid physicians kickbacks for patient referrals and then submitted tainted claims to Medicare, Tricare, and Tennessee Medicaid for services provided to these patients. ⁸²	\$3.246 million
2/13/2019	South Bay Physical Medicine, Inc.; Direct Health Medical Center, Inc. d/b/a San Diego Spine and Rehabilitation; Brett Allan, Sr.; Brett Allan, Jr.; Jeff Allan	Two physical therapy clinics and their owners agreed to pay \$450,000 to resolve FCA allegations that they billed Tricare for services provided solely by unqualified and unauthorized personnel and without the necessary physician supervision. ⁸³	\$450,000
2/25/2019	PhysioHealth, Inc.; Dynamic Therapy Services, LLC	Physical therapy provider and its subsidiary agreed to pay \$2 million to settle self-disclosed FCA allegations that they billed Tricare for services provided by unauthorized personnel, including physical therapy assistants, as if they were provided or supervised by authorized providers. ⁸⁴	\$2 million
2/25/2019	Skyline Urology	Urology practice agreed to pay \$1.85 million to resolve FCA allegations that it billed Medicare for improperly unbundled E&M services that did not qualify to be separately billed from other procedures performed on the same day. As part of the settlement, Skyline entered into a three-year IA with HHS-OIG. ⁸⁵	\$1.85 million

80 <https://ag.ny.gov/press-release/attorney-general-james-announces-9-million-settlement-orthodontist-allowing>.

81 <https://www.justice.gov/usao-mdfl/pr/east-coast-stepping-stones-inc-jacksonville-based-provider-children-autism-pays-united>.

82 <https://www.justice.gov/usao-wdtn/pr/wellbound-memphis-will-pay-3246000-united-states-and-state-tennessee-services-rendered>.

83 <https://www.justice.gov/usao-sdca/pr/san-diego-physical-therapy-clinics-owners-pay-450000-resolve-fraud-allegations>.

84 <https://www.justice.gov/usao-edpa/pr/dynamic-therapy-services-llc-and-physiohealth-inc-pay-2-million-resolve-allegations>.

85 <https://www.justice.gov/opa/pr/skyline-urology-pay-185-million-settle-false-claims-act-allegations-medicare-overbilling>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/27/2019	CareOne Dental Corporation; Liem Do, DDS; Phuong-Oanh Tran, DDS	Dental practice and its owners agreed to pay \$1 million to resolve FCA allegations that they billed Washington Medicaid for: (1) non-covered services disguised as covered procedures; (2) more lucrative procedures than those actually performed; and (3) services that were never provided. As part of the settlement, Dr. Liem Do agreed to permanent exclusion from participating in Medicare and Medicaid. ⁸⁶	\$1 million
3/29/2019	CareWell Urgent Care Centers of MA, P.C.; CareWell Urgent Care of Rhode Island, P.C.; Urgent Care Centers of New England Inc.	Urgent care chain agreed to pay \$2 million to settle allegations that it improperly billed Medicare and Medicaid by: (1) falsely inflating the level of E&M services performed; and (2) failing to properly identify the providers of the E&M services in order to obtain higher reimbursement for services performed by unsupervised nurse practitioners. ⁸⁷	\$2 million
4/4/2019	Oral and Maxillofacial Surgical Associates P.C.; Robert Sorrentino, DDS	Retired oral surgeon and his former practice agreed to pay \$252,000 to resolve FCA allegations that they billed Connecticut Medicaid for general anesthesia and deep sedation services that were not provided and for other medical services which were not performed, were not medically necessary, or were included in other claims. ⁸⁸	\$252,000
4/15/2019	Cardiac Associates, P.C.	Cardiology practice agreed to pay \$399,230.35 to resolve FCA allegations that it billed Medicare and Medicaid for venous Doppler duplex examinations using CPT codes 93970 and 93965, the latter referring to an older, different technology that generally has been replaced and was incorrectly billed. ⁸⁹	\$399,230
4/25/2019	National Spine and Pain Centers; Physical Medicine Associates	Two pain management chains agreed to pay \$3.3 million to resolve FCA allegations that they: (1) submitted claims for services provided by physicians when in fact the services were provided by physician assistants and nurse practitioners; (2) submitted claims for urine drug tests tainted by violations of the Stark Law and/or AKS; and (3) ordered drug tests that were not medically necessary. ⁹⁰	\$3.3 million
5/9/2019	Carolina Physical Therapy and Sports Medicine, Inc.	Physical therapy chain agreed to pay \$790,000 to resolve FCA allegations that it submitted false claims to Medicare and Tricare for: (1) services provided to multiple patients at a time as if they were individually provided; (2) services provided by physical therapy assistants who were not supervised by a physical therapist; and (3) electrical stimulation services that were billed as if they were attended by a therapist or assistant when they were unattended and thus, should have been billed as a lower cost unattended service. ⁹¹	\$790,000

86 <https://www.atg.wa.gov/news/news-releases/ag-ferguson-clark-county-dentists-pay-1-million-over-fraudulent-medicaid-billing>.

87 <https://www.justice.gov/usao-ma/pr/carewell-urgent-care-center-agrees-pay-2-million-resolve-allegations-false-billing>.

88 <https://www.justice.gov/usao-ct/pr/new-haven-oral-surgeon-pays-252k-settle-false-claims-allegations>.

89 <https://www.justice.gov/usao-md/pr/cardiac-associates-pc-agrees-pay-united-states-over-399000-settle-false-claims-act>.

90 <https://www.justice.gov/usao-edva/pr/pain-management-clinics-settle-medicare-civil-fraud-claims>.

91 <https://www.justice.gov/usao-sc/pr/carolina-physical-therapy-and-sports-medicine-inc-pay-790000-resolve-false-billing>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/30/2019	Galichia Medical Group, P.A.; Joseph P. Galichia, M.D.	Cardiology practice and its owner agreed to pay \$5.8 million to resolve FCA allegations that they billed Medicare and various other federal healthcare programs for medically unnecessary cardiac stent procedures. As part of the settlement, Dr. Galichia is excluded from participating in federal healthcare programs for three years. ⁹²	\$5.8 million
5/30/2019	HyperHeal Hyperbarics, Inc.	Hyperbaric oxygen therapy facility agreed to pay \$414,640.25 to resolve FCA allegations that it submitted claims to Tricare for hyperbaric oxygen therapy services for one patient that were not medically necessary and were not supervised by a physician. ⁹³	\$414,640
6/11/2019	Quality Therapy & Consultation Inc.; Frances Parise	Physical therapy center agreed to pay \$1.09 million, and its owner agreed to pay \$160,000, to resolve FCA allegations that they conspired with four nursing facilities to upcode patients' RUG scores in order to receive higher Medicare reimbursement and also provided therapy services to patients who did not need or could not benefit from such services. The four nursing facilities involved also reached settlements related to these charges. As part of the settlement, Frances Parise is excluded from participating in federal healthcare programs for five years. ⁹⁴	\$1.25 million
6/18/2019	Nevada Heart & Vascular Center (Resh), LLP	Cardiology practice agreed to pay \$2.5 million to resolve FCA allegations that it referred Medicare patients to two genetic testing companies in exchange for kickback payments, in violation of the AKS. ⁹⁵	\$2.5 million
6/27/2019	Fusion Physical Therapy and Sports Wellness, P.C.; Carolyn Sue Mazur	Physical therapy company and its owner agreed to pay \$37,500 to resolve FCA allegations that they improperly billed Medicare for services performed by non-credentialed personnel as if they were provided or supervised by credentialed personnel. ⁹⁶	\$37,500
7/2/2019	Wisconsin Community Services, Inc.	Nonprofit community services operator agreed to pay \$537,904.33 to resolve self-disclosed FCA allegations that its pharmacy misrepresented to Medicare and Medicaid the nature of the prescription drugs it dispensed over several years, including billing for brand name drugs when it actually dispensed generic equivalents. ⁹⁷	\$537,904

92 <https://www.justice.gov/opa/pr/kansas-cardiologist-and-his-practice-pay-58-million-resolve-alleged-false-billings>.

93 <https://www.justice.gov/usao-md/pr/hyperbaric-oxygen-therapy-facility-agrees-pay-united-states-over-400000-settle-false>.

94 <https://www.justice.gov/usao-ndil/pr/chicago-area-physical-therapy-center-and-4-nursing-facilities-pay-97-million-resolve>.

95 <https://www.justice.gov/usao-nv/pr/las-vegas-cardiology-practice-agrees-pay-25-million-settlement-claim-involving-medicare>.

96 <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-settles-civil-fraud-lawsuit-against-physical-therapy-center-and>.

97 <https://www.justice.gov/usao-edwi/pr/wisconsin-community-services-inc-voluntarily-discloses-and-agrees-pay-over-500000>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/9/2019	Kansas City Health and Wellness Clinic, P.A.; Ryan Schell; Tyler Schell	Chiropractic clinic and its two former owners agreed to pay \$350,000 to resolve FCA allegations that they improperly billed Medicare for peripheral neuropathy treatments that were medically unnecessary and/or performed by physicians when they were not actually interpreted by any qualified healthcare professional, and that they billed for non-covered services such as the use of mechanical massage chairs as if the claims involved vasopneumatic devices. ⁹⁸	\$350,000
7/18/2019	Comprehensive Pain and Headache Treatment Centers, LLC; Mark Thimineur, M.D.	Pain management practice and its owner agreed to pay \$427,691.90 to resolve FCA allegations that they improperly billed Medicare and Connecticut Medicaid for quantitative urine tests that were not actually performed and separately billed tests that they should have known were encompassed in other tests that they billed. ⁹⁹	\$427,691
8/15/2019	Baldwin Bone & Joint, P.C.	Orthopedic surgery and physical therapy practice agreed to pay \$1.2 million to resolve FCA allegations that it billed Medicare and Tricare for services provided by unauthorized providers, including athletic trainers and an exercise physiologist. The settlement also resolved allegations that defendant submitted claims for services referred by physician shareholders with whom it had improper compensation arrangements that violated the Stark Law. ¹⁰⁰	\$1.2 million
10/4/2019	Retina Institute of California Medical Group; Tom S. Chang, M.D., Inc.; California Eye and Ear Specialists; San Gabriel Ambulatory Surgery Center LP; Tom S. Chang, M.D.; Michael A. Samuel, M.D.; Michael J. Davis, M.D.; Brett Braun	Ophthalmology group and associated physicians and practice groups agreed to pay \$6.65 million to resolve allegations that they violated the FCA by: (1) billing Medicare and California Medicaid for more complex exams than were actually performed; (2) waiving co-payments and deductibles to induce referrals; and (3) billing for services that were not performed, were not medically necessary, were not properly documented, and/or were not in compliance with applicable rules and regulations. ¹⁰¹	\$6.65 million
10/8/2019	Ovation Center of Integrative Medicine; Ron Siscoe	Chiropractic practice and its owner agreed to pay \$98,497.62 to resolve FCA allegations that they billed Medicare for: (1) surgical procedures involving the implantation of an electro-acupuncture device when in fact the devices were applied in an office setting without surgery or anesthesia; and (2) services that were not provided or supervised by the physician indicated on the claim. This settlement followed a voluntary repayment that defendant made in May 2018 after being notified of a Medicare Unified Program Integrity Contractor (UPIC) post-payment medical review of certain of defendant's claims for the electro-acupuncture device at issue. ¹⁰²	\$98,497

98 <https://www.justice.gov/usao-ks/pr/kansas-chiropractors-pay-350000-settle-false-claim-allegations>.

99 <https://www.justice.gov/usao-ct/pr/connecticut-pain-management-doctor-and-his-practice-pay-over-425k-settle-improper-billing>.

100 <https://www.justice.gov/usao-sdal/pr/qui-tam-lawsuit-and-federal-investigation-results-settlement-and-12-million-payment>.

101 <https://www.justice.gov/usao-cdca/pr/eye-doctor-group-physicians-pay-665-million-settle-allegations-they-submitted>.

102 <https://www.justice.gov/usao-edpa/pr/chiropractor-and-related-practice-pay-nearly-100000-resolve-false-claims-act-liability>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/9/2019	Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, Inc.	Dialysis clinic operator agreed to pay \$5.2 million to resolve FCA allegations that it billed Medicare for Hepatitis B tests that were performed more frequently than medically necessary. ¹⁰³	\$5.2 million
10/10/2019	Traverse Anesthesia Associates, P.C.	Anesthesiology practice and six of its anesthesiologists agreed to pay \$607,966 to resolve FCA allegations that they billed Medicare for medically directed anesthesia services when the regulatory requirements and conditions of payment for billing those services were not met. ¹⁰⁴	\$607,966
10/18/2019	Osteo Relief Institute, Inc.; Arizona Health Services, PLLC; Phoenix Pain and Joint Center, LLC; Scatena Chiropractic, Inc.; Physicians Health Group of Kentucky, PLLC; Kentucky Osteo Relief Institute, PSC; Accurate Management Services, LLC; Medical Offices of New Jersey Shore, LLC; Arthritis Treatment of Texas, PLLC; Artemis Health Management, LLC; San Antonio Osteo Relief Center, PA; Texas Spine Clinic, PA; MK Medical Management, LLC; John Rush, M.D.; Scott Mackenzie, D.C.; Cassidy Boelk, D.C.; Anthony Scatena, D.C.; Igal Dubov, D.C.; Brett Mackenzie, D.C.; Kevin Barton, D.C.	Seven former Osteo Relief Institute osteoarthritis clinics and their owners and affiliated entities agreed to pay more than \$7.1 million to resolve allegations that they violated the FCA by: (1) billing Medicare for medically unnecessary viscosupplementation knee injections and custom knee braces; (2) using multiple brands of viscosupplements successively on patients without clinical support; and (3) using discounted viscosupplements reimported from foreign countries. As part of the settlement, defendants have entered into a five-year CIA with HHS-OIG. ¹⁰⁵	\$7.1 million+
10/30/2019	Autism Concepts, Inc.	Therapy services provider for children with autism agreed to pay \$300,000 to resolve FCA allegations that it billed Tricare for individual therapy services when group services were actually provided. ¹⁰⁶	\$300,000

103 <https://www.justice.gov/usao-ma/pr/fresenius-agrees-pay-52-million-resolve-allegations-it-overbilled-medicare-hepatitis-b>.

104 https://www.justice.gov/usao-wdmi/pr/2019_1010_Traverse%20Anesthesia%20Associates.

105 <https://www.justice.gov/opa/pr/former-osteo-relief-institutes-and-their-owners-pay-over-71-million-resolve-allegations>.

106 <https://www.justice.gov/usao-ks/pr/healthcare-provider-children-autism-agrees-pay-300000-settle-false-claims-allegation>.

MEDICAL TRANSPORTATION

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/4/2019	Lee County Fiscal Court; Joseph Broadwell	County ambulance service and its director agreed to pay \$253,930 to resolve allegations that they submitted claims to Medicare for medically unnecessary non-emergency ambulance transport of patients to and from dialysis treatment. ¹⁰⁷	\$253,930
6/20/2019	Hart to Heart Ambulance Services d/b/a Hart to Heart Transportation Services	Ambulance company agreed to pay \$1.25 million to resolve allegations that it submitted claims to Medicare for medically unnecessary ambulance transports. ¹⁰⁸	\$1.25 million
7/9/2019	Unicare Ambulance LLC and PA Paramedics LLC d/b/a EasternCare Ambulance; Damon Wade; Amy Wade	Two ambulance companies and their owners agreed to pay \$459,907.42 to resolve allegations that they made false statements to Medicare officials in an attempt to avoid repaying Medicare overpayments and to conceal the fact that one of the owners had previously had his paramedic license suspended. ¹⁰⁹	\$459,907
7/10/2019	Rural Metro of Southern Ohio, Inc.	Ambulance company agreed to pay \$275,116.22 to resolve allegations that it submitted claims to Medicare for medically unnecessary ambulance transports. ¹¹⁰	\$275,116
7/26/2019	Gallatin County Fiscal Court; Wayne County Fiscal Court	Gallatin County, Kentucky, agreed to pay \$100,000, and Wayne County, Kentucky, agreed to pay \$30,393, to resolve allegations that they provided ambulance transport to a Medicare beneficiary that was medically unnecessary. ¹¹¹	\$130,393
8/29/2019	International SOS Assistance, Inc.; International SOS Government Services, Inc.; International SOS, LP; Air Rescue Americas, Inc.	Provider of overseas healthcare services for the government agreed to pay \$940,000 to resolve allegations that it billed Tricare for aeromedical evacuations at rates that did not take into account discounts received from the third-party air ambulance providers. ¹¹²	\$940,000
9/27/2019	Meridian Mobile Health, L.L.C. d/b/a Capital Ambulance	Ambulance company agreed to pay \$138,285.30 to resolve allegations that it billed Medicare for ambulance transportation of patients being discharged from a hospital when such transportation was not medically necessary. ¹¹³	\$138,285

107 <https://www.justice.gov/usao-edky/pr/lee-county-ambulance-service-and-its-director-agree-pay-253930-resolve-allegations>.

108 <https://www.justice.gov/usao-md/pr/hart-heart-ambulance-services-pay-125-million-settle-federal-false-claims-act-allegations>.

109 <https://www.justice.gov/usao-edpa/pr/bucks-county-ambulance-companies-and-their-owners-agree-450k-judgment-defrauding>.

110 <https://www.justice.gov/usao-edky/pr/rural-metro-southern-ohio-inc-agrees-pay-275116-resolve-allegations-false-claims>.

111 <https://www.justice.gov/file/1187621/download>.

112 <https://www.justice.gov/usao-edpa/pr/defense-contractor-pay-940000-resolve-allegations-withholding-discounts-tricare>.

113 <https://www.justice.gov/usao-me/pr/bangor-ambulance-company-settles-false-claims-act-allegations>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/4/2019	Manuel C. Barit, M.D.	Family physician agreed to pay \$200,000 to resolve FCA allegations that he participated in a scheme to defraud West Virginia Medicaid. Physician also pleaded guilty to criminal healthcare fraud charges. ¹¹⁴	\$200,000
2/5/2019	Craig D. Fishman, M.D.; Jeffrey A. Sheridan, M.D.	Two ophthalmologists agreed to pay \$157,312.32 to resolve FCA allegations that they submitted claims to Medicare for eyelid repair surgeries that were performed simultaneously, but were required to be performed and billed separately. ¹¹⁵	\$157,312
2/8/2019	James Paul "Beau" Adams	Marketing company owner agreed to pay \$339,412.50 to resolve FCA allegations that he received payments from compounding pharmacy OK Compounding, LLC, for referring prescriptions for compounded drugs to the pharmacy. Two individuals affiliated with the pharmacy were indicted in December 2018 in connection with this healthcare fraud scheme. ¹¹⁶	\$339,412
2/12/2019	Dr. Aremmia Tanious; Jefferson Medical Associates	Physician and her practice agreed to pay \$817,635.06 to resolve self-disclosed FCA allegations that they improperly billed Medicare using multiple medical codes when the documentation did not support the billing practice. ¹¹⁷	\$817,635
2/19/2019	Dr. Brandon Claflin	Doctor of osteopathic medicine agreed to pay \$84,666.42 to resolve FCA allegations that he received payments disguised as medical director fees from compounding pharmacy OK Compounding, LLC in exchange for prescribing pain creams. ¹¹⁸	\$84,666
2/21/2019	Dr. Hooshang Poor	Geriatric medicine physician agreed to pay \$680,000 to resolve FCA allegations that he submitted inflated and incorrectly coded claims for nursing home services to Medicare and Massachusetts Medicaid. ¹¹⁹	\$680,000
3/6/2019	Dr. Ricardo Causo	Pediatrician agreed to pay \$125,897.65 to Tennessee to resolve FCA allegations that he submitted claims to Tennessee Medicaid for prolonged services that he did not actually perform. ¹²⁰	\$125,897
3/18/2019	Dr. Jeff Halsell	Doctor of osteopathic medicine agreed to pay more than \$52,000 to resolve FCA allegations that he received payments disguised as medical director fees from compounding pharmacy OK Compounding, LLC in exchange for prescribing the pharmacy's compounded pain creams. ¹²¹	\$52,000+

114 <https://www.justice.gov/usao-sdvw/pr/doctor-enters-civil-settlement-pay-restitution-and-damages-wv-medicaid-program>.
115 <https://www.justice.gov/usao-mdfl/pr/clermont-eye-doctors-agree-pay-over-157000-settle-false-claims-act-liability-improperly>.
116 <https://www.justice.gov/usao-ndok/pr/marketer-agrees-pay-nearly-340000-allegedly-engaging-illegal-kickback-scheme-ok-0>.
117 <https://www.justice.gov/usao-sdms/pr/laurel-based-physicians-group-and-neurologist-agree-pay-almost-one-million-dollars>.
118 <https://www.justice.gov/usao-ndok/pr/tulsa-doctor-will-pay-84666-allegedly-engaging-illegal-kickback-scheme>.
119 <https://www.justice.gov/usao-ma/pr/newton-physician-pay-680000-resolve-allegations-medicare-and-medicaid-fraud>.
120 <https://www.tn.gov/attorneygeneral/news/2019/3/6/pr19-08.html>.
121 <https://www.uspsoig.gov/sites/default/files/document-library-files/2018/DOJ%20News%203-18-19.pdf>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/18/2019	Dr. Mary Johnson	Podiatrist agreed to pay more than \$76,000 to resolve FCA allegations that she received payments disguised as medical director fees from compounding pharmacy OK Compounding, LLC in exchange for prescribing the pharmacy's compounded pain creams. ¹²²	\$76,000+
4/5/2019	Dr. Lam Nguyen	Doctor of osteopathic medicine agreed to pay \$124,139.98 to resolve FCA allegations that he was paid kickbacks by compounding pharmacy OK Compounding, LLC in exchange for prescribing the pharmacy's compounded pain creams. ¹²³	\$124,139
4/5/2019	Dr. Hugo Salguero	Pain medicine physician agreed to pay \$228,301.76 to resolve FCA allegations that he was paid kickbacks by compounding pharmacy OK Compounding, LLC in exchange for prescribing the pharmacy's compounded pain creams. ¹²⁴	\$228,301
4/10/2019	Patricia McAlinden, LCSW	Clinical social worker agreed to pay more than \$145,855.40 to resolve FCA allegations that she billed Medicaid for psychotherapy services that were actually provided by unlicensed individuals. As part of the settlement, McAlinden agreed to a voluntary three-year suspension from the Medicaid program. ¹²⁵	\$145,855
4/23/2019	M. Wagdi Attia, M.D.	Physician agreed to pay \$82,000 to the state of Maryland to resolve FCA allegations that he submitted claims for psychotherapy services without the required amount of face-to-face time with patients and other psychotherapy billing requirements. As part of the settlement, the physician also agreed to retire and not renew his medical license. The physician settled the same allegations with the federal government in December 2018. ¹²⁶	\$82,000
4/24/2019	David Wallace; Timothy Stocksdales	Two former executives of a diabetic testing supply company agreed to pay \$500,000 each to resolve FCA allegations that they caused the company to submit Medicare claims for medically unnecessary supplies and claims tainted by kickbacks to beneficiaries in the form of free or no-cost supplies and co-payment waivers. The United States intervened in a separate FCA suit against the company and its parent. ¹²⁷	\$1 million

122 <https://www.uspsioig.gov/sites/default/files/document-library-files/2018/DOJ%20News%203-18-19.pdf>.

123 <https://www.justice.gov/usao-ndok/pr/two-tulsa-doctors-settle-us-government-allegedly-engaging-illegal-kickback-schemes-0>.

124 <https://www.justice.gov/usao-ndok/pr/two-tulsa-doctors-settle-us-government-allegedly-engaging-illegal-kickback-schemes-0>.

125 <https://www.justice.gov/usao-ct/pr/cheshire-social-worker-pays-145855-settle-false-claims-allegations>.

126 <http://www.marylandattorneygeneral.gov/press/2019/042319a.pdf>.

127 <https://www.justice.gov/usao-mdtn/pr/two-former-arriva-medical-executives-agree-pay-1-million-settle-diabetic-testing-supply>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/30/2019	Gary D. Newsome	Former CEO of the hospital chain Health Management Associates LLC (HMA), agreed to pay \$3.46 million to resolve FCA allegations that he pressured emergency department physicians to recommend medically unnecessary hospital admissions for patients who could have been treated on an outpatient basis and caused HMA to pay kickbacks to physicians and its emergency department staffing company, EmCare, related to the same. HMA and EmCare settled these allegations in 2018 and 2017, respectively, and HMA entered into a non-prosecution agreement. ¹²⁸	\$3.46 million
5/17/2019	Dr. Donald S. Douglas	Physician agreed to pay \$118,000 to resolve FCA allegations that services provided by advanced practice nurses at his clinics were billed to Medicare as if they were provided under physician supervision when they were not and should have been billed at a lower rate. ¹²⁹	\$118,000
6/5/2019	Cathy Grossman; Nassau Pharmacy, Inc.	Pharmacist agreed to pay \$100,000 to resolve FCA allegations that she submitted claims to Medicare and Medicaid for prescriptions that were not picked up, not ordered, or were provided in generic form rather than the billed-for brand name drug from the pharmacy she owned. ¹³⁰	\$100,000
6/6/2019	Kevin Rakin	Former chairman and CEO of medical device company Advanced BioHealing, Inc. (ABH), agreed to pay \$2.5 million to resolve FCA allegations that he knowingly permitted sales representatives to provide doctors and clinics with illegal kickbacks such as travel, entertainment, supplies, and cash in an attempt to induce use or overuse of their human skin substitute, Dermagraft. In January 2017, Shire plc, who acquired ABH in 2011, agreed to pay \$350 million to settle similar federal and state FCA allegations related to the promotion of Dermagraft. ¹³¹	\$2.5 million
6/6/2019	Dr. Nathan Hanflink	Physician agreed to pay \$911,136.75 to resolve FCA allegations that he referred Medicare patients to a drug testing laboratory for lab tests while he had a financial relationship with the laboratory, violating the AKS and Stark Law. As part of the settlement, the physician also entered into a three-year IA with HHS-OIG. ¹³²	\$911,136
7/5/2019	Dr. George Lehner	Physician agreed to pay \$127,072.34 to resolve FCA allegations that he prescribed certain compounded pain creams in exchange for payments disguised as medical director fees from the compounding pharmacy OK Compounding, LLC. ¹³³	\$127,072

128 <https://www.justice.gov/opa/pr/former-ceo-hospital-chain-pay-346-million-resolve-false-billing-and-kickback-allegations>.

129 <https://www.justice.gov/usao-edtx/pr/texarkana-physician-agrees-pay-118000-settle-medicare-billing-fraud-allegations>.

130 <https://www.justice.gov/usao-ndny/pr/nassau-pharmacist-pay-100000-submitting-false-claims-medicare-and-medicaid>.

131 <https://www.justice.gov/usao-mdfl/pr/former-advanced-biohealing-ceo-pay-25-million-settle-false-claims-act-allegations>.

132 <https://www.justice.gov/usao-wdpa/pr/florida-doctor-agrees-pay-91113675-settle-alleged-false-claims-act-violations-arising>.

133 <https://www.justice.gov/usao-ndok/pr/new-york-doctor-will-pay-nearly-130000-allegedly-engaging-illegal-kickback-scheme>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/8/2019	Dr. Sherif Khalil; Beaver Medical Group L.P.	Physician and affiliated practice agreed to pay \$5,039,180 to resolve FCA allegations that they reported diagnosis codes to contracted Medicare Advantage Organizations (MAOs) that were not supported by patients' medical records, in order to increase the payments they received from the MAOs. ¹³⁴	\$5.039 million
8/27/2019	Gregory Sampognaro, M.D.; Warren Strickland, M.D.; Isabella Strickland, M.D.; Cardiology P.C.	Three physicians and a cardiac center agreed to pay a total of \$1,134,003 to resolve FCA allegations that they accepted payments from now-defunct genetic testing company Natural Molecular Testing Corporation (NMTC) in return for ordering tests from NMTC, which NMTC then billed to Medicare. ¹³⁵	\$1.134 million
9/5/2019	Dr. Robert Moreno; Cheryl Moreno; William "Bill" Collins; Accutrack Medical Claims Service, LLC; El Paso Integrated Physicians Group, P.A.	A physician, his practice group, and other affiliated individuals agreed to pay \$2,929,162 million to resolve FCA allegations that they double-billed and over-billed government healthcare programs by combining partially used vials of an infusion drug sold in single-use vials for use in other patients. The settlement also resolved allegations that they submitted claims for unused or diluted vials of the drug. ¹³⁶	\$2.929 million
9/5/2019	Dr. James L. Womack	Orthopedic surgeon agreed to pay \$471,221.46 to resolve FCA allegations that he prescribed certain compounded pain creams in exchange for payments disguised as medical director fees from the compounding pharmacy OK Compounding, LLC. ¹³⁷	\$471,221
9/9/2019	Dr. Augusto Castrillon	Family physician agreed to pay \$2,133,959.30 to resolve allegations that he billed Medicare for unnecessary diagnostic tests. The government identified the physician as a statistical outlier in terms of ordering excessive, complicated tests normally ordered by specialists. ¹³⁸	\$2.133 million
9/17/2019	Richard P. Frey, D.O.; Physicians Alliance Ltd.	Doctor and his practice agreed to pay \$178,398.35 to resolve allegations that he applied an electric acupuncture device on patients, but billed Medicare as if he had surgically implanted neurostimulator electrodes. The "P-Stim" devices actually used were not eligible for Medicare reimbursement. ¹³⁹	\$178,398
9/24/2019	Stefan J. Simoncic, DDS; Triad Oral Surgery	Dentist and his practice agreed to pay \$567,125 to resolve allegations that they submitted claims to North Carolina Medicaid for services that were not medically necessary, did not have supporting documentation, or that violated Medicaid policy. ¹⁴⁰	\$567,125

134 <https://www.justice.gov/opa/pr/medicare-advantage-provider-and-physician-pay-5-million-settle-false-claims-act-allegations>.

135 <https://www.justice.gov/usao-wdwa/pr/physicians-and-cardiac-center-agree-pay-total-more-11-million-resolve-allegations-they>.

136 <https://www.justice.gov/usao-wdtx/pr/justice-department-reaches-settlement-agreement-physicians-and-el-paso-physicians-group>.

137 <https://www.uspsioig.gov/document/doctor-agrees-pay-more-471000-resolve-alleged-false-claims-act-liability-accepting-kickback>.

138 <https://www.justice.gov/usao-sdtx/pr/mission-family-practitioner-pays-2-million-resolve-allegations>.

139 <https://www.justice.gov/usao-edpa/pr/doctor-and-physician-practice-pay-178000-resolve-false-claims-act-liability-arising>.

140 <https://ncdoj.gov/attorney-general-josh-stein-announces-operation-root-canal-medicaid-settlement/>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/26/2019	Dr. Philippe R. Chain	Physician agreed to pay \$300,000 to resolve allegations that he issued or approved invalid prescriptions for compounded medications to Tricare participants through his work with a telemedicine company. The government alleged that the prescriptions were invalid because the physician did not have an established physician-patient relationship with the telehealth patients and did not actually examine or speak with them, and that many of the prescriptions were not medically necessary. ¹⁴¹	\$300,000
10/3/2019	Glenn A. Kline, D.O.; Community Surgical Associates	Surgeon and his practice agreed to pay \$4.25 million to resolve allegations that he referred patients to two hospitals in exchange for payments from the hospital owner in the form of an above-FMV salary. ¹⁴²	\$4.25 million
10/3/2019	Valerie Williams, LPC; Circle of Life Transition Center, LLC	Licensed professional counselor and her business agreed to pay \$45,488.57 to resolve allegations that she billed Medicaid for psychotherapy services as if she had performed them when in fact, they were actually provided by other unlicensed individuals. As part of the settlement, the counselor also agreed to a voluntary seven-year exclusion from Connecticut Medicaid. ¹⁴³	\$45,488
10/15/2019	Dr. Tracey Wellendorf	Otolaryngologist agreed to pay \$1 million to resolve FCA allegations that she submitted claims for endoscopic sinus surgeries that were not medically necessary or were otherwise not coded correctly. As part of the settlement, the physician entered into a three-year IA with HHS-OIG. ¹⁴⁴	\$1 million
11/8/2019	Dr. Jonathan Moore	Podiatrist agreed to pay \$65,404 to resolve FCA allegations that he received payments disguised as medical director fees from compounding pharmacy OK Compounding, LLC in exchange for prescribing the pharmacy's compounded pain creams. ¹⁴⁵	\$65,404
11/12/2019	Dr. Damien Brezinski; Wilmington Health	Physician and his practice agreed to pay more than \$244,000 to resolve FCA allegations that he billed Medicare and Tricare for the insertion of arterial stents when such procedures were not medically necessary. The investigation began with a self-disclosure by a local hospital, which reached a separate settlement, following an internal audit. ¹⁴⁶	\$244,000+

141 <https://www.justice.gov/usao-ct/pr/former-connecticut-physician-pays-300000-settle-false-claims-act-allegations>.

142 <https://www.justice.gov/usao-edpa/pr/lancaster-surgeon-pay-425-million-resolve-false-billing-and-kickback-claims>.

143 <https://www.justice.gov/usao-ct/pr/hartford-licensed-professional-counselor-pays-45k-settle-false-claims-allegations>.

144 <https://www.justice.gov/usao-ndia/pr/northwest-iowa-otolaryngologist-agrees-pay-1000000-resolve-medicare-false-claims>.

145 <https://www.justice.gov/usao-ndok/pr/kentucky-doctor-agrees-pay-65404-allegedly-engaging-illegal-kickback-scheme-ok>.

146 <https://www.justice.gov/usao-ednc/pr/wilmington-doctor-and-medical-practice-settle-civil-fraud-claims-more-244000>.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/14/2019	Sandra Haar	Founder and former CEO of rural health clinic chain agreed to divest the proceeds from the sale of 13 properties to resolve allegations that the clinics billed California Medicaid for: (1) claims for unnecessary services; (2) claims for services performed by unlicensed providers or that were never provided at all; (3) claims for office visits that consisted of nothing more than patients picking up controlled substances in plastic baggies in retail parking lots; and (4) claims for services tainted by kickback payments from a lab in exchange for referring testing from the clinics to the lab. As part of the settlement, Haar and another for-profit company she controlled are excluded from participating in all federal healthcare programs for 20 years, and the CFO of the for-profit company is excluded for five years. Haar was also sentenced to five years in prison following a guilty plea in the parallel criminal investigation. ¹⁴⁷	TBD sale proceeds
11/26/2019	Dr. Ian Reynolds	Orthopedic surgeon agreed to pay \$300,000 to resolve FCA allegations that he received payments disguised as medical director fees from compounding pharmacy OK Compounding, LLC, in exchange for prescribing the pharmacy's compounded pain creams. This was the twelfth settlement since November 2018 associated with a broad investigation into OK Compounding, LLC. ¹⁴⁸	\$300,000
12/5/2019	Noman Thanwy, M.D.	Internist agreed to pay \$176,686 to resolve allegations that he billed Medicare for medically unnecessary peripheral autonomic nervous function tests and vestibular function tests. The government alleged the test results were not used in clinical decision making regarding patient care, and, in some cases, the physician did not have the equipment or training to conduct the testing. The investigation and settlement arose out of DOJ's initiative to dedicate more resources and personnel to reviewing Medicare billing data for irregularities. ¹⁴⁹	\$176,686

¹⁴⁷ <https://www.justice.gov/usao-edca/pr/former-ceo-central-valley-health-clinics-sell-13-properties-resolve-false-claims-act>.

¹⁴⁸ <https://www.justice.gov/usao-ndok/pr/texas-orthopedic-surgeon-pay-300000-settle-false-claims-act-allegations>.

¹⁴⁹ <https://www.justice.gov/usao-md/pr/cambridge-internist-pays-more-176000-united-states-resolve-false-claims-act-allegations>.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/6/2019	Greenway Health, LLC	EHR software developer agreed to pay \$57.25 million to resolve FCA allegations that it caused its users to submit false claims for EHR incentive payments by misrepresenting the capabilities of its EHR product "Prime Suite" and by providing unlawful remuneration to users to induce them to recommend Prime Suite, in violation of the AKS. As part of the settlement, Greenway entered into a five-year CIA with HHS-OIG. ¹⁵⁰	\$57.25 million
2/25/2019	Wellcare Consulting, LLC; David Tsui	Marketing company agreed to pay \$414,108.08 to resolve FCA allegations that it arranged for the referral of prescriptions for compounded drugs to OK Compounding, LLC in exchange for kickback payments from the pharmacy, in violation of the AKS. ¹⁵¹	\$414,108
3/18/2019	Meyers, Rodbell & Rosenbaum, P.A.	Law firm agreed to pay \$250,000 to settle FCA allegations that it failed to reimburse the United States for conditional Medicare payments made on behalf of a firm client after the client received a settlement in a medical malpractice action. As part of the settlement, the firm also agreed to: (1) designate a person at the firm responsible for paying Medicare secondary payer debts; (2) provide training to the designee to ensure timely payments; and (3) periodically review any outstanding debts with the designee to ensure compliance. ¹⁵²	\$250,000
4/12/2019	Sutter Health LLC; Sutter East Bay Medical Foundation; Sutter Pacific Medical Foundation; Sutter Gould Medical Foundation; Sutter Medical Foundation	Nonprofit healthcare services provider Sutter Health LLC and several affiliated entities agreed to pay \$30 million to resolve FCA allegations that the affiliated entities submitted unsupported diagnosis codes for beneficiaries enrolled in Medicare Advantage plans, resulting in the plans and providers being overpaid. ¹⁵³	\$30 million
8/1/2019	Scott Roix d/b/a HealthRight, LLC; Health Savings Solutions, LLC; Vici Marketing, LLC; Vici Marketing Group, LLC	Owner of telemarketing company and several of his businesses agreed to pay \$2.5 million to resolve allegations that they violated the FCA by fraudulently obtaining insurance coverage information from consumers across the country to arrange for them to receive prescription pain creams and other similar products, which resulted in claims being submitted to government programs for prescriptions that were not medically necessary and did not arise from a valid doctor-patient relationship. The settlement also resolved allegations that Roix and his companies sold these prescriptions to pharmacies under the guise of marketing services, and the payments solicited for these services were based on the volume and value of the prescriptions. ¹⁵⁴	\$2.5 million

¹⁵⁰ <https://www.justice.gov/usao-vt/pr/electronic-health-records-developer-pay-second-largest-recovery-history-district-vermont>.

¹⁵¹ <https://www.justice.gov/usao-ndok/pr/north-carolina-marketer-agrees-pay-41410808-allegedly-engaging-illegal-kickback-scheme>.

¹⁵² <https://www.justice.gov/usao-md/pr/maryland-law-firm-meyers-rodbell-rosenbaum-pa-agrees-pay-united-states-250000-settle>.

¹⁵³ <https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-30-million-settle-alleged-overpayment-medicare-advantage>.

¹⁵⁴ <https://www.justice.gov/usao-mdfl/pr/telemarketer-and-his-companies-agree-pay-25-million-settle-allegations-they-operated>.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/4/2019	Saiontz & Kirk, P.A.	Law firm agreed to pay \$91,406.98 to settle FCA allegations that it failed to reimburse the United States for conditional Medicare payments made on behalf of firm clients after the firm received settlement proceeds for the clients. ¹⁵⁵	\$91,406
11/13/2019	Louisiana Department of Health	Louisiana Department of Health agreed to pay \$13,422,550 million to resolve FCA allegations that it fraudulently caused its healthcare contractor to prepare, submit, and pay claims for nursing home and hospice services for certain months before the providers had submitted to Louisiana any claims for those services, in order to capture higher reimbursement for those expenditures before scheduled decreases in the federal share of Louisiana's Medicaid payments. ¹⁵⁶	\$13.422 million

155 <https://www.justice.gov/usao-md/pr/baltimore-plaintiffs-law-firm-saiontz-kirk-pa-pays-united-states-over-90000-settle>.

156 <https://www.justice.gov/opa/pr/louisiana-department-health-pay-1342-million-settle-alleged-false-medicaid-claims-nursing>.

ABOUT BASS, BERRY & SIMS

The Bass, Berry & Sims Healthcare Fraud & Abuse Task Force represents healthcare providers in responding to government 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. Since 2009, Bass, Berry & Sims has served as defendant's counsel in more than half the FCA cases in Tennessee, more than all other firms combined. 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 team includes 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 Law School teaching Healthcare Fraud and Abuse. For more information, please visit our website at www.bassberry.com/healthcare-fraud.

Ranked the fourth largest healthcare firm in the U.S. by **American Health Lawyers Association** (2019)



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Brian Bewley is an experienced healthcare regulatory compliance and enforcement attorney. Drawing upon his experience as a senior healthcare attorney in Washington, D.C. with both HHS-OIG and DOJ, Brian advises and defends clients dealing with complex issues involving compliance with laws governing participation in federal healthcare programs. He has successfully defended companies under investigation pursuant to the FCA and HHS-OIG's Civil Monetary Penalties law. Brian has also handled numerous voluntary disclosures to HHS-OIG and CMS and helped companies navigate their respective obligations under CIAs with the OIG.

Taylor Chenery centers his practice on government compliance and investigations and related litigation, focusing on issues of healthcare fraud and abuse. Taylor has significant experience representing a wide variety of healthcare clients in relation to government inquiries and investigations by the HHS-OIG, U.S. Attorneys' Offices, DOJ, and other federal and state agencies. Taylor regularly litigates lawsuits filed under the FCA and conducts internal investigations for healthcare companies and providers, advising them on compliance-related issues.

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

John Eason represents clients in government enforcement actions, investigations and litigation, particularly involving the FCA. He has represented companies and individuals in responding to inquiries and investigations by DOJ, HHS-OIG and other federal and state agencies regarding healthcare and procurement fraud issues.

Lindsey Brown 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 internal investigations and self-disclosures. She also counsels clients in connection with responding to audits and appeals by government contractors.

Jeff Gibson has extensive experience representing healthcare clients in complex civil litigation and government investigations, including defending individuals and companies facing white collar criminal charges, quasi-criminal civil fraud claims, and compliance violations. He leads internal investigations, addresses compliance issues, and provides crisis management services. Jeff is also a Tennessee Supreme Court Rule 31 Listed General Civil Mediator.

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

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

Lisa Rivera focuses her practice on advising healthcare providers on matters related to compliance and civil and criminal healthcare fraud and abuse, including internal investigations, 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 government investigations and defending FCA lawsuits. He has successfully litigated and resolved numerous healthcare fraud matters and frequently represents clients in connection with Medicare audits and overpayment disputes. Brian is an adjunct professor at Vanderbilt Law School, teaching Healthcare Fraud and Abuse.

Glenn Rose represents clients in complex business disputes and healthcare litigation, including defending FCA lawsuits, conducting internal investigations, and assisting clients with risk management issues.

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, reimbursement and operational matters, including in the context of transactional diligence and structuring, reimbursement, contractual relationships, compliance reviews, self-disclosures and voluntary repayments.

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

Allison Acker defends healthcare providers in connection with alleged violations of the FCA, AKS, Stark Law and other healthcare statutes. She also counsels clients in connection with internal investigations and responding to government inquiries by DOJ, HHS-OIG and the SEC.

Angela Bergman represents clients in internal and government investigations, administrative actions, as well as litigation related to compliance and alleged FCA violations, including home health and hospital billing practices, medical necessity issues, and other fraud and abuse matters.

Christopher Climo advises healthcare clients in connection with government investigations and related civil and criminal litigation under the FCA, AKS and the Stark Law.

Nicholas Deuschle represents healthcare companies in fraud and abuse investigations, enforcements actions, litigation, and criminal prosecutions stemming from government and whistleblower claims brought under the FCA, AKS, Stark Law and other healthcare statutes.

Margaret Dodson represents healthcare providers involved in litigation and investigations involving various state and federal statutes, including the FCA, Stark Law and AKS. She also helps clients respond to government investigations by DOJ, HHS-OIG, U.S. Attorneys' Offices and the SEC.

Kaitlyn Dunn counsels healthcare clients in matters related to regulatory compliance, fraud and abuse, and government investigations. She helps clients respond to civil, criminal and administrative enforcement actions, including those brought under the FCA, AKS and Stark Law. Katie previously served for three years as Associate Counsel at the HHS-OIG, where she was team leader for the New York, Chicago and Kansas City regions.

Scott Gallisdorfer represents healthcare clients in government investigations and complex litigation, with a particular emphasis on fraud and abuse matters. He routinely counsels clients on responding to FCA allegations, making self-disclosures, and investigating compliance issues.

Maleaka Guice provides healthcare regulatory counsel as it relates to compliance, operational and transactional matters.

Kate Hunter-Salas concentrates her practice on investigations and litigation related to inquiries involving alleged violations of the FCA, other federal statutes, and state health regulatory requirements.

Brian Irving represents clients in civil litigation and government investigations, focusing on healthcare fraud matters brought under the FCA. He helps healthcare providers respond to government inquiries brought by DOJ, HHS-OIG and U.S. Attorneys' Offices.

Sara Morgan represents healthcare clients related to various federal and state compliance issues including the FCA, Stark Law and AKS. She works with clients in defense of allegations of healthcare fraud and abuse.

Elaine Naughton provides healthcare regulatory counsel as it relates to transactional and operational matters, including compliance with FCA, Stark Law and AKS. She works with a range of the firm's healthcare clients, including hospitals, health systems, hospice and home health providers, laboratories and specialty pharmacies.

Brianna Powell provides healthcare compliance and fraud and abuse counsel on regulatory, operational and transactional matters, including counsel on compliance with state and federal healthcare statutes and regulations such as the Stark Law, AKS and FCA. Additionally, Brianna assists clients in responding to and appealing commercial and government payor audits.

Molly Ruberg represents clients in connection with internal investigations, government enforcement actions, and civil and criminal proceedings, particularly involving matters of alleged fraud and abuse in the healthcare sector.

Taylor Sample focuses his practice on representing clients in government actions, investigations and related litigation, particularly involving the FCA, Stark Law and AKS. He also assists clients with internal compliance assessments and internal investigations regarding regulatory compliance issues.

Olivia Seraphim represents healthcare clients in government actions, investigations and related litigation arising from fraud and abuse allegations brought under the FCA, AKS, Stark Law, Medicare and Medicaid reimbursement rules, and various other federal and state healthcare statutes and regulations.

Page Smith provides healthcare regulatory counsel as it relates to compliance, operational, fraud and abuse, and transactional matters.

Hannah Webber represents healthcare providers in connection with government enforcement actions, investigations and related litigation. She routinely counsels clients in compliance matters, FCA litigation, self-disclosures and responding to government inquiries. She also has experience representing providers in the managed care space.

Abby Yi represents companies in connection with internal and government investigations concerning white collar and corporate compliance matters. In addition, she regularly works with healthcare companies on healthcare fraud and abuse issues related to alleged violations under the FCA, AKS and Stark Law.

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