10TH ANNUAL

HEALTHCARE FRAUD & ABUSE REVIEW 2021

BASS BERRY SIMS

A LOOK BACK ... A LOOK AHEAD

We are pleased to bring you our 10th annual Healthcare Fraud and Abuse Review. We began the Review a decade ago with the intention of providing comprehensive coverage of the most significant civil and criminal enforcement issues facing healthcare providers each year. During that time, we have endeavored to cover key enforcement initiatives, analyze important case developments and document healthcare fraud settlements across the industry and to present those topics in a readily digestible format for our readers.

While the healthcare industry has dealt with a decade of unprecedented change and challenges, the government's healthcare fraud enforcement efforts have remained consistent. To be sure, areas of enforcement focus have shifted from time to time in order to address public health crises, fraud vulnerabilities within the healthcare industry or the need to prioritize resources. But the foundation has remained the same. The filing of *qui tam* lawsuits under the False Claims Act (FCA) has continued to drive civil enforcement, and the U.S. Department of Justice's (DOJ) strike force model has been the main driver of the government's criminal enforcement efforts.

During 2021, we marked the 35th anniversary of the 1986 amendments to the FCA, which reinvigorated that Civil War-era statute after a long period of dormancy. Over the last 10 years, the government has recovered more than $25 billion in civil fraud settlements and judgments involving the healthcare industry, including $5 billion in FY2021.[1] For their part, *qui tam* relators have received nearly $4 billion in relator share payments, including more than $200 million in FY2021, as a reward for their efforts in bringing healthcare industry-related FCA lawsuits on behalf of the government during that same time period.

We also marked the fifth anniversary of the Supreme Court's landmark decision in ***Universal Health Services v. U.S. ex rel. Escobar***.[2] In that pivotal case, the Supreme Court addressed the FCA's materiality requirement, describing it as rigorous and demanding, and set forth a number of nonexclusive considerations to guide the materiality inquiry. Those important considerations primarily focus on the government's actual conduct with respect to payment of purportedly false claims.

Five years later, the Court's discussion of materiality continues to have a profound impact on the manner in which FCA allegations are pleaded in complaints, investigated by the government and litigated by parties. The Court's opinion has also been the impetus of efforts to amend the FCA because of the perception by certain lawmakers that *Escobar* "has made it all too easy for fraudsters to argue that their obvious fraud was not material simply because the government continued payment."[3] No doubt, healthcare providers defending against creative theories of FCA liability urged by relators or the government where the conduct at issue seemingly has had little or no impact on the government's reimbursement decisions would disagree with that sentiment.

The filing of *qui tam* lawsuits under the False Claims Act has continued to drive civil enforcement, and the U.S. Department of Justice's strike force model has been the main driver of the government's criminal enforcement efforts.

Beyond the FCA's materiality requirement, key FCA issues – particularly those involving FCA pleading standards and the requirement of pleading and proving

1 https://www.justice.gov/opa/press-release/file/1354316/download; https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year. During that same time period, the government has recovered more than $37 billion in total civil fraud enforcement settlements and judgments, including $5.6 in FY2021.

2 https://www.law360.com/articles/1396615/where-fca-litigation-stands-5-years-after-escobar.

3 https://www.grassley.senate.gov/news/news-releases/senators-introduce-of-bipartisan-legislation-to-fight-government-waste-fraud.

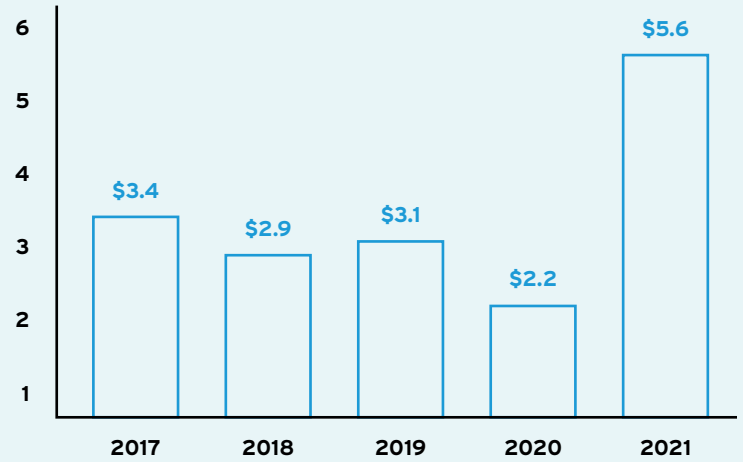
To no one's surprise, we have begun to see enforcement results stemming from fraud schemes associated with the trillions of dollars of pandemic-related relief. At year's end, the U.S. Secret Service warned of "potential fraudulent activity nearing $100 billion."

scienter – are winding their way through the federal court system.[4] And, there is a distinct possibility that the Supreme Court will take up one or more of these issues in the coming years.

To no one's surprise, we have begun to see enforcement results stemming from fraud schemes associated with the trillions of dollars of pandemic-related relief. At year's end, the U.S. Secret Service warned of "potential fraudulent activity nearing $100 billion."[5] Along the way, we saw DOJ announce a number of significant Coronavirus Aid, Relief, and Economic Security (CARES) Act and COVID-19-related enforcement results. There is no question we will continue to see the government focus its efforts on uncovering and prosecuting relief-related fraud in the coming years.

If the last decade of closely following healthcare fraud and abuse developments have taught us anything, we know that each year will pose new enforcement challenges for those involved in the healthcare industry. We trust that our firm's annual **Healthcare Fraud & Abuse Review** will assist healthcare providers in better anticipating those challenges and understanding how those challenges can be best navigated in an ever-changing world.

CIVIL FRAUD RECOVERIES
FY 2017-2021 ($BILLIONS)



4 *See, e.g. Estate of Helmly v. Bethany Hospice & Palliative Care LLC*, 853 F. Appx. 496 (11th Cir. 2021) (affirming dismissal for failure to plead FCA claims in accordance with Rule 9(b)), petition for writ of certiorari pending No. 21-462; *U.S. ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455 (7th Cir. 2021) (affirming dismissal of FCA claims because defendants were alleged to have acted in accordance with an objectively reasonable interpretation of the applicable regulations precluding a determination of scienter under the FCA).

5 https://www.wsj.com/articles/thefts-of-covid-19-relief-funds-total-at-least-100-billion-secret-service-says-11640202072.

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.

CARES ACT/COVID-19 RELIEF

DOJ has scrutinized the receipt and use of the historic and unprecedented CARES Act funding and civil and criminal enforcement actions have followed. As anticipated in last year's Review, pandemic-related fraud has become an enforcement priority with the government devoting significant personnel and resources to this effort and investigations and settlements increasing. In his presentation at the Federal Bar Association's Qui Tam Conference in February, Acting Assistant Attorney General Brian M. Boynton highlighted DOJ's top priority areas for enforcement, noting that the "inevitable fraud schemes" stemming from COVID-19-related funding would likely include false representations related to eligibility, misuse, and false certifications, all of which constitute the type of misconduct the FCA "has long been used to address."[6]

6 *See* presentation of Acting Assistant Attorney General, DOJ Civil Division, at Federal Bar Association's Qui Tam Conference (Feb. 17, 2021) (highlighting DOJ's top priority areas for FCA enforcement in 2021), https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.

CARES Act enforcement actions in 2021 targeted the alleged misappropriation of funds beyond authorized uses for COVID-19 funding, obtaining multiple loans beyond limitations imposed during funding phases, and making false statements to obtain COVID-19 funding.

In May 2021, U.S. Attorney General Merrick B. Garland announced the establishment of a COVID-19 Fraud Enforcement Task Force to "marshal the resources of the Department of Justice" through partnership with other government agencies to enhance enforcement efforts against pandemic fraud.[7] The Attorney General emphasized that the Task Force will augment existing mechanisms within DOJ to pursue these matters and noted that Task Force members include civil and criminal DOJ attorneys, the Federal Bureau of Investigation (FBI), Department of Labor, Department of Treasury, Homeland Security, the Small Business Administration, the newly created Special Inspector General for Pandemic Recovery (SIGPR)[8] and the Pandemic Response Accountability Committee (PRAC),[9] and others. In short, for the largest distribution of economic funding by the government in our history, DOJ will have far more resources to review and investigate the eligibility and use of COVID-19-related funding than typically available for civil and criminal investigations.

CARES Act enforcement actions in 2021 targeted the alleged misappropriation of funds beyond authorized uses for COVID-19 funding[10], obtaining multiple loans beyond limitations imposed during funding phases[11], and making false statements to obtain COVID-19 funding.[12] While only one of these involved a healthcare provider, we anticipate an increase in FCA healthcare investigations related to COVID-19 funding for years to come, as the government is just beginning its review and focus on specific uses of COVID-19 funding. September 2021 marked some of the first reporting deadlines for funding recipients with subsequent deadlines scheduled through 2023, depending on the date COVID-19 funding was received.[13] The final distribution of $9 billion in COVID-19 relief funds to healthcare entities was released on December 14, 2021, with corresponding reporting obligations scheduled for 2023.

7 https://www.justice.gov/opa/pr/attorney-general-announces-task-force-combat-covid-19-fraud.

8 The Special Inspector General for Pandemic Recovery (SIGPR), was created by the CARES Act to conduct, supervise, and coordinate audits and investigations related to any program or funding under portions of the CARES Act, and includes broad subpoena power. *See*, https://www.sigpr.gov/.

9 The Pandemic Response Accountability Committee (PRAC) was created by the CARES Act to support and coordinate independent oversight of the more than $5 trillion pandemic relief spending. *See*, https://www.pandemicoversight.gov/.

10 https://www.justice.gov/opa/pr/owner-jet-charter-company-settles-false-claims-act-allegations-regarding-misappropriation.

11 https://www.justice.gov/usao-edva/pr/Virginia-company-agrees-settle-civil-fraud-allegations-paycheck-protection-program.

12 https://www.justice.gov/usao-edca/pr/bakersfield-medical-practice-agrees-resolve-false-claims-act-allegations-involving.

13 https://www.hrsa.gov/provider-relief/reporting-auditing.

In September 2021, the U.S. Department of Health and Human Services (HHS) announced that it had retained several accounting and consulting firms to conduct audits of COVID-19 relief payments made to healthcare providers.[14] Additionally, the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) stated that it would audit COVID-19 funding uses[15] and, more specifically, whether payments made by Medicare for COVID-19 inpatient discharges billed by hospitals complied with federal requirements.[16] Furthermore, HHS-OIG has expressed program integrity concerns regarding persons and entities that took advantage of the Centers for Medicare & Medicaid Services (CMS) relaxation of rules during the pandemic, such as laboratories performing "add-on" tests to confirm or rule out diagnoses other than COVID-19.[17]

We expect to see a wave of whistleblower *qui tam* lawsuits stemming from the receipt of pandemic-related relief, which will generate numerous additional COVID-19 funding investigations. These will be fueled not only by the typical financial incentives provided by the FCA, but also as a result of issues raised by funding recipients' attempts to adhere to the hastily-issued and ever-evolving guidance provided by the government during the rush of COVID-19 funding amidst the global pandemic crisis. As DOJ's Boynton stated at the Federal Bar Association's Qui Tam Conference, the "False Claims Act will play a significant role in the coming years as the government grapples with the consequences of this pandemic."

THE FUTURE OF THE FALSE CLAIMS ACT

For a law that has been on the books for well over 150 years, it has only been relatively recently that the FCA has been the government's primary civil enforcement tool and a statute relied upon by private parties (relators) to bring suit on behalf of the government through the FCA's *qui tam* provisions. The 1986 FCA amendments paved the way for the statute as we know it today by increasing the damages and penalties available to the government for recovery, increasing the percentages of recovery for *qui tam* relators and implementing protections for whistleblowing activity, among other things.

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Since the 1986 FCA amendments, there have been other amendments intended to strengthen the FCA by addressing court decisions perceived to have weakened the FCA's effectiveness. As the Supreme Court's decision in *Escobar* continues to give rise to fierce legal disputes concerning the FCA's materiality requirement, there were efforts last year to amend the FCA in an attempt to cabin *Escobar*'s impact. Titled the False Claims Amendments Act of 2021, the proposed amendments would "clarify[y] the current law following confusion and misinterpretation of the Supreme Court decision in [*Escobar*], which has made it all too easy for fraudsters to argue that their obvious fraud was not material simply because the government continued payment."[18] Late last year, the proposed amendments were approved by the Senate Judiciary Committee for consideration by the full Senate. It remains to be seen whether the Senate will take up the proposed amendments, but there can be no question that efforts to strengthen the FCA enjoy bipartisan support and will continue in the future.

The government continues to tout the FCA and, in particular, the FCA's *qui tam* provisions, as vital tools in its civil fraud enforcement toolbox as it relates to uncovering fraud in the healthcare industry.

The Supreme Court may very well have the opportunity to evaluate other key legal questions involving the FCA in the coming year. There have been a number of instances in prior years where parties have urged the Supreme Court to take up the pleading standards applicable to FCA claims under Rule 9(b) of the Federal Rules of Civil Procedure (FRCP). Until now, the Supreme Court has declined to take up that issue, but there is a possibility that may change as a result of the petition for writ of certiorari pending following the Eleventh Circuit's decision in ***Estate of Helmly v. Bethany Hospice & Palliative Care, LLC***, to affirm the district court's dismissal of FCA claims for failure to meet Rule 9(b)'s pleading requirements.[19] In October 2021, the Supreme Court requested a response to the petition for writ of certiorari and the petition was distributed for conference earlier this year.

Finally, the government continues to tout the FCA and, in particular, the FCA's *qui tam* provisions, as vital tools in its civil fraud enforcement toolbox as it relates to uncovering fraud in the healthcare industry. And perhaps they are. But the FCA certainly is not the most efficient way to uncover actual healthcare fraud, as FCA investigations of allegations made in *qui tam* lawsuits often drag on for years, with resolutions driven as much by the possibility of crippling damages and per claim penalties or massive defense costs as by an evaluation of the actual merits. As regulators continue to evaluate how to move away from the pay-and-chase model of healthcare fraud enforcement and toward more proactive approaches, whether the FCA retains its place of prominence in the enforcement toolbox certainly must be considered as well.

14 https://www.beckershospitalreview.com/finance/hhs-taps-4-firms-to-audit-provider-relief-fund-grants.html.
15 https://oig.hhs.gov/coronavirus/.
16 https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000515.asp.
17 *See* "Trend Analysis of Medicare Laboratory Billing for Potential Fraud and Abuse with COVID-19 Add-on Testing," at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000489.asp.
18 https://www.grassley.senate.gov/news/news-releases/senators-introduce-of-bipartisan-legislation-to-fight-government-waste-fraud.
19 853 F. App'x 496 (11th Cir. 2021) (affirming dismissal for failure to plead FCA claims in accordance with Rule 9(b)), petition for writ of certiorari pending No. 21-462.

CYBER FRAUD ENFORCEMENT RISK

In October 2021, DOJ announced a new Civil Cyber-Fraud Initiative to pursue FCA liability against government contractors in the cybersecurity space. The initiative seeks to "hold accountable entities or individuals that put U.S. information or systems at risk by knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches."[20]

In October 2021, DOJ announced a new Civil Cyber-Fraud Initiative to pursue FCA liability against government contractors in the cybersecurity space.

The Civil Cyber-Fraud Initiative follows several significant cyberattacks, which are only becoming more prevalent. The new initiative is the first formal step DOJ has taken to combat attacks by focusing on the preventative cybersecurity efforts of government contractors.

The implications for healthcare entities are noteworthy. Health Insurance Portability and Accountability Act (HIPAA) covered entities and business associates are already subject to a complex web of privacy and security requirements. But, the Civil Cyber-Fraud Initiative raises additional enforcement concerns to healthcare entities with the statutory threat of treble damages and staggering statutory penalties under the FCA.

Moreover, the initiative is likely to encourage whistleblowers to be more creative and aggressive in bringing *qui tam* suits under the FCA in asserting that companies are not honoring their cybersecurity obligations. Indeed, some whistleblower practice groups have already put out calls to arms, and Acting Assistant Attorney General Boynton highlighted the role of whistleblowers in his address at the Cybersecurity and Infrastructure Security Agency (CISA) 4th Annual National Cybersecurity Summit.[21] Boynton noted DOJ's reliance on the "inside information" of whistleblowers and their "new and evolving fraud schemes that might otherwise remain undetected."[22]

DOJ has pointed to at least three "common cybersecurity failures" that could result in FCA enforcement: (1) knowing failures to meet cybersecurity standards; (2) knowing misrepresentations of security controls and practices; and (3) failing to timely report suspected breaches, which DOJ views as critical for government agencies to respond, remediate any vulnerabilities, and limit the resulting harm.

Additionally, investigations related to cybersecurity can lead to investigations and enforcement actions by other state and federal agencies and litigation, including: (1) U.S. Securities and Exchange Commission investigations related to the accuracy of information in disclosures and reporting purportedly impacted by data security; (2) the Federal Trade Commission for violations of Section 5 of the Federal Trade Commission Act[23] related to consumer protection; (3) HHS for violations of HIPAA privacy and security rules; and class action suits brought by patients and other individuals, or state attorneys general pursuant to state privacy, security; and/or (4) consumer protection laws.

OPIOID ENFORCEMENT

Amidst the pandemic, combating the opioid epidemic remains a major enforcement priority for the government, as DOJ has noted the ongoing opioid epidemic seems to have been "exacerbated by the pandemic."[24] Attorney General Garland has acknowledged that "[a]gainst the backdrop of the COVID-19 pandemic, the nation is experiencing a precipitous rise in opioid and stimulant misuse and overdoses."[25] According to the Centers for Disease Control and Prevention, "there were an estimated 100,306 drug overdose deaths in the United States during the 12-month period ending in April 2021, an increase of 28.5% from the 78,056 deaths during the same period the year before."[26]

In response, DOJ has committed to "employ every tool at our disposal to address the opioid addiction crisis" and has promised to "aggressively prosecute anyone who is illegally peddling opioids for profit."[27] While the primary target of DOJ's opioid enforcement actions has been pharmaceutical companies, DOJ has committed to investigating those in the opioid distribution chain, including pharmacies, clinics and individual doctors who prescribe and dispense unnecessary opioids.[28]

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In its 2021 annual healthcare fraud takedown, DOJ announced that it brought opioid-related charges against 19 defendants, including several medical professionals, who had prescribed over 12 million doses of opioids and submitted $14 million in false billings.[29] Although criminal enforcement actions have often been the focus of DOJ opioid enforcement efforts, DOJ's Civil Division has also used multiple tools at its disposal,

20 https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative.
21 https://www.natlawreview.com/article/calling-all-cybersecurity-whistleblowers-doj-wants-you-to-report-cyber-fraud.
22 https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-cybersecurity-and.
23 https://www.ftc.gov/news-events/media-resources/protecting-consumer-privacy/privacy-security-enforcement.
24 https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.
25 https://www.justice.gov/opa/pr/department-justice-awards-more-300-million-fight-opioid-and-stimulant-crisis-and-address.
26 https://www.justice.gov/opa/pr/department-justice-awards-more-300-million-fight-opioid-and-stimulant-crisis-and-address.
27 https://www.justice.gov/opa/video/assistant-attorney-general-kenneth-polite-jr-delivers-remarks-health-care-enforcement.
28 https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.
29 https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion.

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including the FCA, in concert with DOJ's criminal enforcement remedies.[30] DOJ has highlighted the FCA's treble damages and penalty provisions as crucial to "return funds to strapped federal health care programs and serve to deter those who seek to profit from the opioid crisis."[31] As the opioid crisis worsens in the shadow of the COVID-19 pandemic, DOJ will almost certainly continue to utilize both criminal and civil enforcement actions in an effort to stem the tide.

THE CONTINUED IMPACT OF *ALLINA*

In 2019, the Supreme Court held in ***Azar v. Allina Health Servs.*** that HHS must comply with notice and comment requirements pursuant to administrative rulemaking processes when issuing any new substantive legal standards.[32] The Supreme Court's decision may very well impact healthcare fraud enforcement decision-making from the government's perspective, as well as the defenses available to healthcare companies facing allegations of a failure to comply certain alleged billing requirements. ***Allina*** involved a challenge by hospitals to a retroactive Medicare rate calculation posted on the internet as guidance, which the Supreme Court determined effectively described and established a new substantive legal standard. Because that new legal standard had not been subjected to the required agency notice and comment rulemaking process, the Supreme Court determined that the standard had been impermissibly imposed by HHS.

In January 2021, at the end of the Trump administration, HHS issued formal rules setting forth the proper use of guidance documents.[33] The rules prohibited the government's use of guidance as a means of creating requirements or prohibitions unless authorized by law or contained in the specific provisions of a contract. Noncompliance with guidance, therefore, may not be treated as a violation of a regulation or statute unless explicitly authorized by law. The HHS final rule is consistent with DOJ's earlier Brand Memo, which provided that DOJ attorneys "may not use its enforcement authority to effectively convert agency guidance documents into binding rules."[34]

Not surprisingly, the change in administrations led to a different approach toward the weight given to regulatory guidance. In a Memorandum issued July 1, 2021, Attorney General Garland rescinded the Brand Memo, describing it as "overly restrictive," and a discouragement to the "development of valuable guidance," and noted that it generated collateral disputes and hampered DOJ's litigation of cases.[35] DOJ attorneys now will be provided with internal guidelines for utilizing agency guidance and guidance may be used in any "appropriate and lawful circumstances," such as for advancing agency deference and persuasive weight for the meaning of the applicable legal requirements. The Memo noted that guidance documents can "serve as an important tool to promote transparency, fairness, and efficiency" and directed that the Justice Manual be revised accordingly.

In October 2021, less than a year after formalizing its final rules on use of guidance, HHS published a proposed rule that would repeal regulations issued by the Trump administration that limited HHS's use of guidance documents.[36] Comments related to the proposed rule were due to HHS in November of 2021. The proposed rule stated that previous guidance created "unnecessary hurdles" to bringing enforcement actions, as well as other limitations, and frustrated HHS's ability to operate as needed, making operations too "cumbersome and burdensome."

The government's evolving view on the extent of the use and impact of agency guidance in connection with FCA enforcement will continue to be an issue to watch in the highly regulated healthcare industry.

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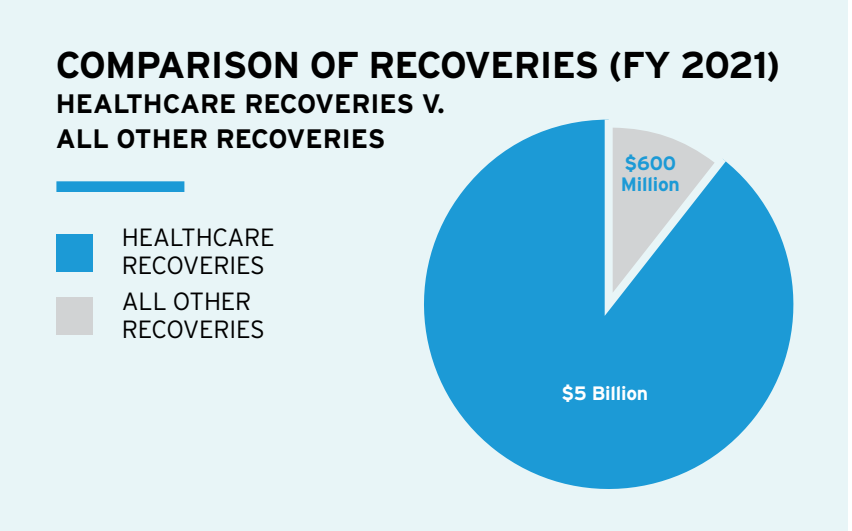
30 https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.
31 https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar.
32 *Azar v. Allina Health Servs*., 139 S. Ct. 1804 (2019).
33 86 Fed. Reg. 3010 (Jan. 14, 2021), codified in 45 C.F.R. Part 1; https://hhs.gov/about/news/2021/01/12/hhs-improves-agency-procedures-relating-transparency-fairness-civil-enforcement-actions.html.
34 https://www.justice.gov/file/1028756/download. The Brand Memo was codified in the DOJ Justice Manual at https://www.justice.gov/jm/1-19000-limitation-issuance-guidance-documents-1.
35 https://www.justice.gov/opa/page/file/1408606/download. The Attorney General also rescinded the earlier Sessions Memo from 2017, which prohibited DOJ from creating and enforcing policies through guidance documents.
36 86 Fed. Reg. 58042-53 (Oct.20, 2021); https://www.federalregister.gov/documents/2021/10/20/2021-22503/department-of-health-and-human-services-proposed-repeal-of-hhs-rules-on-gidance-enforcement-and.

NOTEWORTHY SETTLEMENTS

Following the trend of more than a decade, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2021. Of the $5.6 billion in civil fraud settlements and judgments, recoveries from matters involving the healthcare industry amounted to $5 billion (89%).[37] This is the 13th consecutive year that recoveries in federal civil healthcare fraud matters have exceeded $2 billion and is the largest recovery since FY2014.[38]

37 https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year.

38 https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.



Newly-filed *qui tam* complaints accounted for the vast majority of new civil fraud matters initiated in FY 2021, which is also typical of recent years. Whistleblowers filed 589 new *qui tam* lawsuits, which represented a substantial decrease over the prior year and is the lowest number of new *qui tam* lawsuits since 2010. *Qui tam* lawsuits accounted for more than $1.6 billion of the $5.6 billion recovered in civil enforcement matters.[39]

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

HOSPITALS AND HEALTH SYSTEMS

Hospitals and health systems resolved several notable cases, 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, including arrangements where compensation allegedly exceeded fair market value (FMV) or accounted for the volume or value of physician referrals.[40] In one such case, a hospital agreed to pay over $18 million to resolve allegations that it impermissibly took into account the volume and value of certain physicians' referrals when it repurchased shares from physician-owners aged 63 or older and then resold the shares to younger physicians.[41]

39 The balance of the total civil fraud enforcement settlements and judgments for FY2021 was comprised, in significant part, of recoveries associated with opioid enforcement efforts. *See* https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year.

40 https://www.justice.gov/opa/pr/northern-ohio-health-system-agrees-pay-over-21-million-resolve-false-claims-act-allegations; https://www.justice.gov/opa/pr/prime-healthcare-services-and-two-doctors-agree-pay-375-million-settle-allegations-kickbacks.

41 https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations.

A number of settlements by hospitals and health systems involved the failure to adhere to reimbursement or coverage requirements,[42] including one such settlement by St. Joseph's Hospital and an affiliated physician practice for $10 million related to alleged concurrent and overlapping surgeries.[43] Many others resolved cases related to medical necessity issues, including allegations of inappropriately billing or coding claims.[44] In the largest settlement involving a hospital or health system in FY 2021, Sutter Health and affiliated entities agreed to pay $90 million and enter into a five-year Corporate Integrity Agreement (CIA) to resolve allegations that they submitted unsupported diagnosis codes to Medicare Advantage plans to increase reimbursement.

LONG-TERM CARE PROVIDERS

DOJ continued its focus on the medical necessity of services rendered by long-term care providers. Multiple skilled nursing facilities (SNF), home health companies and a hospice company resolved allegations that they billed federal healthcare programs for services that were either medically unnecessary or not rendered at all.[45] In addition, two providers of rehabilitation services for SNF patients settled allegations that they billed Medicare for rehabilitation therapy services that were not medically necessary, reasonable or skilled.[46]

Other settlements involving long-term care providers related to alleged violations of the AKS and the Stark Law. As one example, home health agency operator BAYADA Home Health Care, Inc., and several affiliated entities agreed to pay $17 million to resolve FCA allegations that they purchased two home health agencies in order to obtain referrals of Medicare beneficiaries from other retirement communities operated by the seller of the home health agencies, in violation of the AKS.[47]

COMPARISON OF TOTAL RECOVERIES:
INTERVENED V. DECLINED CASES
SETTLEMENTS AND JUDGMENTS (FY 2017-2021)

YEAR	INTERVENED CASES	DECLINED CASES
2017	$2.55 billion	$602.68 million
2018	$2.00 billion	$135.22 million
2019	$1.94 billion	$305.52 million
2020	$1.51 billion	$193.88 million
2021	$1.19 billion	$479.01 million

The pharmaceutical and medical device sectors of the healthcare industry continued to constitute a significant source of recovery within the healthcare industry last year Many of the larger settlements in these sectors related to product defects and many others involved allegations of AKS violations.

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

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42 https://www.justice.gov/usao-wdny/pr/upper-allegheny-health-system-pay-27-million-settle-false-claims-act-allegations; https://www.justice.gov/usao-mdpa/pr/geisinger-community-health-services-agrees-18-million-civil-settlement.

43 https://www.justice.gov/usao-az/pr/neurosurgical-associates-ltd-and-dignity-health-dba-st-josephs-hospital-paid-10-million.

44 https://www.justice.gov/opa/pr/ascension-michigan-pay-28-million-resolve-false-claims-act-allegations; https://www.justice.gov/opa/pr/county-medical-center-and-county-agree-pay-114-million-resolve-false-claims-act-allegations; https://www.justice.gov/usao-cdil/pr/federal-and-state-authorities-reach-settlement-blessing-hospital-over-medicare-and; https://www.justice.gov/usao-ndtx/pr/hospital-pay-more-3-million-settle-whistleblower-suit.

45 https://www.justice.gov/usao-mdtn/pr/savaseniorcare-llc-agrees-pay-112-million-resolve-false-claims-act-allegations; https://www.justice.gov/usao-edca/pr/california-s-second-largest-skilled-nursing-facility-operator-pays-450000-resolve-false; https://www.justice.gov/usao-edmi/pr/usmm-and-vpa-pay-85-million-resolve-overpayment-medicare-claims-laboratory-and; https://www.justice.gov/usao-or/pr/bend-resident-and-affiliated-residential-care-company-agree-pay-29-million-settle-health; https://www.justice.gov/opa/pr/crossroads-hospice-agrees-pay-55-million-settle-false-claims-act-liability.

46 https://www.justice.gov/opa/pr/contract-rehabilitation-therapy-providers-agree-pay-84-million-resolve-false-claims-act; https://www.justice.gov/opa/pr/interface-rehab-pay-2-million-resolve-false-claims-act-allegations.

47 https://www.justice.gov/usao-nj/pr/home-health-agency-operator-pay-17-million-resolve-false-claims-act-kickback-allegations.

Three significant settlements in July 2021 reflected DOJ scrutiny of product quality and performance in the medical device space. Three medical device companies agreed to pay $22 million, $27 million and $38.75 million, respectively, to resolve claims that they had sold defective products.[48] Specifically, Avanos Medical, Inc., allegedly sold surgical gowns that did not meet the standards with which the gowns were labeled. St. Jude Medical, Inc., allegedly sold implantable defibrillators without disclosing that the devices' batteries could lose power prematurely. And, Alere, Inc., allegedly sold defective blood coagulation monitors used by Medicare beneficiaries taking anticoagulant drugs. All three settlements highlight DOJ's heightened attention to FCA violations that directly involve patient safety.

Several significant settlements involved alleged failure to collect co-pays from Medicare beneficiaries. In May 2021, Incyte Corporation agreed to pay $12.6 million to resolve allegations that it channeled money through a foundation to fund co-pays for Medicare and TRICARE beneficiaries.[49] Incyte was the fund's sole donor and allegedly pressured the foundation to fund co-pays for patients who were ineligible for assistance under the foundation's own guidelines. In August, a mail-order diabetic testing supply company agreed to pay $160 million to resolve allegations that they paid kickbacks to patients by routinely waiving and failing to make reasonable efforts to collect Medicare co-payments, among other allegations.[50]

The government continued to pursue cases involving alleged kickbacks. Three generic pharmaceutical manufacturers agreed to pay $447.2 million to settle allegations that they paid and received kickbacks through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers.[51] The government alleged that these arrangements were no more than price-fixing schemes. As part of the resolution, each of the companies also entered into a five-year CIA with HHS-OIG that includes unique internal monitoring and price transparency provisions.

In addition, a medical device company agreed to pay $16 million to resolve FCA allegations that it made payments to a surgeon that were disguised as royalty payments for the surgeon's contributions to two devices, but were actually made in exchange for his use and recommendation of the company's devices, in violation of the AKS.[52]

48 https://www.justice.gov/opa/pr/avanos-medical-inc-pay-22-million-resolve-criminal-charge-related-fraudulent-misbranding-its; https://www.justice.gov/usao-md/pr/st-jude-medical-agrees-pay-27-million-allegedly-selling-defective-heart-devices; https://www.justice.gov/usao-nj/pr/medical-device-companies-pay-3875-million-settle-false-claims-act-allegations.

49 https://www.justice.gov/usao-edpa/pr/pharmaceutical-manufacturer-agrees-pay-126-million-resolve-allegations-it-provided.

50 https://www.justice.gov/usao-mdtn/pr/mail-order-diabetic-testing-supplier-and-its-parent-company-agree-pay-160-million.

51 https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

52 https://www.justice.gov/opa/pr/medical-device-company-arthrex-pay-16-million-resolve-kickback-allegations.

LAB AND DIAGNOSTIC SERVICE PROVIDERS

Several laboratory and diagnostic service providers settled allegations relating to AKS violations, with the alleged improper remuneration taking such forms as free report interpretation services,[53] sham research payments,[54] and salaries of employees of the referring provider.[55] Multiple other settlements in this sector of healthcare involved billing for medically unnecessary or duplicative services[56] and services provided or ordered without valid physician oversight.[57]

BEHAVIORAL HEALTH

Multiple behavioral health companies settled allegations related to billing for services provided by unlicensed or unqualified providers.[58] Other settlements resolved allegations of billing for medically unnecessary or upcoded services. In one such case, a healthcare company, two of its hospitals and an affiliated substance abuse treatment center agreed to pay over $10 million and enter a five-year CIA to resolve allegations that they submitted claims for medically unnecessary inpatient psychiatric admissions and claims tainted by AKS violations involving the provision of free long-distance van transportation to induce patients to use their facilities.[59]

INDIVIDUAL PROVIDERS AND PRACTICE GROUPS

The government continued its focus on individual actors and their roles in healthcare fraud schemes. This included a focus on credentialed healthcare providers, who the government views as important gatekeepers in relation to federal healthcare programs. In one notable case, a physician agreed to pay $2 million to resolve allegations that he prescribed controlled substances without a valid medical purpose, in violation of the Controlled Substances Act (CSA); many of those prescriptions were paid by Medicare and Medicaid, resulting in violations of the FCA.[60] That physician also pleaded guilty to related criminal charges and was excluded by CMS for at least 10 years.

53 https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-kickback-and-false.

54 https://www.justice.gov/usao-sdca/pr/pain-management-organization-pays-51-million-settle-criminal-medicare-kickback.

55 https://www.justice.gov/usao-sc/pr/georgia-genetic-testing-laboratory-pay-200000-resolve-anti-kickback-statute-claims.

56 https://www.justice.gov/usao-ct/pr/healthcare-company-and-lab-pay-845k-resolve-federal-and-state-false-claims-act; https://www.justice.gov/usao-ma/pr/md-labs-and-its-co-founders-agree-pay-16-million-resolve-allegations-fraudulent-billing.

57 https://www.justice.gov/usao-nj/pr/california-genetic-testing-lab-agrees-pay-357584-resolve-false-claims-act-allegations; https://www.justice.gov/usao-de/pr/akumin-corporation-pay-us-over-700000-resolve-health-care-fraud-allegations; https://www.justice.gov/usao-nj/pr/virginia-diagnostic-testing-lab-agrees-pay-14-million-resolve-false-claims-act.

58 https://www.justice.gov/usao-ct/pr/connecticut-behavioral-health-clinician-group-pays-100k-settle-false-claims-allegations; https://www.justice.gov/usao-ct/pr/behavioral-health-provider-pays-273k-settle-improper-billing-allegations; https://www.justice.gov/usao-edwi/pr/milwaukee-area-community-support-program-facilities-agree-pay-390080-resolve-false; https://www.justice.gov/usao-edva/pr/ndutime-youth-family-services-and-its-ceo-settle-false-claims-act-allegations-relating.

59 https://www.justice.gov/opa/pr/ohio-treatment-facilities-and-corporate-parent-agree-pay-1025-million-resolve-false-claims.

60 https://www.justice.gov/usao-edpa/pr/center-city-doctor-pleads-guilty-illegally-distributing-controlled-substances-and.

The government resolved a number of FCA cases with medical providers in which DOJ alleged that the providers misrepresented services rendered in a manner that increased the reimbursement or permitted the providers to bill for services that were not reimbursable.

The government resolved a number of FCA cases with medical providers in which DOJ alleged that the providers misrepresented services rendered in a manner that increased the reimbursement or permitted the providers to bill for services that were not reimbursable.[61] Such cases included three providers who settled claims that they had improperly billed Medicare and Medicaid for the provision of electro-acupuncture stimulation devices as if the devices had to be implanted surgically when they were not.[62]

Finally, there were multiple settlements by individuals relating to medically unnecessary services, including vascular surgeries, diagnostic testing, cardiac procedures and urinalysis testing.[63] In one such case, a cardiologist agreed to pay $6.75 million to resolve claims that he billed for ablations and stent procedures that were not needed and performed by technicians who were not qualified to administer the procedures; he was also accused of falsifying patient records to obscure those facts.[64]

OTHER ENTITIES AND PROVIDERS

Multiple other entities and providers settled FCA allegations related to causing the submission of false claims. In one notable settlement, electronic health record (EHR) vendor athenahealth, Inc., agreed to pay over $18 million to resolve allegations that it engaged in three marketing schemes in violation of the AKS that caused providers to submit false claims related to federal EHR incentive payments. The vendor allegedly: (1) invited customers and prospective customers to all-expenses-paid "bucket list" events; (2) entered into "Conversion Deals" whereby it paid competitors to refer customers when their products were discontinued, tied to the value and volume of business ultimately converted; and (3) paid fees to customers for each referral that signed up for the product.[65]

Private equity firms also settled FCA allegations related to causing the submission of false claims. In one such case, H.I.G. Capital, LLC, the private equity owner of a mental health clinic operator, agreed to pay $19.95 million, and two former executives of the clinic operator agreed to pay $5.05 million, to resolve FCA allegations that they knew the clinic operator employed individuals who were unlicensed, unqualified, or otherwise providing services in violation of state Medicaid regulations, and they caused false claims to be submitted to Massachusetts Medicaid by failing to adopt recommendations to bring the operator into compliance.[66] Similarly, Ancor Holdings LP agreed to pay a portion of a $15.35 million settlement to resolve allegations that it caused an ambulatory testing provider in its portfolio to submit false claims by allowing an alleged kickback scheme it learned about through diligence to continue after entering an agreement to manage the provider.[67]

61 *See, e.g.*, https://dockets.justia.com/docket/texas/txndce/3:2021cv00157/343353; https://www.justice.gov/usao-md/pr/howard-county-physician-pays-more-660000-resolve-false-claims-act-allegations-fraudulent; https://www.justice.gov/usao-wdtx/pr/healthcare-practitioners-pay-over-1-million-resolve-false-claims-act-liability-arising.

62 https://www.justice.gov/usao-mdtn/pr/united-states-and-tennessee-resolve-claims-three-providers-false-claims-act-liability.

63 https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-resolution-civil-and-criminal-healthcare-fraud-charges; https://www.justice.gov/usao-edmi/pr/cardiologist-dinesh-shah-pays-2-million-resolve-false-claims-act-allegations-relating; https://www.justice.gov/usao-cdil/pr/federal-and-state-authorities-reach-settlement-quincy-medical-group-over-medicare-and; https://www.justice.gov/opa/pr/texas-pain-management-physicians-agree-pay-39-million-resolve-allegations-relating.

64 https://www.justice.gov/usao-mdfl/pr/orlando-cardiologist-pays-675-million-resolve-allegations-performing-unnecessary.

65 https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks.

66 https://www.mass.gov/news/private-equity-firm-and-former-mental-health-center-executives-pay-25-million-over-alleged-false-claims-submitted-for-unlicensed-and-unsupervised-patient-care.

67 https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-kickback-and-false.

FALSE CLAIMS ACT UPDATE

The FCA continues to be the federal government's primary civil enforcement tool for pursuing liability with respect to healthcare providers that have allegedly defrauded federal healthcare programs. As in previous years, there continues 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

Five years after the Supreme Court's watershed 2016 decision in ***Universal Health Services v. U.S. ex rel. Escobar***, this decision continues to have a profound impact on how the FCA's materiality element is pleaded, litigated and analyzed by courts.[68] In *Escobar*, the Supreme Court described the materiality element as "rigorous" and "demanding," and set forth several nonexclusive factors to guide the inquiry. These factors, which mainly focus on the government's likely or actual response to the defendant's alleged misconduct, include the following: (1) whether the government has expressly identified compliance with the relevant statutory, regulatory or contractual requirement as a condition of payment; (2) whether the government consistently refuses to pay claims in other cases based on noncompliance with the requirement; (3) whether the government has continued to pay the defendant's claims with knowledge of the defendant's noncompliance or alleged misrepresentations; and (4) whether compliance with the requirement goes to the essence of the government's bargain, or instead is minor or insubstantial.

Five years after the Supreme Court's watershed 2016 decision in ***Universal Health Services v. U.S. ex rel. Escobar***, this decision continues to have a profound impact on how the FCA's materiality element is pleaded, litigated and analyzed by courts.

As in years past, the application of these factors continues to play a prominent role in the resolution of FCA cases at both the pleading and summary judgment stages, yet courts have not always analyzed these factors consistently. In particular, recent cases reflect a growing disagreement about the extent to which the FCA's materiality element requires a "holistic" review, or, on the other hand, whether one or more of the individual factors identified in *Escobar* – particularly the government's continued payment of claims after learning of the alleged noncompliance – may be dispositive of the materiality inquiry on their own.

Largely at the invitation of *qui tam* relators and the government, several courts hewed toward a more "holistic" approach to materiality, conducting detailed analyses of *all* (or at least most) of the *Escobar* factors, and weighing them against each other, to determine whether the materiality element has been satisfied. These cases have tended to reflect a hesitancy to dismiss FCA lawsuits on materiality grounds, especially because such a far-reaching analysis of multiple factors often ends in the conclusion that the allegations or evidence on materiality is mixed, and therefore the question of materiality should be determined by the factfinder.

In ***U.S. ex rel. Bibby v. Mortgage Investors Corp.***, for instance, the Eleventh Circuit cited the supposedly "holistic" nature of the materiality analysis as a reason for reversing the district court's grant of summary judgment for the defendant mortgage lender.[69] That dismissal had been based on the immateriality of regulations that prohibited lenders from charging certain closing costs to veterans on government-insured loans. Although the Tenth Circuit acknowledged that the government had continued to guarantee loans even after learning about impermissible closing costs, it cited other *Escobar* factors that purportedly

68 579 U.S. 176 (2016).

69 987 F.3d 1340 (11th Cir. 2021).

cut the other way – for example, that the closing costs regulations were conditions of payment and essential to the bargain – as a reason for denying summary judgment and leaving materiality to be resolved by the factfinder at trial.[70]

Several district courts have adopted similar approaches in healthcare cases, citing a need for discovery and a more thorough analysis of the underlying facts as a reason not to dismiss cases on materiality grounds at the pleading stage.

For example, in ***U.S. ex rel. McIver v. ACT for Health, Inc.***, the district court held that materiality had been plausibly alleged even though the government had continued to make payments to the defendant after learning about alleged violations of home health licensure requirements.[71] While the district court acknowledged that the continued payments *could* reflect a lack of materiality, it noted that discovery might evince additional evidence relevant to materiality – particularly concerning the nature of the government's knowledge – and thus declined to dismiss the relator's claims at the pleading stage.[72] Echoing this reasoning, in ***U.S. ex rel. Frey v. Health Management Systems***, the district court emphasized that a relator cannot be expected "to know precisely the Government's prosecutorial practices without the benefit of discovery," and thus held that the relator's materiality allegations survived a motion to dismiss.[73]

Several district courts have cited a need for discovery and a more thorough analysis of the underlying facts as a reason not to dismiss cases on materiality grounds at the pleading stage.

As these cases illustrate, a more "holistic" approach to the materiality analysis usually benefits relators, but that is not always the case. For example, in ***U.S. ex rel. Foreman v. AECOM***, the Second Circuit analyzed several *Escobar* materiality factors and reached mixed conclusions about their weight and importance.[74] On balance, however, the Second Circuit held that the district court had correctly dismissed all but one of the relator's claims because the overall picture suggested the alleged violations of contractual recordkeeping requirements "were not plausibly material to the government's payment decision." Most important to this conclusion was that the government had continued to pay the defendant's claims despite having actual knowledge of the alleged violations.

In other cases, however, courts have eschewed the "holistic" approach to materiality favoring a more searching focus on individual *Escobar* factors. And, in many of these cases – which are arguably more faithful to *Escobar's* description of the materiality requirement as "rigorous" and "demanding" – courts have continued to cite the government's continued payment of the defendant's claims (or similar claims by other parties) as a reason for dismissing FCA claims.

Focusing on the government's actual response to alleged regulatory violations, courts also dismissed several cases that involved purported violations of program conditions of participation because they would not automatically have resulted in the cessation of payments by the government.

Take the district court's decision in ***U.S. ex rel. Druding v. Care Alternatives***, a case initially dismissed on falsity grounds but remanded to the district court by the Third Circuit.[75] On remand, the district court once again granted summary judgment for the defendant, but this time on materiality grounds. Emphasizing the "demanding" nature of the FCA's materiality element, the district court held that the relators could not establish that element because "[n]othing in the record … suggest[ed] the Government ever refused any of [the defendant's] claims" despite the government having received the allegedly flawed or inadequate documentation at issue. In reaching this decision, the district court specifically rejected the relators' plea for it to apply "a holistic assessment of a falsehood's capacity to affect the government's payment decision."

In another example of this same reasoning, the district court in ***United States v. Boston Scientific Corp.*** granted summary judgment for a defendant while reasoning that even if certain of the defendant's statements to the government were blatantly false, they were nonetheless immaterial to the approval of a U.S. Food and Drug Administration (FDA) application.[76] That was because the government had access to the true information yet still approved the medical devices in question.

Likewise, focusing on the government's actual response to alleged regulatory violations, courts also dismissed several cases that involved purported violations of program conditions of participation because they would not automatically have resulted in the cessation of payments by the government.

70 In *U.S. ex rel. Cimino v. IBM Corp.*, 3 F.4th 412 (D.C. Cir. 2021), the D.C. Circuit reached much the same conclusion, but at the pleading stage. It held that although additional litigation might ultimately show that the government's continued payment of claims refuted materiality, plausible allegations that the defendant's misrepresentations were capable of affecting the government's payment decision were sufficient to preclude dismissal under Rule 12(b)(6).

71 536 F. Supp. 3d 839 (D. Colo. 2021).

72 *See also U.S. ex rel. Sirls v. Kindred Healthcare, Inc.*, 517 F. Supp. 3d 367 (E.D. Pa. 2021) (surveying three different arguments by defendants about a lack of materiality but concluding none was independently sufficient to defeat materiality at the pleading stage).

73 2021 WL 4502275 (N.D. Tex. Oct. 1, 2021); *see also U.S. ex rel. Menoher v. FPoliSolutions, LLC*, 2021 WL 3513860 (W.D. Pa. Aug. 10, 2021) (holding materiality allegations were sufficient for pleading purposes while noting that the relator's failure to provide examples of the government's refusal to pay in similar situations, as well as the government's decision not to intervene, were not dispositive).

74 19 F.4th 85 (2d Cir. 2021).

75 2021 WL 5923883 (D.N.J. Dec. 15, 2021).

76 2021 WL 3604848 (D. Minn. Aug. 13, 2021); *see also U.S. ex rel. Yu v. Grifols USA, LLC*, 2021 WL 5827047 (S.D.N.Y. Dec. 8, 2021) (granting motion to dismiss on materiality grounds because the government had not withdrawn FDA approval for the drug at issue even after learning about allegations that the defendants had concealed and falsified information to obtain the approval).

In ***U.S. ex rel. Torricer v. Liberty Dialysis-Hawaii LLC***, the district court explained that the alleged violations of dialysis documentation regulations were not prerequisites for payment of individual claims, and it relied on that fact as a basis for why those violations were not material as a matter of law.[77] The district court noted that such violations were policed through an administrative process that provided for alternative sanctions instead of termination of payment, which "added attenuation" between the violation and the government's payment decision.

> While the lack of any impact on payment should support a defense that alleged contractual or regulatory violations are immaterial, defendants should consider that courts do require meaningful support for such a defense.

Similarly, in ***U.S. ex rel. Zaldonis v. Univ. of Pittsburgh Med. Ctr.***, the district court deemed alleged violations of surgical informed consent regulations immaterial primarily because those regulations were conditions of participation subject to an administrative enforcement system that would not automatically result in the denial of the defendant hospital's claims for payment.[78]

Still, while the lack of any impact on payment should support a defense that alleged contractual or regulatory violations are immaterial, defendants should consider that courts do require meaningful support for such a defense. Illustrating this point, in ***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.***, the Seventh Circuit reversed a district court's dismissal of FCA claims on materiality grounds, rejecting the defendant's "barebones assertion" that the government was aware of the material facts but had continued to pay the defendant's claims.[79] The Seventh Circuit noted that "this argument [was] better saved for a later stage" because no one could yet "say what the government did and did not know."

Of course, relators cannot rely on merely conclusory assertions about the government's payment decisions either. In ***United States v. DaVita Inc.***, for example, the district court dismissed a relator's FCA claims based on its conclusory materiality allegations.[80] The district court explained that "the mere assertion that the Government would not have fulfilled Defendants' reimbursement claims had they known that the [care at issue] was 'medically unnecessary' failed to satisfy the FCA's 'demanding materiality standard.'"

One notable aspect of *Escobar* was that it focused on the implied false certification theory of FCA liability – the idea that a defendant implicitly certifies compliance with material statutory, regulatory and contractual requirements by submitting a claim for payment. While *Escobar* did not purport to limit its materiality analysis to claims based on that theory, a few courts have somewhat puzzlingly suggested that the materiality factors it identified have less importance under other theories of liability.

> Most FCA allegations against healthcare defendants do not involve blatantly false statements or "obviously wrong" conduct, but instead deal with purported violations of highly technical and complex statutory and regulatory requirements.

Consider, for instance, the district court's decision in ***U.S. ex rel. Bid Solve, Inc. v. CWS Marketing Group, Inc.***[81] In that case, which was based on a fraudulent inducement theory, the district court rejected the defendant's argument that its misrepresentations could not have been material since the government awarded the relevant contract and continued payments after learning about the relator's fraud allegations. Distinguishing the implied certification claim in *Escobar* from the fraudulent inducement claim there, the district court held that the government's continued payments were less relevant because the initial fraud tainted all subsequent actions under the contract. As a result, in the district court's view, the government's continued payment was insufficient to undermine the relator's plausible claim that the defendant's misrepresentations were material.

Likewise, in ***United States v. Wavefront, LLC***, the district court noted that "*Escobar*'s references to noncompliance with statutory, regulatory, or contractual requirements … do not apply as logically to [a] fraudulent inducement theory."[82] Partly for that reason, the district court rejected the defendants' argument that "the Government's failure to allege violations of statutory, regulatory, or contractual requirements warrant[ed] dismissal," instead reasoning that the defendants' misstatements in contract proposals were material to the award of the contracts – and ultimately to payment.

Along the same lines, courts have also suggested that *Escobar*'s materiality factors may be less important in cases involving *factually false* representations rather than legally false. For example, in ***U.S. ex rel. Gray v. Mitias Orthopaedics, PLLC***, the district court explained that assessing materiality did not require examining the nature of any alleged regulatory or contractual violations because the defendant had billed the government for different – and more expensive – drugs than it supplied to patients.[83] Rejecting the defendant's regulatory argument that the drugs it supplied were still eligible for payment, the district court described the defendant's conduct as "clearly and obviously wrong" as a matter of "simple honesty and common sense."

77 512 F. Supp. 3d 1096 (D. Haw. 2021).
78 2021 WL 1946661 (W.D. Pa. May 14, 2021).
79 17 F.4th 732 (7th Cir. 2021).
80 2021 WL 1087769 (C.D. Cal. Feb. 1, 2021); *see also, e.g., U.S. ex rel. Williams v. Med. Support Los Angeles*, 2021 WL 6104016 (C.D. Cal. Nov. 29, 2021) (dismissing FCA claims on materiality grounds based in part on the lack of plausible factual allegations that the government would not have paid the defendant's claims had it known the true facts).
81 2021 WL 4819899 (D.D.C. Oct. 15, 2021).
82 2021 WL 37539 (D.N.J. Jan. 5, 2021).
83 512 F. Supp. 3d 689 (N.D. Miss. 2021).

Unlike in ***Mitias***, however, most FCA allegations against healthcare defendants do *not* involve blatantly false statements or "obviously wrong" conduct, but instead deal with purported violations of highly technical and complex statutory and regulatory requirements. Accordingly, healthcare industry defendants should expect that *Escobar*'s "rigorous" and "demanding" materiality analysis will continue to play a key role in the vast majority of FCA cases, and that the government's payment or non-payment of similar claims will remain a critical factor for determining whether materiality can be established.[84]

GOVERNMENT INTERVENTION AND DISMISSAL AUTHORITY

Because *qui tam* lawsuits are brought by a relator on behalf of the United States, key components of the FCA allow the United States to control such lawsuits and include the government's ability to take over such lawsuits through intervention and the statutory authority to dismiss *qui tam* lawsuits even where a relator may be pursuing the underlying FCA claims. Recent cases have continued to examine the limits of the government's statutory intervention and dismissal authority under the FCA.

Following the filing of a *qui tam* lawsuit under seal by a relator, the FCA provides the government with a period of 60 days to investigate the relator's allegations. The district court can extend that 60-day period only for "good cause" upon the government's request. While district courts traditionally have allowed the government wide latitude in connection with requests to extend the seal period, there have been increasing instances in recent years where courts have declined to extend the seal period.

If the government declines to intervene in the *qui tam* lawsuit, the government may intervene following declination only upon a showing of "good cause" to warrant late intervention. With district courts willing to more closely scrutinize government requests to extend the FCA's seal period, the government has increasingly couched its decision not as declination (as the FCA provides) but as a decision to decline to intervene while continuing to investigate. When the government moved for late intervention following such a declination in ***U.S. ex rel. Odom v. SouthEast Eye Assocs.***, the district court determined that the government failed to meet the FCA's good cause standard and denied the government's motion.[85] The government had declined intervention following more than two years of investigation but then sought intervention six months later, claiming the emergence of "new evidence" resulting from continued investigation. The district court disagreed, concluding that the government's submission of new evidence was "tepid" and did not satisfy the FCA's good cause standard. It remains to be seen whether other district courts will more closely scrutinize the purported "good cause" offered by the government, whether in relation to extending the seal period or late intervention.[86]

84 Only confirming as much, in one somewhat unique decision this year, a district court relied on *Escobar* to dismiss government FCA claims premised on alleged violations of *state* regulatory requirements that the court deemed to be unlawful and unenforceable under the federal Social Security Act. *See United States v. Walgreen Co.*, 2021 WL 5760307 (W.D. Va. Dec. 3, 2021).

85 No. 3:17-cv-00689, Dkt. No. 104 (M.D. Tenn. Feb. 24, 2021).

86 *See U.S. ex rel. Ross v. Independent Health Corp.*, 2021 WL 3492917 (W.D.N.Y. Aug. 9, 2021) (granting the government's motion for late intervention after finding demonstration of good cause to support such intervention).

The government's FCA dismissal authority also has been more aggressively challenged in recent years, deepening a long-existing circuit split concerning the appropriate standard when deciding whether to grant such a request made by the government.

The government's FCA dismissal authority also has been more aggressively challenged in recent years, deepening a long-existing circuit split concerning the appropriate standard when deciding whether to grant such a request made by the government. This split centers on whether the government'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***, 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 Co. v. Baird-Neece Packing Corp.***

The Third Circuit became the latest federal appellate court to consider the FCA's dismissal standard in ***U.S. ex rel. Polansky v. Executive Health Resources, Inc.***[87] The relator alleged that the defendant had assisted hospitals in billing claims as inpatient that should have been billed as outpatient. After the United States declined intervention, the relator litigated the case for years before the United States moved to dismiss it because it considered the expense of responding to discovery to outweigh any potential recovery. The district court granted dismissal and the relator appealed, stating that the dismissal was "shocking" after he and his attorneys had invested years and $20 million in the case.

On appeal, the Third Circuit affirmed the district court's decision to grant the government's motion for dismissal. In reaching that conclusion, the Third Circuit determined that the government must intervene before it can seek to exercise its statutory dismissal authority, which must be supported by "good cause." The Third Circuit then went on to consider the standard applicable to a motion for dismissal by the government, concluding that Rule 41(a) of the FRCP governs requests for voluntary dismissal and should apply to such a motion filed by the government to dismiss FCA litigation. In reaching that conclusion, the Third Circuit declined to follow the standards set forth in ***Swift*** or ***Sequoia Orange***, but rather adopted the standard articulated by the Seventh Circuit in ***U.S. ex rel. CIMZNHCA, LLC v. UCB, Inc.***[88] The Third Circuit ultimately determined that the analysis undertaken by the district court readily satisfied Rule 41(a)'s requirements.

87 17 F.4th 376 (3d Cir. 2021).

88 970 F.3d 835 (7th Cir. 2020).

In ***U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.***, the Fifth Circuit assumed but did not decide, that the standard articulated in ***Sequoia Orange*** should apply.[89] There, the government moved for dismissal of the relator's FCA claims based on concerns that there was not sufficient factual and legal support to prove AKS violations; the substantial cost and burdens for the United States if the *qui tam* actions were to continue; policy interests of Medicare and other federal healthcare programs; and the investigative methods employed by the relator's parent organization. The Fifth Circuit affirmed the district court's granting the government's motion to dismiss, determining that dismissal was appropriate under the ***Sequoia Orange*** standard.

None of the competing appellate court standards has served as a serious impediment to the government's ability to intervene and dismiss a relator's *qui tam* lawsuit. But, it is worth continuing to watch how courts grapple with this issue as the government continues to exercise this statutory authority.[90]

DEVELOPMENTS IN PLEADING STANDARDS

At the pleading stage, FCA complaints are subject to Rule 8(a)'s plausibility standard and Rule 9(b)'s heightened pleading standard for fraud. This requirement is meant to shield defendants from frivolous lawsuits and provide meaningful notice of alleged wrongdoing. In applying Rule 9(b), all courts demand specific allegations of a fraudulent "scheme" carried out by the defendant, but courts differ as to how detailed the allegations must be to connect that scheme to actual claims submitted to the government for payment. FCA complaints that fail to meet the hurdles established by Rule 9(b) are routinely dismissed.

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Pleading the Details of a Fraudulent Scheme

To survive a motion to dismiss under Rule 9(b), complaints asserting FCA claims must identify the particular details of the defendant's fraud – the "who, what, when, where, and how" of the alleged fraudulent scheme. This does not mean the relator is required to prove its case in the complaint, but Rule 9(b) certainly requires some level of factual specificity.

For instance, in ***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.***, the Seventh Circuit reiterated that district courts should not "take an overly rigid view" of Rule 9(b)'s requirements, and "the specific details that are needed to support a plausible claim of fraud will depend on the facts of the case."[91] In that case, Molina, a managed care organization, contracted with a state health department to provide various healthcare services, including skilled nursing, for Medicaid beneficiaries on a capitated payment basis. Molina subcontracted with GenMed to provide the skilled nursing services. In less than a year, Molina terminated the contract with GenMed and did not find another contractor to provide the services, but continued to keep the payments for those services from the state. The district court dismissed the relator's resulting FCA suit, finding that the complaint failed to allege the majority of his bases for liability adequately and that Molina knew that the provision of skilled nursing services was material.

> While a relator does not have to prove its case in a complaint, conclusory allegations of fraud are often found to fall short under Rule 9(b).

The Seventh Circuit reversed, holding that the relator had sufficiently pleaded an FCA claim, explaining that "Rule 9(b) requires specificity, but it does not insist that a plaintiff literally prove his case in the complaint." The Seventh Circuit concluded that the relator pleaded numerous details about the when, where, how, and to whom allegedly false representations were made, plausibly supporting the inference that the defendant included false information about the services being provided to new enrollees in its claims. In making this inference, the Seventh Circuit asked, "How else could [Molina] have asked for its capitation payments based on these additional beneficiaries?"

While a relator does not have to prove its case in a complaint, conclusory allegations of fraud are often found to fall short under Rule 9(b). In ***U.S. ex rel. Paul v. Biotronik, Inc.***, the district court dismissed the relator's second amended complaint that contained only conclusory allegations that Biotronik, a medical device company, engaged in a kickback scheme by inducing physicians to use products and services through prohibited incentives.[92] For instance, the district court found that the complaint alleged Biotronik generally engaged in fraudulent acts between 2014 and 2019, or cited specific dates gifts were bought for referral physicians without stating when the referral physician was given the gift. Because the relator failed to plead sufficient facts that provided details as to "who, what, when, or how" the payment of money was given to the referring physicians, the district court determined that the complaint failed to meet Rule 9(b)'s heightened pleading standard.

As in years past, certain relators attempted to use statistical analysis to meet Rule 9(b)'s pleading requirements. For example, in ***U.S. ex rel. Integra Med Analytics LLC v. Mariner Health Care, Inc.***, the relator alleged that Mariner, a SNF operator, violated the FCA by engaging in a scheme to falsify information about the amount of rehabilitation needed for patients and failing to report and return overpayments from Medicare.[93] To support these allegations, the relator relied on testimony from former employees and patients of the SNFs and data from algorithms and statistical analysis. In its motion to dismiss, Mariner

89 4 F.4th 255 (5th Cir. 2021).
90 *See also U.S. ex rel. Vanderlan v. Jackson HMA, LLC*, 2021 WL 41310 (S.D. Miss. Jan. 5, 2021) (applying the *Swift* standard and granting the government's motion for dismissal).
91 17 F.4th 732 (7th Cir. 2021).
92 2021 WL 211474 (M.D. Fla. Jan. 21, 2021).
93 2021 WL 4259907 (N.D. Cal. Aug. 5, 2021).

asserted that statistical analysis could not satisfy Rule 9(b) since the complaint revolved around allegations of medically unnecessary treatment, which is subjective in nature. The district court disagreed and found that the relator's complaint included specific allegations carrying "empirical reliability and probative value of its statistical study." Citing the Supreme Court's decision in *Tyson Foods, Inc. v. Bouaphakeo*,[94] the district court reasoned that the use of statistical evidence in pleading turns on how reliable it is in establishing the elements of the relevant cause of action. The district court noted that the transparency in the relator's formula sufficiently put Mariner on notice of its misconduct and that the relator had alleged enough specific details about the fraudulent scheme, in addition to statistical analysis, to satisfy Rule 9(b).

District courts often allow relators the opportunity to cure deficient allegations through amended pleadings. In ***U.S. ex rel. SW Challenger, LLC v. eviCore Healthcare MSI, LLC***, the relators alleged in a second amended complaint that a utilization management vendor for managed care organizations improperly engaged in a scheme to automate the decision-making process for determining whether a service is medically necessary for Medicare and Medicaid beneficiaries.[95] The district court granted defendant's motion to dismiss, pointing out the deficiencies in the relators' complaint. The district court noted the absence of allegations regarding records or billings submissions to managed care companies, and the fact that, even though the complaint described several individuals involved in the scheme, the complaint failed to identify who submitted the unnecessary authorization forms and how the scheme took place. After detailing the relators' pleading failures, the district court allowed the relators to remedy the deficiencies in a third amended complaint.[96]

As in years past, certain relators attempted to use statistical analysis to meet Rule 9(b)'s pleading requirements.

Courts differ, however, in the latitude afforded to relators in amending their *qui tam* complaint. In ***U.S. ex rel. Gutman v. Chicago Vein Institute***, the district court dismissed the relator's second amended complaint with prejudice. The relator alleged that, while working at a vein care clinic, the clinic performed unnecessary procedures, improperly upcoded certain procedures to more expensive procedures, and improperly offered employees a bonus plan for patient referrals, all in violation of the FCA.[97] The district court dismissed the amended pleading, finding that the relator provided no "transactional-level details" as to the scheme, such as specific unnecessary procedures or specific instances where

94 577 U.S. 442 (2016).
95 2021 WL 3620427 (S.D.N.Y. Aug. 13, 2021).
96 *See also U.S. ex rel. Raffington v. Bon Secours Health System, Inc.*, 2021 WL 4762054 (S.D.N.Y. Oct. 13, 2021) (granting in part, denying in part, relator's motion to amend the complaint for the seventh time after finding certain new allegations were futile because they did not relate back to the original complaint and finding other allegations were referenced in prior versions of the complaint).
97 2021 WL 170674 (N.D. Ill. Jan. 19, 2021).

Courts continued to take divergent approaches to whether relators can satisfy Rule 9(b)'s particularity requirement without identifying specific representative false claims filed due to a fraudulent scheme. Some circuits have continued to take a rigid approach, requiring relators to plead specific details of false claims submitted. Others have taken a more flexible approach that would allow the submission of false claims to be inferred from the circumstances. It is possible that the Supreme Court could address this issue as a result of a petition for writ of certiorari filed late last year.

defendants paid a referral or bonus. Given that the case had been pending for four years, the relator had the opportunity to conduct discovery, and the relator had already amended her complaint, the district court ruled that any further amendments would be futile.

Pleading the Submission of False Claims

Courts continued to take divergent approaches to whether relators can satisfy Rule 9(b)'s particularity requirement without identifying specific representative false claims filed due to a fraudulent scheme. Some circuits have continued to take a rigid approach, requiring relators to plead specific details of false claims submitted. Others have taken a more flexible approach that would allow the submission of false claims to be inferred from the circumstances. It is possible that the Supreme Court could address this issue as a result of a petition for writ of certiorari filed late last year.

In recent years, the Sixth and Eleventh Circuits have applied the presentment requirement strictly, and two rulings this year were no exception. In ***U.S. ex rel. Owsley v. Fazzi Associates, Inc.***, the Sixth Circuit affirmed the dismissal of a relator's claim that the defendant exaggerated home health patients' conditions to inflate claims for payment.[98] The Sixth Circuit acknowledged that the relator described in detail a fraudulent upcoding scheme, but held the relator failed to plead the submission of false claims with particularity. Specifically, the Sixth Circuit held that, although the relator did allege personal knowledge of billing practices used in the alleged fraudulent scheme, she failed to allege facts identifying any specific false claims in a way that would give the defendants notice of a claim she alleged was fraudulent.

In ***Estate of Helmly v. Bethany Hospice and Palliative Care, LLC***, the Eleventh Circuit affirmed the dismissal of two relators' claims for failure to plead with particularity the submission of an actual false claim.[99] The relators alleged that the defendant hospice

98 16 F.4th 192 (6th Cir. 2021).
99 853 F. App'x 496 (11th Cir. 2021).

companies operated a referral scheme in violation of the AKS, and as a result, submitted false claims for payment to Medicare. The relators alleged that Bethany Hospice doctors referred Medicare beneficiaries to Bethany Hospice and that nearly all of Bethany Hospice's patients were covered by Medicare. They also alleged that they had a general knowledge of billing practices, reviewed referral and billing data and confirmed that claims were submitted with other employees. The relators argued that taken together, these allegations lent sufficient indicia of reliability to plead presentment with particularity. The Eleventh Circuit disagreed, reasoning the relators did not have "the personal knowledge or level of participation that can give rise to some indicia of reliability" in the absence of particular facts about representative false claims. Rejecting the relators' reliance on the hospice company's Medicare-dependent business model, the Eleventh Circuit explained, "numerical probability is not an indicium of reliability."

Consistent with the controlling appellate precedent, several district courts within the Eleventh Circuit dismissed relators' claims for failing to plead presentment with adequate particularity.

As referenced above, the relators in ***Estate of Helmly*** filed a petition for certiorari in September, urging the Supreme Court to resolve what they claim is a split among the circuits in how the presentment requirement is applied under Rule 9(b). In opposing certiorari, Bethany Hospice downplayed the notion of a circuit split, claiming the Eleventh Circuit's standard is in line with the more lenient standard applied in other circuits.[100] That petition remains before the Supreme Court.

Consistent with the controlling appellate precedent, several district courts within the Eleventh Circuit dismissed relators' claims for failing to plead presentment with adequate particularity. The district court in ***U.S. ex rel. Musachia v. Pernix Therapeutics, LLC***, dismissed the relator's claims that a free shipping and co-pay waiver program violated the AKS and resulted in false claims.[101] First, the district court held that the relator's spreadsheet referencing fifty detailed examples of prescriptions filled did not include information such as dates, billing information or amounts charged or paid sufficient to identify a specific false claim. Second, the district court held that the relator did not otherwise plead "specific knowledge about billing practices – i.e., that the person was directly involved with submitting claims to the Government" and thus lacked other indicia of reliability that false claims were submitted.

Similarly, in ***U.S. ex rel. Paul v. Biotronik, Inc.***, discussed above, the relator provided 85 examples of patients implanted with devices or placed on home monitoring as a result of an alleged kickback scheme, including dates, products, procedures, invoices and the rendering provider.[102] Nonetheless, the district court held that the relator failed to satisfy Rule 9(b) because she did not allege key facts for those patients such as dates the claims were submitted or the amounts of the claims, nor did she include any allegations of personal knowledge of billing practices.

In ***U.S. ex rel. Zafirov v. Florida Med. Assocs. LLC***, the district court dismissed a relator's complaint alleging that the defendants employed a two-part scheme where physician defendants brought in patients for medically unnecessary appointments and health maintenance organization defendants submitted false and incorrect diagnosis codes to the government to increase capitated payments.[103] The district court found that the complaint failed to allege facts showing that the defendants submitted a false claim to the government. While the complaint described the defendants' specific conduct as consistent with allegations that the defendants submitted false claims, the district court pointed out that Rule 9(b) "requires more than inferences, consistencies, and suppositions." And, even though the complaint alleged that the defendants submitted "hundreds of thousands" of false claims, the complaint failed to provide the dates that the codes were submitted, who submitted the claims and how the claims were material to the government.[104]

The Seventh Circuit has often taken a less strict view of the presentment requirement. "Mindful" of the Seventh Circuit's warning against taking an "overly rigid view" of the pleading requirements of Rule 9(b), the district court in ***U.S. ex rel. Snider v. Centers for Pain Control, Inc.***, denied the defendants' motion to dismiss the relators' claims that their marketing practices violated the AKS and resulted in false claims.[105] The relator alleged that the defendant clinic and its physician owner offered free massage therapy with the purchase of trigger point therapy, thereby illegally inducing Medicare and Medicaid patients to purchase trigger point therapy. The relator pointed to six patients who were not charged for massages on the same day they received trigger point therapy and alleged that patients who were charged for massages did not purchase trigger point therapy, identifying different billing codes used. Lastly, he alleged that 90% of CPC's patients were Medicare or Medicaid beneficiaries. In contrast to the Eleventh Circuit's rejection in ***Estate of Helmly*** of numerical probabilities supporting an indicia of reliability, the district court here concluded that the allegations created a "reasonable inference that at least some of the patients who purchased trigger point therapy for the free massage incentive received some government aid."

100 *See also U.S. ex rel. Byrd v. Acadia Healthcare Co.*, 2021 WL 1081121 (M.D. La. Mar. 18, 2021) (granting defendant's motion to dismiss, explaining that while the particular contents of a false claim need not always be presented, this does not absolve the relator of the burden of otherwise identifying sufficient details; "[t]his circuit applies Rule 9(b) to fraud complaints with bite and without apology").

101 2021 WL 2826429 (N.D. Ala. July 7, 2021).

102 2021 WL 211474 (M.D. Fla. Jan. 21, 2021).

103 2021 WL 4443119 (M.D. Fla. Sept. 28, 2021).

104 *See also United States v. Health First, Inc.*, 2021 WL 301089 (M.D. Fla. Jan. 22, 2021) (dismissing complaint where 300-page list of Medicare claims did not specify whether the patient was unlawfully referred or which entity or individual billed the claims); *Payne v. Sanon*, 2021 WL 307370 (M.D. Fla. Jan. 29, 2021) (dismissing complaint where relator alleged patient dates of testing and testing procedures, but no allegations about claims actually submitted to the government); *U.S. ex rel. Stone v. Nature Coast Emergency Medical Foundation, Inc.*, 2021 WL 3134725 (M.D. Fla. Mar. 26, 2021) (dismissing complaint where relator failed to "provide any factual basis for [her] conclusory statement … that bills were submitted to the [g]overnment as a result of [defendant's] schemes"); *U.S. ex rel. Fernandez v. Freedom Health, Inc.*, 2021 WL 2954415 (M.D. Fla. May 26, 2021) (dismissing relator's complaint, holding that relator's alleged communications with executive about the intention to submit encounter data to reimbursement under Medicare Advantage did not show that the relator was personally in a position to know that false claims were submitted and had a factual basis for his alleged personal knowledge).

105 2021 WL 1783314 (N.D. Ind. May 5, 2021).

The First Circuit has also been willing to infer that false claims were presented from the circumstances alleged in the pleadings, and district courts within the First Circuit have reflected this approach. In ***U.S ex rel. Carbon v. Care New England Health Sys.***, the relator alleged that the defendant owners and operators of an inpatient rehabilitation facility (IRF) admitted patients that did not meet the strict regulatory requirements for admission, resulting in false claims for payment for these IRF services.[106] In holding that the relator plausibly alleged that the defendants submitted actual false claims, the district court analyzed the relator's allegations regarding at least one example patient. The relator alleged facts explaining why that patient did not qualify for admission to the IRF and that he was admitted anyway. Taking these allegations as true, the district court concluded that the patient was improperly admitted to the IRF, and because the patient's only insurer was Medicare, the IRF must have billed Medicare for the improper admission, "unless [the patient] stayed in the [IRF] for a week free of charge." The district court acknowledged counterarguments against such an inference, but it reasoned that if a patient were admitted to the IRF, their insurance would be billed, and if the insurer is the government, the government would have been billed. "Thus, there is a logical connection between the admission of at least one patient . . . and improper billing." The district court characterized its assumption as reasonable given that there were significant financial returns on IRF admissions, that the defendant hospital system was facing significant financial losses after an acquisition of a failing hospital, and it is "incredibly unlikely" that a hospital facing financial difficulties would allow patients to be treated for free when they are insured.

This year both appellate and district courts issued numerous notable holdings concerning the issue of establishing falsity in FCA litigation.

Like the First Circuit, the Third Circuit has recognized exceptions to a strict presentment requirement and its district courts have followed suit. In ***U.S. ex rel. Menoher v. FPoliSolutions, LLC***, the district court concluded that the relator's complaint sufficiently alleged that a Department of Energy contractor falsely billed time employees spent working on other projects to the government.[107] The defendants argued that the relator needed to plead facts about specific invoices and that the court cannot presume the necessary details, such as the context, dates, amounts and submissions. The district court disagreed, explaining that the Third Circuit has never required the plaintiff to identify a specific claim at the pleading stage, but rather the relator can allege particular details of a scheme to submit false claims coupled with "reliable indicia that lead to a strong inference that claims were actually submitted." The district court denied the motion to dismiss and found that the relator adequately cited several examples where the defendants manipulated the timekeeping records, paired with approximate dates outlining their conduct.

106 2021 WL 4860736 (D.R.I. 2021).
107 2021 WL 3513860 (W.D. Pa. Aug. 10, 2021).

DEVELOPMENTS REGARDING FALSITY

This year both appellate and district courts issued numerous notable holdings concerning the issue of establishing falsity in FCA litigation.

Supreme Court Declines to Review Objective Falsity Standard

In prior years, we discussed the growing divide among federal appellate courts about whether a disagreement of medical opinion can establish that a physician's clinical judgment about patient treatment and any attendant certifications were "false" under the FCA. Specifically, the Third Circuit in ***U.S. ex rel. Druding v. Care Alternatives***[108] and the Ninth Circuit in ***U.S. ex rel. Winter v. Gardens Regional Hospital***[109] found that unreasonably held medical opinions or subjectively dishonest certifications could give rise to FCA liability. In contrast, the Eleventh Circuit in ***United States v. AseraCare***[110] held that a mere difference of clinical opinion could not render a physician's clinical judgment false. Although the Supreme Court was presented with an opportunity to weigh in on this issue, in February the Court declined to grant the defendant's petition for certiorari in ***Druding***. This is an issue worth monitoring to see how it continues to unfold in district and appellate courts.

False Certification

Appellate and district courts continued to evaluate express and implied false certification claims. The Seventh Circuit held in ***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.***, that the relator's complaint stated a claim based on false certification by alleging that the defendant misleadingly omitted critical facts when seeking payment from the government.[111] The relator alleged that the defendant, which had a contract to provide nursing facility services to government health plan beneficiaries, stopped offering SNF services that it was contractually required to provide. The Seventh Circuit held that the complaint adequately pleaded that by continuing to seek reimbursement after it ceased providing SNF services, the defendant impliedly falsely certified that patients had access to SNF services when they actually did not.

Appellate and district courts continued to evaluate express and implied false certification claims.

In ***U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.***, the relator alleged that the defendants had falsely certified that unlicensed staff members were appropriately supervised at the defendant mental-health center.[112] Applying state medical practice regulations, the district court found at summary judgment that the relator had established falsity where, for example, unlicensed staff members were supervised

108 952 F.3d 89 (3d Cir. 2020).
109 953 F.3d 1108 (9th Cir. 2020).
110 938 F.3d 1278 (11th Cir. 2019).
111 17 F.4th 732 (7th Cir. 2021).
112 2021 WL 2003016 (D. Mass. May 19, 2021).

by social workers who were ineligible to provide supervision and where the supposed supervisors provided only administrative or licensing supervision that included no clinical discussion of patients.

In ***U.S. ex rel. Harbit v. Consultants in Gastroenterology, P.A.***, the defendants argued that the relators failed to plead false certification of medical necessity because the relators' complaint relied upon and repeatedly cited interpretive guidance under the Medicare Act, which was not promulgated through public notice and comment.[113] The district court rejected that argument, holding that the relators' claims were not based on interpretive guidance but merely used it to show what resources were available to the defendants and to provide background information about the relevant regulations that the relators alleged were violated and that provided the basis for the defendants' alleged false certifications.

In ***U.S. ex rel. Higgins v. Boston Scientific Corp.***, the district court addressed whether false statements made to the FDA to obtain approval for two types of medical devices could constitute false certifications to support an FCA claim.[114] Although the defendant did not submit claims directly to the government in relation to the devices, the relator argued that the defendant caused third-party providers to falsely certify that the devices were medically necessary when, in fact, they were defective, misbranded and not medically necessary. At summary judgment, the district court held that genuine issues of fact existed with respect to four of the defendant's alleged false statements that could constitute misrepresentations that caused false claims to be submitted to the government. The district court, however, held that no reasonable jury could find that the defendant's alleged misrepresentations were material to the FDA's device approval decision and granted summary judgment in favor of the defendant.

The district court reached a split falsity ruling in ***U.S. ex rel. Mbabazi v. Walgreen Co.***[115] The relators there alleged that Walgreens violated the FCA by submitting claims to Pennsylvania Medicaid without first determining whether beneficiaries had other insurance. On a motion to dismiss, the district court agreed with Walgreens that the relators failed to allege an express false certification claim because the complaint alleged no facts showing that other coverage was available. Yet, the district court held that the relators had pleaded an implied false certification claim by alleging that Walgreens failed to disclose it and did not try to determine whether other coverage was available, in violation of regulations requiring it to do so.

In other rulings, district courts continued to examine the intersection of *Escobar* and falsity. In ***U.S. ex rel. Torricer v. Liberty Dialysis-Hawaii LLC***, for example, the district court held that the relator failed to sufficiently allege either an express false certification or an implied false certification and accordingly granted the defendants' motion to dismiss.[116] The district court found that even though the relator plausibly alleged that the defendant made claims for payment while having deficient plans of care in violation of Medicare regulations, a relator must do more to allege falsity after *Escobar* than allege the mere submission of a noncompliant claim. After supplemental briefing on the subject, the district court held that it would be futile to grant the relator leave to amend to include missing details about the claims submission process because the claim forms used by the defendant did not include any express certification and only included boilerplate statements of compliance that were not sufficient to state a viable cause of action.

In ***U.S. ex rel. Kelley v. McKesson Corp.***, the relators argued that their complaint alleged either express or implied false certification.[117] The district court disagreed and granted the defendant's motion to dismiss, holding that under *Escobar* and subsequent Ninth Circuit cases, relators must allege specific representations about the goods or services provided in a claim for payment in order to state a claim on an implied false certification theory. The relators' allegations that the defendant was in breach of various contracts and violated numerous laws and regulations did not suffice to allege a false claim.

The relator in ***U.S. ex rel. Freedman v. BAYADA Home Health Care, Inc.***, alleged that the defendant fraudulently induced a government contract.[118] The district court noted that fraudulent inducement may create FCA liability without fraudulent claims if the fraudulently induced contract results in government payment. The relator, however, failed to allege any facts showing that the defendant's misrepresentations during its bid concerned the government or induced the government to enroll it as a Medicare provider. The district court held that the defendant's contract with the county – which was negotiated, executed and performed without any federal government involvement – could not give rise to FCA liability.

In ***U.S. ex rel. Govindarajan v. Dental Health Programs, Inc.***, the district court ruled that the relator failed to plead that the defendant dental services provider falsely certified compliance with various requirements in federal grant contracts.[119] Although the relator contended that the defendants' certifications of compliance were false based on a bevy of alleged misconduct – including that the defendants violated nonprofit organization requirements and improperly assigned managerial duties to other entities – the district court found the relator's allegations were merely conclusory and thus insufficiently pleaded to establish falsity.

Worthless Services

In ***U.S. ex rel. SW Challenger, LLC v. eviCore Healthcare MSI, LLC***, the district court addressed whether claims submitted for allegedly worthless services were false for purposes of pleading an FCA claim.[120] The relator alleged that the defendant caused false claims to be submitted by providing worthless utilization management and prior authorization services to the managed care organizations with which it contracted. The district court granted the defendant's motion to dismiss because, even accepting the relator's allegations as true, the relator alleged only that the defendant failed to provide *some* of the prior authorization and utilization management services that it contracted to provide. Thus, the relator failed to plead the falsity of the claims submitted because the services were not so worthless that they were "equivalent of no performance at all."

113 2021 WL 1197124 (D.S.C. Mar. 30, 2021).
114 2021 WL 3604848 (D. Minn. Aug. 13, 2021).
115 2021 WL 4453600 (E.D. Pa. Sept. 28, 2021).
116 512 F. Supp. 3d 1096 (D. Haw. 2021).
117 2021 WL 583506 (N.D. Cal. Feb. 6, 2021).
118 2021 WL 1904735 (D.N.J. May 12, 2021).
119 2021 WL 3213709 (N.D. Tex. July 29, 2021).
120 2021 WL 3620427 (S.D.N.Y. Aug. 13, 2021).

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

To establish an FCA violation, a relator or the government must plead and prove that the defendant acted with actual knowledge, deliberate ignorance or reckless disregard of the conduct that caused the submission of false claims. Recent cases have considered whether defendants were alleged to have had an objectively reasonable interpretation of the regulatory provision at issue. Where courts have reached that conclusion, relators have faced a significant obstacle in pleading and proving scienter under the FCA.

For example, in ***U.S. ex rel. Schutte v. SuperValu, Inc.***, the Seventh Circuit became the latest appellate court to hold that, based on the Supreme Court's opinion in ***Safeco Ins. Co. v. Burr***, the FCA requires an objective scienter standard, under which defendants do not act "knowingly" if: (1) their interpretation of the relevant statute or regulation was objectively reasonable, even if mistaken; and (2) "authoritative guidance" did not warn them away from their interpretation.[121] In ***Schutte***, the relators alleged that the defendants' pharmacies falsely reported their "usual and customary" (U&C) prices to Medicare and Medicaid by improperly listing their retail cash prices as their U&C price, rather than lower prices provided to customers requesting a match of a competitor's price. Applying the objective scienter standard, the Seventh Circuit affirmed summary judgment in favor of the defendants, finding that their interpretation of the regulatory definition of U&C price – to include their retail cash prices but exclude price matches that "depended upon the prices charged by local competitors" and were provided upon customer request – was objectively reasonable and that no authoritative guidance during the relevant period warned defendants away from their interpretation.

> To establish an FCA violation, a relator or the government must plead and prove that the defendant acted with actual knowledge, deliberate ignorance or reckless disregard of the conduct that caused the submission of false claims.

In discussing the objective scienter standard, the Seventh Circuit held that a defendant's subjective intent is "irrelevant" because "[a] defendant might suspect, believe, or intend to file a false claim, but it cannot *know* that its claim is false if the requirements for that claim are unknown." The Seventh Circuit stressed that this standard "does not shield bad faith defendants that turn a blind eye to guidance indicating that their practices are likely wrong," given the second prong of ***Safeco's*** standard. On that point, the Seventh Circuit explained that "authoritative guidance," at a minimum, "must come from a governmental source – either circuit court precedent or guidance from the relevant agency" and "must have a high level of specificity to control an issue."

In ***U.S. ex rel. Skibo v. Greer Labs., Inc.***, the Fourth Circuit also affirmed summary judgment for the defendants based on the relators' failure to demonstrate scienter in a case involving an ambiguous regulatory provision. There, the relators alleged that a manufacturer of allergenic extracts for physicians violated FDA regulations by not obtaining independent licenses for custom mixes of its licensed extracts. While the Fourth Circuit did not expressly apply the objective scienter standard, it found persuasive the "strong evidence" of industry understanding of the regulation and defendants' "openly act[ing] according to that understanding" based on its advertising and interactions with the FDA.[122]

Courts also grappled with applying the objective scienter standard at the motion to dismiss stage. In ***Lupinetti v. Exeltis USA, Inc.***, the relator alleged that the defendants falsely labeled and identified their prenatal vitamins as requiring prescriptions – with "Rx" or "prescription only" on the product – in order to prevent state Medicaid programs from excluding them from coverage.[123] In granting the defendants' motion to dismiss in part for failure to plead scienter, the district court held, relying on ***Schutte***, that the defendants had an objectively reasonable belief that they were legally permitted to describe their prenatal vitamins as "prescription only," and that there was no "authoritative guidance" to the contrary. The district court reasoned that the relator cited no statute or regulation preventing the defendants from labeling their prenatal vitamins as "prescription only," disagreeing with the relator's interpretation of FDA statutes in the process, and that publicly available CMS guidance "expressly anticipates that some prenatal vitamins will be prescription only."

By contrast, in ***U.S. ex rel. Kuzma v. N. Arizona Healthcare Corp.***, the district court denied the defendants' motion to dismiss and rejected the defendants' arguments that they had an "objectively reasonable interpretation" and a "good faith interpretation" of the applicable statute and regulations.[124] The relator alleged that a hospital and health system engaged in a scheme to receive federal-share Medicaid funds in violation of Medicaid regulations on non-bona fide provider-related donations. The defendants interpreted the statue and regulations at issue to have a sequential timing requirement in order for a donation to be considered non-bona fide. In finding that the defendants' interpretation was not objectively reasonable, the court noted that the defendants' "narrow" timing reading was "contrary to the clear intent of the statute and regulations" and not supported by any "authoritative sources." As to whether the defendants had a good-faith interpretation, the district court explained that was a "factual issue" that could not be resolved on a motion to dismiss.

Beyond the objective scienter standard, the Supreme Court has said that the scienter requirement is "rigorous" and must be "strictly enforced." But Rule 9(b) says that plaintiffs may allege knowledge "generally." Courts continued to reach varying results in trying to square these requirements when evaluating the sufficiency of the allegations in FCA complaints.

121 9 F.4th 455 (7th Cir. 2021) (relying on *Safeco Ins. Co. v. Burr*, 551 U.S. 47 (2007)).

122 841 F. App'x 527, 529 (4th Cir. 2021).

123 2021 WL 5407424 (N.D. Ill. Nov. 19, 2021).

124 2021 WL 75827 (D. Ariz. Jan. 8, 2021).

Beyond the objective scienter standard, the Supreme Court has said that the scienter requirement is "rigorous" and must be "strictly enforced." But Rule 9(b) says that plaintiffs may allege knowledge "generally." Courts continued to reach varying results in trying to square these requirements when evaluating the sufficiency of the allegations in FCA complaints.

In several cases, courts found the allegations of scienter to be insufficient and therefore subject to dismissal on a motion to dismiss. Recognizing that FCA plaintiffs may allege scienter, generally these courts nonetheless reasoned that to satisfy Rule 8(a), plaintiffs must still allege *facts* that show the defendant acted with the requisite scienter – merely alleging that the defendant acted "knowingly," without more, is not enough.

In ***U.S. ex rel. Sheoran***, for example, the relator alleged that the defendant "knowingly" submitted false claims for opiates that had been improperly prescribed.[125] Explaining that the scienter requirement imposes a "high bar," the Sixth Circuit upheld the dismissal of the complaint because it did not describe how the defendant "could have concluded the prescriptions were false or fraudulent in some way." The district court reached a similar conclusion in ***U.S. ex rel. Scollick v. Narula***, holding that the complaint should be dismissed where the relator alleged that the defendant "knowingly" abetted fraudulent conduct but "provided no further factual allegations to support this naked assertion."[126]

Yet, other courts found allegations of scienter to be sufficient to survive a motion to dismiss. In ***U.S. ex rel. Integra Med Analytics LLC v. Mariner Health Care, Inc.***, the relator alleged that the operator of a SNF submitted claims for medically unnecessary services.[127] The district court held that the allegations of scienter passed muster where the complaint stated that the defendant "directed its staff to bill for non-therapeutic activities" and detailed instances where management pressured staff to prioritize billing over actual patient needs. Likewise, in ***U.S. ex rel. Mbabazi v. Walgreen Co.***, the district court found that the relator sufficiently pleaded scienter where the complaint alleged that Walgreen falsely certified that beneficiaries did not have other insurance "without undertaking any effort to identify or use other coverage before billing Pennsylvania Medicaid."[128]

Another issue courts addressed was the requirement to prove a defendant's knowledge of materiality. In *Escobar*, the Supreme Court held that FCA liability turns on "whether the defendant knowingly violated a requirement that the defendant *knows is material* to the Government's payment decision." The first part of this formulation – that plaintiffs must prove that the defendant knew about the alleged violation – is well-recognized and uncontroversial. But, does *Escobar* mean that plaintiffs must also prove that the defendant *knew* the alleged violation was *material* to the government? And what would that proof look like? These often overlooked questions from the *Escobar* decision have recently received more attention from the lower courts.

In ***U.S. ex rel. Prose v. Molina Healthcare of Illinois, Inc.***, the Seventh Circuit grappled with these issues at the pleading stage.[129] The relator alleged that Molina defrauded the government by continuing to accept capitated payments for providing a nursing facility services package, even after it ceased offering SNF services that had previously been part of that package. The district court granted Molina's motion to dismiss, reasoning that although the complaint sufficiently alleged that Molina knew it had violated a contractual requirement to provide SNF services, there were only conclusory allegations that Molina knew this requirement was material to payment. On appeal, however, the Seventh Circuit reversed, finding that the complaint plausibly alleged that "as a sophisticated player in the medical-services industry, Molina was aware that these kinds of services play a material role in the delivery of Medicaid benefits."

In ***U.S. ex rel. Martino-Fleming v. S. Bay Mental Health Ctr.***, the district court similarly acknowledged that the FCA "requires an additional showing of scienter" as to the materiality element.[130] And the district court denied the defendants' motion for summary judgment where it found that testimony from the defendant's corporate officers could show that the defendant knew the alleged violations were material.

Finally, in one noteworthy decision in a criminal matter, ***United States v. Nora***, the Fifth Circuit vacated a defendant's conviction for criminal healthcare fraud after finding there was insufficient proof that he knew his company's kickback scheme was illegal.[131] Interestingly, the Fifth Circuit agreed with the prosecution that the defendant knew his home health agency was paying physicians to refer new patients. But, the Fifth Circuit overturned the

125 858 F. App'x 876 (6th Cir. June 4, 2021).

126 2021 WL 737077 (D.D.C. Feb. 25, 2021); *see also U.S. ex rel. Jones v. Sutter Health*, 2021 WL 3665939 (N.D. Cal. Aug. 18, 2021) (granting dismissal where relator alleged that defendant made "conclusory allegations that Defendants knowingly submitted false claims" but did "not set out allegations that support her assertion that Defendants had knowledge of fraud"); *United States v. DaVita, Inc.*, 2021 WL 1087769 (C.D. Cal. Feb. 1, 2021) (granting dismissal where relator's scienter allegations "necessarily depended on" the "conclusiveness" of a medical research study that the court found "inconclusive" and where relator's allegations demonstrated that the underlying timing issue of dialysis treatment was a "challenging and discretionary decision").

127 2021 WL 4259907 (N.D. Cal. Aug. 5, 2021).

128 2021 WL 4453600 (E.D. Pa. Sept. 28, 2021); *see also United States v. Wavefront, LLC*, 2021 WL 37539 (D.N.J. Jan. 5, 2021) (explaining that pleading scienter "generally at this stage" is sufficient because "[w]ithout the benefit of discovery," the government "cannot be expected to cite extensive facts demonstrating [defendants'] knowledge of the falsity and materiality of each alleged misrepresentation" in their proposals for government contracts).

129 17 F.4th 732 (7th Cir. 2021).

130 2021 WL 2003016 (D. Mass. May 19, 2021); *see also United States v. Wavefront, LLC*, 2021 WL 37539 (D.N.J. Jan. 5, 2021) (finding that the complaint sufficiently alleged that the defendants acted with knowledge of the materiality of the falsehoods).

131 988 F.3d 823 (5th Cir. 2021).

conviction because the evidence did not show the defendant knew these practices were fraudulent or unlawful, thus preventing a finding that the defendant "willfully" violated the AKS, as required to sustain a criminal conviction.

REVERSE FALSE CLAIMS

Under the FCA's "reverse false claim" provision, 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 from the government.

Analysis of the FCA's reverse false claim provision often focuses on that provision's relationship to traditional FCA violations. Courts typically continue to require that some additional allegations or evidence be presented to support reverse false claim liability beyond a defendant's alleged "direct" violations of § 3729(a)(1)(A) or (a)(1)(B) of the FCA.

In ***U.S. ex rel. Foreman v. AECOM***, the Second Circuit affirmed dismissal of the relator's reverse false claims because they were based on the same factual allegations as the relator's claims under § 3729(a)(1)(A) and 3729(a)(1)(B).[132] The Second Circuit determined that § 3729(a)(1)(G) does not create a cause of action for reverse false claims that are duplicative of traditional false claims; instead, § 3729(a)(1)(G) applies only where a defendant makes an additional false statement in order to avoid paying money to the government. As a result, the Second Circuit held that the false statement underlying a traditional false claim cannot serve as the false statement supporting a reverse false claim. Numerous district courts adopted reasoning similar to the Second Circuit's, dismissing reverse false claims that were found to be duplicative or redundant of traditional, "direct" false claims allegations under § 3729(a)(1)(A) and (a)(1)(B).[133]

Courts also dismissed reverse false claims allegations where the relator failed to plead a specific payment obligation with the specificity required by Federal Rule of Civil Procedure 9(b). In ***U.S. ex rel. Paul v. Biotronik, Inc.***, the district court held that the relator did not sufficiently plead that the defendant owed a payment obligation to the government.[134] The district court stated that alleging a general belief that a government-funded healthcare program paid for the identified patients' procedures failed to plead a specific payment obligation with sufficient particularity. Similarly, in ***U.S. ex rel. SW Challenger, LLC v. eviCore Healthcare MSI, LLC***, the district court dismissed a reverse false claim based only on allegations that the defendant "retain[ed] Government funds to which they were not entitled" because the relators did not identify a specific, independent obligation to pay the government.[135]

In ***United States v. Cockerell Dermatopathology, P.A.***, on the other hand, the district court held that the government adequately pleaded an actionable reverse false claim.[136] The government alleged that the defendant was obligated to repay funds to the government based on a Memorandum of Understanding (MOU) that it executed regarding the repayment of certain claims, as well as two retraction letters that the defendant sent to the government acknowledging that it received certain claims in error. The district court held that the government pleaded with sufficient particularity under Rule 9(b) that the MOU and retraction letters constituted an obligation to repay funds to the government for purposes of pleading a reverse false claim. The district court further held that the government's direct false claims were based on a separate course of conduct – the submission of thousands of false claims to the government for payment – and, therefore, the alleged reverse false claims were not redundant or duplicative of the direct false claims because the reverse false claims were based on executing the MOU and submitting the retraction letters.

PUBLIC DISCLOSURE BAR

The public disclosure bar is meant to deter opportunistic relators from filing parasitic lawsuits by preventing a relator from maintaining a *qui tam* complaint that alleges substantially the same information as has been previously disclosed to the public, unless the relator is an "original source" of the FCA allegations.[137]

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Although no longer jurisdictional, the public discourse bar is still a strong affirmative defense for defendants facing allegations of fraud that are duplicative of publicly-disclosed information. Once a defendant has asserted the public disclosure bar, the district court must determine: (1) whether a public disclosure has previously occurred; (2) whether that disclosure was substantially similar to the relator's allegations; and, if so, (3) whether the relator is nevertheless an "original source" of the FCA allegations.

132 2021 WL 5406437 (2d Cir. Nov. 19, 2021).

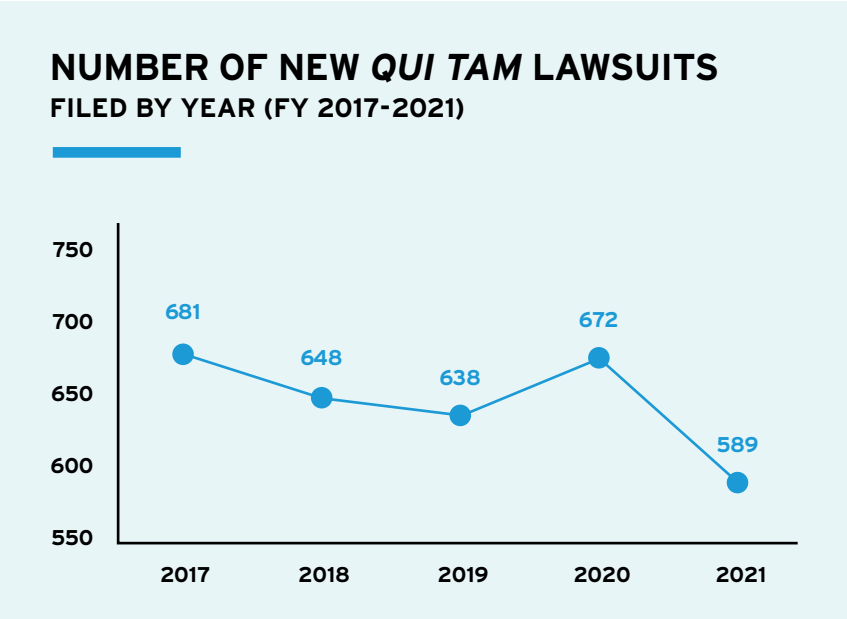
133 *See U.S. ex rel. Harbit v. Consultants in Gastroenterology, P.A.*, 2021 WL 1197124 (D.S.C. Mar. 30, 2021); *U.S. ex rel. McClinton v. Southerncare, Inc.*, 2021 WL 2587162 (S.D. Miss. June 23, 2021); *U.S. ex rel. Mbabazi v. Walgreen Co.*, 2021 WL 4453600 (E.D. Pa. Sept. 28, 2021). Although one district court allowed the government to plead theories in the alternative and to allege that the same conduct supported both direct and reverse false claims, that ruling likely is no longer good law after the Second Circuit's opinion in *Foreman*. *See United States v. Omnicare, Inc.*, 2021 WL 1063784 (S.D.N.Y. Mar. 19, 2021).

134 2021 WL 211474 (M.D. Fla. Jan. 21, 2021).

135 2021 WL 3620427 (S.D.N.Y. Aug. 13, 2021); *see also United States v. Walgreen Co.*, 2021 WL 5760307 (W.D. Va. Dec. 3, 2021) (dismissing reverse false claim allegations for failure to plead an obligation to repay funds).

136 2021 WL 4894173 (N.D. Tex. Oct. 20, 2021).

137 31 U.S.C. § 3730(e)(4).



What Must Have Been Previously Disclosed?

Courts generally agree that to bar future allegations of fraud, a public disclosure must, at minimum, place the government on notice of potential wrongdoing. But, the level of specificity required for a qualifying public disclosure can vary from case to case and court to court. Most courts have adopted the D.C. Circuit's "Springfield formula," which mandates that the prior disclosure must contain the false statement or claim (X), along with the true set of facts showing the falsity of the statement or claim (Y), which taken together would reasonably allow the conclusion that fraud has occurred (Z).

For example, in ***U.S. ex rel. Bibby v. Mortgage Investors Corp.***, two mortgage brokers alleged that Mortgage Investors Corp. was charging veterans prohibited fees and then falsely bundling those fees with other allowable charges together on a single line of their HUD-1 forms.[138] On appeal, the defendant argued that the fraud was previously disclosed by a consumer protection lawsuit in which one of the defendant's HUD-1 forms was filed on the docket. The Eleventh Circuit found that the previously-disclosed HUD-1 form only contained the false statement (X), but did not include any information showing how or why the statement was false (Y), and therefore did not lead to an inference of fraud (Z).

The Sixth Circuit applied this same formula in ***U.S. ex rel. Rahimi v. Rite Aid Corp.***[139] There, the relator filed suit alleging that Rite Aid misrepresented its U&C price to the government because it did not take into account the discounts offered to customers enrolled in its Rx Savings Program. The Sixth Circuit held that the public disclosure bar applied because the "essential elements" (X&Y) of the allegations were previously disclosed in a press release from the Connecticut Attorney General, which stated that Rite Aid excluded Medicare and Medicaid beneficiaries from its Rx Savings Program; that Connecticut passed a law mandating Rite Aid bill its Medicaid program at the lowest price offered to consumers, including any member discount programs; and that Rite Aid in turn raised its Rx Savings Program prices, but only in Connecticut. Although the relator argued that the press release contained "no suggestion of billing fraud against Rite Aid," the Sixth Circuit held that the press release and surrounding news coverage placed the essential elements of the fraud "in plain sight."

Multiple courts have held that no magic words of fraud are required to be included in prior public disclosures. In ***U.S. ex rel. Sanders v. USAA Fed. Sav. Bank***, the relators alleged that USAA and Navy Federal were running "affinity programs" in which they shared portions of the real estate brokers' commissions with their members in violation of the Real Estate Settlement Procedures Act and the Truth in Lending Act.[140] The district court dismissed the claims under the public disclosure bar because USAA and Navy Federal publicly advertised these programs, which were also the subject of numerous news articles spanning several decades, noting: "it matters not that the conduct was not specifically labeled as fraudulent" by the articles discussing those programs.[141]

Likewise, in ***U.S. ex rel. Rigsby v. State Farm Fire & Cas. Co.***, the district court concluded that even though the prior public disclosures did not expressly allege fraud, the relators "could have synthesized an inference of fraud from the publicly available information" because the disclosures revealed both that State Farm represented to FEMA it had performed line-by-line estimates for which it requested payment under the normal schedule (X), and that State Farm had in fact performed an expedited claims-handling procedure which was entitled to a lower flat fee adjustment (Y).[142]

At least one district court also held that additional interpretive effort of public information by a relator does not change the nature of the disclosure itself. In ***U.S. ex rel. Sirls v. Kindred Healthcare, Inc.***, the district court recognized that the relator expended the additional effort of obtaining an expert to analyze information received through a Freedom of Information Act (FOIA) request in order to craft his allegations.[143] The district court, however, held that because the FOIA request disclosed public information that included all of the essential elements from which the fraud could be inferred, the fact that the relator utilized an expert to review and analyze that information did not change the fact that the essential elements had already been disclosed.

Some courts have required more. In ***U.S. ex rel. Grant v. Zorn***, the relator alleged that the defendants were engaged in an improper upcoding scheme.[144] The defendants argued that the relator's upcoding allegations were barred by the public disclosure bar because the upcoding practices were the subject of two prior letters from AdvanceMed. But, the

138 987 F.3d 1340 (11th Cir. 2021).
139 3 F.4th 813 (6th Cir. 2021).
140 2021 WL 3513663 (W.D. Va. Aug. 10, 2021).
141 The district court in *U.S. ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 2021 WL 3240280 (E.D.N.Y. July 30, 2021), applied a similar analysis of this formula to a publicly-disclosed SEC filing.
142 2021 WL 1170086 (S.D. Miss. Mar. 26, 2021).
143 517 F. Supp. 3d 367 (E.D. Pa. 2021).
144 2021 WL 4145724 (S.D. Iowa Mar. 8, 2021).

district court disagreed, finding that although the AdvanceMed letters disclosed "suspicious patterns" in the defendants' billing practices and a "recurring lack of documentation to support those billing practices," the letters did not actually accuse the defendants of knowingly or intentionally engaging in those practices – which the district court found to be an essential element of the fraud. Because the letters were meant to serve only as "additional education," the district court found that they did not carry an inference of wrongdoing and thus could not satisfy the requirements of the public disclosure bar.

When Is a Relator an Original Source?

Even if a relator's allegations are substantially the same as prior public disclosures, the relator may nevertheless maintain an action if he or she qualifies as an "original source." An "original source" is a person who either "voluntarily disclosed" the information in a complaint prior to any public disclosure or has "knowledge that is independent of and materially adds to" the public disclosures and "voluntarily provided" that information to the government before filing the *qui tam* complaint.[145]

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Whether the Relator Pleaded Entitlement to the Original Source Exception

Because the public disclosure bar is often raised during the motion to dismiss stage of litigation, multiple courts this year held that it is the relators' obligation to plead entitlement to the original source exception in their *qui tam* complaints. For example, in both ***U.S. ex rel. Zafirov v. Florida Med. Assocs. LLC***,[146] and ***U.S. ex rel. Guzman v. Insys Therapeutics, Inc.***,[147] the district court dismissed the relators' complaints without prejudice and with leave to amend because although the relators claimed to be original sources, they did not plead allegations showing they were entitled to this exception to the public disclosure bar.

Whether the Relator's Knowledge Is Direct and Independent

Several courts dismissed claims under the public disclosure bar where relators failed to plead sufficient facts demonstrating that their knowledge was "direct and independent" of the public disclosures. In ***Solis v. Millennium Pharms., Inc.***, the Ninth Circuit affirmed the district court's dismissal under the public disclosure bar, holding that the relator could not show "direct knowledge" of the fraud because his allegations were "speculative" and failed to identify any actual instances of false claims for reimbursement.[148]

Similarly, in ***United States v. Kindred Healthcare, Inc.***, the district court held that the relator's boilerplate allegations of "direct and independent knowledge" were insufficient to satisfy the pleading standard because he failed to explain *how* he learned of the relevant information.[149] The district court in ***Cameron-Ehlen Grp., Inc. v. Fesenmaier*** likewise held that the relator could not claim the benefit of the "original source" exemption where the relator merely elicited the disclosure from another individual.[150] And, the district court in ***U.S. ex rel. Rigsby v. State Farm Fire & Cas. Co.*** held that the relators failed to plead "direct and independent knowledge" in their amended complaint because the record indicated that, at the time of their original complaint, the relators were not even aware of the rule they later alleged had been violated.[151]

> Even if a relator's knowledge of fraud is direct and independent of a prior disclosure, the relator still does not qualify as an original source if the relator fails to materially add to the prior disclosures.

Whether the Relator Materially Adds to Prior Disclosures

Even if a relator's knowledge of fraud is direct and independent of a prior disclosure, the relator still does not qualify as an original source if the relator fails to materially add to the prior disclosures. For example, similar to the Sixth Circuit's 2020 decision in ***U.S. ex rel. Maur v. Hage-Korban***, the district court in ***U.S. ex rel. Zafirov v. Florida Med. Assocs. LLC*** determined that allegations of continuing misconduct, which had been disclosed in a prior FCA case and public settlement were not material additions to those disclosures because the CIA remained in effect with active oversight by the government of the underlying allegations.[152] The relator could not be an "original source" of the alleged fraud because the government was still supervising the defendant's actions and receiving disclosures.

Whether the Disclosure Was Voluntary

The "voluntary" requirement of the original source exception has been important in decisions. Courts have consistently held that merely complying with a government investigation is not considered voluntarily disclosing that information to the government for purposes of the public disclosure bar.

In ***Cameron-Ehlen Grp., Inc. v. Fesenmaier***, the district court applied this same logic to ongoing litigation.[153] The defendant was the relator in another FCA action alleging that Precision Lens was engaged in an unlawful kickback scheme. After disclosing information

145 31 U.S.C. § 3730(e)(4)(B).
146 2021 WL 4443119 (M.D. Fla. Sept. 28, 2021).
147 2021 WL 4306020 (C.D. Cal. May 19, 2021).
148 852 F. App'x 298 (9th Cir. 2021).
149 417 F. Supp. 3d 367 (E.D. Pa. 2021).
150 2021 WL 5011375 (D. Minn. Oct. 28, 2021).
151 2021 WL 1170086 (S.D. Miss. Mar. 26, 2021).
152 2021 WL 4443119 (M.D. Fla. Sept. 28, 2021).
153 2021 WL 5011375 (D. Minn. Oct. 28, 2021).

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. Recent cases have examined the bar's application to related cases, whether amending a complaint can save it from the bar, and whether the bar is jurisdictional in nature.

about the scheme to the FBI, but before filing his *qui tam* case, Fesenmaier filed for Chapter 7 bankruptcy, during which he did not list the potential FCA case among his assets and liabilities. As a result, Precision Lens filed its own FCA case alleging that because Fesenmaier failed to disclose the potential FCA litigation in his bankruptcy petition, his FCA claims were "legally false" and his retention of a portion of the recovery was fraudulent. Precision Lens conceded that its allegations had been previously disclosed through Fesenmaier's FCA litigation, but claimed it was an original source because it voluntarily disclosed information underlying its case during Fesenmaier's deposition in the prior FCA litigation. The district court held that Precision Lens could not qualify as an original source because it had not "voluntarily disclosed" the information. Rather, the district court found that Precision Lens's disclosure was "clearly motivated by Precision Lens's self-interested desire to defend itself in the Fesenmaier litigation and shift focus of that fraud investigation from Precision Lens to Fesenmaier."

FIRST-TO-FILE BAR

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In ***U.S. ex rel. Mohajer v. Omnicare, Inc.***, the district court granted the defendants' motion to dismiss based on application of the first-to-file bar.[155] Both the underlying *qui tam* action and an earlier-filed action alleged that a long-term care pharmacy dispensed drugs to individuals at long-term care facilities based on invalid prescriptions (*e.g.*, expired or run out of refills). In assessing whether the relators' action was "related" to the earlier-filed lawsuit, the court commented that "[r]elatedness is not a difficult threshold to meet," and "focuses on" the "essential facts" and "whether the later complaint alleges a *fraudulent scheme* the government already would be equipped to investigate based on the first complaint." Even though the relators provided "finer details" of the purported fraud (*e.g.*, the pharmacy dispensing illegal refills through different processes and staff sometimes intentionally entering wrong information into the system), the court found that the first-to-file bar applied because "both complaints allege the same fraudulent scheme" whereby the pharmacy manipulated "its internal systems in such a way so as to allow the consistent and unchecked dispensation of drugs without valid prescriptions." Following Second Circuit precedent, the district court noted that the relators could not save their *qui tam* action from the first-to-file bar by amending or supplementing their complaint.

By comparison, in ***U.S. ex rel. Fitzer v. Allergan, Inc.***, the district court found the first-to-file bar inapplicable and reasoned that "[t]he bar exists to prevent multiple *qui tam* suits focused on the same conduct, not to preclude two suits that focus on entirely different conduct, but which both happen to involve the use of the same website."[156] There, the relator alleged that the manufacturer of the LAP-BAND used a physician locator on its website to conduct a kickback scheme by providing surgeons with free advertising on the website to induce them to recommend the device and by implementing a quota of LAP-BAND surgeries that a physician needed to perform each year for inclusion on the physician locator. The defendants asserted that a prior suit filed against them was a "related" action, triggering the first-to-file bar, because it also alleged a kickback scheme involving LAP-BAND's promotional practices. The district court disagreed, explaining that a "close comparison" of the two actions revealed that they "focused" on different fraudulent schemes: whereas this case "focused exclusively" on the website and its use to increase sales through the physician locator, the earlier action "focused on" an elaborate scheme to cover up a design defect in the device. The district court noted that the mere fact that the prior complaint referenced use of the website to drive sales was insufficient to apply the bar.

Mohajer and ***Fitzer*** also reflected the ongoing circuit split regarding the jurisdictional nature of the first-to-file bar, with the latter noting it is jurisdictional based on Fourth Circuit precedent and the former noting the opposite based on Second Circuit precedent.

GOVERNMENT ACTION BAR

The government action bar originates from the FCA's statutory text, which states that "[i]n no event may a person bring [a *qui tam* action] which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil monetary penalty proceeding in which the Government is already a party."[157]

In ***U.S. ex rel. Vermont Nat'l Tel. Co. v. Northstar Wireless LLC***, the district court granted the defendants' motion to dismiss for lack of jurisdiction based on the government action bar.[158] The relator alleged that a large telecommunications company manipulated the Federal Communications Commission's (FCC) auction rules to obtain fraudulent small

154 31 U.S.C. § 3730(b)(5).
155 525 F. Supp. 3d 447 (S.D.N.Y. 2021).
156 2021 WL 4133713 (D. Md. Sept. 10, 2021).
157 31 U.S.C. § 3730(e)(3).
158 531 F. Supp. 3d 247 (D.D.C. 2021).

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business discounts on spectrum licenses by using shell companies and secret agreements. The district court found that the bar applied based on a prior FCC administrative proceeding involving the same allegations and reached two notable holdings. First, the bar is not tied to the *actual imposition* of penalties and instead only requires that the allegations at issue be the "*subject of*" an administrative civil monetary penalty proceeding, "leaving open the logical possibility" that a government investigation occur that uncovers no wrongdoing that would support a penalty (as happened here). Second, the bar is not limited to *particular parties*, as it applies on the basis of "allegations or transactions." On this point, the relator argued that the government action bar should not apply to certain defendants who were not parties to the FCC proceeding. The district court disagreed, reasoning that the relator's interpretation of the bar was inconsistent with the statute's text and the "broader purpose" of the bar was to preclude *qui tam* actions that take "support" from the government's "host case" "without giving any proper or useful return to the government."

STATUTE OF LIMITATIONS

The statute of limitations can significantly limit or require dismissal of an FCA claim. Under 31 U.S.C. § 3731(b), an action asserting FCA claims must be brought within the later of: (1) six years after the FCA violation occurred; or (2) three years after the United States official charged with responsibility to act knew or should have known the material facts, up to 10 years after the violation. In the 2019 decision ***Cochise Consultancy v. U.S. ex rel. Hunt***, the Supreme Court held that both limitation periods apply to a declined *qui tam* action.[159] That is, a relator may proceed with a declined *qui tam* action filed more than six years after the FCA violation occurs if it is filed within three years of when the relevant government official – and not the relator – should have known the material facts.

In ***United States v. Reliance Medical Systems, LLC***, the district court rejected the defendants' argument that certain of the government's claims were time-barred by the six year statute of limitations in § 3731(b)(1). The government filed a complaint on September 8, 2014. The defendants argued that claims based on acts prior to September 8, 2008 were time-barred, reasoning that the three year statute of limitations in § 3731(b)(2) did not apply since the government was on notice of the allegations in its complaint at least as of July 26, 2011, the date of a surreptitious recording referenced in the government's complaint. The district court rejected this argument, finding that while the recording provided some pertinent information, the complaint contained extensive allegations that went well beyond the information contained in the recording and were based on the government's continued investigation and the defendants' 2013 responses to government subpoenas.[160]

In ***United States v. Aniemeka***, the government filed a complaint on May 26, 2017, alleging that the defendants accepted kickbacks between February 24, 2009, and August 16, 2010. The defendants moved to dismiss on statute of limitations grounds, attaching an affidavit that explained that while one of the defendants signed a tolling agreement that would render the complaint timely, she did so unwillingly and not understanding the full consequences of the agreement. Explaining that a statute of limitations affirmative defense may be granted on a motion to dismiss only when the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense, the district court took notice of the tolling agreement – which the government attached to its opposition to dismissal – for the limited purpose of determining that the allegations in the complaint did *not* set forth everything necessary for the defense and denied the motion to dismiss. The defendants filed motions for reconsideration and for leave to file a motion for judgment on the pleadings, arguing the relevant dates for the statute of limitations defense were contained in the complaint and that the district court was wrong to consider the existence of the tolling evidence when deciding otherwise. The district court denied both motions, citing various cases that also relied on the existence of tolling agreements for the limited purpose of determining that the allegations of the complaint itself did not set forth everything necessary to satisfy the defendants' affirmative statute of limitations defense.[161]

Similarly, the district court in ***U.S. ex rel. Sperandeo v. Neurological Institute and Specialty Ctrs., Inc.***, rejected the defendants' motion to dismiss argument that any allegations of conduct prior to six years before the relator's complaint were barred by the statute of limitations. The relator countered that he alleged an ongoing fraud, and although some of the alleged violations occurred more than six years before the filing of the complaint, none occurred more than 10 years prior to the complaint. Without discussing the relator's ongoing fraud argument, the district court decided that the allegations in the complaint did not set forth all of the elements necessary to satisfy the affirmative defense of a statute of limitations violation and thus the defense was not an independent ground on which the complaint could be dismissed.[162]

In contrast, the district court determined that the FCA's statute of limitations barred the relator's claims in ***U.S. ex rel. Allen v. Good Samaritan Hosp. of Cincinnati***. The relator accused a hospital of submitting false claims related to medically unnecessary surgeries by a neurosurgeon, with the last such claim submitted in August 2010. The district court held that the suit should have been brought no later than August 2016 – six years after the last fraudulent act alleged in the complaint (August 8, 2010), or three years after the U.S. Attorney investigated the healthcare fraud scheme and indicted the neurosurgeon

159 139 S. Ct. 1507 (2019).

160 2021 WL 5234401 (C.D. Cal. Nov. 10, 2021).
161 2021 WL 949344 (N.D. Ill. Mar. 12, 2021).
162 2021 WL 1177071 (N.D. Ind. Mar. 29, 2021).

for related billing (August 7, 2013). The relator argued that the investigation underlying the indictment concerned the *neurosurgeon*'s conduct rather than the hospital's alleged conduct, and thus, the August 2013 indictment date did not hold significance for purposes of the second prong of § 3731(b). The district court rejected this argument, holding that because both the neurosurgeon and GSH allegedly participated in the same fraudulent scheme, the government reasonably should have known of the facts underlying the hospital's role in the scheme once it uncovered enough evidence to indict the neurosurgeon in August 2013.[163]

DISCOVERY

Motions to Stay

Because of heightened pleading standards in FCA cases, courts often face motions to exercise their discretion to stay discovery pending resolution of pending motions to dismiss. In such circumstances, courts weigh the harm in delaying discovery with the possibility that the motion will be granted and significantly narrow the issues in dispute, dispose of the entire case or enable the filing of an amended complaint. In the FCA context, many courts recognize that the pleading requirements imposed by Rule 9(b) will be a "nullity" if the relators receive a ticket to the discovery process without identifying a single claim, and will grant motions to stay based on this consideration when the pending motions challenge the legal sufficiency of the underlying complaint on particularity grounds.

> Because of heightened pleading standards in FCA cases, courts often face motions to exercise their discretion to stay discovery pending resolution of pending motions to dismiss.

In one such case, ***U.S. ex rel. Ernst v. College Park Ancillary, LLC***, the magistrate judge granted the defendants' motion for a stay of discovery pending ruling on the defendants' motion to dismiss. Recognizing the general rule that discovery is not stayed based merely on the pendency of dispositive motions, the magistrate judge nevertheless found that the defendants established that a stay was appropriate by "set[ting] out in detail" why the complaint suffered from the same pleading deficiencies as the original and first amended complaint. The magistrate judge agreed that the dispositive motion "very possibly could finally conclude the case" or at least narrow the issues. The magistrate judge acknowledged that a stay of discovery supported the purposes of Rule 9(b), because "allowing non-particular fraud claims to proceed to discovery defeats Rule 9(b)'s purposes of bringing an early end to frivolous claims which bring reputational damage."[164]

The district court reached the same conclusion to stay discovery pending resolution on the motions to dismiss in ***Fernandez v. Freedom Health, Inc.***, noting its "preliminary peek" at the merits of the motions to determine whether a stay was warranted "suggests that the pending motions to dismiss may result in dismissal of the Complaint as currently pleaded."[165] In ***U.S. ex rel. Williams v. Medical Support Los Angeles, Inc.***, the district court also exercised its inherent authority to stay discovery pending resolution of a motion to dismiss, adopting the reasoning that while in most cases postponing discovery when a motion to dismiss is pending "does not make sense," "False Claims Act cases are different." The district court noted that staying discovery pending resolutions of motions to dismiss in the FCA context supports one of the purposes of Rule 9(b)'s particularity requirement, which is to inhibit the filing of a complaint as a pretext for the discovery of unknown wrongs. In ***U.S. ex rel. Zafirov v. Florida Med. Assocs. LLC***, the district court's rationale for staying discovery until a ruling on the pending motion to dismiss was more straightforward than philosophical. The district court simply noted, "a stay will allow the undersigned to better manage this inherited case."[166]

By contrast, in ***United States v. Insys Therapeutics, Inc.***, the district court refused to issue a stay pending resolution of the defendants' respective motions to dismiss, finding the burden to the defendants did not outweigh considerations related to the inconvenience and expense inherent in requiring a revised 26(f) report and amending the scheduling order in the case. The district court reasoned that the defendants had not offered any specific, non-stereotypical statements in support of a stay and stated it was not convinced that the plaintiff would be unable to state a claim against the relevant defendants.[167]

In ***U.S. ex rel. Bell v. Cross Garden Care Center, LLC***, the district court denied the relator's request to stay any ruling on the defendants' pending motion for summary judgment before resolving discovery-related litigation between the government and a former defendant and the government's final intervention decision. While the case was under seal, the United States brought an action to enforce a Civil Investigative Demand (CID) seeking documents from a former defendant, Cross Senior Care. The Eleventh Circuit affirmed the district court's order requiring production of documents and remanded to the district court to set a timeframe for production. At the time of the relator's request for a stay, the mandate still had not been issued. The relator argued that a stay was appropriate because: (1) the CID documents would "bolster [her] summary judgment motion or at least establish material issues of fact that could defeat the motion against her," and (2) the United States' notice of declination noted it would only make its final intervention decision after its investigation, so she would not be able to participate in any eventual reward should the summary judgment motion be decided in the defendant's favor and the government later intervene. The district court rejected the motion for stay, reasoning: (1) the defendants' summary judgment motion was filed after the parties completed discovery and not premature; (2) the relator had not diligently pursued the documents subject to the CID during discovery or sought to extend the discovery deadline; and (3) the relator's vague assertions that additional discovery would

163 2021 WL 4262342 (S.D. Ohio Sept. 19, 2021).
164 2021 WL 533830 (D. Kan. Feb. 12, 2021).
165 2021 WL 2954309 (M.D. Fla. Mar. 25, 2021).
166 2021 WL 2401937 (M.D. Fla. June 11, 2021).
167 2021 WL 4307404 (C.D. Cal. Apr. 14, 2021).

produce needed, but unspecified facts, failed to satisfy Rule 56(d)'s requirement that she specifically demonstrate how postponement of a ruling would enable her, by discovery or other means, to rebut the movant's she absence of a genuine issue of fact.[168]

Scope of Discovery

FCA litigation frequently includes extensive discovery requests over broad time periods, given the nature of the allegations at issue. When disputes over the scope of discovery arise, some courts attempt to craft creative solutions and compromises to strike a balance between competing fairness and burden concerns.

In ***United States v. Allergan, Inc.***, the district court was called on to resolve three discovery disputes in an action alleging false claims in the marketing and implementation of a breast implant trial program.[169] The disputes centered on: (1) the number of additional custodians, if any, on which the defendant would be required to conduct keyword searches of electronically stored information (ESI); (2) whether, or to what extent, Allergan should collect text messages and subject them to keyword searches; and (3) whether the collection of ESI for keyword searches should end as of the lawsuit's filing date (February 2018) or some later date based on the relator's allegation of an ongoing fraud scheme.

FCA litigation frequently includes extensive discovery requests over broad time periods, given the nature of the allegations at issue.

As to the number of custodians, the defendants had already searched and provided documents for 35 custodians. The relators asserted the need to have search terms applied to 36 additional custodians while the defendants proposed adding only 14, which the defendants argued was sufficient to cover relevant roles, times and regions. After making a number of theoretical assumptions about timing of review, the district court adopted the defendant's proposal of adding 14 custodians, but allowed the relator to choose an additional three and replace up to five of the defendants' proposed 14 with individuals from the relator's list of 36.

Regarding text messages, the district court ordered a staged process. First, the relators were ordered to provide a digestible description (no greater than 150 words) to the defendants regarding the types of text messages in which the relator was most interested. Second, the defendant would share the relator's description with the 52 proposed text message custodians and ask them to estimate: (1) if they ever used text messages in the manner described by the relator (never, rarely, occasionally, frequently or daily); and (2) the approximate date range of relevant text messages. Finally, the defendant would provide a chart with the custodians' information to the relator within 14 days of receiving the relators' description of requested text messages, from which the relator would be allowed to pick no more than 3 custodians for text discovery.

Finally, regarding the end date for ESI discovery, the district court rejected the defendant's argument that searching two additional years of ESI was unduly burdensome, reasoning that the defendant imposed the February 2018 limit knowing that the relator did not agree with it. The district court was more sympathetic to the defendant's arguments that the operative complaint contained no particularized facts of ongoing fraud. As a compromise resolution, the district court ordered the defendant to execute the relator's proposal to search 15 custodians' data for the time period of February 2018 through October 31, 2018, the day before the *qui tam* complaint was unsealed. For the time period of November 1, 2018, through March 31, 2020, the district court adopted the defendant's proposal that it could self-collect documents relevant to the issues in the lawsuit after interviewing relevant custodians with knowledge.

In ***U.S. ex rel. Simpson v. Bayer A.G.***, the defendants served a subpoena on CMS for paper records, and the United States, which had declined to intervene in the action, moved to quash.[170] The government's declaration in support of the motion to quash noted the subpoena would have required CMS to produce 230 million pages of records contained in over 91,000 boxes dispersed at several government storage sites around the country. The special master granted the motion to quash, finding the defendants had failed to demonstrate the relevance of the records or that they contained information that could not be obtained from other sources. The United States then moved to shift the costs and expenses CMS incurred because of the defendants' subpoena under FRCP 45(d)(1) and 45(d)(2)(B). The special master denied the motion, finding that sanctions under Rule 45(d)(2)(B) were only available where a court has issued an order compelling production in response to a motion by a party seeking discovery, and that sanctions under Rule 45(d)(1) were discretionary and unwarranted in this case because: (1) the defendants' subpoena was not issued in bad faith or for improper purposes, and (2) CMS did not actually have to collect, analyze or produce the records, even if CMS found it inconvenient to gather the information necessary for its declaration in support of the motion to quash.

The district court affirmed on both grounds, emphasizing that the defendants engaged in multiple meet-and-confer attempts regarding the scope of their subpoena, offered to review a meaningful sample of the records to reduce the burden and offered a potential stipulation as an alternative to getting the actual documents.

BREACHES OF THE SEAL

Under the FCA's seal provision, 31 U.S.C. § 3730(b)(2), *qui tam* complaints "shall remain under seal for at least 60 days." The 60-day seal period is intended to permit the government to decide whether to intervene, and the government can seek an extension of the initial period.[171] When adjudicating issues regarding the seal in *qui tam* actions, courts are asked to balance these statutory requirements with the common-law right of public access to judicial records. In ***U.S. ex rel. Meythaler v. Encompass Health Corp.***, the relator simultaneously dismissed his *qui tam* complaint and moved the court to keep the action under seal even after its dismissal.[172] The district court found that the relator's professed fear of retaliation

168 2021 WL 289343 (M.D. Fla. Jan. 28, 2021).
169 2021 WL 969215 (C.D. Cal. Mar. 1, 2021).
170 2021 WL 363705 (D.N.J. Feb. 2, 2021).
171 31 U.S.C. § 3730(b)(3).
172 2021 WL 871347 (N.D. Ala. Mar. 9, 2021).

by the defendants was insufficient to overcome the presumption of public access, but maintained the seal as to the government's filings that contained details of the government's investigative process.

Similarly, the relator in ***U.S. ex rel. Doe v. Horizon Therapeutics PLC*** sought to maintain the seal after the government declined to intervene.[173] Again, the relator pointed to risks to "professional reputation and blackballing that could occur should Defendants, Relator's current employer, or any other entities or persons become aware of Relator's whistleblowing activities." Citing that a "strong presumption of public access attaches to judicial documents," and that the complaint and amended complaint are judicial documents, the district court denied the relator's motion to extend the seal. The district court further highlighted that "[c]ourts generally do not find that the risk of employer retaliation outweighs the presumption of public access to documents filed in FCA actions."

By contrast, in ***U.S. ex rel. Smith v. Carolina Comprehensive Health Network, PA***, the government sought a permanent seal as to several of its filings on the docket after declining intervention.[174] Finding that the government's extension memoranda disclosed "non-public procedures and strategies that reveal, to some extent, how the United States handles fraud investigations," the district court granted the government's motion. In doing so, the district court permitted the government to permanently redact information in its memoranda before those filings were unsealed.

While the bulk of litigation pertaining to the FCA seal provisions addresses parties' requests to maintain the seal, the seal provisions can implicate other matters as well. For instance, in ***U.S. ex rel. Raffington v. Bon Secours Health System, Inc.***, the relator sought leave to file a seventh amended complaint after the government had declined to intervene and discovery had concluded.[175] In addressing the defendants' statute of limitations argument, the district court found that claims in the proposed seventh amended complaint could not relate back to the original complaint. Specifically, the district court ruled that there was no relation back under Federal Rule of Civil Procedure 15(c) because no notice was given of the complaint due to the FCA's seal requirement. Accordingly, the relator's new allegations could only relate back to the date that the case was unsealed rather than the date it was filed.

EXCESSIVE FINES CLAIMS

In ***U.S. ex rel. Yates v. Pinellas Hematology & Oncology, P.A.***, the Eleventh Circuit became the first federal court of appeals to directly address whether the Eighth Amendment's Excessive Fines Clause applies to the monetary award in a declined FCA case.[176] The defendant was a clinical laboratory with multiple locations, some of which had Clinical Laboratory Improvement Amendments (CLIA) certificates required to conduct lab tests, and others of which did not. The jury found that the defendant submitted 214 claims to Medicare in which it falsely represented that tests were performed at locations with CLIA certificates, when in fact they had been performed at locations without CLIA certificates. The jury found that the United States had sustained $755.54 in actual damages. The district court trebled the government's actual damages and imposed $5,000, the lowest per claim civil penalty, for each of the 214 violations, resulting in a total judgment of $1.179 million. The defendant challenged this award on appeal under the Excessive Fines Clause.

The Eleventh Circuit held that "the damages and statutory penalties awarded in a non-intervened FCA *qui tam* action are subject to the Eighth Amendment's prohibition on excessive fines." The Eleventh Circuit reached this conclusion by joining the Fourth, Eighth and Ninth Circuits in accepting "that FCA monetary awards are fines for the purposes of the Excessive Fines Clause, precisely because they are at least in part punitive." The Eleventh Circuit also held that monetary awards in declined cases are "imposed by the United States" – such that they fall under the federal constitution – because they are required by a federal statute and arise in cases brought on behalf of the United States in which the United States exercises significant control over the ultimate disposition of the action.

> The FCA protects whistleblowers from adverse employment actions related to their whistleblowing activities.

Turning to the judgment against the defendant, the Eleventh Circuit found that the total award of $1.179 million passed constitutional muster, noting that the defendant engaged in repeated fraud, that it acted with the requisite scienter, that fraud imposed considerable harm on the United States and that the district court imposed the lowest per claim civil penalty.

The Eleventh Circuit also gave deference to Congress's imposition of treble damages and significant per claim civil penalties, noting that defendants who submit false claims to Medicare are "squarely in the FCA's crosshairs." On this point, two judges issued a concurring opinion, cautioning that giving "great deference to Congress's judgment about the excessiveness of the fine" "seems a bit like letting the driver set the speed limit."

RETALIATION

The FCA protects whistleblowers from adverse employment actions related to their whistleblowing activities.[177] To establish a prima facie claim under the statute's anti-retaliation provision, 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. Once this is done, the burden shifts to the employer to give a legitimate, non-retaliatory reason for the termination, which the employee can rebut by showing it was pre-textual.[178]

173 2021 WL 3500911 (S.D.N.Y. Aug. 9, 2021).
174 2021 WL 325705 (M.D.N.C. Feb. 1, 2021).
175 2021 WL 4762054 (S.D.N.Y. Oct. 13, 2021).
176 2021 WL 6133175 (11th Cir. Dec. 29, 2021).
177 31 U.S.C. § 3730(h).
178 *See, e.g.*, *Toledo v. HCA Healthcare, Inc.*, 2021 WL 4990821 (S.D. Tex. Oct. 27, 2021).

Post-Employment Retaliation

A circuit split has emerged on the question of whether the FCA's anti-retaliation provision protects individuals from retaliation by their *prior employer* after their employment ends. Before 2021, the only circuit court to have addressed the question (the Tenth Circuit) and most district courts had concluded that the FCA does not protect individuals from alleged post-employment retaliation.[179] In ***U.S. ex rel. Felten v. William Beaumont Hosp.***, however, the Sixth Circuit rejected the reasoning from these cases in holding that the FCA's anti-retaliation provision can encompass acts taken by an employer against a former employee.[180]

The Sixth Circuit's opinion involved allegations from a physician-scientist that his former employer interfered with up to 40 employment applications that he submitted to various institutions, ultimately blacklisting him from academic medicine. In holding that a former employee can raise retaliation claims for a post-employment adverse action, the Sixth Circuit observed that the text of the FCA is not explicitly limited to current employees. Acknowledging that its holding created a split with the Tenth Circuit, the Sixth Circuit relied on the Supreme Court's interpretation of Title VII's analogous anti-retaliation provision to find that: (1) the FCA provision does not have a temporal qualifier accompanying the term "employee" that would limit it to only current employees; (2) the dictionary definition of "employee" does not inherently exclude former employees; and (3) the remainder of the FCA implies that it covers former employees, as remedies such as reinstatement can be awarded only to former employees. The Sixth Circuit left open the issue of whether blacklisting a former employee from future employment is an adverse employment action, as the lower court had yet to decide that question.

One notable development occurred after the Sixth Circuit's ruling that will be worth watching in the year ahead. Proposed amendments to the FCA were introduced in Congress that would revise the statute to expressly extend relief to former employees for post-employment retaliation.[181]

Protected Activity and the Underlying Fraud

The first question in assessing an FCA retaliation claim is whether the plaintiff engaged in protected activity, which includes: (1) an employee's lawful actions "in furtherance of" an FCA action or (2) "other efforts to stop 1 or more violations" of the FCA.[182] While the specific standards courts apply in assessing these two prongs of protected activity may vary, courts generally require that an employee's actions relate to a fraud against the government, and not merely general compliance or regulatory concerns, to qualify as protected activity.

For example, in ***U.S. ex rel. Skibo v. Greer Labs., Inc.***, the Fourth Circuit affirmed summary judgment in favor of the defendant where one of the plaintiffs argued that her raising concerns about FDA violations established that she engaged in protected activity.[183] The plaintiff's testimony established that "at best" she raised concerns about FDA regulatory compliance, which was part of her job description, but she never alleged that she "raised an issue of *false* or *fraudulent* conduct beyond a regulatory violation that would constitute an FCA violation."

In ***Hickman v. Spirit of Athens, Ala., Inc.***, the Eleventh Circuit affirmed the district court's grant of summary judgment to the employer where plaintiffs believed that their employer was misusing federal funds automatically distributed from the Tennessee Valley Authority (TVA) and had taken steps to investigate and audit the alleged misuse prior to their termination.[184] The Eleventh Circuit found that plaintiffs failed to establish they engaged in protected activity because they knew their employer received the funds without submitting a claim to the federal government and without any limitations from the TVA. The Eleventh Circuit noted that it had yet to consider the meaning of "other efforts to stop [an FCA] violation" in the statutory text and recognized that other circuits had interpreted it to require an "objectively reasonable belief" that the employer is violating or soon will violate the FCA, but the Eleventh Circuit ultimately declined to adopt a standard. It held that even if a "reasonable belief" is "all that is required," the plaintiffs' actions failed to meet that standard. The Eleventh Circuit reasoned that "at a minimum," plaintiffs must "show that the activity they were fired over had *something* to do with the [FCA] – or at least that a reasonable person might have thought so," considering that FCA liability "arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal procedures." This threshold requirement "matters," the Eleventh Circuit stressed, because "[i]t is not enough for an employee to suspect fraud [or] misuse of federal funds." Instead, an employee "must suspect that her employer has made a false claim to the federal government."

Relying in part on ***Hickman***, the district court in ***Simon v. HealthSouth of Sarasota Ltd. P'ship*** granted the defendants' motion for summary judgment, explaining that to establish protected activity, a plaintiff "must not only show that she subjectively believed" that her employer "was violating the FCA, but also that her belief was objectively reasonable in light of the facts and record presented."[185] The plaintiff alleged her employer retaliated against her for raising complaints about the alleged use of false diagnoses by employed physicians. While crediting the plaintiff's testimony at the summary judgment stage that she did, in fact, make complaints about alleged fraud, even absent documented evidence, the district court held that the plaintiff's action was not protected activity because she lacked an objectively reasonable basis to believe that the defendants were submitting false claims. In so holding, the district court highlighted: (1) the plaintiff's lack of involvement with hospital billing; (2) her general lack of knowledge about diagnosis coding; and (3) evidence indicating that medical professionals could reasonably differ in opinion regarding the underlying diagnosis coding issue.

In contrast, in ***Heckman v. UPMC Wellsboro***, the district court found the plaintiff's allegations that he informed defendant-hospitals that they were in violation of Federally Qualified Health Center program requirements sufficient to constitute "an effort to stop" an FCA violation, even though the plaintiff failed to specifically allege that he referenced

179 *See, e.g.*, *Knight v. Standard Chartered Bank*, 531 F. Supp. 3d 755 (S.D.N.Y. 2021) (noting that "an FCA retaliation claim must be based on actions that occurred during the plaintiff's employment" and listing supporting cases).
180 993 F.3d 428 (6th Cir. 2021).
181 False Claims Amendment Act of 2021, S. 2428, 117th Cong. § 4 (2021).
182 31 U.S.C. § 3730(h)(1).
183 841 F. App'x 527 (4th Cir. 2021).
184 985 F.3d 1284 (11th Cir. 2021).
185 2021 WL 533539 (M.D. Fla. Feb. 12, 2021).

the FCA in his conversations with hospital officials.[186] The district court noted these efforts were "at least one step removed from the typical 'efforts' involving complaints of fraud," but found them sufficient at the pleading stage.

In ***Gatti v. Granger Medical Clinic, P.C.***, the plaintiff compliance officer offered evidence of an array of whistleblowing actions, most of which the district court held to be protected, including reporting about the legality of billing practices outside her normal chain of command and telling her supervisor she filed a *qui tam* action.[187] But, notably, the district court also held that the compliance officer's reference to a *qui tam* attorney in a subsequent conversation with the clinic's CEO was *not* protected conduct. The plaintiff had referred to a *qui tam* attorney only after being told of the clinic's reorganization plans and being reassigned to a different supervisor, and when the CEO asked her to explain the basis for a *qui tam* action, the plaintiff refused. Furthermore, the plaintiff failed to show evidence connecting the reorganization and new supervisor to the alleged fraudulent billing practices. Thus, the district court interpreted the reference to a *qui tam* attorney as merely an attempt to avoid the negative consequences of refusing her employer's explicit direction – not protected activity.

The district court in ***Mehlman v. Cincinnati Children's Hosp. Med. Ctr.*** likewise limited what kind of actions constitute "other efforts" to stop an FCA violation.[188] A physician was suspended after raising concerns that another physician was performing allegedly unnecessary and risky procedures. The district court granted the employer hospital's motion to dismiss the retaliation claim, reasoning that allegations that the plaintiff complained about unnecessary procedures out of concern for the health outcomes and safety of patients – without any reference to fraud – are insufficient to plead protected activity.

Employer Notice

To satisfy the second element of a prima facie FCA retaliation claim, an employee must show that the employer knew about the employee's protected activity because, logically, there can be no retaliation without such notice.

The district court in ***Vaughn v. Harris County Hosp. Dist.*** examined the notice requirement in denying an employer's motion to dismiss where the employee allegedly made four complaints about fraud to his employer.[189] While observing that employers generally will not have notice of protected activities that are consistent with the employee's job duties, the district court reasoned that internal complaints can be considered sufficient notice where the complaints are put in terms of fraud, go outside of the normal chain of command, or "otherwise objectively demonstrate[] the possibility of *qui tam* litigation." The district court found that the defendant was on notice of possible litigation because the plaintiff pleaded that: (1) his job duties did not include his protected activities; (2) his protected activities involved reporting fraud to the compliance committee and other people outside the normal chain of command; and (3) he characterized his complaints as fraud on the government.

By contrast, in ***U.S. ex rel. Raney v. Amedisys, Inc.***, the district court granted an employer's motion to dismiss, finding that the employer was not on notice of protected activity because the employee did not allege that her protected activity implicated false billing to Medicare and, rather, alleged generally that "everyone involved kn[ew] of the fraud."[190] Without allegations that the employee clued the employer into the possibility of FCA liability, the district court held that the complaint could not advance past the pleading stage. Likewise, in ***U.S. ex rel. Manieri v. Avanir Pharm., Inc.***, the district court granted an employer's motion to dismiss where the employee did not allege that he affirmatively reported fraud to his employer and, instead, relied on threadbare allegations that his employer should have known that his concerns related to an allegedly illegal kickback scheme.[191]

Adverse Action Because of Protected Activity

Finally, an FCA retaliation plaintiff must show a causal connection between an adverse employment action and the protected activity. This element consists of two discrete inquiries: (1) whether the employee actually suffered an adverse employment action; and (2) whether the adverse employment action occurred *because of* the protected activity.

The Sixth Circuit explored the baseline of an adverse employment action in ***El-Khalil v. Usen***, affirming the district court's grant of summary judgment to the employer, a medical center, and holding that a negative recommendation on staffing privileges is not, in and of itself, an adverse employment action.[192] There, the physician's staffing privileges had lapsed, and in reviewing his application for reappointment, the employer's Medical Executive Committee voted unanimously to recommend against his reappointment. The Sixth Circuit articulated two reasons that the recommendation was not an adverse employment action: (1) the employee did not have staffing privileges before the recommendation was issued, so there was no significant change to his employment status; and (2) only the medical center's governing body could approve or deny staffing privilege applications, meaning that the committee's recommendation was not an official company act.

Regarding the standard to demonstrate causation, several courts concluded a plaintiff must prove that the adverse action was a "but-for" cause of the protected activity, not merely that the protected activity was one motivating factor. For example, in ***Raney***, the district court dismissed the retaliation claim because the employee failed to plead any facts plausibly alleging that her employer would not have terminated her if she had not engaged in protected activity.[193] The district court noted that the plaintiff's allegations about not receiving a reasonable explanation for termination and possibly being terminated because of her protected activity were insufficient to show "but-for" causation. Yet, in ***U.S. ex rel. Rehfeldt v. Compassionate Care Hospice Grp., Inc.***, the district court held that, at the motion to dismiss stage, the "but-for" standard is not onerous and can be met by showing "that the protected activity and the negative employment action are not completely unrelated."[194] Further, in ***U.S. ex rel. Barrick v. Parker-Migliorini Int'l, LLC***, another district court explained that the "but-for" test does not require the protected activity to be the

186 2021 WL 2826716 (M.D. Pa. July 7, 2021).
187 2021 WL 1171719 (D. Utah Mar. 29, 2021).
188 2021 WL 3560571 (S.D. Ohio Aug. 11, 2021).
189 2021 WL 4464190 (S.D. Tex. Aug. 4, 2021).
190 2021 WL 4458874 (N.D. Ala. Sept. 29, 2021).
191 2021 WL 857102 (N.D. Ohio Mar. 8, 2021).
192 2021 WL 4621828 (6th Cir. Oct. 7, 2021).
193 2021 WL 4458874 (N.D. Ala. Sept. 29, 2021).
194 2021 WL 2229057 (M.D. Ga. June 2, 2021).

"sole cause" of the adverse employment action, making room for retaliation claims with multiple "but-for" causes.[195]

Other courts, however, continued to apply the "motivating factor" test for causation. For instance, in ***Gatti***, the district court granted summary judgment for the employer because the record did not show that its decision to terminate the plaintiff "was motivated, at least in part, by the employee's engaging in protected activity."[196] The employer offered evidence that it terminated the employee after she openly refused to comply with the medical clinic's reorganization plans. The employee, on the other hand, relied solely on temporal proximity to satisfy causation, which, under Tenth Circuit precedent, was insufficient to survive summary judgment. Additionally, the district court found that the employer's reason for termination was not pretext for retaliation because the employer provided an adequate explanation for changing its reorganization plan to include terminating the employee, namely that she refused to comply with the original plan that would have continued her employment.

Other courts, however, continued to apply the "motivating factor" test for causation

Finally, the district court held a bench trial in ***New York ex rel. Khurana v. Spherion Corp.*** and found that an employee who was terminated seven months after engaging in protected activity did not establish a causal connection between the protected activity and his termination.[197] The district court observed that plaintiff's retaliation claim was "undermined by the passage of time between the alleged protected activity and his termination" and the "glaring absence" of any direct evidence of causation.

195 2021 WL 2717952 (D. Utah June 30, 2021).
196 529 F. Supp. 3d 1242 (D. Utah 2021).
197 511 F. Supp. 3d 455 (S.D.N.Y. 2021).

STARK LAW/ ANTI-KICKBACK STATUTE

Relationships between potential referral sources proved again to be fertile ground for enforcement activities. The government and relators remained focused on AKS and Stark Law violations in multiple FCA cases across various sectors of the healthcare industry.

LAB AND MARKETING PRACTICES

Certain laboratory marketing services continued to generate enforcement activity under the AKS.

In ***United States v. Mallory***, the Fourth Circuit affirmed a $114 million judgment in an FCA case in which the government alleged two laboratories, a contracted marketing company and related executives engaged in a scheme to pay kickbacks to physicians in exchange for referrals for medically unnecessary tests reimbursed by federal healthcare programs in violation of the AKS.[198] The laboratory defendants paid the marketing company a percentage of their revenue based on the number of ordered blood tests and the marketing company paid its salespeople commissions based on sales volume. The laboratories also paid physicians for drawing patients' blood and processing the blood samples.

Certain laboratory marketing services continued to generate enforcement activity under the AKS.

The Fourth Circuit found that a reasonable jury could have concluded that the defendants willfully paid volume-based commissions to independent contractors and knowingly violated the AKS. The Fourth Circuit observed that in-house and outside counsel warned defendants such commission payments could violate the AKS. In rejecting the defendants' argument that commissions to salespeople can never be kickbacks under the AKS, the Fourth Circuit explained that federal courts have frequently upheld AKS violations based on commission payments to third parties who are not employees. The Fourth Circuit also joined the other circuits in adopting the so-called "one-purpose test," upholding the district court's jury instruction.

In ***U.S. ex rel. Lutz v. Lab. Corp. of Am. Holdings***, the relators alleged that Laboratory Corporation of America Holdings (LabCorp) knowingly provided in-office phlebotomists to draw and process blood samples for doctors who received kickbacks for these services through processing and handling fees paid by the laboratory defendants in ***Mallory***.[199] In denying LabCorp's motion for summary judgment, the district court noted that evidence in the record reflected LabCorp may have provided or did provide in-office phlebotomists to three doctors who were receiving processing and handling fees from the other laboratories and those phlebotomists may or did draw blood for tests performed by the other laboratories in addition to LabCorp testing. The district court found there were material factual disputes as to whether and when LabCorp knew the other laboratories paid kickbacks to doctors who LabCorp knew used its phlebotomists and whether LabCorp assented to the other laboratories' referral scheme by continuing to provide phlebotomists for blood draws tested by the other laboratories in exchange for LabCorp's own testing referrals.

FILE ACCESS THEORY OF REFERRALS UNDER THE AKS

The "file access theory" of referrals and related remuneration received continued scrutiny as a basis for AKS violations. In the latest development in ***Stop Illinois Health Care Fraud, LLC v. Sayeed*** on remand from the Seventh Circuit, the district court reviewed whether a management services arrangement between Healthcare Consortium of Illinois (HCI) and a management company generated prohibited referrals in violation of the AKS after HCI granted the management company access to its patient

The "file access theory" of referrals and related remuneration received continued scrutiny as a basis for AKS violations.

198 988 F.3d 730 (4th Cir. 2021).

199 2021 WL 2457693 (D.S.C. Jun. 16, 2021).

records.[200] The relator alleged that HCI, an organization focused on coordinating services to enable low-income seniors to continue living at home, allowed a management company and its affiliated home health agency and physician practice access to HCI's patient records to identify, solicit and obtain patients in need of home healthcare.

The district court found that the defendants had violated the AKS because the defendants intended the $5,000 monthly payments pursuant to the management agreement to be remuneration for access to HCI's patient records used to solicit clients, which the district court had previously concluded constitutes a referral under the AKS. The district court noted that the management company's owner testified that the monthly payments were payments for access to the patient data, and he believed the management services agreement gave the management company the right to solicit HCI's clients. Further, the district court determined that the arrangement did not meet the AKS personal services and management contracts safe harbor because the management services agreement did not specifically identify accessing client data or soliciting HCI's clients as covered within the agreement such that the agreement did not include all of the services provided under the arrangement, as required by the safe harbor.

Alleged pharmaceutical marketing schemes also continued to be a focus in FCA litigation.

PHARMACEUTICAL MARKETING PRACTICES

Alleged pharmaceutical marketing schemes also continued to be a focus in FCA litigation. In ***U.S. ex rel. Gharibian v. Valley Campus Pharmacy, Inc.***, the relator alleged his former employer, Campus Pharmacy, engaged in certain marketing schemes resulting in prohibited kickbacks to physician offices in violation of the AKS and FCA.[201] Specifically, the relator alleged that prior authorization services provided by the defendant to physicians conferred a substantial pecuniary benefit to prescribers. The relator also alleged that other forms of remuneration induced referrals, such as cultivating relationships through providing free lunches to providers and purchasing needed software for physician offices. The relator claimed the defendants actively instructed sales staff to circumvent limits on gifts to physicians by instructing employees to assign "every other purchase you make to another [physician] in that facility within that practice."

The district court held the prior authorization services did not constitute remuneration because the defendant, among other factors, offered this service openly to all. The district court also concluded that, while the lunch and software purchases could constitute potential remuneration under the AKS, the relator failed to address the defendant's argument and thus waived the issue. Additionally, the district court noted the relator failed to adequately plead scienter and granted the defendant's motion to dismiss on the basis that the relator failed to plead allegations sufficient to support a claim that the defendants violated the FCA.

In ***U.S. v. Blair***, the defendant, a non-pharmacist owner of Blair Pharmacy, was indicted and later charged for allegedly devising a scheme in violation of the AKS.[202] Blair allegedly created modified compound drug prescription forms with modified lists of chemical ingredients and also paid independent sales marketers, such as Atlas Group, LLC, to market his compound drugs and provide prescription forms to doctors. Blair then allegedly paid a 50% commission for each successfully reimbursed prescription claim Atlas referred to the pharmacy. Blair also allegedly failed to bill for and collect co-payments and co-insurance from beneficiaries of federal healthcare programs. The district court denied Blair's motion to dismiss holding, among other things, that waivers of co-payments and co-insurance can be viewed as remuneration under the AKS and can form the basis of a criminal AKS action. Blair also unsuccessfully argued that the AKS is impermissibly vague and does not provide fair warning of what constitutes illegal conduct.

At least one case resulted in the government bringing an action against an alleged co-conspirator. In ***U.S. v. Taneja,*** the government brought a two-count complaint against the defendant alleging he violated and conspired to violate the FCA *for causing* claims to be submitted to TRICARE in violation of the AKS.[203] The government alleged that Oldsmar Pharmacy (in which the defendant had a financial interest), paid kickbacks to a marketing company, that in turn marketed compound medications (pain and scar creams) to patients and then referred those patients to Oldsmar Pharmacy for fulfillment of the prescriptions for those medications. The defendant sought dismissal of these claims arguing that the complaint did not sufficiently plead that he caused the presentment of false claims to TRICARE.

The district court denied the defendant's motion noting that the government's complaint alleges that the defendant was a substantial factor in bringing about the false claims by: (1) initiating the discussions with the marketing company; (2) proposing a referral arrangement whereby Oldsmar Pharmacy would pay the marketing company a percentage of the amount insurance paid to Oldsmar Pharmacy for prescriptions referred by the marketing company; (3) meeting with the owner of Oldsmar Pharmacy and the marketing company to discuss how they "were going to distribute the money," resulting in a handshake agreement between the three of them; (4) subsequently emailing the marketing company and disputing its characterization of the agreed financial terms; and (5) being involved in all of the discussions with counsel about how to solve the problem of Oldsmar Pharmacy paying the marketing company for TRICARE claims.

The district court also highlighted that the government's complaint alleged that the defendant was an experienced healthcare executive who was aware of the AKS prohibitions and that the submission of claims to TRICARE as a result of the kickback arrangement was reasonably foreseeable when the defendant began consulting with counsel regarding the arrangement given that TRICARE prescriptions were being referred under the scheme.

In ***U.S. ex rel. Heller v. Guardian Pharmacy, LLC***, the relator alleged that Guardian Pharmacy of Atlanta, LLC (Guardian) and its parent company provided various free or below FMV services to assisted living communities and personal care homes to induce them to select Guardian as their preferred pharmacy, in violation of the AKS and the FCA. Guardian allegedly provided free services for electronic systems used to maintain

200 2021 WL 2331338 (N.D. Ill. June 8, 2021).
201 2021 WL 4816648 (C.D. Cal. June 23, 2021).
202 2021 WL 4339132 (D. Md. Sept. 23, 2021).
203 2021 WL 3518206 (M.D. Fla. Aug. 4, 2021).

Support services and other payments offered by pharmaceutical and medical device companies also continued to draw scrutiny as potential improper inducements under the AKS.

daily medication administration records for each patient, free or below FMV medication management services, and free or below cost education classes and skills checks to the communities' staff members. By providing such services, Guardian allegedly hoped to obtain preferred partner status with long-term care communities who could steer their residents to select Guardian as their pharmacy to fill their prescriptions, which were reimbursed by federal healthcare programs.

In denying Guardian's motion to dismiss, the district court found that the relator adequately pleaded that Guardian provided unlawful remuneration through its free or discounted services because the complaint identified: (1) the independent value of several of these services to the communities; (2) the services were not integrally related to the other services Guardian offers, such as prescription fulfillment; and (3) the one purpose of providing these services was to induce communities to contract with Guardian as their preferred pharmacy. Further, the district court found that the relator sufficiently identified alleged false claims through estimates of the number of residents at each contracted community and annual sales revenue from federal payors for communities who received Guardian's free or discounted services, as well as four customers and 20 specific representative claims submitted to federal payors. The district court granted the motion to dismiss filed by Guardian's parent company because the relator did not plead allegations against it that were sufficiently particularized to pierce the corporate veil.

CO-PAY ASSISTANCE AND CO-PAY ASSISTANCE DONATIONS BY PHARMA COMPANIES

Support services and other payments offered by pharmaceutical and medical device companies also continued to draw scrutiny as potential improper inducements under the AKS.

In ***U.S. v. Teva Pharms. USA, Inc.***, the government filed suit against Teva Pharmaceuticals (Teva) alleging violations of the AKS and the FCA arising from Teva's alleged conspiracy with pharmacy and charitable foundations to use donations from Teva to subsidize Medicare patients seeking co-pay assistance to purchase Teva's multiple sclerosis drug, Copaxone, resulting in false claims.[204] While Teva asserted that it merely hoped that the donations would be used to cover patient co-pays, the government alleged that Teva structured donations to ensure that the donations were used solely for co-pay assistance associated with Copaxone. The government alleged that while Teva avoided a formal return on investment (ROI) analysis of its foundation support, handwritten notes from a meeting purportedly indicate that the company informally calculated its donations and substantial ROI.

204 2021 WL 4132592 (D. Mass. Sept. 9, 2021).

The district court denied Teva's motion to dismiss holding that the government sufficiently alleged that Teva's scheme resulted in patients seeking prescription reimbursement from Medicare that were tainted by kickbacks.

In ***Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.*** (further discussed in a later section), a district court dismissed Pfizer's request for a declaratory judgment that its co-pay assistance program did not violate the AKS.[205] The court ruled that the AKS does not require a "corrupt" intent or quid pro quo, only "that payments are made with an intent to influence a decision about medical care or purchases." The AKS applied to Pfizer's program, the court held, simply because the co-pay assistance payments were intended to influence Medicare Part D participants' decisions, which was sufficient to constitute inducement under the AKS. The court recognized that without co-pay assistance, some Medicare beneficiaries would forego tafamidis, the drug at issue which is the only one approved to treat Transthyretin Amyloid Cardiomyopathy, a rare but serious heart condition. Yet the court found it was bound by the statute to rule against Pfizer.

The government and relators continued to pursue FCA cases involving allegations of improper inducements to physicians and noncompliant physician compensation arrangements in violation of the Stark Law and AKS with mixed success.

PHYSICIAN INDUCEMENTS AND COMPENSATION ARRANGEMENTS

The government and relators continued to pursue FCA cases involving allegations of improper inducements to physicians and noncompliant physician compensation arrangements in violation of the Stark Law and AKS with mixed success.

Akron General Health System, Inc. (AGHS), a regional hospital system based in Akron, Ohio, agreed to pay $21.25 million to resolve FCA allegations of improper relationships with certain referring physicians.[206] AGHS was acquired at the end of 2015 by the Cleveland Clinic Foundation (Cleveland Clinic). Shortly after the acquisition, Cleveland Clinic found potential compliance concerns related to certain physician arrangements and made a self-disclosure to the government.

In addition to this self-disclosure, the settlement also resolved allegations in ***U.S. ex rel. Brouse v. Akron General Health System, Inc.***, in which the former compliance officer (as the relator) alleged AGHS had initiated an aggressive strategy to increase control over healthcare delivery around its hospital location by buying physician practices and/or employing physicians to control patient referrals. AGHS allegedly paid the physicians

205 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).
206 https://www.justice.gov/opa/pr/northern-ohio-health-system-agrees-pay-over-21-million-resolve-false-claims-act-allegations.

excessive compensation to ensure a substantial referral stream. AGHS treated each physician as a cost center and tracked the "contribution margin" of every physician to ensure significant practice losses were allegedly made up through inpatient referrals for hospital services. This settlement demonstrates the importance of an effective compliance program to proactively address issues, as Cleveland Clinic received cooperation credit by making the self-disclosure and was able to resolve the allegations based upon single damages.

In ***U.S. ex rel. Jennings v. Flower Mound Hospital Partners, LLC***, Flower Mound Hospital Partners, LLC (Flower Mound Hospital) entered into a multi-million dollar settlement to resolve Stark Law allegations related to physician ownership.[207] The Stark Law's "whole hospital" exception allows referring physicians to have physician ownership or investment interests in a hospital provided that the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself. Decisions related to which physicians may have ownership interests cannot take into account the volume or value of a physician's referrals to the hospital. Flower Mound Hospital, a partially physician-owned hospital in Flower Mound, Texas, agreed to pay $18.2 million for alleged Stark Law and AKS violations involving its repurchase of shares from physician-owners aged 63 or older and the re-selling of the same shares to younger physicians. The government alleged Flower Mound Hospital impermissibly took into account the volume or value of certain physicians' referrals when it: (1) selected the physicians to whom the shares would be resold; and (2) determined the number of shares each physician would receive.

In ***U.S. v. Genesis Glob. Healthcare***, the relators filed suit against a vascular surgical center, its related entities, and several physician-investors alleging the physicians profited by way of referrals back to the entities in which they had ownership interests.[208] The relators alleged the physicians were told that if they invested $100,000, they would receive returns of $175,000 within the first year, and it made more sense for them financially to refer patients to the entities in which they had ownership interests than to third-party providers. The relators argued this arrangement was in direct violation of the Stark Law. The relators also claimed the physician-investors' financial investments in the surgery center created a kickback scheme whereby the physician-investors would refer patients to the surgery center for (allegedly unnecessary) vascular procedures in exchange for profit distributions and "other payments." The district court granted in part and denied in part the motions to dismiss filed by the defendants. Specifically, the district court concluded that the relators pled a viable AKS violation, but that aspects of the relator's complaint constituted "quintessential shotgun pleading," which the court gave the relators leave to address.

In ***U.S. ex rel. Fitzer v. Allergan***, the district court dismissed a *qui tam* action in which the relator, a bariatric surgeon, alleged two medical device companies engaged in an AKS scheme by providing surgeons free advertising in exchange for their high utilization of LAP-BAND medical devices in their surgeries.[209] Specifically, the relator alleged the defendants operated a "physician locator" website that allowed potential patients to input their zip codes to identify bariatric surgeons in their area who could perform the surgery required to implant the LAP-BAND device. The locater would provide prospective patients with a link to the local surgeons' websites and, for a period of time, their seminar schedules where patients could enroll in seminars and meet the surgeons listed on the website. The relator alleged the website became a powerful tool for patients to find surgeons who could perform LAP-BAND surgery and, in turn, "provided a constant flow of business to the included surgeons." The defendants used the physician locator, the relator alleged, to conduct a kickback scheme "by providing surgeons with valuable free advertising on [their website] in order to induce surgeons to recommend" the defendants' medical device "instead of alternative operations." Central to the relator's theory was the allegation that the defendants implemented a quota of LAP-BAND surgeries that a physician needed to perform each year to be included on the physician locator. The district court granted the defendant's motion to dismiss based largely on the relator's conclusory allegations that the defendants knew they were acting in violation of the AKS. The district court noted that "conclusory allegations [that] raise a mere possibility rather than a plausibility" that defendants acted with the requisite intent are not enough to sustain an AKS violation.

In ***U.S. ex rel. Schroeder v. Medtronic, Inc.***, the relator, a regional sales manager for a competitor medical device company, alleged Medtronic orchestrated unlawful kickback schemes at multiple hospitals in violation of the FCA.[210] Medtronic allegedly bribed hospital staff through unlawful kickbacks to purchase its devices over competitors and to purchase grossly excessive inventory so that Medtronic could increase the sales of its medical devices and create a near monopoly of its products at hospitals (allegedly also leading to unnecessary procedures). The relator further alleged the remuneration took the form of weekly/daily lunches for key hospital employees, iPads, iPhones, NASCAR and other entertainment tickets, as well as frequent nights at bars and restaurants in exchange for their purchasing Medtronic devices exclusively. The district court denied the defendant's motion to dismiss the AKS claims, but granted its motion related to the medically unnecessary procedures and off-label marketing claims.

In ***United States v. Health First, Inc.***, the relator, a multi-specialty physician group, alleged the defendants, which included a multi-specialty physician group, a health system that owned the group, several of the group's cardiologists and oncologists, and executives of both, engaged in a scheme to financially reward doctors for referring patients internally within the health system and for prescribing drugs billed to Medicare in violation of the AKS, the Stark Law and the FCA.[211] Among other things, the health system allegedly paid additional compensation to doctors in exchange for the doctors' termination of their medical directorships with competitors. The health system also purportedly inflated the work relative value units conversion factor to artificially inflate physician compensation. The relator alleged internal referrals from the defendant physician group increased after the health system acquired the group and doctors who referred more patients received increased compensation.

207 https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations.
208 2021 WL 4268279 (S.D. Ga. Sept. 20, 2021).
209 2021 WL 4133713 (D. Md. Sept. 10, 2021).
210 2021 WL 4168140 (D. Kan. Sept. 14, 2021).
211 2021 WL 301089 (M.D. Fla. Jan. 22, 2021).

The district court dismissed the relator's *qui tam* claims for failure to plead with particularity under Rule 9(b). The district court explained the allegations did not specify which doctors were overpaid for their referrals, how or when oncologists received bonuses based on drug administration, how the health system defendant paid the physician group based on referrals, or which Medicare claims were tainted because of improper referrals or kickbacks for drug administration. The allegations also did not directly connect the compensation strategies with the number of referrals. Although the relator provided an over 300-page list of Medicare claims, the list was missing key details, such as whether the patients were referred to the health system, who billed Medicare for the claims, or whether the Medicare claim was for a drug attached to an improper kickback, and therefore the relator did not sufficiently allege a false claim was submitted.

In ***U.S. ex rel. Dr. Kuo Chao v. Medtronic PLC***, the relator, a neuroradiologist, alleged that the Medtronic defendants violated the AKS and the FCA by aggressively promoting Pipeline, a Medtronic medical device used for aneurysms. The Medtronic defendants allegedly provided kickbacks to physicians in the form of proctoring fees, mini-vacations at lavish resorts and paid travel expenses without travel occurring. Additional kickbacks to the physicians allegedly included investments in side businesses, excessive payments for data collection, funding awards to hospitals and doctors through grants and fellowships, prominent research roles and hiring doctor-owned companies to work on the defendants' studies.[212] In granting the defendants' motion to dismiss, the district court found the relator failed to sufficiently plead each of its AKS claims. The complaint made only generalized allegations of overpayments and legal conclusions without providing factual information on the FMV of payments to physicians or a description of doctors being paid for work not performed or travel never taken. The complaint also failed to provide specific information regarding the medical necessity of the doctors' services, instances in which the defendants reduced funding for providers who decreased their usage of Pipeline or details on why the physicians' purchases were inappropriate.

OTHER INDUCEMENTS

In ***U.S. ex rel. Watt v. VirtuOx, Inc.***, the relator alleged four schemes against VirtuOx, an at-home oxygen testing company. Specifically, the relator alleged that VirtuOx: (1) misidentified San Francisco, California as its location for billing claims rather than Coral Springs, Florida (to increase reimbursements); (2) billed for unnecessary or redundant "spot check" oximetry testing; (3) unlawfully promoted a non-FDA device; and (4) used kickbacks to induce durable medical equipment (DME) companies to refer data interpretation work to it. The district court rejected each of these allegations, granting the defendant's motion to dismiss. In reaching that conclusion, the district court noted, "while [the relator] has set forth facts showing that VirtuOx has violated Medicare guidance, as well as offered and provided incentives in exchange for referrals of service, [the relator] has failed to nudge her False Claims Act 'claims across the line from conceivable to plausible.'"[213]

The district court explained the relator adequately described VirtuOx's providing something of value (free or deeply discounted pulse oximeters) to at least one DME company in exchange for that company's referral of diagnostic services for VirtuOx. The district court found the relator also sufficiently alleged VirtuOx submitted claims to Medicare for performing that kind of diagnostic service for hundreds of thousands of patients over the relevant years. The district court concluded, however, that the relator failed to allege any fact connecting the two, stating "there is nothing from which the Court could infer that any of VirtuOx's Medicare claims actually arose out of the kickback scheme."

212 2021 WL 4816647 (C.D. Cal. Apr. 12, 2021).
213 2021 WL 3883944 (S.D. Fla. Aug. 31, 2021).

MANAGED CARE/ MEDICARE ADVANTAGE

Medicare Advantage enrollment has more than doubled in the last decade. In 2020, 24 million (or 36% of Medicare-eligible individuals) elected to enroll in a Medicare Advantage plan. Payments made by CMS to Medicare Advantage plans amount to over $200 billion annually. By 2023, it is anticipated that payments made to Medicare Advantage Organizations (MAOs) will reach $250 billion.

Medicare Advantage plans are operated by privately-owned MAOs, which administer the Medicare benefit under Medicare Part C. Unlike Medicare's fee-for-service reimbursement model, Medicare Advantage plans are compensated on a monthly basis with a fixed capitation payment for each member. The amount of the capitated payment is based on a "risk score" that is assigned to each beneficiary and is based on medical history, demographics and other considerations. A beneficiary's risk score and corresponding capitation payment amount are intended to reflect the anticipated cost to manage a beneficiary's care relative to other beneficiaries.

To calculate a beneficiary's risk score, CMS looks to the medical records, which contain the risk-adjusting diagnoses submitted by MAOs. MAOs are required to "certify (based on best knowledge, information, and belief) that the data it submits" for risk adjustment are "accurate, complete, and truthful."[214] Much of the government's enforcement efforts in this space concern allegations that risk-adjusting diagnosis codes (i.e., those diagnosis codes that can impact the capitated payment amount), were either inaccurate or not properly supported in the underlying medical record.

NOTEWORTHY MEDICARE ADVANTAGE AND RISK ADJUSTMENT SETTLEMENTS

Sutter Health and affiliated entities agreed to pay $90 million to resolve FCA allegations that they submitted unsupported diagnosis codes for Medicare Advantage beneficiaries in order to receive inflated reimbursements. The government intervened in a *qui tam* action as to claims submitted for one foundation, and the resolution resolves both the intervened and non-intervened claims in the underlying *qui tam*. As a part of the settlement, the health system and entities entered into a five-year CIA with HHS-OIG.[215]

PENDING LITIGATION RELATING TO MEDICARE ADVANTAGE AND RISK ADJUSTMENT

In ***U.S. ex rel. Osinek v. Kaiser Permanente***, the United States intervened in six *qui tam* complaints alleging that members of the Kaiser Permanente (Kaiser) consortium violated the FCA by submitting inaccurate diagnosis codes for its Medicare Advantage beneficiaries in order to receive higher reimbursements.[216] The government filed its complaint in intervention, consolidating the six individual *qui tam* lawsuits.[217] The government's complaint focuses on Kaiser's alleged improper use of addenda in medical records and asserts that between 2009 and 2018 Kaiser added approximately 500,000 diagnoses via addenda that were unsupported in the medical record and has alleged damages "in the range of $1 billion."

More specifically, the government contends that Kaiser improperly utilized medical record addenda by: (1) setting progressively higher risk score targets which were increasingly difficult to meet; (2) conducting "data mining" and one-way chart reviews of patient records; (3) using queries to add new diagnoses via addenda that had nothing to do with the original patient visit and requiring physicians to justify refusals to add diagnoses; and (4) using financial incentives to pressure Permanente physicians to create improper addenda, including through coding parties, which were known as the "dash for cash," by adding diagnoses that were not supported in the underlying medical record. The government

214 42 C.F.R. § 422.504.

215 See https://www.justice.gov/opa/pr/sutter-health-and-affiliates-pay-90-million-settle-false-claims-act-allegations-mischarging.

216 The six individual complaints are: (1) *U.S. ex rel. Osinek v. Kaiser Permanente*, No. 13-cv-3891, Dkt. No. 1 (N.D. Cal. Aug. 22, 2013); (2) *U.S. ex rel. Taylor v. Kaiser Permanente*, No. 21-cv-3894, Dkt. No. 4 (D. Colo. Nov. 2, 2014); (3) *U.S. ex rel. Stein and Bone v. Kaiser Foundation Health Plan Inc.*, No. 16-cv-3331, Dkt. No. 1 (C.D. Cal. May 15, 2016); (4) *U.S. ex rel. Bryant and Hernandez v. Kaiser Permanente*, No. 18-cv-1347, Dkt. No. 1 (N.D. Cal. Mar. 1, 2018); (5) *U.S. ex rel. Bicocca v. Kaiser Permanente Medical Group, Inc.*, No. 21-cv-3124, Dkt. No. 1 (E.D. Cal. Feb. 10, 2020); and (6) *U.S. ex rel. Arefi v. Kaiser Foundation Health Plan Inc.*, No. 16-cv-1558, Dkt. No. 1 (N.D. Cal. Sept. 4, 2015).

217 No. 3:13-cv-03891, Dkt. No. 110 (N.D. Cal. Oct. 25, 2021).

further alleges that Permanente physicians submitting the addenda for these diagnoses "often did not tell their patients that they supposedly had the diagnoses for which the Kaiser Health Plans claimed payment." Finally, the government contends that Kaiser had knowledge that these practices were improper and ignored red flags and internal complaints.

In ***United States v. Anthem, Inc.***, the United States filed suit against Anthem concerning the defendant's Medicare risk-adjustment data submissions to CMS.[218] The allegations involve Anthem's knowing failure to delete inaccurate diagnosis codes submitted to CMS for risk adjustment purposes. The government alleged that Anthem conducted a one-sided review of beneficiaries' medical charts with the goal of adding diagnosis codes to submit to CMS to gain revenue, without also identifying and deleting inaccurate codes. The matter is ongoing.

In ***U.S. ex rel. Cutler v. Cigna Corp.***, the pending *qui tam* lawsuit alleges that Cigna-HealthSpring submitted fraudulent claims by misrepresenting the diagnoses of its beneficiaries in violation of the FCA.[219] The relator contends that Cigna-HealthSpring created a program ultimately designed to raise plan members' risk scores to inflate monthly capitated payments by inappropriately capturing diagnoses not supported in the underlying medical record. According to the complaint, Cigna-HealthSpring encouraged nurses to diagnose beneficiaries with exaggerated medical problems, promoted falsification of diagnoses and reported health conditions not supported by medical documentation or reliable clinical information. On September 29, 2021, the district court granted Cigna-HealthSpring's motion to transfer the matter to the U.S. District Court for the Middle District of Tennessee, where the matter remains pending.[220]

In ***U.S. ex rel. Ross v. Independent Health Assoc.***, the United States intervened in a *qui tam* lawsuit alleging that a health insurer defrauded the government by submitting false patient data to wrongfully inflate Medicare Advantage payments.[221] The government's complaint alleges that Independent Health improperly submitted and received payment for risk-adjusting diagnoses codes that were not supported in the underlying medical record. The government further contends that Independent Health created a subsidiary, which sought to capture additional risk-adjusting diagnoses codes through retrospective one-way chart review and utilizing an addenda process in which providers were sent "leading and suggestive forms" aimed at capturing additional diagnosis codes.

In ***U.S. ex rel. Fernandez v. Freedom Health, Inc.***, a relator filed a *qui tam* lawsuit alleging that Freedom Health, Inc., Optimum Healthcare, Inc. and Physician Partners, LLC (defendants) intentionally submitted incorrect and/or unsubstantiated risk adjustment data as part of a scheme to increase their capitation payments.[222] Specifically, the relator alleges, among other things, that Physician Partners: (1) forged primary care physicians' prescriptions for leg and cardiac scans; (2) pressured its patients to schedule leg and cardiac screenings even though the tests were not medically necessary; and (3) badgered National Diagnostic Systems (NDS) into using diagnosis codes relating to serious diagnoses to increase the risk score for the defendants' Medicare Advantage members to receive enhanced payments from Medicare.

The district court granted the defendants' motion to dismiss in this declined *qui tam* action based on the relator's failure to plead with the requisite particularity under Rule 9(b), but permitted the relator leave to amend. The relator's counsel has since filed a motion for a stay of the action because of an inability to contact the relator because the relator had been incarcerated pending trial on federal healthcare fraud charges, which remains pending.

OVERPAYMENT RULE

Under the Medicare Part C Overpayment Rule, MAOs must report and return "overpayments" to CMS within 60 days of identification.[223] According to the Overpayment Rule's preamble, any diagnosis that has been submitted by a Medicare Advantage insurer for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment. Essentially, this rule requires Medicare Advantage insurers to refund amounts they *know* were overpayments, *i.e.*, payments they *are aware* lack support in a beneficiary's medical records.

In ***UnitedHealthcare Ins. Co. v. Azar***, UnitedHealthcare filed suit seeking a determination that the Overpayment Rule violates actuarial equivalence and the same methodology requirements.[224] Those provisions entitle plans to receive payments equal to the amount CMS would expect to spend covering identical beneficiaries insured by traditional Medicare and require CMS to use the same criteria to measure risk in both traditional Medicare and Medicare Advantage programs. The Overpayment Rule, conversely, results in different payments for identical beneficiaries because it relies on both supported and unsupported codes to calculate risk in the Medicare fee for service program but only supported codes in the Medicare Advantage program, which means Medicare Advantage plans are not paid the same as CMS for identical beneficiaries. In fact, "it makes Medicare Advantage beneficiaries appear artificially healthier than their CMS counterparts, and inevitably underpays the plans."

Siding with UnitedHealthcare in September 2018, the district court vacated the Medicare Part C Overpayment Rule finding it was "arbitrary and capricious" and "violate[d] the statutory mandate of 'actuarial equivalence.'"[225] The government subsequently appealed the district court's opinion to the D.C. Circuit.

In a highly anticipated decision, the D.C. Circuit reversed the district court and held that the Overpayment Rule does not violate the Medicare statute's "actuarial equivalence" and "same methodology" requirements, and is not arbitrary and capricious as an unexplained departure from prior policy.[226]

218 No. 1:20-cv-02593, Dkt. No. 1 (S.D.N.Y. Mar. 26, 2020).
219 No. 7:17-cv-07515-KMK-JCM, Dkt. No. 94 (S.D.N.Y. Oct. 2, 2017).
220 No. 3:21-cv-00748 (M.D. Tenn.)
221 *U.S. ex rel. Ross v. Independent Health Assoc.*, No. 1:12-cv-00299-WMS, Dkt. No. 142 (W.D.N.Y. Sept. 13, 2021) (complaint in intervention).
222 2021 WL 2954415 (M.D. Fla. May 26, 2021).

223 42 U.S.C. §1320a-7k(d)(1)-(2)).
224 *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018); *UnitedHealthcare Ins. Co. v. Becerra et al.*, 2021 WL 3573766 (D.C. Cir. 2021).
225 *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 176 (D.D.C. 2018).
226 *UnitedHealthcare Ins. Co. v. Becerra*, 2021 WL 3573766 (D.C. Cir. 2021).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

Regulatory and enforcement agencies continued to monitor the activities of pharmaceutical and medical device manufacturers with heightened scrutiny.

OFF-LABEL MARKETING AND USE

Pharmaceutical and medical device companies continued to face scrutiny related to promotion of off-label uses.

Two cases from the last year indicate a willingness of courts to allow FCA claims based on off-label use and marketing when the complaint sufficiently alleges noncompliance with certain FDA regulations. In ***Dan Abrams Co. LLC v. Medtronic, Inc.***, the Ninth Circuit affirmed in part and reversed in part the district court's dismissal of the relator's FCA complaint.[227] The relator alleged that Medtronic marketed devices for an off-label, contraindicated use. In dismissing the claim, the Ninth Circuit confirmed that the federal government does not distinguish between on-label and off-label use in determining whether to pay claims. The relator further alleged that Medtronic defrauded the FDA into granting Subject Devices Class II clearance by misrepresenting to the FDA that the devices in question could be used for their intended, on-label use. The Ninth Circuit followed its decision in *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, and allowed the relator's fraud on the FDA theory claim to go forward.

Pharmaceutical and medical device companies continued to face scrutiny related to promotion of off-label uses.

Additionally, in ***U.S. ex rel. Ebu-Isaac v. Insys Therapeutics, Inc.***, the district court denied BelHealth's motion to dismiss, and granted in part and denied in part Linden Care's motion to dismiss an FCA lawsuit.[228] The relator alleged that BelHealth and Linden Care coordinated with each other and Insys to market and promote off-label use of Insys' fentanyl spray, Subsys. Moreover, the relator alleged that Linden Care, directed by BelHealth, submitted claims without disclosing noncompliance with the FDA, Medicaid Act and the CSA. In denying the motion to dismiss, the district court found that the relator's complaint sufficiently distinguished and alleged each corporate entity's liability. Further, the district court found that the relator sufficiently alleged falsity on an implied false certification theory, consistent with *Campie*. The district court, however, denied the relator's equitable claim because, according to the district court, the FCA does not authorize a private party to make equitable claims on behalf of the government.

In ***U.S. ex rel. Kennedy v. Novo***, a case involving the FCA and the Food, Drug, and Cosmetic Act (FDCA) arising from the same set of facts, the D.C. Circuit ruled that the government's FDCA lawsuit against and settlement with Novo Nordisk did not constitute an "alternate remedy" under the FCA, 31 U.S.C. § 3730(c)(5), that a relator could recover.[229]

In this matter, a relator filed a FCA complaint in October 2010 alleging, among other things, that Novo Nordisk violated the FCA by causing people to submit millions of dollars in false claims to the federal government for payment under federal healthcare programs. The whistleblower alleged that Novo Nordisk marketed its diabetes drug Victoza for use by pre-diabetics even though the FDA had not approved Victoza for the treatment of pre-diabetics, and instructed sales representatives not to mention the "unknown risk" of thyroid cancer to doctors.

In July 2017, the United States filed a notice of intervention in the district court advising that the United States, Novo Nordisk and the whistleblower reached a settlement in the case, in which Novo Nordisk agreed to pay $46.5 million to resolve the matter. The district court awarded the relator 18% of the recovery, which was roughly $7.8 million plus interest. Four days later, the government filed a separate complaint against Novo Nordisk (to which the whistleblower was not a party), in the same court for violation of the FDCA. The government alleged that Novo Nordisk introduced Victoza into interstate commerce as an unlawfully "misbranded" drug because it "failed to comply with the Victoza Risk Evaluation and Mitigation Strategy" (a condition of Victoza's FDA approval) and that Novo Nordisk provided its sales force with "certain messages and tactics" that created the "false or misleading impression" that the warning about thyroid cancer on Victoza's label was "erroneous, irrelevant, or unimportant."

227 850 F. App'x 508 (9th Cir. 2021).

228 2021 WL 3619958 (C.D. Cal. June 9, 2021).

229 *U.S. ex rel. Kennedy v. Novo*, 5 F.4th 47 (D.C. Cir. 2021).

Twenty months later, the FCA relator separately moved the district court to award her a share of the FDCA Settlement, arguing that the FDCA Settlement was an "alternate remedy" under the False Claims Act, 31 U.S.C. § 3730(c)(5), and so she was statutorily entitled to a share of that recovery as part of the FCA settlement.[230] The D.C. Circuit reviewed *de novo* the meaning of the FCA's provision governing alternate remedies and held that the provision only allows a relator to recover a share with the claim pursued if the alternate remedy is of the type that could have been pressed under the FCA. The D.C. Circuit reasoned that "misbranding bears little resemblance to the types of fraudulent behavior that the FCA identifies and proscribes," and a misbranding claim "seeks to protect the public from being misled by the drug company's marketing tactics…by pursuing equitable relief and penalties or fines," as opposed to seeking to recover damages for any use of falsity or fraud to deprive the government of its money or property, which is the hallmark of litigation under the FCA.

REMUNERATION UNDER AKS

In ***U.S. ex rel. Musachia v. Pernix Therapeutics, LLC***, the relator, a former sales representative at Pernix, claimed to have been instructed to advertise and market a prescription direct fulfillment program for ZoHydro to physicians and their office staff.[231] The relator alleged that by providing free overnight delivery and waiving co-payments of ZoHydro to patients, including those whose prescriptions are paid or partially paid by government healthcare programs, the defendants induced patients to order ZoHydro prescriptions and caused claims to be submitted for payment to the government in violation of the AKS and FCA. The district court ultimately dismissed the complaint, holding that the exhibits submitted by the plaintiff did not reference free shipping to federally insured patients, nor did they support that co-payments were improperly waived.

OPEN PAYMENTS PROGRAM

In ***U.S. ex rel. Frain v. Medicrea USA Corp.***, Medicrea International, a French medical device manufacturer, and its American affiliate Medicrea USA Inc., agreed to pay $1 million to the United States and participating states to resolve allegations that the companies violated the AKS and FCA in connection with entertaining U.S.-based physicians during a 2013 conference in France.[232] The companies also agreed to pay another $1 million to resolve related allegations that they violated the physician Open Payments Program for failing to fully report those physician-entertainment expenses to CMS. The settlement resolved allegations that Medicrea: (1) provided items of value in the form of meals, alcoholic beverages, entertainment and travel expenses to U.S.-based physicians at events surrounding the 2013 conference; (2) induced physicians to purchase or order Medicrea's spinal devices, and that this resulted in false claims to federal healthcare programs; and (3) failed to properly report the expenses to CMS as required by the Open Payments Program, which requires manufacturers and others to disclose certain payments and other transfers of value to physicians, including indirect payments. This was among the first settlements to resolve allegations under both the FCA and Open Payments Program.

CO-PAYMENT ASSISTANCE PROGRAMS

In ***Pfizer, Inc. v. U.S. Dep't of Health and Hum. Servs.***, Pfizer filed suit against HHS, seeking a declaratory judgment that one, or both, of two co-payment assistance programs, would not violate the AKS.[233] Under the first assistance program (the Charity Program), Pfizer would make donations to an existing independent charity to develop a co-payment assistance fund specifically for patients with a particular heart condition for which Pfizer's drug is the only FDA-approved pharmacological treatment (the Drug). Under the second assistance program (the Direct Program), Pfizer would directly subsidize co-payments for the Drug for eligible Medicare Part D beneficiaries who had been prescribed the Drug.

Before filing suit, Pfizer requested an advisory opinion from OIG with respect to both proposed co-payment assistance programs. OIG rejected Pfizer's request for an advisory opinion for the Charity Program because the same or substantially the same course of conduct was under investigation. OIG accepted Pfizer's advisory opinion request relating to the Direct Program but told Pfizer the result likely would be unfavorable. Pfizer filed suit before OIG issued the unfavorable opinion, asking the court to declare that both the Charity Program and the Direct Program did not violate the AKS. The government moved to dismiss Pfizer's claim or for summary judgment.

The district court dismissed Pfizer's claims.[234] With respect to the Charity Program, the district court held that Pfizer's claim did not satisfy prudential ripeness criteria, stating that "the prudent approach is the one envisioned by the law, permitting Pfizer and OIG to review the program and reach definitive conclusions." With respect to the Direct Program, Pfizer had asserted that AKS liability requires either that the Direct Program be administered with corrupt intent, or that the payments made through the Direct Program otherwise constitute an improper quid pro quo, where Pfizer directly influences a doctor's or patient's decision to prescribe or purchase the Pfizer drug. The district court rejected Pfizer's argument, noting that the text of the AKS makes clear that the mental state elements do not include corrupt intent and stating that, "in other words, the AKS means what it says." Pfizer has appealed the decision.

SPEAKER PROGRAMS AND INTERACTIONS WITH PHYSICIANS

The government's focus on the relationship between manufacturers and physicians will certainly continue following HHS-OIG's Special Fraud Alert issued in November 2020. The industry and its trade associations provided updated ethical guidance for members in 2021. For example, the PhRMA Code on Interactions with Health Care Professionals (PhRMA Code) is a voluntary code of ethics that applies to pharmaceutical company interactions

230 By way of reminder, the alternate-remedy provision of the FCA provides in relevant part: Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the [False Claims Act] action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. 31 U.S.C. § 3730(c)(5).

231 2021 WL 2826429 (N.D. Ala. July 7, 2021).

232 https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians.

233 No. 1:20-cv-04920 (S.D.N.Y. Jun. 26, 2020).

234 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

Three generic pharmaceutical manufacturers – Taro Pharmaceuticals USA, Inc., Sandoz Inc. and Apotex Corporation – agreed to pay a total of $447.2 million to resolve allegations that the companies conspired to fix the price of various generic drugs, which resulted in higher drug prices for federal healthcare programs and beneficiaries.

with U.S. healthcare professionals. The PhRMA Code provides guidance and reinforces that pharmaceutical company interactions with healthcare professionals must be compliant. PhRMA updated its principles applicable to company-sponsored speaker programs and clarified other provisions of the PhRMA Code in response to recent government activity in this space. The updated PhRMA Code is effective as of January 1, 2022.

The PhRMA Code recognizes that company-sponsored speaker programs provide important substantive educational information about drugs and disease states. As a result, the purpose of a speaker program should be to present substantive educational information designed to help address a bona fide educational need among attendees. Invitations should be limited to those who have a bona fide educational need for the information presented. In addition, meals offered as an incidental business courtesy to attendees of company-sponsored speaker programs should be modest as judged by local standards, no alcohol should be paid for or provided, and high-end restaurants and other such venues are not appropriate locations for speaker programs. Finally, repeat attendance at a speaker program on the same or substantially the same topic where a meal is provided to the attendee is generally not appropriate, unless the attendee has a bona fide educational need to receive the information presented. Attendance by speakers as participants at programs after speaking on the same or substantially the same topic is also generally not appropriate. See the updated PhRMA Code for more information.[235]

235 https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf.

PRICE FIXING

Three generic pharmaceutical manufacturers – Taro Pharmaceuticals USA, Inc., Sandoz Inc. and Apotex Corporation – agreed to pay a total of $447.2 million to resolve allegations that the companies conspired to fix the price of various generic drugs, which resulted in higher drug prices for federal healthcare programs and beneficiaries.[236] The government alleged that between 2013 and 2015, all three companies paid and received compensation prohibited by the AKS through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers for certain generic drugs manufactured by the companies. Taro agreed to pay $213.2 million, Sandoz agreed to pay $185 million, and Apotex agreed to pay $49 million. Each company also entered a five-year CIA with HHS-OIG that included internal monitoring and price transparency provisions, risk assessment programs, executive recoupment provisions and compliance-related certifications from company executives and board members.

In addition, all three companies previously entered into deferred prosecution agreements with the Antitrust Division to resolve related criminal charges and paid fines unrelated to the FCA penalties.[237] Taro paid a criminal penalty of $205.6 million and admitted to conspiring with two other generic drug companies to fix prices. Sandoz paid a criminal penalty of $195 million and admitted to conspiring with four other generic drug companies to fix prices. Apotex paid a criminal penalty of $24.1 million and admitted to conspiring to increase and maintain the price of a product called Pravastatin.

CERTIFICATES OF MEDICAL NECESSITY

Bioventus, LLC, a global medical technology company, agreed to pay the government $3.6 million to resolve FCA allegations that Bioventus submitted improperly completed certificates of medical necessity (CMN) for medically unnecessary devices. This resolution stemmed from a written self-disclosure made by Bioventus to HHS-OIG, which later transferred the matter to the U.S. Attorney's Office for the Middle District of North Carolina. The self-disclosure was triggered when Bioventus discovered that sales representatives were completing Section B of the CMN for a device that stimulated bone growth called Exogen. This was improper because Medicare requires that Section B of the CMN be completed by the treating physician or the physician's office. The government praised Bioventus for self-disclosing this issue stating, "Better to catch it and self-disclose than for us to discover it and come calling." [238]

236 https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

237 *United States v. Taro Pharmaceuticals U.S.A., Inc.*, No. 20-cr-13 (E.D. Pa.) (Information & Deferred Prosecution Agreement filed 7/23/20); *United States v. Sandoz*, Inc., No. 20-cr-111 (E.D. Pa.) (Information & Deferred Prosecution Agreement filed March 3, 2020); *United States v. Apotex Corp.*, No. 20-cr-169 (E.D. Pa.) (Information & Deferred Prosecution Agreement filed May 6, 2020).

238 https://www.justice.gov/usao-mdnc/pr/bioventus-agrees-pay-more-36-million-resolve-false-claims-act-violations.

APPENDIX
2021 NOTABLE SETTLEMENTS

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/24/2021	Grant Memorial Hospital	Hospital agreed to pay more than $320,000 to resolve FCA allegations that it submitted claims to federal healthcare programs using the NPIs of credentialed physicians for services actually performed by non-credentialed physicians.[1]	**$320,175**
3/5/2021	TidalHealth Nanticoke	Hospital agreed to pay more than $179,000 to resolve self-disclosed Civil Monetary Penalties Law (CMPL) allegations that it submitted claims for nursing services provided by individuals who were not properly licensed.[2]	**$179,725**
3/19/2021	Swedish Health Services d/b/a Swedish Medical Center	Hospital agreed to pay more than $67,000 to resolve self-disclosed CMPL allegations that it employed a person that it knew or should have known was excluded from participation in federal healthcare programs.[3]	**$67,359**
5/5/2021	Dignity Health d/b/a St. Joseph's Hospital; Neurosurgical Associates, LTD	Health system and affiliated physician practice agreed to pay $10 million to resolve allegations that they submitted claims to Medicare for concurrent and overlapping surgeries in violation of regulations and reimbursement policies. As part of the settlement, the physician practice entered into a five-year CIA with HHS-OIG.[4]	**$10 million**
5/25/2021	Upper Allegheny Health System	Health system that operates dental clinics agreed to pay $2.7 million to resolve federal and state FCA allegations that it submitted claims to Medicaid for dental services performed using hand pieces that had not been properly sterilized.[5]	**$2.7 million**
7/2/2021	Akron General Health System, Inc.	Hospital system agreed to pay $21.25 million to resolve FCA allegations that it compensated physicians in excess of FMV in exchange for the referrals of patients, in violation of the AKS and Stark Law. Cleveland Clinic Foundation, which acquired the hospital system in 2015, self-disclosed the physician compensation arrangements and received cooperation credit in the settlement. The settlement also resolves related allegations made by a former director of internal audit in a *qui tam* action.[6]	**$21.25 million**

1 https://www.justice.gov/usao-ndwv/pr/west-virginia-hospital-pay-more-300000-medicare-fraud.
2 https://oig.hhs.gov/fraud/enforcement/tidalhealth-nanticoke-agreed-to-pay-179000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-services-by-unlicensed-nurse/.
3 https://oig.hhs.gov/fraud/enforcement/swedish-medical-center-agreed-to-pay-67000-for-allegedly-violating-the-civil-monetary-penalties-law-by-employing-an-excluded-individual/.
4 https://www.justice.gov/usao-az/pr/neurosurgical-associates-ltd-and-dignity-health-dba-st-josephs-hospital-paid-10-million.
5 https://www.justice.gov/usao-wdny/pr/upper-allegheny-health-system-pay-27-million-settle-false-claims-act-allegations.
6 https://www.justice.gov/opa/pr/northern-ohio-health-system-agrees-pay-over-21-million-resolve-false-claims-act-allegations.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/19/2021	Prime Healthcare Services; Dr. Prem Reddy; Dr. Siva Arunasalam	Hospital system, its physician CEO and a physician agreed to pay $37.5 million to resolve federal and state FCA allegations that: (1) Prime paid above FMV to purchase the physician's practice to induce referrals to the hospital, then compensated the physician through an employment agreement that was improperly based on the volume and value of his referrals, in violation of the AKS; (2) a hospital and the physician used the physician's billing number to submit claims to Medicare and Medi-Cal for services that were actually provided by a physician whose billing privileges they knew had been revoked; and (3) hospitals submitted inflated invoices for implantable medical hardware to Medi-Cal and other government payors.[7] The settlement resolves allegations raised in two *qui tam* lawsuits in which the government declined to intervene. Prime agreed to pay $33.725 million, with the CEO and physician agreeing to pay $1.775 million and $2 million, respectively. As part of the settlement, Prime and its CEO entered into a five-year CIA with HHS-OIG.	**$37.5 million**
7/21/2021	CHRISTUS St. Vincent Hospital	Hospital agreed to pay more than $560,000 to resolve allegations related to an employed physician's billing practices. After the hospital self-disclosed concerns, the government concluded that the hospital billed federal healthcare programs for services the physician did not provide or properly supervise.[8]	**$563,809**
7/23/2021	SpectraCare Health Systems, Inc.	Nonprofit integrated healthcare services company agreed to pay $1 million to resolve FCA allegations that it submitted claims to Medicaid for services that were billed without proper or complete documentation, billed more than once, or otherwise improperly billed, and that it failed to return overpayments.[9]	**$1 million**
8/5/2021	Ascension Michigan; Providence Park Hospital; St. John Hospital and Medical Center; St. John Macomb Oakland Hospital; Ascension Crittenton Hospital	Hospital system and four of its hospitals agreed to pay $2.8 million to resolve FCA allegations that they submitted claims and retained overpayments related to a gynecologist's services that were not medically necessary, not performed as represented or were never performed. The settlement resolved Ascension's self-disclosure related to improper billing and additional *qui tam* allegations.[10]	**$2.8 million**
8/6/2021	San Mateo County Medical Center; San Mateo County	Medical center and county agreed to pay $11.4 million to resolve FCA allegations that they billed Medicare for inpatient admissions that were not reasonable or necessary, including patients admitted for social reasons and lack of available alternative placements. As a part of the settlement, the medical center and county entered into a five-year CIA with HHS-OIG.[11]	**$11.4 million**

7 https://www.justice.gov/opa/pr/prime-healthcare-services-and-two-doctors-agree-pay-375-million-settle-allegations-kickbacks.
8 https://www.justice.gov/usao-nm/pr/christus-st-vincent-hospital-santa-fe-new-mexico-reaches-settlement-fraudulent-health.
9 https://www.justice.gov/usao-mdal/pr/spectracare-health-systems-inc-agrees-pay-1-million.
10 https://www.justice.gov/opa/pr/ascension-michigan-pay-28-million-resolve-false-claims-act-allegations.
11 https://www.justice.gov/opa/pr/county-medical-center-and-county-agree-pay-114-million-resolve-false-claims-act-allegations.

HOSPITALS AND HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/17/2021	Blessing Hospital	Hospital agreed to pay approximately $2.82 million to resolve self-disclosed FCA allegations that it submitted claims to Medicare and Medicaid for medically unnecessary cardiac catheterizations.[12] Physician group that formerly employed the physician who performed the procedures entered into a separate settlement regarding these allegations.	**$2.82 million**
8/27/2021	John Peter Smith Hospital	Hospital agreed to pay more than $3.3 million to resolve FCA allegations that it improperly appended billing modifiers to claims, resulting in double billing for certain aspects of bundled payments.[13]	**$3.3 million**
8/30/2021	Sutter Health; Sutter Bay Medical Foundation d/b/a Palo Alto Medical Foundation, Sutter East Bay Medical Foundation, and Sutter Pacific Medical Foundation; Sutter Valley Medical Foundation d/b/a Sutter Gould Medical Foundation and Sutter Medical Foundation	Health system and affiliated entities agreed to pay $90 million to resolve FCA allegations that they submitted unsupported diagnosis codes for Medicare Advantage Plan beneficiaries to receive inflated reimbursements for beneficiaries. As part of the settlement, Sutter Health, Sutter Bay Medical Foundation and Sutter Valley Medical Foundation entered into a five-year CIA with HHS-OIG. [14]	**$90 million**
11/1/2021	Geisinger Community Health Services	Health system agreed to pay more than $18.5 million to resolve self-disclosed FCA allegations that it submitted claims to Medicare for home health and hospice services that violated rules and regulations regarding certification of terminal illness, patient election of hospice care and physician face-to-face encounters with home health patients.[15]	**$18.514 million**
12/2/2021	Flower Mound Hospital Partners, LLC	Hospital agreed to pay $18.2 million to resolve FCA allegations that it repurchased shares from physician-owners and resold the shares to younger physicians. In determining which physicians purchased the shares and how many each would be able to purchase, the hospital allegedly considered the value and volume of referrals generated by the physicians, in violation of the AKS and Stark Law.[16]	**$18.2 million**

12 https://www.justice.gov/usao-cdil/pr/federal-and-state-authorities-reach-settlement-blessing-hospital-over-medicare-and.
13 https://www.justice.gov/usao-ndtx/pr/hospital-pay-more-3-million-settle-whistleblower-suit.
14 https://www.justice.gov/opa/pr/sutter-health-and-affiliates-pay-90-million-settle-false-claims-act-allegations-mischarging.
15 https://www.justice.gov/usao-mdpa/pr/geisinger-community-health-services-agrees-18-million-civil-settlement.
16 https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/19/2021	Allstate Hospice LLC; Verge Home Care LLC; Onder Ari; Sedat Necipoglu	Hospice provider, home health provider and their owners agreed to pay more than $1.8 million to resolve FCA allegations that they submitted claims to Medicare that were tainted by improper compensation arrangements and referral relationships, in violation of the AKS and Stark Law. The providers allegedly paid referral sources above FMV for medical directorship services and provided physicians other gifts and benefits, including travel and sporting event tickets. Allstate also sold interests in the company to five different physicians which ultimately netted them substantial quarterly dividends.[17]	**$1.847 million**
3/10/2021	Pediatric Services of America, Inc.	Pediatric home health provider agreed to pay almost $275,000 to resolve self-disclosed CMPL allegations that it submitted claims to two state Medicaid programs for services provided by individuals who were either excluded or did not have a valid Medicaid provider agreement.[18]	**$274,753**
4/12/2021	CareCo Medical, Inc.; Helga Pfanner	Home health provider and its owner/CEO agreed to pay $28,246 to resolve allegations that they employed a physical therapist who was excluded from participation in all federal healthcare programs. The physical therapist was excluded from all federal healthcare programs in 2015 after he defaulted on his obligations under an Integrity Agreement (IA) with HHS-OIG.[19]	**$28,246**
5/4/2021	Healthy Home & Family, Inc.; Belinda Bivens; Mary Stockson	Home health provider and its owners agreed to pay more than $300,000 to resolve allegations that they submitted claims to the Missouri Medicaid program that billed for more hours than were actually spent providing care to beneficiaries and that they intentionally altered timesheets and other records. As part of the resolution, the company agreed to submit a corrective action plan and be subject to a one-year provider enrollment agreement.[20]	**$302,127**
8/26/2021	At Home Care LLC d/b/a At Home Care Group; Kevin Cox	Home health provider and its owner agreed to pay $2.9 million to resolve state and federal FCA allegations that they billed Oregon Medicaid for in-home care that was not actually provided. The company also pleaded guilty to two counts of making a false claim for healthcare payment. As part of the resolution, AHCG and its owner were excluded from participating in Medicare, Medicaid and all other federal healthcare programs for 15 and 8 years, respectively.[21]	**$2.9 million**

17 https://www.justice.gov/usao-sdtx/pr/hospice-home-health-agency-and-owners-pay-over-18m-resolve-claims-concerning-physician.
18 https://oig.hhs.gov/fraud/enforcement/pediatric-services-of-america-agreed-to-pay-274000-for-allegedly-violating-the-civil-monetary-penalties-law-by-employing-an-excluded-individual-and-submitting-claims-for-services-provided-by-an-individual-without-a-valid-provider-agreement/.
19 https://www.justice.gov/usao-ct/pr/home-health-company-pays-28k-employing-excluded-individual.
20 https://ago.mo.gov/home/news/2021/05/04/missouri-attorney-general-obtains-$300-000-settlement-in-medicaid-fraud-case.
21 https://www.justice.gov/usao-or/pr/bend-resident-and-affiliated-residential-care-company-agree-pay-29-million-settle-health.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/8/2021	BAYADA Home Health Care Inc.; BAYADA Health LLC; BAYADA Home Care; BAYADA	Home health company operator agreed to pay $17 million to resolve FCA allegations that it purchased two home health agencies to obtain referrals of Medicare beneficiaries from other retirement communities operated by the seller of the home health agencies, in violation of the AKS.[22]	**$17 million**
10/8/2021	U.S. Medical Management, LLC; VPA, P.C.	Two home health service providers agreed to pay $8.5 million to resolve FCA allegations that they submitted claims to Medicare for medically unnecessary or unreasonable laboratory and diagnostic testing services.[23]	**$8.5 million**
11/3/2021	Great Lakes Home Healthcare Specialists, LLC; Great Lakes Therapy Housecalls, P.C.; James A. Harvey	Home health agency, affiliated physical therapy provider and their owner agreed to pay $450,000 to resolve FCA allegations that they submitted fraudulent claims to Medicare for: (1) therapy services that were not actually provided; (2) services provided by an employee who was actually on maternity leave at the time; (3) services provided to homebound beneficiaries by an unqualified social worker; and (4) claims for which they altered the dates of physician signatures on certifications of beneficiary eligibility for home health services. In September 2021, the former office manager of the physical therapy provider entity, Daniel R. McGoran, agreed to pay more than $75,000 to resolve allegations related to his role in the alleged scheme.[24]	**$450,000**
11/22/2021	PruittHealth, Inc.	Home health agency and its affiliated entities agreed to pay $4.2 million to resolve FCA allegations that they improperly billed Medicare and Medicaid for home health services that were not eligible for reimbursement because, among other things, they did not have the required face-to-face certifications or plans of care, and they did not document the beneficiary's homebound status or need for the home health services. The settlement also resolves allegations that PruittHealth became aware of payments for home health services to which it was not entitled, but failed to disclose or refund the overpayments in a timely manner.[25]	**$4.2 million**
11/23/2021	Carrefour Associates LLC; Crossroads Hospice of Cincinnati LLC; Crossroads Hospice of Cleveland LLC; Crossroads Hospice of Dayton LLC; Crossroads Hospice of Northeast Ohio LLC; Crossroads Hospice of Tennessee LLC	Hospice chain agreed to pay $5.5 million to resolve FCA allegations that it billed Medicare for hospice services provided to patients with Alzheimer's or dementia who were not terminally ill.[26]	**$5.5 million**

22 https://www.justice.gov/usao-nj/pr/home-health-agency-operator-pay-17-million-resolve-false-claims-act-kickback-allegations.
23 https://www.justice.gov/usao-edmi/pr/usmm-and-vpa-pay-85-million-resolve-overpayment-medicare-claims-laboratory-and.
24 https://www.justice.gov/Usao-wdmi/pr/2021_1103_Harvey.
25 https://www.justice.gov/usao-ndga/pr/home-health-agency-pay-42-million-settle-false-claims-act-allegations-0.
26 https://www.justice.gov/opa/pr/crossroads-hospice-agrees-pay-55-million-settle-false-claims-act-liability.

HOSPICE AND HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/15/2021	Professional Family Care Services, Inc.	Home health provider agreed to pay more than $45,000 to resolve allegations that it billed the Department of Veterans Affairs (VA) for services provided to an Army veteran by an employee who was also living with the veteran and falsified time sheets related to the care. The former employee was also convicted of wire fraud and sentenced to 12 months in prison, and ordered to pay over $90,000 in restitution related to the conduct.[27]	**$45,486**

27 https://www.justice.gov/usao-ednc/pr/fayetteville-home-health-services-company-agrees-settle-false-claims-act-allegations.

SKILLED NURSING FACILITIES (SNF) AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/1/2021	Longwood Management Corp.; Intercommunity Healthcare and Rehabilitation Center	SNF operator and an affiliated center agreed to pay more than $121,000 to resolve self-disclosed CMPL allegations that they employed an individual that they knew or should have known was excluded from participating in the California Medicaid program and that no Medi-Cal payments could be made for items or services the individual furnished.[28]	**$121,783**
5/10/2021	Care Initiatives	SNF operator agreed to pay $214,200 to resolve allegations that the United States was entitled to restitution for the federal share of Medicaid funds that an affiliated facility received for a 10 week period that residents were suffering from or testing positive for COVID-19. The United States alleged that repayment of these funds was warranted due to the facility's practices surrounding COVID-19 infections, including the facility's procedures and criteria for screening symptomatic employees.[29]	**$214,200**
5/21/2021	SavaSeniorCare LLC	SNF operator agreed to pay $11.2 million to resolve FCA allegations that its corporate-wide policies and practices caused facilities to submit claims for medically unreasonable, unnecessary or unskilled rehabilitation therapy services. As part of the resolution, the company entered into a chain-wide five-year CIA with HHS-OIG.[30]	**$11.2 million**
6/29/2021	Plum Healthcare Group, LLC; Azalea Holdings LLC d/b/a McKinley Park Care Center	SNF and its parent company agreed to pay more than $450,000 to resolve FCA allegations that an employee falsified and submitted claims to Medicare for services not provided. The government further alleged that when the SNF's management became aware of the issue, it did not conduct an adequate investigation or submit a refund for the full amount management knew had been overbilled, or otherwise disclose the misconduct to the government.[31]	**$451,439**
7/2/2021	Select Medical Corporation; Encore GC Acquisition LLC	Former parent company of a SNF chain and its successor-in-interest agreed to pay $8.4 million to resolve FCA allegations that the chain's corporate policies and practices resulted in the submission of false claims to Medicare for rehabilitation therapy services that were not medically necessary, reasonable or skilled.[32]	**$8.4 million**
8/16/2021	Norridge Gardens	SNF agreed to pay $360,000 to resolve FCA allegations that it: (1) upcoded patients' Resource Utilization Group (RUG) scores to receive higher Medicare reimbursement; (2) billed for therapy services provided to patients who did not need or could not benefit from such services; and (3) billed for services not provided or that were provided without a physician order.[33]	**$360,000**

28 https://oig.hhs.gov/fraud/enforcement/longwood-management-corp-and-intercommunity-healthcare-and-rehabilitation-center-agreed-to-pay-121000-for-allegedly-violating-the-civil-monetary-penalties-law-by-employing-an-excluded-individual/.
29 https://www.justice.gov/usao-ndia/pr/dubuque-care-facility-s-owner-agrees-repay-federal-medicaid-funds-resolve-allegations.
30 https://www.justice.gov/usao-mdtn/pr/savaseniorcare-llc-agrees-pay-112-million-resolve-false-claims-act-allegations.
31 https://www.justice.gov/usao-edca/pr/california-s-second-largest-skilled-nursing-facility-operator-pays-450000-resolve-false.
32 https://www.justice.gov/opa/pr/contract-rehabilitation-therapy-providers-agree-pay-84-million-resolve-false-claims-act.
33 https://www.justice.gov/usao-ndil/pr/suburban-chicago-nursing-facility-pay-360000-resolve-false-claims-act-allegations.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/25/2021	Bioventus, LLC	A medical technology company agreed to pay more than $3.6 million to resolve allegations, originating from a self-disclosure to HHS-OIG, that the company billed Medicare for a bone growth stimulator when some of the medical necessity forms included in claim submissions had been completed by sales representatives instead of physicians or a physician's office.[34]	**$3.609 million**
3/2/2021	A Perfect Fit for You, Inc. (APFFY); Margaret A. Gibson; Shelley Bandy	DME provider agreed to pay more than $20 million and one of its co-owners, Margaret Gibson, agreed to pay $4 million to resolve state and federal FCA allegations that they submitted false claims to Medicaid for equipment never ordered or received by patients, some of whom were deceased for many years prior to the claims' submission. APFFY was also sentenced to five years of probation and ordered to pay a $2 million criminal fine and more than $10 million in restitution.[35] In connection with this conduct, the United States and North Carolina previously obtained a $34.709 million civil default judgment against APFFY's other co-owner, Shelley Bandy. Bandy pleaded guilty to related criminal charges in December 2020 and was sentenced to 30 months' imprisonment and ordered to pay $374,800 in restitution on August 27, 2021. APFFY self-reported suspected fraudulent activity related to the above conduct after appointment of a receiver.[36]	**$24.139 million (civil)** **$12.444 million (criminal)**
4/1/2021	Bristol-Myers Squibb	Pharmaceutical manufacturer agreed to pay $75 million, plus interest, to resolve FCA allegations that it underpaid required quarterly rebates owed under the Medicaid Drug Rebate Program.[37]	**$75 million**
5/3/2021	Medical Designs LLC; Sicage LLC; Wilson Asfora, M.D.	Two medical device distributorships and their neurosurgeon owner agreed to pay more than $4.4 million to resolve FCA allegations relating to alleged violations of the AKS and medically unnecessary surgeries. The government alleged three separate kickback schemes led to tainted claims and claims for medically unnecessary surgeries in which: (1) the two distributorships paid Dr. Asfora profit distributions in exchange for his use of their own devices; (2) Medical Designs split profits with Dr. Asfora when he used certain devices for which it acted as a distributor; and (3) Dr. Asfora received kickbacks in the form of meals and alcohol paid through a restaurant he owned from another device company in exchange for the use of its devices. Each distributorship will also pay $100,000 to resolve allegations that it violated the Open Payments Program by not reporting payments to Dr. Asfora, and all three parties are excluded from participation in federal healthcare programs for six years.[38]	**$4.4 million**

34 https://www.justice.gov/usao-mdnc/pr/bioventus-agrees-pay-more-36-million-resolve-false-claims-act-violations.
35 https://www.justice.gov/usao-ednc/pr/north-carolina-durable-medical-equipment-corporation-sentenced-10-million-healthcare.
36 https://www.justice.gov/usao-ednc/pr/co-owner-north-carolina-durable-medical-equipment-company-sentenced-prison-role.
37 https://www.justice.gov/usao-edpa/pr/bristol-myers-squibb-pay-75-million-resolve-false-claims-act-allegations-underpayment.
38 https://www.justice.gov/opa/pr/neurosurgeon-and-two-affiliated-companies-agree-pay-44-million-settle-health-care-fraud.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/4/2021	Incyte Corporation	Pharmaceutical manufacturer agreed to pay $12.6 million to resolve FCA allegations that it channeled money through a foundation to pay co-pays for its myelofibrosis drug to induce Medicare and TRICARE beneficiaries to purchase it, in violation of the AKS. The government also alleged that as the sole donor to the fund, Incyte used its influence to pressure the foundation to pay the co-pays of government beneficiaries taking its drug that did not have myelofibrosis, and thus were not eligible for assistance from the fund.[39]	**$12.6 million**
5/19/2021	Medicrea International; Medicrea USA Inc.	French medical device manufacturer and its U.S. affiliate agreed to pay $1 million to resolve FCA allegations that they violated the AKS by providing entertainment and travel expenses to U.S. doctors in connection with a scoliosis conference in France to induce the physicians to purchase or order its spinal devices. The companies agreed to pay an additional $1 million to resolve allegations that the manufacturer violated CMS's Open Payments Program by not reporting the entertainment expenses to CMS.[40]	**$2 million**
7/8/2021	St. Jude Medical, Inc.	St. Jude Medical, Inc. agreed to pay $27 million to resolve FCA allegations that it caused the submission of false claims by knowingly selling defective heart devices to healthcare facilities that, in turn, implanted the devices into patients insured by federal healthcare programs.[41]	**$27 million**
7/8/2021	Avanos Medical, Inc.	Medical device distributor agreed to pay more than $22 million under a deferred prosecution agreement (DPA) to resolve a criminal healthcare fraud charge related to misbranding surgical gowns. As part of the DPA, Avanos admitted that between 2014 and 2015, it falsely marketed its MicroCool gowns as meeting the standards for the highest protection level for surgical gowns and thus eligible for use in surgeries and other high-risk procedures involving patients suspected of having infectious diseases.[42]	**$22.228 million**
7/8/2021	Alere Inc.; Alere San Diego Inc.	Two medical device manufacturers agreed to pay $38.75 million to resolve FCA allegations that they knowingly billed Medicare for defective point-of-care blood coagulation testing devices.[43]	**$38.75 million**

39 https://www.justice.gov/usao-edpa/pr/pharmaceutical-manufacturer-agrees-pay-126-million-resolve-allegations-it-provided.
40 https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians.
41 https://www.justice.gov/usao-md/pr/st-jude-medical-agrees-pay-27-million-allegedly-selling-defective-heart-devices.
42 https://www.justice.gov/opa/pr/avanos-medical-inc-pay-22-million-resolve-criminal-charge-related-fraudulent-misbranding-its.
43 https://www.justice.gov/usao-nj/pr/medical-device-companies-pay-3875-million-settle-false-claims-act-allegations.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/2/2021	Arriva Medical, LLC; Alere Inc.	Mail-order diabetic testing supplier and its parent agreed to pay $160 million to resolve intervened FCA allegations that they made or caused false claims to be submitted to Medicare that were: (1) tainted by kickbacks to Medicare beneficiaries in the form of free glucometers or waived co-pays; (2) false because the patient was not eligible to receive a new glucometer; or (3) false because the patient was deceased. Arriva's two founders previously paid $1 million to resolve allegations that they participated in the scheme.[44]	**$160 million**
8/25/2021	SuperCare Health, Inc.	DME and home respiratory services provider agreed to pay more than $3.3 million to resolve FCA allegations that it billed Medicare and Medicaid for non-invasive ventilator services that were not medically necessary or reasonable.[45]	**$3.315 million**
10/1/2021	Taro Pharmaceuticals USA, Inc.	Pharmaceutical manufacturer agreed to pay more than $213 million to resolve FCA allegations related to price fixing for certain generic drugs. The government alleged that Taro and two other pharmaceutical manufacturers, Sandoz and Apotex, paid and received compensation prohibited by the AKS in connection with agreements on price, supply and allocation of customers for certain generic drugs, resulting in higher drug prices for federal healthcare programs and beneficiaries. As part of the resolution, the company entered into a five-year CIA with HHS-OIG. Taro entered into a deferred prosecution agreement with DOJ's Antitrust division in 2020 for related criminal charges and paid a $205.6 million criminal penalty.[46]	**$213.2 million**
10/1/2021	Sandoz Inc.	Pharmaceutical manufacturer agreed to pay $185 million to resolve FCA allegations related to price fixing for certain generic drugs. The government alleged that Sandoz and two other pharmaceutical manufacturers, Taro and Apotex, paid and received compensation prohibited by the AKS in connection with agreements on price, supply and allocation of customers for certain generic drugs, resulting in higher drug prices for federal healthcare programs and beneficiaries. As part of the resolution, the company entered into a five-year CIA with HHS-OIG. Sandoz entered into a deferred prosecution agreement with DOJ's Antitrust division in 2020 for related criminal charges and paid an additional $195 million criminal penalty.[47]	**$185 million**

44 https://www.justice.gov/usao-mdtn/pr/mail-order-diabetic-testing-supplier-and-its-parent-company-agree-pay-160-million.
45 https://www.justice.gov/usao-cdca/pr/downey-company-provides-home-respiratory-services-agrees-pay-over-33-million-resolve.
46 https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.
47 https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

PHARMACEUTICAL AND DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/1/2021	Apotex Corp.	Pharmaceutical manufacturer agreed to pay $49 million to resolve FCA allegations related to price fixing for certain generic drugs. The government alleged that Apotex and two other pharmaceutical manufacturers, Taro and Sandoz, paid and received compensation prohibited by the AKS in connection with agreements on price, supply and allocation of customers for certain generic drugs, resulting in higher drug prices for federal healthcare programs and beneficiaries. As part of the resolution, the company entered into a five-year CIA with HHS-OIG. Apotex entered into a deferred prosecution agreement with DOJ's Antitrust division in 2020 for related criminal charges and paid a $24.1 million criminal penalty.[48]	**$49 million**
11/8/2021	Arthrex Inc.	Medical device manufacturer agreed to pay $16 million to resolve FCA allegations that it paid kickbacks to a surgeon in the form of sham royalty payments for the surgeon's contributions to its SutureBridge and SpeedBridge products when the payments were in fact intended to induce the surgeon's use and recommendation of the products. As part of the resolution, the company entered a five-year CIA with HHS-OIG.[49]	**$16 million**
11/9/2021	kaléo, Inc.	Pharmaceutical manufacturer of an injectable drug indicated for use to reverse opioid overdose agreed to pay $12.7 million to resolve FCA allegations that it paid kickbacks to increase prescriptions for its drug, Evzio, through a scheme whereby kaléo: (1) directed prescribing physicians to certain preferred pharmacies that falsified prior authorization paperwork to obtain the prescription drug; (2) waived co-pays for government beneficiaries; and (3) provided illegal remuneration to prescribing physicians and their office staff to induce and reward prescriptions.[50]	**$12.7 million**
12/8/2021	Entellus Medical	Medical device manufacturer agreed to pay $1.2 million to settle FCA allegations that it paid kickbacks to the CEO and medical director of an ENT practice to induce the practice's physicians to use the medical device company's products and to increase the number of sinus surgeries requiring the company's products. The CEO/medical director entered into a separate settlement regarding these allegations.[51]	**$1.2 million**

48 https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.
49 https://www.justice.gov/opa/pr/medical-device-company-arthrex-pay-16-million-resolve-kickback-allegations.
50 https://www.justice.gov/opa/pr/kal-o-inc-agrees-pay-127-million-resolve-allegations-false-claims-anti-overdose-drug.
51 https://www.justice.gov/usao-ndga/pr/dr-jeffrey-m-gallups-and-entellus-medical-agree-pay-42-million-resolve-false-claims-act.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/25/2021	McElroy Pharmacy, Inc.; Jeffrey Eshelman	Pharmacy and its pharmacist co-owner agreed to pay a $2.9 million consent judgment to resolve civil FCA and CSA allegations that they: (1) dispensed controlled substances, including hydrocodone, without prescriptions; and (2) dispensed generic versions of drugs but billed Medicare for the brand-name drugs. As part of the resolution, both the pharmacy and Jeffrey Eshelman are permanently prohibited from dispensing controlled substances and Eshelman is excluded from federal healthcare programs for nine years.[52]	**$2.9 million**
5/11/2021	AlixaRx, LLC	Long-term care pharmacy operator agreed to pay $2.75 million to resolve FCA and CSA allegations that it billed Medicare for fraudulently requested emergency refills of Schedule II controlled substances when the refills were not emergencies and no written prescriptions were ever obtained and also submitted claims to Medicare Part D after the same claims had already been reimbursed through claims paid to the long-term care facilities under Medicare Part A.[53]	**$2.75 million**
8/5/2021	Kass Management & Consulting, LLC; Belmont Pharmacy, LLC; Bensalem Pharmacy; Big Oak Pharmacy, Inc.; Doylestown Drugs, LLC; Family One Pharmacy; Penndel Drugs, Inc.; Penlar Pharmacy; Medical Plaza Pharmacy; Kaushal Patel; Mark Zulewski	Pharmacy chain owner, his consulting company, affiliated pharmacies and an employed pharmacist, Mark Zulewski, agreed to pay $250,000 to resolve FCA allegations that Kaushal Patel hired Zulewski to work in his pharmacies with knowledge Zulewski had been convicted of a felony controlled substance offense and was excluded from participating in federal healthcare programs as a result. The government also alleged that despite this knowledge, Zulewski was granted broad administrative authority, including filling prescriptions as needed when pharmacists-in-charge at certain pharmacies were unavailable.[54]	**$250,000**
8/9/2021	David Tsui; Lois Tsui	Owners of a now-defunct compounding pharmacy agreed to pay more than $1 million to resolve FCA allegations that they submitted claims to TRICARE tainted by payments to physicians and marketers intended to induce referrals and compounded drug prescriptions. The settlement also resolves allegations that the owners misrepresented their joint ownership of the pharmacy to conceal the fact that David Tsui was excluded from participating in federal healthcare programs.[55]	**$1.083 million**

52 https://www.justice.gov/usao-edpa/pr/lancaster-county-pharmacy-and-pharmacist-agree-resolve-civil-allegations-dispensing.
53 https://www.justice.gov/usao-ndga/pr/alixarx-llc-agrees-pay-275-million-resolve-allegations-it-improperly-dispensed.
54 https://www.justice.gov/usao-edpa/pr/pharmacy-owner-and-pharmacist-employee-previously-convicted-felon-agree-pay-250000.
55 https://www.justice.gov/usao-mdnc/pr/former-owners-hillsborough-compounding-pharmacy-pay-108299194-resolve-false-claims-act.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/4/2021	Olive Street Pharmacy, LLC; Irina Shlafshteyn	A pharmacy and a pharmacy technician agreed to pay more than $1.5 million to resolve FCA and CSA allegations that they repeatedly dispensed controlled substances despite "red flags" for diversion and dispensed the oral fentanyl spray Subsys to patients who were not medically qualified to receive the drug. As part of the resolution, Irina Shlafshteyn surrendered her Missouri pharmacy technician license, is permanently enjoined from dispensing controlled substances or being employed by any establishment that does so and is excluded from participating in federal healthcare programs for 10 years. Olive Street terminated its enrollment in the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy Program (TIRF REMS) and is permanently enjoined from seeking re-enrollment. Olive Street also entered into a three-year CIA with HHS-OIG.[56]	**$1.508 million**
10/25/2021	Curant, Inc.; Curant Health Georgia, LLC; Curant Health Florida, LLC; Patrick Dunham; Scott Zepp; Marc O'Connor; Pankajkumar Patel	Pharmacy chain, its owners and related entities agreed to pay $4.6 million to resolve FCA allegations that they billed TRICARE for: (1) prescription drugs at higher than their U&C price to other patients; (2) medically unnecessary compound creams; and (3) claims tainted by kickbacks in the form of waived beneficiary co-pays and payments to marketers for arranging for doctors to send prescriptions to Curant. The settlement also resolves allegations that Curant failed to return overpayments to TRICARE after learning about them.[57]	**$4.6 million**
12/8/2021	Plymouth Towne Care Pharmacy, Inc. d/b/a People's Drug Store; Shaska Pharmacy LLC d/b/a Ray's Drugs; Riad "Ray" Zahr	Two specialty pharmacies and their pharmacist owner agreed to pay $1 million to resolve FCA allegations that they submitted prior authorization requests to Medicare for a drug used to reverse the effects of opioid overdose that were not reviewed or signed by prescribing physicians. The settlement also resolves allegations that the pharmacies filled prescriptions for the drug without collecting or attempting to collect co-payments from Medicare beneficiaries, in violation of the AKS.[58]	**$1 million**
12/13/2021	LAN Apothecary, Inc.; Bachtu "Theresa" M. Phan	Pharmacy and its owner agreed to pay $1 million to resolve FCA allegations that they billed Medicare for medication that was never dispensed. As part of the resolution, the parties entered a CIA with HHS-OIG.[59]	**$1 million**

56 https://www.justice.gov/usao-edmo/pr/creve-coeur-pharmacy-and-owner-agree-pay-150780850-resolve-lawsuit-alleging-dispensing.
57 https://www.justice.gov/usao-ndga/pr/atlanta-pharmacy-pay-46-million-settle-false-claims-act-allegations-regarding-compound.
58 https://www.justice.gov/usao-ma/pr/pharmacist-and-two-pharmacies-agree-resolve-allegations-false-claims-anti-overdose-drug.
59 https://www.justice.gov/usao-edpa/pr/philadelphia-pharmacy-and-its-owner-agree-pay-1-million-resolve-false-claims-act.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/6/2021	Exceltox Laboratories, LLC	Diagnostic laboratory agreed to pay $357,584 to resolve FCA allegations that it billed Medicare for genetic tests that were performed without valid physician oversight. A contractor involved in the allegations previously pleaded guilty to conspiracy to commit healthcare fraud and was sentenced to 50 months in prison in May 2019.[60]	**$357,584**
1/11/2021	AutoGenomics, Inc.	Genetic testing laboratory agreed to pay more than $2.5 million to resolve FCA allegations that it billed Medicare for genetic tests tainted by payments the lab paid to a healthcare marketing company for referrals, in violation of the AKS. A residential nursing home operator previously entered a $1 million settlement regarding these allegations.[61]	**$2.538 million**
2/1/2021	Akumin Corporation; Delaware Open MRI Radiology Associates, LLC	Diagnostic imaging services provider agreed to pay nearly $750,000 to resolve FCA allegations that it billed Medicare for more than 1,500 procedures performed without the requisite physician supervision or for which Akumin was unable to determine whether a physician was present.[62]	**$749,600**
2/5/2021	Secon of New England, LLC d/b/a Secon Laboratories; Sterling Healthcare Opco, LLC d/b/a Cordant Health Solutions	Laboratory services provider and its subsidiary agreed to pay $845,108 to resolve FCA allegations that they: (1) submitted claims to Connecticut Medicaid for medically unnecessary urine drug tests for residents at a behavioral health residential treatment center; and (2) failed to report and return overpayments related to the tests.[63]	**$845,108**
3/4/2021	Heart Center Research, LLC	Medical research company agreed to pay $1.1 million to resolve FCA allegations that its member physicians referred patients for genetic testing in exchange for kickbacks from a now-defunct molecular testing company, in violation of the AKS.[64]	**$1.1 million**
7/9/2021	GENETWORx Laboratories	Diagnostic laboratory agreed to pay $1.4 million to resolve FCA allegations that it billed Medicare for genetic tests that were performed without valid physician oversight. A contractor involved in the allegations previously pleaded guilty to conspiracy to commit healthcare fraud and was sentenced to 50 months in prison in May 2019.[65]	**$1.4 million**

60 https://www.justice.gov/usao-nj/pr/california-genetic-testing-lab-agrees-pay-357584-resolve-false-claims-act-allegations.
61 https://www.justice.gov/usao-wdwi/pr/autogenomics-inc-agrees-pay-over-25-million-allegedly-paying-kickbacks.
62 https://www.justice.gov/usao-de/pr/akumin-corporation-pay-us-over-700000-resolve-health-care-fraud-allegations.
63 https://www.justice.gov/usao-ct/pr/healthcare-company-and-lab-pay-845k-resolve-federal-and-state-false-claims-act.
64 https://www.justice.gov/usao-wdwa/pr/medical-research-company-agrees-pay-11-million-settle-allegation-it-received-kickbacks.
65 https://www.justice.gov/usao-nj/pr/virginia-diagnostic-testing-lab-agrees-pay-14-million-resolve-false-claims-act.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/21/2021	Alliance Family of Companies LLC; Ancor Holdings LP	Ambulatory electroencephalography (EEG) testing company and private investment company agreed to pay more than $15 million to resolve FCA allegations that Alliance: (1) paid kickbacks to referring physicians in the form of free EEG test-interpretation reports, thereby enabling primary care physicians who were not neurologists to bill the government as if they had interpreted the tests; (2) used an inaccurate billing code for certain EEG testing to generate higher reimbursements; and (3) billed for a specialized digital analysis that it did not actually perform. The settlement also resolves allegations that Ancor Holdings caused false claims because it learned of the kickback scheme during diligence, but allowed the conduct to continue once it entered into a management agreement with Alliance. As part of the resolution, Alliance entered into a five-year CIA with HHS-OIG.[66]	**$15.345 million**
7/22/2021	Bluewater Toxicology, LLC	Clinical laboratory agreed to pay more than $1.25 million to resolve self-disclosed FCA allegations that it improperly billed federal healthcare programs for claims that misrepresented the number of drug classes tested or lacked the required supporting physician documentation, and for specimen validity testing, despite Medicare guidelines stating that such testing should not be billed separately.[67]	**$1.252 million**
8/6/2021	National Spine & Pain Centers, LLC (NSPC); Physical Medicine Associates, Ltd. (PMA)	Physician management services organization and an affiliate physician group agreed to pay $5.1 million to resolve FCA and AKS allegations that NSPC and PMA employees solicited and received kickbacks in the guise of clinical research payments from a defunct genetic testing company in exchange for referrals. Nine individuals face pending criminal charges in connection with the alleged scheme.[68]	**$5.1 million**
9/16/2021	Alpha Genomix Laboratories, Inc.	Genetics testing laboratory agreed to pay no less than $35,000 and a percentage of its future gross annual revenues up to $200,000 to resolve FCA allegations that it paid kickbacks to a now-defunct counseling group to induce genetic testing referrals. Specifically, the government alleged that the lab paid the salary of an individual who primarily worked for the counseling group. The counseling group's owner was sentenced to three years of probation and ordered to pay restitution after pleading guilty to related healthcare fraud and drug offenses in February 2020.[69]	**$35,000**

66 https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-kickback-and-false.
67 https://www.justice.gov/usao-edky/pr/mount-washington-laboratory-agrees-pay-12-million-resolve-allegations-false-claims.
68 https://www.justice.gov/usao-sdca/pr/pain-management-organization-pays-51-million-settle-criminal-medicare-kickback.
69 https://www.justice.gov/usao-sc/pr/georgia-genetic-testing-laboratory-pay-200000-resolve-anti-kickback-statute-claims.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/20/2021	MD Spine Solutions LLC d/b/a MD Labs Inc.; Denis Grizelj; Matthew Rutledge	Clinical laboratory and two of its owners and co-founders agreed to pay no less than $11.6 million, with future contingent payments up to $16 million based on specific criteria, to resolve FCA allegations that they billed federal healthcare payors for medically unnecessary urine drug tests by performing both presumptive and confirmatory urine drug tests on the same sample simultaneously. As part of the resolution, the laboratory and the owners entered into a five-year CIA with HHS-OIG. A pain management practice entered into a separate settlement related to these allegations.[70]	**$11.6 million**
12/7/2021	Princeton Pathology Services P.A.	Pathology practice agreed to pay $2.4 million to resolve FCA allegations that it billed Medicare for procedures that require written analysis by a pathologist when the corresponding medical records did not contain the required written substantiation. As part of the resolution, the practice entered into a three-year IA with HHS-OIG.[71]	**$2.4 million**

70 https://www.justice.gov/usao-ma/pr/md-labs-and-its-co-founders-agree-pay-16-million-resolve-allegations-fraudulent-billing.
71 https://www.justice.gov/usao-nj/pr/pathology-practice-agrees-pay-24-million-resolve-false-claims-act-allegations.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/1/2021	Behavioral Management, LLC; Neil Quatrano	Behavioral health practice and its owner agreed to pay more than $100,000 to resolve FCA allegations that they improperly: (1) billed Medicaid for services provided by unlicensed individuals; (2) billed for one-on-one sessions when group sessions were actually provided; and (3) billed claims that falsely represented that biofeedback was provided when it was not.[72]	**$100,843**
3/5/2021	Oglethorpe Inc.; Cambridge Behavioral Hospital; Ridgeview Behavioral Hospital; The Woods at Parkside	Healthcare company, two of its hospitals and an affiliated substance abuse treatment facility agreed to pay $10.25 million to resolve FCA allegations that they provided free long-distance van transportation to patients to induce them to use their facilities, in violation of the AKS. The settlement also resolves allegations that the company and two hospitals submitted or caused the submission of claims to Medicare for medically unnecessary inpatient psychiatric admissions and associated services. As part of the resolution, Oglethorpe entered a five-year CIA with HHS-OIG.[73]	**$10.25 million**
4/6/2021	Today's Youth LLC; Maurice Stuckey; Joyce Anderson	In-home family therapy and counseling provider and its owners agreed to pay $273,000 to resolve FCA allegations that they improperly billed Medicaid for services provided by unlicensed individuals.[74]	**$273,000**
6/25/2021	Connecticut Addiction Medicine, LLC; Dr. Jay Benson; Dr. Mahboob Aslam	Behavioral health and addiction medicine practice and its two owners agreed to pay more than $1 million to resolve FCA allegations that they submitted claims to Medicare and Medicaid for medically unnecessary urine drug tests.[75]	**$1.002 million**
6/29/2021	Health Care & Rehabilitation Services of Southeastern Vermont	Substance abuse and mental health services provider agreed to pay more than $170,000 to resolve self-disclosed FCA allegations that it submitted claims to federal healthcare programs for services provided by an employee who was excluded from participating in federal healthcare programs.[76]	**$170,038**
8/25/2021	Carenow Services, LLC; Leena Karun	Psychotherapy services provider and its CEO agreed to pay $2 million to resolve FCA allegations that they billed Medicare and Medicaid for psychotherapy services provided at nursing homes and SNFs that were medically unnecessary, improperly documented or upcoded to reflect services performed at higher intensity levels than justified.[77]	**$2 million**

72 https://www.justice.gov/usao-ct/pr/connecticut-behavioral-health-clinician-group-pays-100k-settle-false-claims-allegations.
73 https://www.justice.gov/opa/pr/ohio-treatment-facilities-and-corporate-parent-agree-pay-1025-million-resolve-false-claims.
74 https://www.justice.gov/usao-ct/pr/behavioral-health-provider-pays-273k-settle-improper-billing-allegations.
75 https://www.justice.gov/usao-ct/pr/connecticut-addiction-medicine-provider-pays-1-million-settle-improper-billing.
76 https://www.justice.gov/usao-vt/pr/united-states-attorney-s-office-resolves-false-claims-act-investigation-improper.
77 https://www.justice.gov/usao-ndga/pr/georgia-psychotherapy-services-provider-pay-2-million-resolve-false-claims-allegations.

BEHAVIORAL HEALTH AND SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/26/2021	Connections Community Support Programs, Inc.	Community-based behavioral health provider agreed to two consent judgments totaling over $15 million to resolve FCA and CSA allegations. The provider agreed to pay more than $13.758 million to resolve FCA allegations that it billed Medicare for upcoded mental health services and other ineligible claims. The provider also agreed to pay more than $1.62 million to resolve CSA allegations that it did not keep proper records of its use of controlled substances and transferred controlled substances between locations without proper documentation.[78]	**$15.379 million**
9/3/2021	Bell Therapy, Inc.; Phoenix Care Systems, Inc.	Therapy clinic operator and its parent company agreed to pay more than $390,000 to resolve FCA allegations that two of its facilities licensed to provide Community Support Programs submitted claims to Wisconsin Medicaid for services provided by unqualified individuals, group services that were billed as if they were individual services, and non-face-to-face services that were not eligible for payment.[79]	**$390,080**
9/16/2021	NDUTIME Youth & Family Services, Inc.; Teshana Gipson	Mental health services provider and its CEO agreed to pay $700,000 to resolve state and federal FCA allegations that they billed Virginia Medicaid for: (1) services that they did not provide; (2) services that were provided by unlicensed individuals; and (3) services provided without the requisite initial assessment completed by a licensed counselor.[80]	**$700,000**
11/3/2021	Access Hospital Dayton, LLC; Dr. John Johnson	Psychiatric hospital and its owner agreed to pay $425,000 to resolve FCA allegations that they billed Medicare and Ohio Medicaid for diagnostic testing that was: (1) performed during patients' inpatient stays at the hospital and thus ineligible for separate reimbursement; (2) not used in the management of patients' conditions; and (3) not medically necessary.[81]	**$425,000**

78 https://www.justice.gov/usao-de/pr/connections-community-support-programs-agrees-judgments-over-15-million-resolve-health.
79 https://www.justice.gov/usao-edwi/pr/milwaukee-area-community-support-program-facilities-agree-pay-390080-resolve-false.
80 https://www.justice.gov/usao-edva/pr/ndutime-youth-family-services-and-its-ceo-settle-false-claims-act-allegations-relating.
81 https://www.justice.gov/usao-sdoh/pr/dayton-psychiatric-hospital-and-owner-agree-pay-425000-resolve-claims-unnecessary.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/12/2021	Spinal Decompression Clinic of Texas	Spinal decompression clinic agreed to pay more than $330,000 to resolve FCA allegations that it billed Medicare for surgical procedures involving the implantation of neurostimulator electrodes when in fact the procedures involved the non-surgical application of electro-acupuncture devices in an office setting.[82]	**$330,898**
1/28/2021	Fun Life Adult Day Care; Monarch Elder Care	Two affiliated adult day health centers agreed to pay more than $1 million to resolve allegations that they improperly submitted claims to Massachusetts Medicaid for services not provided or that were in excess of permissible *per diem* billing requirements. As part of the resolution, both centers agreed to contract with an independent compliance monitor to oversee a three-year independent compliance program.[83]	**$1.061 million**
2/1/2021	Collier Anesthesia Pain, LLC; Tampa Pain Relief Center, Inc.	Two pain management clinics agreed to pay $1.665 million to resolve FCA allegations that they engaged in a kickback scheme by causing affiliated surgery centers to waive co-payments for surgical facility fees to induce patients to receive injection procedures. The settlement also resolves allegations that the clinics improperly billed for Evaluation and Management (E&M) and psychological testing services.[84]	**$1.665 million**
2/5/2021	Southeastern Physical Therapy; Darren Cady	A physical therapy company and its owner agreed to pay $152,000 to settle allegations that they billed the VA for medical devices that were not medically necessary and received kickbacks from the manufacturer of the devices in exchange for prescribing them. The government also alleged that the owner provided a copy of his signature to a salesperson, who then used it to complete medical necessity forms included with invoices and that he did not examine patients before prescribing the device.[85]	**$152,000**
3/2/2021	Allergy and Asthma Associates, Inc.	Allergy and asthma treatment center agreed to pay $2.15 million to resolve FCA allegations that they double-billed and over-billed Medicare and Medicaid by combining partially used vials of an asthma treatment sold in single-use vials for use in other patients. In June 2020 the medical practice also pleaded guilty to one count of criminal healthcare fraud related to the allegations.[86]	**$2.15 million**

82 https://www.justice.gov/usao-edtx/pr/texas-company-agrees-reimburse-medicare-improper-billing-related-neurostimulators.
83 https://www.mass.gov/news/ag-secures-more-than-1-million-from-two-adult-day-health-centers-over-allegations-of-improper.
84 https://www.justice.gov/usao-mdfl/pr/pain-clinic-pays-more-16-million-settle-false-claims-act-and-kickback-allegations.
85 https://www.justice.gov/usao-wdnc/pr/southeastern-physical-therapy-and-owner-pay-152000-settle-false-claims-allegations.
86 https://www.justice.gov/usao-wdva/pr/allergy-and-asthma-associates-roanoke-pleads-guilty-criminal-charge-enters-civil.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
4/8/2021	Doctors Care, P.A.; UCI Medical Affiliates of South Carolina, Inc.	Urgent care provider network and its management company agreed to pay $22.5 million to resolve FCA allegations that they submitted claims to Medicaid, Medicare and TRICARE for services provided by non-credentialed providers. As part of the settlement, both companies entered into a five-year CIA with HHS-OIG.[87]	**$22.5 million**
4/16/2021	Preferred Pain Management & Spine Care, P.A. (PPM); Dr. David Spivey	Pain management company and its owner agreed to pay more than $789,000 to resolve FCA allegations that it improperly billed federal healthcare programs for medically unnecessary urine drug tests. The settlement also resolves allegations that PPM submitted claims to Medicare for specimen validity testing during 2014 and 2015, despite explicit guidance from Medicare beginning in January 2014 stating that such testing should not be separately billed to Medicare.[88]	**$789,292**
4/20/2021	Massachusetts Eye and Ear Infirmary; Massachusetts Eye and Ear Associates, Inc.; Foundation of the Massachusetts Eye and Ear Infirmary, Inc.	Provider of services related to eye, ear, nose and throat issues agreed to pay $2.678 million to resolve FCA allegations that it improperly billed Medicare and MassHealth for procedures that were not separately billable from the office visits at which they were performed.[89]	**$2.678 million**
4/21/2021	Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists (CPS); Dr. Peter B. Kroll; Dr. Steven R. Dickerson; Dr. Gilberto A. Carrero; Dr. Richard J. Muench; Russell S. Smith, D.C.	A now-defunct pain clinic operator, its four majority owners and a former executive agreed to pay more than $4.1 million to resolve intervened FCA allegations that CPS's pain clinics submitted claims to federal healthcare programs for medically unnecessary and/or non-reimbursable testing and electro-auricular acupuncture.[90]	**$4.121 million**
4/28/2021	Hanora Medical Center, PLLC; Dr. Benjamin C. Udoh	Internal medicine practice and its physician operator agreed to pay $300,000 to resolve FCA allegations that they billed Medicare and Medicaid for medically unnecessary Autonomic Nervous System testing. As part of the resolution, the parties entered into a three-year IA with HHS-OIG.[91]	**$300,000**

87 https://www.justice.gov/usao-sc/pr/south-carolina-s-largest-urgent-care-provider-and-its-management-company-pay-225-million.
88 https://www.justice.gov/usao-mdnc/pr/winston-salem-nc-pain-management-company-pay-78929295-resolve-allegations-false-claims.
89 https://www.justice.gov/usao-ma/pr/massachusetts-eye-and-ear-agrees-pay-26-million-resolve-false-claims-act-allegations.
90 https://www.justice.gov/usao-mdtn/pr/comprehensive-pain-specialists-and-former-owners-agree-pay-41-million-settle-fraud.
91 https://www.justice.gov/usao-ednc/pr/fayetteville-north-carolina-physician-agrees-pay-30000000-resolve-allegedly-fraudulent.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/26/2021	HEAG Pain Management Center, P.A.; Dr. Kwadwo Gyarteng-Dakwa	A pain management practice and its physician owner agreed to pay $500,000 to resolve FCA allegations that they billed Medicare and Medicaid for medically unnecessary diagnostic nerve conduction tests that were often performed by unqualified staff, despite coverage rules requiring a physician perform the tests. The practice and physician owner entered into a three-year IA with HHS-OIG as part of the resolution.[92]	**$500,000**
6/8/2021	Campbell Medical Group PLLC; Johnson Medical Group PLLC d/b/a Campbell Medical Clinic; Suhyun An	Chiropractic clinic and its chiropractor owner agreed to pay $2.6 million to resolve allegations that they billed Medicare and TRICARE for surgical procedures involving the implantation of neurostimulator devices when in fact the procedures involved the non-surgical application of electro-acupuncture devices in an office setting. As part of the resolution, the clinics and chiropractor owner are excluded from participation in federal healthcare programs for 10 years.[93]	**$2.6 million**
6/10/2021	SPR Medical Group (f/k/a Atlas Medical Group) d/b/a Superior Physical Medicine	A medical group agreed to pay more than $338,000 to resolve self-disclosed FCA allegations that it billed Medicare for surgical procedures involving the implantation of an electro-acupuncture device when in fact the devices were not implanted and no surgery was performed.[94]	**$338,150**
6/11/2021	Discover Optimal Healthcare; Weigner Healthcare Management Group, LLC; Jason Weigner	Chiropractic practice, chiropractor and his affiliate agreed to pay $662,492 to resolve FCA allegations that they billed federal healthcare programs for surgical procedures involving the implantation of neurostimulator devices when in fact the procedures involved the non-surgical application of electro-acupuncture devices in an office setting.[95]	**$662,492**
6/11/2021	Yucha Medical Pain Management & Chiropractic Rehabilitation, LLC; Randolph E. Yucha; Rodney Gabel	Chiropractic practice and two chiropractors agreed to pay $143,486 to resolve FCA allegations that they billed federal healthcare programs for surgical procedures to implant neurostimulator electrodes when the procedures performed were actually the non-surgical application of a device.[96]	**$143,486**
6/14/2021	Park Square Urgent Care, Inc.; Primacare, Inc.; Biltmore Medical; Biltmore Medical A; Advanced Urgent Care; Zaheer Shah, M.D.	Urgent care center, a physician and affiliated entities agreed to pay $650,000 to resolve allegations that they submitted claims to Medicare and Medicaid for more complex urine drug testing than they actually performed.[97]	**$650,000**

92 https://www.justice.gov/usao-mdnc/pr/greensboro-physician-and-pain-management-practice-pay-500000-resolve-allegations-health.
93 https://www.justice.gov/usao-sdtx/pr/wrongful-billing-results-26m-settlement-and-10-year-exclusion-federal-health-care.
94 https://www.justice.gov/usao-wdtx/pr/healthcare-practitioners-pay-over-1-million-resolve-false-claims-act-liability-arising.
95 https://www.justice.gov/usao-edpa/pr/two-pa-chiropractic-practices-pay-over-800000-resolve-alleged-false-claims-act.
96 https://www.justice.gov/usao-edpa/pr/two-pa-chiropractic-practices-pay-over-800000-resolve-alleged-false-claims-act.
97 https://www.justice.gov/usao-ri/pr/us-recovers-650000-local-providers-who-billed-medicare-and-medicaid-screening-tests-not.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/22/2021	Palladium Primary Care, P.A.; Premiere Health Care Plus, P.A.; Dr. George Osei-Bonsu	Two medical practices and a doctor agreed to pay $330,000 to resolve FCA allegations that they billed Medicare and Medicaid for nerve conduction studies and arterial studies that were: (1) not medically necessary; (2) not supported by patient records; (3) not eligible for reimbursement.[98]	**$330,000**
6/23/2021	El Paso Ear, Nose & Throat Associates	ENT group agreed to pay $750,000 to resolve FCA allegations that they billed federal healthcare programs for more expensive E&M services than were actually provided.[99]	**$750,000**
6/25/2021	NaphCare Inc.	Company that subcontracts with physicians to provide services to prison inmates agreed to pay more than $690,000 to resolve FCA allegations that it billed the Federal Bureau of Prisons for higher-level services than were actually provided.[100]	**$694,593**
6/28/2021	Surgical Care Affiliates, LLC; Orlando Center for Outpatient Surgery, LP	Outpatient surgery center and its affiliate agreed to pay $3.4 million to resolve FCA allegations that they submitted claims to Medicare and TRICARE for medically unnecessary lithotripsy procedures. The settlement also resolves allegations that the surgery center paid a urologist who performed the procedures at the center per-procedure payments to induce the urologist to perform such procedures at the center, in violation of the AKS.[101]	**$3.4 million**
7/20/2021	Arthritis and Osteoporosis Center; Dr. Enrico Arguelles	A now-defunct medical practice and its rheumatologist owner agreed to pay more than $2 million to resolve FCA allegations that they billed federal healthcare programs for medically unnecessary or improper MRI scans, rheumatoid arthritis treatments and other upcoded patient visits.[102]	**$2.071 million**
7/23/2021	Interface Rehab	Rehabilitation therapy provider agreed to pay $2 million to resolve FCA allegations that it submitted or caused the submission of false claims to Medicare for medically unnecessary or unreasonable therapy services provided at 11 SNFs. The SNF operator and 27 other affiliated SNFs previously agreed to pay $16.7 million to resolve allegations related to their role in the alleged conduct in July 2020.[103]	**$2 million**

98 https://www.justice.gov/usao-mdnc/pr/acting-us-attorney-hairston-and-ag-stein-announce-330000-health-care-fraud-settlement.
99 https://www.justice.gov/usao-wdtx/pr/justice-department-reaches-settlement-agreement-physicians-group-el-paso-over.
100 https://www.justice.gov/opa/pr/prison-health-care-provider-naphcare-agrees-settle-false-claims-act-allegations.
101 https://www.justice.gov/usao-mdfl/pr/surgical-care-affiliates-and-orlando-surgery-center-agree-pay-34-million-settle-false.
102 https://www.justice.gov/usao-mt/pr/former-billings-rheumatologist-settles-alleged-health-care-fraud-claims-2-million.
103 https://www.justice.gov/opa/pr/interface-rehab-pay-2-million-resolve-false-claims-act-allegations.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/2/2021	North Georgia Healthcare Center, Inc. (NGHC); DeLaine Hunter; Dr. Gary Smith	Nonprofit clinic and its CEO agreed to pay $130,000 to resolve FCA allegations that they caused the submission of medically unnecessary Schedule II drugs that were prescribed by a former physician, Dr. Smith, without appropriate medical review and judgment. The government alleged that physician assistants – and not Dr. Smith – saw most of the patients at NGHC and Dr. Smith routinely signed prescriptions, including for Schedule II drugs, for patients he had neither seen nor evaluated. As part of the resolution, Dr. Smith consented to a voluntary exclusion from federal healthcare programs for 10 years.[104]	**$130,000**
8/11/2021	Cornell Scott-Hill Health Corporation (CSH)	Community healthcare center agreed to pay $350,000 to resolve FCA allegations that it improperly billed Connecticut Medicaid for certain dental services. Specifically, the government alleged CSH instituted a policy requiring patients to receive dental cleanings and dental exams on separate days so that the center could bill Connecticut Medicaid for two encounters.[105]	**$350,000**
8/12/2021	Tri-County Hospitalists, LLC	Physician-owned medical group agreed to pay $200,000 to resolve FCA allegations that it billed Medicare for medically unnecessary advanced care planning and tobacco cessation counseling, including cessation services provided to patients who did not use tobacco.[106]	**$200,000**
8/13/2021	L.A. Vision LLC; Lisa Azinheira	Optometry practice and optician owner agreed to pay more than $678,000 to resolve FCA allegations that they billed Connecticut Medicaid using a code covering miscellaneous services each time they submitted a claim for eyeglasses, despite no miscellaneous services being provided. The settlement also resolves allegations that the practice encouraged Medicaid beneficiaries to select extra pairs of eyeglasses then submitted claims for multiple pairs of eyeglasses that were not medically necessary. The practice and optician entered into a three-year IA with HHS-OIG as part of the resolution.[107]	**$678,901**
8/19/2021	Nevada Advanced Pain Specialists	Pain management practice agreed to pay $1 million to resolve allegations that it billed Medicare for medically unnecessary confirmatory urine drug tests despite failing to first receive the results from presumptive urine drug tests.[108]	**$1 million**

104 https://www.justice.gov/usao-ndga/pr/north-georgia-health-clinic-and-its-ceo-agree-pay-13000000-settle-false-claims-act.
105 https://www.justice.gov/usao-ct/pr/health-center-pays-350k-settle-improper-billing-allegations-related-medicaid-dental.
106 https://www.justice.gov/usao-edpa/pr/tri-county-hospitalists-llc-agrees-pay-200000-resolve-allegations-overbilling-medicare.
107 https://www.justice.gov/usao-ct/pr/hartford-optician-and-business-pay-more-678k-resolve-false-claims-act-allegations.
108 https://www.justice.gov/usao-ma/pr/nevada-medical-practice-agrees-pay-1-million-resolve-allegations-false-medicare.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
9/21/2021	Align Health and Holistic Medical Center, Inc.; Align Health Management, Inc.; Eric Anderson, P.A. d/b/a Anderson Chiropractic Clinic	Two pain clinics, their owners and a former employee agreed to pay $163,400 to resolve FCA allegations that they improperly billed Medicare for a procedure involving electro-acupuncture devices using a code that indicated the devices were surgically implanted when in fact they were not. The clinics and their owners entered into a three-year IA with HHS-OIG as part of the resolution.[109]	**$163,400**
10/20/2021	Colonial Family Practice, LLC	Physician-owned primary and urgent care practice agreed to pay $1.25 million to resolve FCA allegations that its clinics billed federal healthcare programs for medically unnecessary services and falsified medical records to support the claims. The settlement also resolves allegations that the practice created a protocol that resulted in the systematic billing of medically unnecessary kidney dysfunction tests by adding the test to a panel run on most of its patients.[110]	**$1.25 million**
10/27/2021	Samir Mullick, MD, SC d/b/a Pediatric Associates; Dr. Samir Mullick	Pediatric clinic chain and its owner agreed to pay more than $700,000 to resolve FCA allegations that they submitted claims to Medicaid for medically unnecessary testing and treatments as well as claims that relied on falsified diagnosis codes to justify unnecessary and otherwise non-reimbursable office visits.[111]	**$706,599**
10/28/2021	RehabAuthority, LLC	Physical therapy provider agreed to pay $4 million to resolve FCA allegations that it improperly billed federal healthcare programs for one-on-one outpatient therapy sessions that were not provided.[112]	**$4 million**
11/1/2021	Infectious Disease Consultants of Georgia	An infectious disease clinic agreed to pay $325,000 to resolve FCA allegations that it billed Medicare for infusion services that were provided by unlicensed or unapproved individuals.[113]	**$325,000**

109 https://www.justice.gov/usao-edtn/pr/local-providers-agree-settle-allegations-improper-billing-electro-acupuncture-devices.
110 https://www.justice.gov/usao-sc/pr/united-states-reaches-125-million-settlement-south-carolina-family-practice-clinics.
111 https://www.justice.gov/usao-edwi/pr/pediatric-associates-samir-mullick-md-sc-and-dr-samir-mullick-agree-pay-over-700000.
112 https://www.justice.gov/usao-mn/pr/physical-therapy-provider-pay-4-million-resolve-alleged-false-claims-act-violations.
113 https://www.justice.gov/usao-mdga/pr/infectious-disease-clinic-agrees-pay-325k-resolve-fraud-claims.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/9/2021	Ambulatory Anesthesia of Atlanta, LLC; The Endoscopy Center, LLC (Savannah); Endoscopy Consultants, LLC; Gastrointestinal Specialists of Georgia, P.C.; Georgia Endoscopy Center, LLC; G.I. Diagnostics Endoscopy Center, L.L.C.; North Fulton Medical Center, Inc.; DCA Diagnostics, L.L.C.; Northside Anesthesiology Consultants, LLC; Northwest Georgia Orthopaedic Surgery Center, LLC; United Surgical Partners International, Inc.; Wellbrook Endoscopy Center, P.C.; Arif A. Aziz, M.D.; Jean Calhoun; Jay A. Cherner, M.D.; David Finkelman, M.D.; Alan M. Fixelle, M.D.; Eugene H. Hirsh, M.D.; A. Steven McIntosh, M.D.; Stanford Plavin, M.D.; M. Thomas Riddick, M.D.; Bruce A. Salzberg, M.D.; Gary S. Simon, M.D.; David N. Socoloff, D.O.	Several outpatient surgery centers, their physician-owners, an administrator and three anesthesia providers agreed to pay more than $28 million to resolve FCA allegations that they billed for services tainted by kickbacks, in violation of the AKS. The anesthesia providers allegedly made payments for drugs, supplies, equipment and labor, and provided free staffing for a number of the surgery centers to induce the surgery centers to name them the exclusive anesthesia providers for the centers.[114]	**$28 million**
11/29/2021	Quincy Medical Group	Medical practice agreed to pay $500,000 to resolve FCA allegations that it billed Medicare and Medicaid for medically unnecessary cardiac catheterization procedures performed by one of its formerly employed physicians.[115] The hospital where the physician performed the procedures entered into a separate settlement regarding these allegations.	**$500,000**
12/21/2021	Integrated Pain Associates, PLLC; Central Texas Day Surgery Center, LLC	A pain clinic and associated ambulatory surgery center agreed to pay more than $836,000 to resolve FCA allegations that they overbilled Medicare, Medicaid and TRICARE for more units or levels of various injections and procedures than were actually administered.[116]	**$836,702**

114 https://www.justice.gov/usao-ndga/pr/anesthesia-providers-and-outpatient-surgery-centers-pay-more-28-million-resolve.
115 https://www.justice.gov/usao-cdil/pr/federal-and-state-authorities-reach-settlement-quincy-medical-group-over-medicare-and.
116 https://www.justice.gov/usao-wdtx/pr/pain-clinic-and-ambulatory-surgery-center-agree-pay-836k-resolve-allegations.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2021	Dr. James P. Anderson	A physician agreed to pay $1 million to resolve allegations that he billed Medicare and TennCare for an electro-acupuncture stimulation device as if the device had to be implanted surgically when it did not. The physician entered into a three-year IA with HHS-OIG as part of the resolution.[117]	**$1 million**
1/4/2021	Charles F. Spencer; Total Family Physicians Center PLLC d/b/a Total Family Health & Wellness	A chiropractor and his medical group agreed to pay $700,000 to resolve allegations that they billed Medicare and TennCare for an electro-acupuncture stimulation device as if the device had to be implanted surgically when it did not.[118]	**$700,000**
1/4/2021	Mitchell P. Shea; Chiro2Med of Tennessee P.C.	A chiropractor and his medical group agreed to pay $20,000 to resolve allegations that he billed Medicare and TennCare for an electro-acupuncture stimulation device as if the device had to be implanted surgically when it did not.[119]	**$20,000**
1/22/2021	Estate of Dr. Patrick T. Hunter	A urologist's estate agreed to pay $1.75 million to resolve allegations that he billed for kidney stone procedures that were not medically necessary because they were not medically indicated or because no kidney stones were in the patients. The settlement also resolved allegations that the urologist performed the procedures at a surgery center from which he allegedly received kickback payments.[120]	**$1.75 million**
1/25/2021	Elevani Health Group, PLLC; Agilium, Inc.; Chad Glines	A management services company, its owner and a medical practice agreed collectively to pay $150,000 to resolve allegations that they submitted claims to Medicare for the surgical implantation of neurostimulation devices when electro-acupuncture devices that were not surgically implanted were used.[121]	**$150,000**
2/4/2021	Kelly Wolfe; Regency Inc.	A business owner and her company agreed to pay more than $20 million to resolve allegations that they fraudulently established DME companies by submitting falsified paperwork. The companies then allegedly billed Medicare for equipment that was not medically necessary and used marketing techniques that violated the AKS. In addition to the civil settlement, the owner pleaded guilty to related criminal charges.[122]	**$20.333 million**

117 https://www.justice.gov/usao-mdtn/pr/united-states-and-tennessee-resolve-claims-three-providers-false-claims-act-liability.
118 https://www.justice.gov/usao-mdtn/pr/united-states-and-tennessee-resolve-claims-three-providers-false-claims-act-liability.
119 https://www.justice.gov/usao-mdtn/pr/united-states-and-tennessee-resolve-claims-three-providers-false-claims-act-liability.
120 https://www.justice.gov/usao-mdfl/pr/estate-deceased-urologist-agrees-pay-more-17-million-settle-false-claims-act-liability.
121 https://dockets.justia.com/docket/texas/txndce/3:2021cv00157/343353.
122 https://www.justice.gov/opa/pr/florida-businesswoman-pleads-guilty-criminal-health-care-and-tax-fraud-charges-and-agrees-203.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/3/2021	Dr. Ashok Kumar	A physician agreed to pay $215,228 to resolve allegations that he received compensation as a medical director from a hospital that exceeded the FMV of his services and was an effort to incentivize him to make referrals to the hospital, in violation of the Stark Law and the AKS. The hospital and six of its owners previously agreed to pay $8.1 million to settle similar allegations. The physician entered into a three-year IA with HHS-OIG as part of the resolution.[123]	**$215,228**
3/8/2021	Dr. Feng Qin; Qin Medical P.C.	A physician and his practice agreed to pay $800,000 to resolve allegations that he billed Medicare for vascular surgery procedures that he routinely performed regardless of whether they were medically necessary and, at multiple points, misrepresented patient conditions in medical records to justify the procedures. The physician also consented to exclusion from federal healthcare programs for four years, and the prosecution of related criminal charges was deferred for one year.[124]	**$800,000**
3/8/2021	Vedat Obuz; Lotus Clinics P.C./Lotus Family Medicine	A physician and his practice agreed to pay $106,255 to resolve allegations that they billed for procedures performed by nurse practitioners as if the procedures had been performed by the physician.[125]	**$106,255**
3/9/2021	Dr. Hugo A. Rojas	A primary care physician agreed to pay $350,000 to resolve allegations that he violated the CSA and FCA by: (1) pre-signing prescriptions for controlled substances and being out of the state when the prescriptions were issued; (2) issuing prescriptions for controlled substances to patients who were either not examined or were examined by non-physicians; and (3) billing Medicare for services that were provided by other individuals while he was travelling.[126]	**$350,000**
3/18/2021	Dr. Truc Le	A physician agreed to pay $475,000 to resolve allegations that he certified patients for home health services based solely on the forms provided by the home health company without examining the patients. He also allegedly received payments from the agency for referrals, in violation of the AKS.[127]	**$475,000**
3/18/2021	Dr. Dinesh M. Shah; Michigan Physicians Group, P.C.	A cardiologist and his practice agreed to pay $2 million to resolve FCA allegations that they billed Medicare, Medicaid and TRICARE for diagnostic tests that were medically unnecessary or not conducted. The cardiologist and the practice entered into a three-year IA with HHS-OIG as part of the resolution.[128]	**$2 million**

123 https://www.justice.gov/usao-cdca/pr/south-bay-doctor-settles-federal-lawsuit-alleging-he-accepted-illegal-kickbacks-patient.
124 https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-resolution-civil-and-criminal-healthcare-fraud-charges.
125 https://www.justice.gov/usao-nj/pr/new-jersey-physician-and-medical-practice-agree-pay-106255-resolve-false-claims-act.
126 https://www.justice.gov/usao-wdtx/pr/san-antonio-physician-agrees-pay-350000-resolve-allegations-he-pre-signed-prescriptions.
127 https://www.justice.gov/usao-sdtx/pr/physician-pays-nearly-half-million-dollars-resolve-home-health-care-fraud-allegations.
128 https://www.justice.gov/usao-edmi/pr/cardiologist-dinesh-shah-pays-2-million-resolve-false-claims-act-allegations-relating.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/23/2021	Dr. Domonique Randall	The former owner and sole-shareholder of a children's autism therapy provider agreed to pay more than $2.7 million to resolve allegations that nine of the company's locations submitted claims to TRICARE that: (1) did not correctly identify the provider of services; (2) could not be substantiated by medical records; or (3) covered services allegedly provided on dates when the individual providers billed excessive hours.[129]	**$2.729 million**
3/26/2021	Philip McHugh	A former owner of a diagnostic testing laboratory agreed to pay more than $2 million to resolve allegations that he caused the now-defunct laboratory to submit false claims to Medicare by participating in the following kickback schemes: (1) providing urine drug testing equipment to two physicians; (2) the laboratory paying an individual volume-based commission and then a salary in exchange for the individual working with physician groups to induce referrals; and (3) providing loans to two physicians in exchange for referrals.[130]	**$2.022 million**
3/30/2021	Douglas Smith	A former owner of a now-defunct diagnostic testing laboratory entered a consent judgment to pay $4.5 million to resolve allegations that he paid kickbacks to the owner of a medical practice in exchange for referrals to the company's laboratories.[131]	**$4.5 million**
4/7/2021	Stacy Hawkins	The CFO of a physical medicine clinic and licensed chiropractor, agreed to pay $273,000 to resolve allegations that her clinic billed Medicare for surgical procedures involving the implantation of neurostimulator electrodes, when the procedures performed were actually the non-surgical application of electro-acupuncture devices.[132]	**$273,000**
4/19/2021	Dr. Njideka Udochi	A family practice physician agreed to pay more than $660,000 to resolve allegations that she billed Medicare for the surgical implantation of neurostimulator devices when the patients received acupuncture devices that were not surgically implanted.[133]	**$663,094**
5/14/2021	Dr. Gunjan Dhir; Dr. Gaurav Puri	Two dentists, their dental management companies, and certain affiliated pediatric dental practices agreed to pay $3.1 million to resolve allegations that they billed the Texas Medicaid for fillings in children that were not actually performed. The settlement also resolves allegations that they submitted or caused the submission of claims using erroneous Medicaid provider numbers misrepresenting the dentists who performed pediatric procedures.[134]	**$3.1 million**

129 https://www.justice.gov/usao-sdtx/pr/former-children-s-autism-service-provider-pays-over-27-million-resolve-health-care.
130 https://www.justice.gov/usao-wdnc/pr/owner-defunct-urine-drug-testing-laboratory-agrees-pay-over-2-million-resolve.
131 https://www.justice.gov/usao-wdnc/pr/court-enters-45-million-judgment-against-owner-defunct-urine-drug-testing-laboratory.
132 https://www.justice.gov/usao-sdtx/pr/chiropractor-pays-settle-allegations-arising-electro-acupuncture-device-billing.
133 https://www.justice.gov/usao-md/pr/howard-county-physician-pays-more-660000-resolve-false-claims-act-allegations-fraudulent.
134 https://www.justice.gov/usao-ndtx/pr/dentists-pay-31-million-resolve-allegations-they-submitted-false-claims-services-not.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/10/2021	Harold Ledger	A podiatrist agreed to pay $535,000 to resolve FCA allegations that he billed Medicare for surgical procedures involving the implantation of neurostimulators when in fact the devices were not implanted and did not require surgery.[135]	**$535,000**
6/10/2021	Dr. Yurii Borshch	A pain physician agreed to pay more than $183,000 to resolve allegations that his practice billed Medicare for surgical procedures involving the implantation of neurostimulators when in fact the devices were electro-acupuncture devices that were not implanted and did not require surgery.[136]	**$183,190**
6/11/2021	Dr. Marte A. Martinez, Jr.	A pain physician and anesthesiologist agreed to pay more than $340,000 to resolve allegations that he billed Medicare for the surgical implantation of neurostimulator devices when the patients received acupuncture devices that were not surgically implanted.[137]	**$340,437**
6/15/2021	Loren D. Sherwood	A former physician agreed to pay at least $21,000 to resolve allegations that he issued prescriptions for controlled substances after his medical license expired, in violation of the CSA, and caused the submission of claims for such prescriptions to Medicare in violation of the FCA. The physician agreed to never practice medicine again or seek a medical license in any state and to not seek reinstatement of his DEA controlled substances registration.[138]	**$21,000**
7/16/2021	Dr. Lance Kim; Florida Neurological Center, LLC	A neurologist and his practice agreed to pay $800,000 to resolve allegations that the neurologist issued prescriptions for an expensive drug (Acthar Gel®) which was not medically necessary or reasonable.[139]	**$800,000**
8/3/2021	John Davis	The former CEO of a pain management company agreed, in resolving civil FCA allegations, to be permanently excluded from participation in federal healthcare programs or employment in any industry in which he might play a direct or indirect role in causing claims to be submitted to federal healthcare programs. He was previously convicted on criminal charges related to the matter but had his sentence commuted.[140] The pain management company, its four majority owners and a former executive entered into a separate settlement related to these allegations.	**Non-monetary (Exclusion)**

135 https://www.justice.gov/usao-wdtx/pr/healthcare-practitioners-pay-over-1-million-resolve-false-claims-act-liability-arising.
136 https://www.justice.gov/usao-wdtx/pr/healthcare-practitioners-pay-over-1-million-resolve-false-claims-act-liability-arising.
137 https://www.justice.gov/usao-sdtx/pr/pain-doctor-pays-settle-allegations-arising-false-billing.
138 https://www.justice.gov/usao-co/pr/former-ridgway-physician-agrees-forgo-practicing-medicine-and-pay-penalty-resolve.
139 https://www.justice.gov/usao-mdfl/pr/ocala-neurologist-agrees-pay-800000-resolve-allegations-prescribing-medically.
140 https://www.justice.gov/usao-mdtn/pr/former-ceo-comprehensive-pain-specialists-resolves-civil-lawsuit-united-states.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/25/2021	Gary Stein	A chiropractor agreed to pay more than $290,000 to resolve allegations that he billed the U.S. Department of Labor's Office of Workers' Compensation Programs for extended medical examination services provided to a federal employee receiving Federal Employees Compensation Act benefits, when the services were not actually provided at the level billed.[141]	**$290,197**
9/15/2021	Dr. Ashish Pal	A cardiologist agreed to pay $6.75 million to resolve allegations that he billed for medically unnecessary ablations and vein stent procedures, often performed by technicians who were not qualified to administer the procedures, and, to justify the treatments, the cardiologist made misrepresentations in medical records. The physician and his practice concurrently entered into a three-year IA with HHS-OIG as part of the resolution.[142]	**$6.75 million**
9/28/2021	Dr. Stephen Padnes	A physician agreed to pay $2 million to resolve allegations that he prescribed controlled substances without a valid medical purpose, in violation of the CSA, and many of these prescriptions were paid for by Medicaid and Medicare, resulting in FCA violations. The physician also pleaded guilty to related criminal charges and will be excluded from participating in Medicare for at least 10 years.[143]	**$2 million**
10/1/2021	Kate Cordisco	A Certified Registered Nurse Practitioner agreed to pay $21,000 to resolve allegations that she received a per-patient consulting fee from a marketing company in exchange for ordering DME for patients with whom she did not have an existing relationship and without any physical examination of the patients.[144]	**$21,000**
10/12/2021	Dr. Llewellyn Simon	An internal medicine physician agreed to pay $640,000 to resolve allegations that he received fees as a medical director of a former home health agency that were above FMV and based on his referral of patients to the agency, in violation of the AKS.[145]	**$640,000**
10/18/2021	Jae Lee	The former CEO of a now-defunct medical testing laboratory agreed to pay $1.1 million to resolve kickback allegations that the lab received payments from at least two other laboratories in exchange for the referrals of testing for beneficiaries of government healthcare programs which his lab was not eligible to conduct. The laboratories paying for the referrals previously reached settlements in the matter, and the CEO pleaded guilty to related criminal charges.[146]	**$1.1 million**

141 https://www.justice.gov/usao-edny/pr/long-island-chiropractor-settles-federal-fraud-allegations.
142 https://www.justice.gov/usao-mdfl/pr/orlando-cardiologist-pays-675-million-resolve-allegations-performing-unnecessary.
143 https://www.justice.gov/usao-edpa/pr/center-city-doctor-pleads-guilty-illegally-distributing-controlled-substances-and.
144 https://www.justice.gov/usao-mdpa/pr/certified-registered-nurse-practitioner-pay-21000-resolve-civil-liability-alleged.
145 https://www.justice.gov/usao-wdla/pr/physician-agrees-pay-640000-resolve-allegations-anti-kickback-violations.
146 https://www.justice.gov/usao-wdwa/pr/doj-and-ceo-defunct-medical-testing-laboratory-settle-false-claims-act-and-anti.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/21/2021	Dr. Gina Sohn	A dentist agreed to pay $100,000 to resolve allegations that she billed TRICARE for fillings that were not actually performed.[147]	**$100,000**
10/22/2021	Dr. Robert Wills	A pain management physician who was former co-owner of a pain clinic agreed to pay $2.1 million to resolve allegations that he and his clinic ordered urine drug tests conducted at the clinic's in-house laboratory that were not medically necessary. The other co-owner of the now-defunct clinic also reached a settlement in the case.[148]	**$2.1 million**
10/22/2021	Dr. Brannon Frank	A pain management physician who was former co-owner of a pain clinic agreed to pay $1.8 million to resolve allegations that he and his clinic ordered urine drug tests conducted at the clinic's in-house laboratory that were not medically necessary. The other co-owner of the now-defunct clinic also reached a settlement in the case.[149]	**$1.8 million**
11/15/2021	Dr. Emad Bishai	An anesthesiologist and pain management physician agreed to pay more than $520,000 to resolve allegations that he: (1) billed for surgical procedures involving the implantation of neurostimulator electrodes when in fact the procedures involved the non-surgical application of electro-acupuncture devices, and (2) made false statements when applying for a loan from the Paycheck Protection Program. The physician also agreed to be excluded from federal healthcare programs for seven years.[150]	**$523,331**
11/15/2021	Willie "Billy" C. Conley, Jr.	A pharmacist who was former owner of a pharmacy agreed to pay $275,000 to resolve allegations that he and his pharmacy filled prescriptions for controlled substances despite red flags indicating that the prescriptions were not medically necessary – specifically, they were prescribed by a doctor recently convicted for healthcare fraud and unlawfully dispensing controlled substances.[151]	**$275,000**
11/19/2021	Dr. Eric Benson	A physician agreed to pay $110,000 to resolve allegations that he prescribed opioids and other controlled substances without a legitimate medical purpose and outside the course of professional practice, in violation of the CSA, and caused the submission of false claims for such prescriptions. As part of the settlement, the physician agreed to certain restrictions on his ability to see new patients for whom opioids were already prescribed.[152]	**$110,000**

147 https://www.justice.gov/usao-mdpa/pr/dentist-south-korea-pay-100000-resolve-civil-liability-violations-false-claims-act.
148 https://www.justice.gov/opa/pr/texas-pain-management-physicians-agree-pay-39-million-resolve-allegations-relating.
149 https://www.justice.gov/opa/pr/texas-pain-management-physicians-agree-pay-39-million-resolve-allegations-relating.
150 https://www.justice.gov/usao-sdtx/pr/woodlands-pain-doctor-pays-half-million-dollars-fraudulent-ppp-and-billing-allegations.
151 https://www.justice.gov/usao-sdga/pr/pharmacist-pay-275000-settle-claims-related-alleged-unlawful-dispensation-controlled.
152 https://www.justice.gov/usao-id/pr/ost-falls-doctor-pays-110000-settle-allegations-he-overprescribed-opioids.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/24/2021	Henry Alfonso Coley	The founder of a nonprofit organization that provides services to developmentally disabled individuals, including Medicaid beneficiaries, agreed to pay $220,000 to resolve allegations that his organization submitted cost reports to the state that claimed as allowable expenses millions of dollars that was not spent on providing care to disabled individuals, but instead spent on for-profit companies owned by them, on salaries for his family members and on his personal expenses. The founder agreed to never work for or accept payments from any entity that receives reimbursement from federal healthcare programs and entered into a 15-year voluntary exclusion agreement with HHS-OIG.[153]	**$220,000**
12/1/2021	Matthew Thibaut	A medical sales representative agreed to pay $100,000 to resolve allegations that he sold electro-acupuncture devices to providers, knowing that they would bill Medicare for procedures involving surgical implantation of devices instead of the non-surgical use of the electro-acupuncture devices.[154]	**$100,000**
12/8/2021	Dr. Jeffrey M. Gallups	The founder, former CEO and medical director of an ENT practice agreed to pay $3 million to settle allegations that, in exchange for kickback payments from a medical device company, he directed the practice's physicians to use the medical device company's products and to increase the number of sinus surgeries requiring the company's products. The medical device company entered into a separate settlement regarding these allegations. This settlement also resolved allegations that the former CEO directed the practice's physicians to order toxicology and genetic tests from a now-defunct laboratory, regardless of medical necessity, in exchange for the laboratory paying "commissions" to the clinic equaling 50% of the revenue from these tests.[155]	**$3 million**
12/10/2021	Dr. James J. Cole	A physician agreed to pay $125,000 to resolve allegations that he prescribed controlled substances in combinations disfavored by the medical community, outside the usual course of a professional practice, and without a legitimate medical purpose, in violation of the CSA, and caused the submission of false claims to Medicare for such prescriptions. The physician also agreed to forfeit his medical license and prescribing privileges.[156]	**$125,000**

153 https://www.justice.gov/usao-sdny/pr/us-attorney-files-civil-fraud-lawsuit-against-non-profit-and-settles-fraud-claims.
154 https://www.justice.gov/usao-sdtx/pr/cypress-medical-sales-representative-agrees-settle-allegations-regarding.
155 https://www.justice.gov/usao-ndga/pr/dr-jeffrey-m-gallups-and-entellus-medical-agree-pay-42-million-resolve-false-claims-act.
156 https://www.justice.gov/usao-ndny/pr/former-albany-physician-pays-125000-overprescribing-opioids.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/13/2021	Dr. Kevin Cooper; Cooper Family Medical Center	A physician and his practice agreed to pay $375,000 to settle allegations that he billed Medicare for the surgical implantation of neurostimulator devices when the devices actually used were acupuncture devices that do not require surgery.[157]	**$375,000**
12/15/2021	Dr. David Bellamah; Bellamah Vein & Surgery, PLLC d/b/a Bellamah Vein Center	A vascular surgeon and his practice agreed to pay more than $3.7 million to resolve allegations that he and his staff utilized improper techniques in performing and analyzing ultrasounds and used false ultrasound findings to conduct and bill for medically unnecessary and unreasonable services. The surgeon and the practice entered into a three-year IA with HHS-OIG as part of the resolution.[158]	**$3.746 million**

157 https://www.justice.gov/usao-sdms/pr/physician-agrees-pay-375000-resolve-false-claims-act-allegations-p-stim-device-fraud.
158 https://www.justice.gov/usao-mt/pr/missoula-vascular-surgeon-settles-alleged-health-care-fraud-claims-37-million.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/28/2021	athenahealth, Inc.	A developer of EHR services agreed to pay $18.25 million to resolve allegations that it engaged in three marketing schemes in violation of the AKS that caused providers to submit false claims related to federal EHR incentive payments. The EHR developer allegedly: (1) invited customers and prospective customers to all-expenses-paid "bucket list" events; (2) entered into "Conversion Deals" whereby it paid competitors to refer customers when their products were discontinued, tied to the value and volume of business ultimately converted; and (3) paid fees to customers for each referral that signed up for the product.[159]	**$18.25 million**
3/16/2021	Jack Lee Stapleton; Jack Hunter Stapleton	The former owners of a telemarketing company agreed to pay at least $4 million to settle claims that they used telemarketing to solicit patients to accept compounded drugs even if the drugs were not medically necessary, obtained prescriptions for the drugs and then provided the prescriptions to compounding pharmacies that agreed to pay the telemarketers half of the TRICARE reimbursement for each prescription. The telemarketing company allegedly paid telemedicine providers to issue the prescriptions, often without a patient exam.[160]	**$4 million**
3/24/2021	Rural/Metro Corporation	An ambulance service provider agreed to pay $650,000 to settle allegations that it submitted claims to Medicare for ambulance transports when the patients either did not require ambulance transport or were not qualified for the services. The government also alleged that the provider lacked proper documentation showing the reasons for the ambulance transports.[161]	**$650,000**
4/30/2021	CareCloud Health, Inc. f/k/a CareCloud Corporation	An EHR software developer agreed to pay more than $3.8 million to resolve allegations that it provided its current customers with cash equivalent credits, cash bonuses and percentage success payments in exchange for recommending its product to potential customers and agreeing in writing to not provide negative information about the company's products, in violation of the AKS. The government alleged the company violated the FCA because the kickback payments rendered false the company's claims for federal EHR incentive payments.[162]	**$3.806 million**

159 https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks.
160 https://www.justice.gov/opa/pr/former-owners-telemarketing-company-agree-pay-least-4-million-resolve-false-claims-act.
161 https://www.justice.gov/usao-mdfl/pr/ruralmetro-corporation-agrees-pay-650000-settle-civil-false-claims-relating-ambulance.
162 https://www.justice.gov/usao-sdfl/pr/miami-based-carecloud-health-inc-agrees-pay-38-million-resolve-allegations-it-paid.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/10/2021	University of Miami	A university agreed to pay $22 million to settle FCA allegations that it: (1) improperly billed at certain hospital facilities that were converted from physician offices because it failed to provide proper notice to beneficiaries of the conversion, even after a Medicare Administrative Contractor informed the university that its notice practices were deficient; (2) billed for laboratory tests that were not medically necessary; and (3) caused a hospital to submit inflated claims for laboratory testing performed at a related institute in violation of related party regulations, by controlling the hospital's decision to purchase the tests at inflated rates in exchange for the university's surgeons continuing to perform surgeries at the hospital. The hospital reached a separate settlement related to these last allegations.[163]	**$22 million**
10/14/2021	H.I.G. Growth Partners, LLC; H.I.G. Capital, LLC; Peter J. Scanlon; Kevin P. Sheehan	Private equity owner of a mental health clinic operator agreed to pay $19.95 million, and two former executives of the clinic operator agreed to pay $5.05 million, to resolve FCA allegations that they: (1) knew the clinic operator employed individuals who were unlicensed or unqualified to perform the services they were providing, or who provided services in unsupervised settings, in violation of state Medicaid regulations; and (2) caused false claims to be submitted to the Massachusetts Medicaid agency by failing to adopt recommendations to bring the operator into compliance. The mental health services operator entered into a prior settlement relating to the allegations.[164]	**$25 million**

163 https://www.justice.gov/usao-sdfl/pr/university-miami-pay-22-million-settle-claims-involving-medically-unnecessary.
164 https://www.mass.gov/news/private-equity-firm-and-former-mental-health-center-executives-pay-25-million-over-alleged-false-claims-submitted-for-unlicensed-and-unsupervised-patient-care.

ABOUT BASS, BERRY & SIMS

The Bass, Berry & Sims Healthcare Fraud & Abuse Task Force represents healthcare providers in responding to inquiries and investigations by DOJ, HHS-OIG, various states' Attorneys General offices, and other federal and state agencies, and in related litigation.

We have a proven track record of representing healthcare providers throughout the United States in civil and criminal investigations and healthcare fraud-related litigation. We have successfully defended healthcare providers in FCA litigation in trial and appellate courts, secured dismissals of FCA allegations in numerous cases and have negotiated favorable resolutions on behalf of our clients where appropriate. Furthermore, we routinely counsel healthcare providers on implementing state-of-the-art compliance programs and assist clients in navigating self-disclosure and other compliance-related matters.

Our team includes former members of DOJ and HHS-OIG with significant experience handling healthcare fraud matters on behalf of the government. Our attorneys are frequent speakers on healthcare fraud and abuse topics, and three of our members serve as Adjunct Professors of Law teaching Healthcare Fraud and Abuse at both Vanderbilt University Law School and Belmont University College of Law. For more information, please visit our website at **www.bassberry.com/healthcare-fraud**.

TOP-RANKED NATIONAL HEALTHCARE PRACTICE

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Healthcare practice and Healthcare Government Investigations and Fraud attorneys recognized by *Chambers USA* (2021).

Firm recognized by Law360 as a Practice Group of the Year winner in the Health Care category (2020).

In 2021, our team launched its new Healthcare Fraud & Abuse Resource Center, which provides a central location for healthcare leaders to access tools and information, including:

- An innovative, searchable database featuring more than 1,300 significant (FCA) settlements from the last decade.
- The most recent edition of our Healthcare Fraud & Abuse Annual Review, an in-depth and comprehensive analysis of the past year's court decisions involving the FCA and enforcement developments affecting the healthcare industry.
- A video library where visitors can watch segments (some for CLE credit) about fraud and abuse issues facing the healthcare industry, as well as practical tips and takeaways for preparing for, responding to and resolving a healthcare fraud investigation.

Access the Healthcare Fraud & Abuse Resource Center at **www.fraudinhealthcare.com**.

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

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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.

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Matthew Curley is co-chair of Bass, Berry & Sims' Healthcare Fraud Task Force and 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.

JOHN C. EASON

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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

Member | 202.827.2964 | lfetzer@bassberry.com

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 M. GAFFNEY

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Lauren Gaffney represents healthcare clients concerning regulatory compliance and healthcare fraud matters. She counsels clients through internal investigations and related resolutions such as self-disclosures and voluntary repayments. She also counsels clients in connection with responding to audits and appeals by government contractors.

SCOTT D. GALLISDORFER

Member | 615.742.7926 | scott.gallisdorfer@bassberry.com

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.

JEFF H. GIBSON

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

ANNA M. GRIZZLE

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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 matters and government investigations. Anna routinely advises on the reporting and repayment of overpayments and in responding to payor audits and has advised a number of healthcare clients in self-disclosures, including disclosures made through the physician self-referral (Stark Law) and HHS-OIG disclosure protocols.

STEWART W. KAMEEN

Counsel | 202.827.2962 | stewart.kameen@bassberry.com

Stewart Kameen advises healthcare clients on all aspects of federal and state healthcare laws and regulations, with a particular emphasis on fraud and abuse regulatory counseling, corporate compliance, internal investigations and government enforcement actions, *qui tam* litigation, and transactional matters. Stewart is able to counsel providers drawing on his unique perspective informed by his experience working at HHS-OIG as Senior Counsel in the Office of Counsel to the Inspector General – Industry Guidance Branch – where he handled OIG advisory opinion requests, drafted several proposed and final regulations associated with the Regulatory Sprint to Coordinated Care, and consulted with DOJ relating to various enforcement matters.

JOHN E. KELLY

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John Kelly is the Managing Partner of the firm's Washington, D.C. office, a former DOJ healthcare fraud prosecutor, and an experienced trial lawyer who represents healthcare providers, health systems, payors, pharmaceutical manufacturers, medical device companies, and executives in compliance investigations and government enforcement actions concerning the FCA, AKS, Stark Law, FDCA, and FCPA. John also has extensive experience in the managed care and risk adjustment space. John held a number of leadership positions at DOJ, 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.

JENNIFER E. MICHAEL

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Jennifer Michael draws on her experience as the former Chief of the Industry Guidance Branch at the U.S. Department of Health and Human Services (HHS), Office of Counsel to the Inspector General (OCIG) to help healthcare providers and life science companies avoid potential fraud and abuse landmines and defend them in fraud and abuse investigations. Jennifer helps her clients structure their arrangements to comply with the federal Anti-Kickback Statute (AKS), the federal Civil Monetary Penalty (CMP) law, and other state and federal fraud and abuse laws and navigate government investigations under the federal False Claims Act (FCA). She also leads internal investigations for healthcare companies to identify and quantify potential overpayments from federal healthcare programs; advises on fraud risks of existing and proposed arrangements in connection with pending and proposed transactions; and designs, implements, and evaluates compliance programs.

LISA S. RIVERA

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Lisa Rivera advises healthcare providers on matters related to compliance and internal investigations, as well as responding to government investigations and enforcement of civil and criminal healthcare fraud. Lisa previously served for 13 years as an Assistant U.S. Attorney, with 10 of those years spent 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 the review and coordination of all criminal and civil healthcare fraud investigations, as well as handling her own civil and criminal healthcare cases. She is an adjunct professor teaching Healthcare Fraud and Abuse at Belmont University College of Law.

BRIAN D. ROARK

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Brian Roark is co-chair of Bass, Berry & Sims' 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 B. ROSE

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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.

MOLLY K. RUBERG

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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.

DANIELLE M. SLOANE

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Danielle Sloane helps life sciences 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 K. TAMULIS

Member | 202.827.2999 | jtamulis@bassberry.com

Julia Tamulis provides guidance on government investigations of healthcare providers concerning potential fraud and abuse matters, including under the AKS, Stark Law, and FCA. She assists healthcare companies with internal compliance reviews and investigations and advises healthcare providers on Medicare appeals related to government audits. Julia previously was an attorney-advisor for HHS's Departmental Appeals Board.

SENIOR ATTORNEYS & ASSOCIATES

MICHAEL K. BASSHAM

Michael Bassham represents healthcare clients in government enforcement and compliance actions concerning the federal and state Stark Laws, AKS, and FCA. He works closely with providers to help them navigate the complex Medicaid requirements in relation to fraud and abuse regulations. Michael spent more than seven years as Chief Deputy General Counsel and then General Counsel of the Bureau of TennCare, the Tennessee Medicaid program. Before that, he prosecuted civil healthcare fraud cases for more than a decade at the Tennessee Attorney General's Office.

A.J. BOLAN

A.J. Bolan represents clients in response to government actions, investigations and other litigation related to claims brought under various federal and state regulations. In addition, A.J. regularly counsels healthcare companies on healthcare fraud and abuse matters related to alleged violations under the False Claims Act, Anti-Kickback Statute, the Stark Law, and Medicare and Medicaid reimbursement rules.

NATHAN F. BROWN

Nathan Brown focuses his practice on representing clients in investigations and related litigation, and government actions, particularly involving the False Claims Act, Anti-Kickback Statute and Stark Law. In addition, Nathan assists corporate clients with internal compliance assessments and internal investigations regarding regulatory compliance matters.

GARRAH CARTER-MASON

Garrah Carter-Mason represents clients in complex business litigation and government investigations. She recently completed a clerkship with the Honorable Judge Eli J. Richardson of the U.S. District Court for the Middle District of Tennessee.

HANNAH CHOATE

Hannah Choate advises clients related to government enforcement and internal investigations. Hannah works with clients to respond to allegations of healthcare fraud and abuse from various regulators, including HHS-OIG, DOJ, and various U.S. Attorneys' Offices. Hannah draws on her experience as a former Assistant United States Attorney where she focused on Affirmative Civil Enforcement matters and managed a caseload of civil fraud matters.

DANIELLE DUDDING IRVINE

Danielle Dudding Irvine defends healthcare providers and pharmaceutical companies in connection with alleged violations of the FCA, AKS, and other healthcare statutes. She also counsels clients in connection with internal compliance investigations.

BRIAN IRVING

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.

SHEANIVA H. MURRAY

Sheaniva Murray represents clients in response to government actions, investigations, and other litigation related to claims brought under various federal and state regulations. In addition, Sheaniva regularly counsels healthcare companies on healthcare fraud and abuse matters related to alleged violations under the FCA, AKS, Stark Law, and Medicare and Medicaid reimbursement rules.

JACQUELYN PAPISH

Jacquelyn Papish represents healthcare clients in a range of high-stakes litigation matters. She also defends clients against government investigations involving compliance with the FCA and AKS.

BRIANNA R. POWELL

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, FCA, and EMTALA. Additionally, Brianna assists clients in conducting internal investigations and responding to and appealing commercial and government payor audits.

TAYLOR M. SAMPLE

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.

PAGE MINTON SMITH

Page Minton Smith provides healthcare regulatory counsel as it relates to compliance, operational, fraud and abuse, and transactional matters. She also assists clients with internal investigations and in responding to potential legal and regulatory violations and government investigations.

BRIANA SPRICK SCHUSTER

Briana Sprick Schuster concentrates her practice on complex litigation matters, helping healthcare companies achieve cost-effective, creative, and favorable resolutions no matter how challenging the dispute. Briana also counsels clients in their contract and business negotiations to help them avoid costly future disputes, advising clients related to breach of contract, fraud, misrepresentation, interference with business relations, and other business torts.

HANNAH E. WEBBER

Hannah Webber represents hospitals and other healthcare providers in connection with government enforcement actions, investigations, and related litigation. She routinely counsels clients in compliance matters, FCA litigation, and responses to state and federal government inquiries. She has experience representing providers in the not-for-profit and academic medicine spaces.

ABBY YI

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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