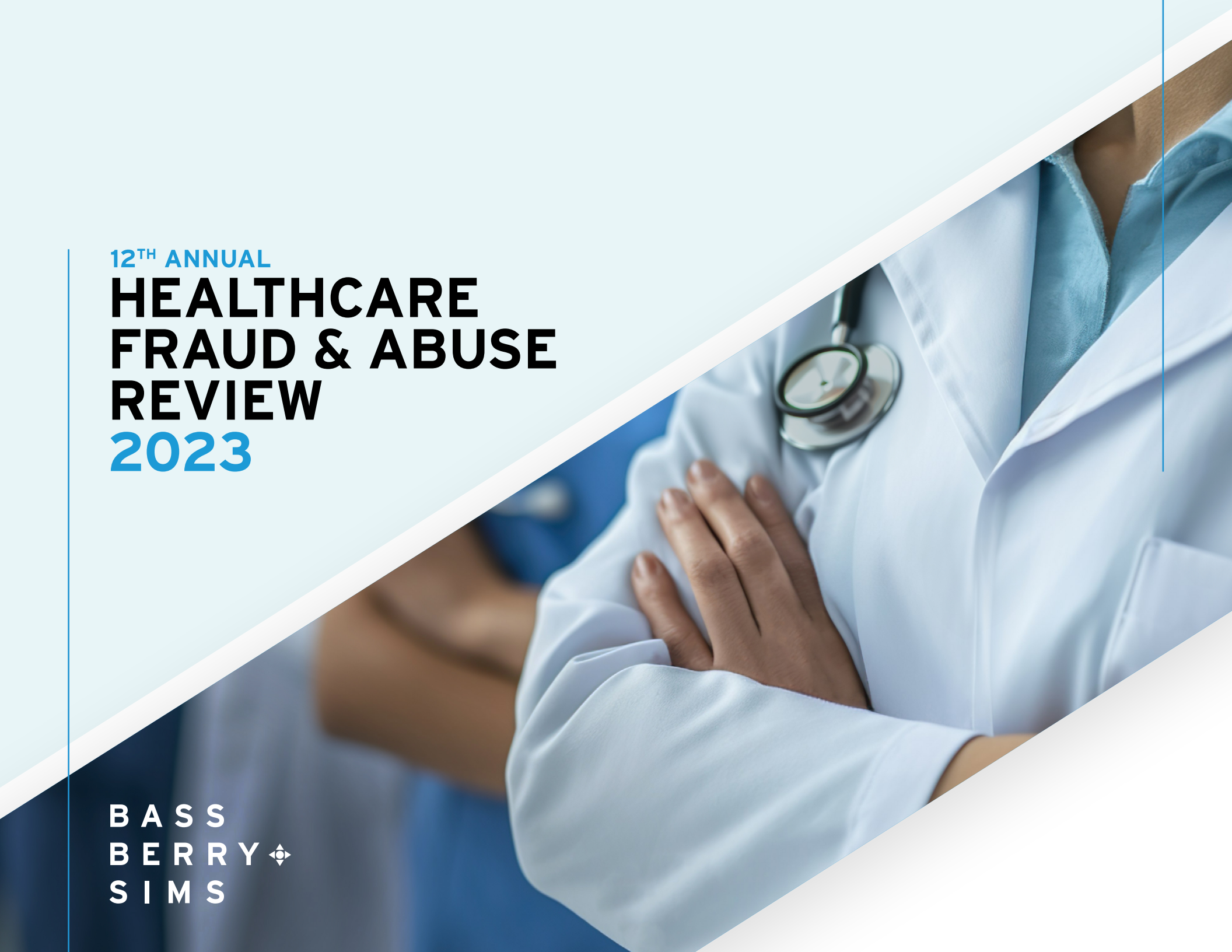
12TH ANNUAL

HEALTHCARE FRAUD & ABUSE REVIEW 2023



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A LOOK BACK … A LOOK AHEAD

We are pleased to bring you our 12th annual Healthcare Fraud & Abuse Review. Our Review provides comprehensive coverage of the most significant civil and criminal enforcement issues facing healthcare providers. Each year, we endeavor to cover key enforcement initiatives, analyze important case developments and document healthcare fraud settlements across the industry and present those topics in a readily digestible format for our readers.

The filing of *qui tam* lawsuits under the False Claims Act (FCA) involving healthcare providers remained the driving force behind the government's civil enforcement efforts. Over the last 10 years, more than 6,600 FCA *qui tam* lawsuits have been filed by relators and 712 of those lawsuits were filed in the preceding year.[1] For their efforts, *qui tam* relators have recovered more than $4.5 billion in relator share awards during the last decade, amassing more than $349 million in 2023. Civil enforcement actions initiated by the U.S. Department of Justice (DOJ) significantly increased as well, with 500 such lawsuits filed last year.

To no one's surprise, DOJ continued to aggressively pursue criminal enforcement efforts involving the healthcare industry. Traditional fraud schemes involving telemedicine, clinical labs and durable medical equipment (DME) remained a top priority, with DOJ announcing its annual healthcare fraud enforcement action in June 2023 involving more than $2.5 billion in intended fraud loss and 78 defendants charged across 15 federal judicial districts.[2] The takedown continued the approach from prior years by focusing in significant part on telemedicine fraud, including charges against 11 defendants in connection with the submission of over $2 billion in fraudulent claims resulting from telemedicine schemes.

Criminal enforcement efforts involving COVID-19 relief funds and related fraud schemes also remained a key focus on the part of the government. In April 2023, DOJ announced a COVID-19 healthcare fraud criminal takedown of over $490 million in COVID-19-related false

1 https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023.

2 https://www.justice.gov/opa/pr/national-enforcement-action-results-78-individuals-charged-25b-health-care-fraud.

billings and 18 defendants charged across nine federal judicial districts.[3] This takedown, built on the success of previous COVID-19 enforcement actions, more than tripled the fraud amount at issue compared to the prior year's takedown. DOJ identified fraud schemes concerning the Health Resources and Services Administration (HRSA) COVID-19 Uninsured Program (UIP) as one of the most significant schemes at issue in the takedown. Those schemes included a lab owner charged for allegedly submitting over $358 million in false and fraudulent claims to Medicare, HRSA and a private insurance company for laboratory testing involving COVID-19 screening testing for nursing homes and other facilities with vulnerable elderly populations. To increase reimbursements, the lab owner added claims for unnecessary respiratory pathogen panel tests. These enforcement efforts will undoubtedly continue in the future.

In 2023, the FCA landscape was dominated by two Supreme Court opinions that considered the FCA's scienter requirement and the government's FCA dismissal authority. Given the importance of these issues, these cases warrant significant attention. But they were not the only key FCA legal issues considered by courts last year. At the appellate level, an important circuit split has deepened concerning the requirements for pleading and proving FCA claims based on alleged violations of the Anti-Kickback Statute (AKS). With the AKS recently celebrating its 50th anniversary, we expect that FCA cases alleging AKS violations will remain a top point of focus for healthcare providers, relators and the government.

As has been the case for the last decade, healthcare providers will continue to face heightened enforcement scrutiny and the risk of *qui tam* lawsuits in the coming year. We trust that our firm's annual **Healthcare Fraud & Abuse Review** will assist healthcare providers in better anticipating those challenges and understanding how best to navigate them in an ever-changing world.

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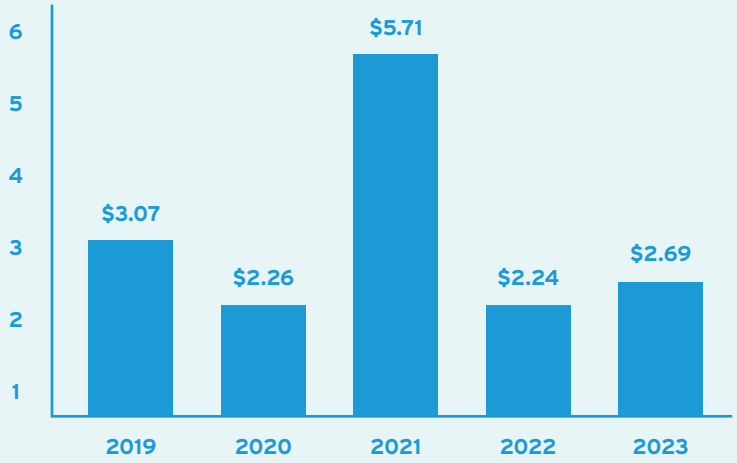
CIVIL FRAUD RECOVERIES

FY 2019-2023 ($BILLIONS)



3 https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-covid-19.

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.

THE FUTURE OF THE FALSE CLAIMS ACT

Last year, we previewed key cases in which the Supreme Court had decided to grant certiorari involving interpretation of the FCA's scienter element, as well as the government's dismissal authority under the FCA over the objection of a *qui tam* relator. Considering the small number of FCA opinions by the Supreme Court over the last decade, the Court's decision to weigh in on two separate FCA issues was truly noteworthy. It certainly will be worth watching how lower courts deal with the implications of these important Supreme Court decisions.

The FCA's Scienter Element

To establish an FCA violation, the plaintiff must prove that the defendant acted with the requisite scienter, which the statute defines as actual knowledge, deliberate ignorance or reckless disregard. In recent years, a key development regarding the FCA's scienter element has been the application of the objective intent standard taken from the Supreme Court's opinion in ***Safeco Ins. Co. v. Burr***, a case involving the Fair Credit Reporting Act (FCRA). Under the standard articulated in *Safeco*, a defendant facing FCRA liability could not be found to have acted "knowingly" if: (1) its interpretation of the relevant statute or regulation was "objectively reasonable" (even if ultimately mistaken); and (2) no "authoritative guidance" warned the defendant away from that interpretation.[4]

Since the Supreme Court's opinion in *Safeco*, courts increasingly applied that standard in FCA cases, holding that a relator or the government could not satisfy the FCA's scienter element if the defendant's interpretation of an ambiguous statute or regulation was objectively reasonable and the defendant had not been sufficiently warned away from that interpretation. The most important case to address that particular issue had been ***U.S. ex rel. Schutte v. SuperValu Inc.***, where a divided Seventh Circuit panel held that the *Safeco* objective reasonableness standard applied to FCA claims.[5]

In a unanimous opinion announced near the end of 2023's term, the Supreme Court reversed the Seventh Circuit's opinion in *Schutte* and held that *Safeco's* holding was "tied to the FCRA's particular text" and has no application to the FCA's definition of knowledge.[6] Instead,

4 551 U.S. 47, 69-70 & n.20 (2007).
5 9 F.4th 455 (7th Cir. 2021).
6 598 U.S. 739 (2023).

In a unanimous opinion announced near the end of 2023's term, the Supreme Court reversed the Seventh Circuit's opinion in *Schutte* and held that *Safeco*'s holding was "tied to the FCRA's particular text" and has no application to the FCA's definition of knowledge.

the Supreme Court looked to the language of the FCA and its roots in common law fraud and reasoned that all three scienter terms under the FCA — actual knowledge, deliberate ignorance and reckless disregard — "focus primarily on what [defendants] thought and believed." The key question being "what the defendant thought when submitting the false claim."

The Supreme Court allowed for the possibility that a defendant might make a "forgivable mistake" by "honestly read[ing]" the applicable law to permit its conduct, in which case there would not be FCA liability. But, if the defendant subjectively had actual knowledge, deliberate ignorance or reckless disregard that its claims were false when it submitted them, then "it does not matter whether some other, objectively reasonable interpretation of" the statute would have permitted the defendant's conduct. Put differently, the facial ambiguity of a statute or regulation "alone is not sufficient to preclude a finding that" a defendant knew its claims were false. As a result, defendants facing FCA liability may no longer avail themselves of the so-called *Safeco* defense as it relates to the FCA's scienter element.

The Government's FCA Dismissal Authority

The FCA has long provided the government the authority to dismiss a *qui tam* lawsuit over a relator's objection. The statute specifically states that "[t]he Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."[7] Of course, that makes sense given that *qui tam* lawsuits are brought by a relator on behalf of the government and the government remains the real party in interest.

Lower courts have disagreed about the standard that the government must meet to secure dismissal, a question that the FCA itself does not address. Some courts, such as the D.C. Circuit, had held that the government possesses an "unfettered right" to dismiss FCA actions, which is not subject to any second-guessing by the court. Other courts, such as the Ninth Circuit, had held that government motions to dismiss were subject to a form of rational basis review, which required the government to show a "rational relation" between the dismissal of the FCA action and a "valid government purpose."

In ***U.S. ex rel. Polansky v. Executive Health Resources***, the Supreme Court directly considered the government's power to dismiss a *qui tam* lawsuit filed by a relator under the FCA over a relator's objection.[8] *Polansky* involved allegations that the defendant had defrauded Medicare by assisting hospitals with charging inpatient rates for what should have been outpatient services. The government originally declined to intervene but then moved to dismiss the action years later, citing burdensome discovery obligations and its skepticism about the merits of the relator's claims. The district court granted the motion, reasoning that the government's rationale met even the nominally more stringent "rational relation" test applied by the Ninth Circuit.

The Third Circuit then affirmed, but on slightly different reasoning. It first held that the government must intervene in the action for "good cause" before exercising its dismissal power. But, the Third Circuit deemed the government's motion to dismiss to include a request to intervene and determined that the government's desire to dismiss the action was itself good cause for intervention. The Third Circuit then held that the government's motion to dismiss should be governed by Rule 41(a), the federal rule that ordinarily applies to voluntary motions to dismiss and which requires a justification that "the court considers proper" when a dismissal request comes after an answer has been filed. The Third Circuit then found that the government's reasons for requesting dismissal in *Polansky* were properly based on the litigation costs the government would have faced had the case continued, potential misconduct by the relator and the action's "doubtful" prospects for success.

The Supreme Court's 8-1 decision in *Polansky* affirmed the Third Circuit "across the board." The Court first confirmed that the government must intervene in an FCA action before it may move to dismiss over a relator's objection. Relying on the statutory structure and language, the Court held that the statutory provision authorizing the government to move to dismiss "presuppose[s] that the Government has in fact intervened." As a result, the government cannot move to dismiss, the Court reasoned, if it had not first intervened. At the same time, the Court rejected the relator's argument — not previously endorsed by any court — that the government can move to dismiss *only* if it intervenes at the first available opportunity, when the case remains under seal.

The Court reasoned that later intervention, which the FCA makes available when the government establishes "good cause," provides the government the same rights as when it intervenes earlier, including the right to move to dismiss. The government's interests in dismissing a case do not necessarily "diminish in importance because the Government waited to intervene," and thus the government need not "take a back seat" to the relator in directing the litigation in that scenario. Although the Court did not directly address what the government must show to establish "good cause" for later intervention, it observed in a footnote that the Third Circuit had found that the government's desire to dismiss itself amounted to good cause and that the relator had not challenged that conclusion in the Supreme Court.

7 31 U.S.C. § 3730(c)(2)(A).

8 599 U.S. 419 (2023).

> **Not surprisingly, defendants facing potential FCA liability have seized on Justice Thomas's dissent and have sought dismissal of *qui tam* lawsuits on that basis – but largely without success.**

Finally, the Court concluded that government motions to dismiss FCA actions are governed by the ordinary operation of Rule 41(a), subject to the FCA's requirement that the relator receive notice of the motion and an opportunity for a hearing.

Under Rule 41(a), if the defendant has already filed an answer and all parties have not stipulated to dismissal, the district court may dismiss the action at the plaintiff's request only by court order and "on terms that the court considers proper." Although the "proper terms" analysis usually focuses on the defendant's interests, the Supreme Court explained in *Polansky* that the analysis in an FCA case must also account for the relator's interests – including the reality that most relators will "want their actions to go forward, and many have by then committed substantial resources." Even so, however, the Court explained that government motions to dismiss FCA actions "will satisfy Rule 41 in all but the most exceptional cases."

Indeed, the Supreme Court emphasized that "the Government's views are entitled to substantial deference" because *qui tam* lawsuits are brought on the government's behalf to vindicate injuries to the government. As such, "[i]f the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion" – even if the relator "presents a credible assessment to the contrary."

Applying those principles in *Polansky*, the Supreme Court concluded that the case before it was "not a close call." The government had identified burdens and costs associated with future discovery and explained why the action was likely to fail on the merits, which were together more than "proper terms" for dismissal. In fact, the Court noted that the kinds of grounds the government offered in *Polansky* would almost always be sufficient to support dismissal "[a]bsent some extraordinary circumstance."

The Constitutionality of the FCA's *Qui Tam* Provision

The story in *Polansky*, however, did not end with the majority opinion. Justice Thomas dissented to address what he called "serious constitutional questions" about the FCA's *qui tam* provisions. Justice Thomas noted that the "*qui tam* provisions have long inhabited something of a constitutional twilight zone," while observing that "[t]here are substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation." Justice Thomas's dissent did not attempt to resolve those arguments, but did suggest that they may be appropriate for the Court to address in a later case.

Notably, Justice Thomas was not alone in this view. Justice Kavanaugh, joined by Justice Barrett, wrote that he "agree[d] with Justice Thomas" that *qui tam* actions raise "substantial" Article II questions and suggested that "the Court should consider the competing arguments … in an appropriate case."

Not surprisingly, defendants facing potential FCA liability have seized on Justice Thomas's dissent and have sought dismissal of *qui tam* lawsuits on that basis – but largely without success. In ***U.S. ex rel. Wallace v. Exactech, Inc.***, the district court denied the defendant's motion to dismiss and for judgment on the pleadings, which was filed after multiple years of proceedings.[9] First, the district court determined that the FCA's *qui tam* provision does not violate the Appointments Clause of Article II of the Constitution, which gives the president the power to nominate with Senate approval "all other offices of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by law." The district court explained that a *qui tam* relator is not an "officer" because the relator's duties are temporary and not continuous and the relator does not wield governmental power. Second, the district court concluded that the FCA's *qui tam* provision does not violate the "Take Care Clause" of Article II of the Constitution, which directs the president to "take Care that the Laws be faithfully executed." The district court noted that the executive branch maintains sufficient control over a *qui tam* relator with the ability to intervene or move to dismiss the action resulting in a situation in which relators proceed with a level of oversight that a normal civil litigant does not. When considered in light of the historical evidence that the Constitution's drafters intended for the Constitution to interact with *qui tam* statutes, the district court concluded that the FCA's *qui tam* provisions were constitutional.[10]

Without question, defendants involved in FCA *qui tam* litigation will continue to press the argument that the FCA's *qui tam* provisions implicate constitutional concerns. With at least three Supreme Court Justices seemingly willing to consider such an issue if it ever were to make it before the Court for review, there seems little for defendants to lose in pressing forward on this issue.

THE FUTURE OF THE ANTI-KICKBACK STATUTE

AKS's Causation Element

In recent years, the link between an AKS violation and FCA liability has been put to the test, resulting in a growing circuit split. Under the 2010 amendments to the AKS, a claim for items or services "resulting from" an AKS violation automatically "constitutes a false or fraudulent claim for purposes of [the FCA.]" But what is required to prove that a claim "resulted from" an AKS violation continues to divide courts.

9 2023 WL 8027309 (N.D. Ala. Nov. 20, 2023).

10 Numerous other district courts have likewise rejected constitutional challenges to the FCA's *qui tam* provision. *See, e.g.*, *U.S. ex rel. Thomas v. Mercy Care*, 2023 WL 7413669 (D. Ariz. Nov. 9, 2023) (citing Ninth Circuit precedent affirming the constitutionality of the FCA's *qui tam* provision); *U.S. ex rel. Miller v. ManPow, LLC*, 2023 WL 8290402 (C.D. Cal. Aug. 30, 2023) (rejecting constitutional challenges to the FCA's *qui tam* provision).

As discussed in last year's review, the Eighth Circuit's decision in ***U.S. ex rel. Cairns v. D.S. Medical LLC***, requiring a plaintiff to establish "but-for" causation to prove that a false claim "resulted from" an AKS violation, split from the Third Circuit's prior decision in ***U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.***, which required only some "link" between the claim for payment and the AKS violation.[11]

The Sixth Circuit has since weighed in, issuing its opinion in ***U.S. ex rel. Martin v. Hathaway*** and agreeing with the Eighth Circuit that "the ordinary meaning of 'resulting from' is but-for causation" and cautioning that under a lesser standard "much of the workaday practice of medicine" could be considered an AKS violation.[12] The First Circuit is also poised to take up the issue after two district courts within the First Circuit reached conflicting conclusions. In July, the district court in ***United States v. Teva Pharmaceuticals USA, Inc.***, relied on the Third Circuit's ***Greenfield*** decision to hold that the government need only establish a "sufficient causal connection" less than the strict "but-for" standard adopted by other courts.[13] Later in the year, however, the district court in ***United States v. Regeneron Pharmaceuticals, Inc.***, held that the "resulting from" language does require "but-for" causation, finding *Greenfield* to be "fraught with problems."[14] While the Supreme Court denied a petition for certiorari in *Martin*, the continued divergence among courts may soon require the Supreme Court to weigh in on this issue.

AKS's Intent Element

In another key AKS development, the Supreme Court denied Pfizer's petition for writ of certiorari in ***Pfizer Inc. v. U.S. Dept. Health & Hum Servs***.[15] Pfizer argued, first at the administrative level and ultimately to the Second Circuit, that its program for providing co-payment assistance to Medicare beneficiaries did not violate the AKS because it was not administered with "corrupt" intent, nor did it constitute "improper influence" on physicians' or patients' decision-making. The Second Circuit agreed with the government that neither a "corrupt" intent nor an attempt to exert "improper" influence were necessary elements under a straightforward reading of the AKS, which requires only that a defendant willfully offer remuneration to induce the purchase of their drug. Although the Supreme Court denied certiorari in that case, a similar challenge was raised in ***Pharmaceutical Coalition for Patient Access v. U.S. Dept. Health & Hum Servs***.[16] Like Pfizer, PCPA challenged the government's application of the AKS, asserting that the phrase "to induce" within the AKS requires both a *quid pro quo* exchange and an element of corruption. Early in 2024, the district court rejected PCPA's reading of the AKS and granted the government's motion to dismiss for lack of subject matter jurisdiction and its motion for summary judgment. The district court concluded that the government's interpretation of the AKS "adheres faithfully [to] the statute's plain text, comports with its context, and does not offend its history."[17]

11 *Cairns*, 42 F.4th 828 (8th Cir. 2022); *Greenfield*, 880 F.3d 89 (3d Cir. 2018).
12 63 F.4th 1043 (6th Cir. 2023).
13 2023 WL 4565105 (D. Mass. July 14, 2023).
14 2023 WL 7016900 (D. Mass. Oct. 25, 2023).
15 *Pfizer v. U.S. Dept. Health & Hum Servs.*, No. 22-339 (Jan. 9, 2023).
16 *Pharmaceutical Coalition for Patient Access v. U.S. Dept. Health & Hum Servs.*, No. 22-cv-00714 (E.D. Va.).
17 2024 WL 187707 (E.D. Va. Jan. 17, 2024).

PROVIDER RELIEF ENFORCEMENT EFFORTS

The government has continued to emphasize oversight and enforcement connected to pandemic-related provider relief funds. Following the appointment of a Director for COVID-19 Fraud Enforcement and the establishment of multiple DOJ Strike Force teams throughout the country, enforcement actions against healthcare providers have ramped up considerably. Deputy Assistant Attorney General Lisa H. Miller emphasized in remarks that pandemic fraud remains a high priority for DOJ, highlighting DOJ's "whole of government approach to identifying, investigating, and prosecuting COVID-19 related health care fraud."[18]

In connection with its National COVID-19 Health Care Fraud Enforcement Action, DOJ announced criminal charges against 18 defendants in nine districts for alleged participation in fraud schemes involving healthcare services that resulted in over $490 million in COVID-19-related false billings to federal programs and theft from federally funded pandemic programs.[19] These actions included charges against defendants who allegedly defrauded the HRSA COVID-19 UIP. For example, DOJ charged the owner of a COVID-19 testing lab in California for allegedly submitting over $358 million in false and fraudulent claims to Medicare, HRSA and a private insurance company for laboratory testing. The government alleged that, when billing for COVID-19 testing, the lab falsely submitted claims for additional respiratory pathogen panel tests even though ordering providers and facility administrators did not want or need the tests. DOJ's announcement also included charges against a California doctor who allegedly submitted fraudulent claims to the HRSA UIP, billed for services that were not rendered and billed for services that were not medically necessary. That doctor and two other individuals were also charged for allegedly submitting more than 70 fraudulent loan applications through the Paycheck Protection Program (PPP) and Economic Injury Disaster Loan (EIDL) Program.

FCA actions associated with provider relief, PPP loans and other COVID-19 relief programs have become more prevalent. Four California companies and their owner agreed to pay $600,000 to settle FCA allegations related to improperly inflating PPP applications.[20] The government alleged that the companies improperly inflated the employee headcount on the companies' PPP loan applications by impermissibly including non-employee contract workers who were, in fact, employed by other, unrelated entities. In another matter, two Florida companies agreed to pay $325,000 to resolve FCA allegations that they provided false information in support of a PPP loan forgiveness application when one of the businesses certified it had paid wages to employees who were actually employed by the other company.[21] An automotive management company agreed to pay $9 million to resolve FCA allegations that it provided false information in support of a PPP loan forgiveness application when it certified that it was a small business

18 https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-lisa-h-miller-delivers-remarks-american-bar-association.
19 https://www.justice.gov/usao-cdca/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat.
20 https://www.justice.gov/opa/pr/california-agricultural-companies-and-their-owner-agree-pay-600000-settle-false-claims-act-0.
21 https://www.justice.gov/opa/pr/florida-resorts-agree-pay-325000-settle-false-claims-act-allegations-relating-false.

The CSA applies to every actor in the controlled substances supply chain, including manufacturers, distributors, pharmacies and practitioners.

with fewer than 50 employees.[22] In fact, the company shared common operational control with dozens of entities across the country with more than 3,000 employees in total, making the company not eligible for the PPP loan that was forgiven.

The pursuit of provider relief-related fraud remains an enforcement priority for DOJ. We have seen early enforcement actions tend to focus on outlier individual providers and practices, but we expect to see increasing numbers of actions against larger providers and organizations as the government's investigations and enforcement activities continue and grow in sophistication.

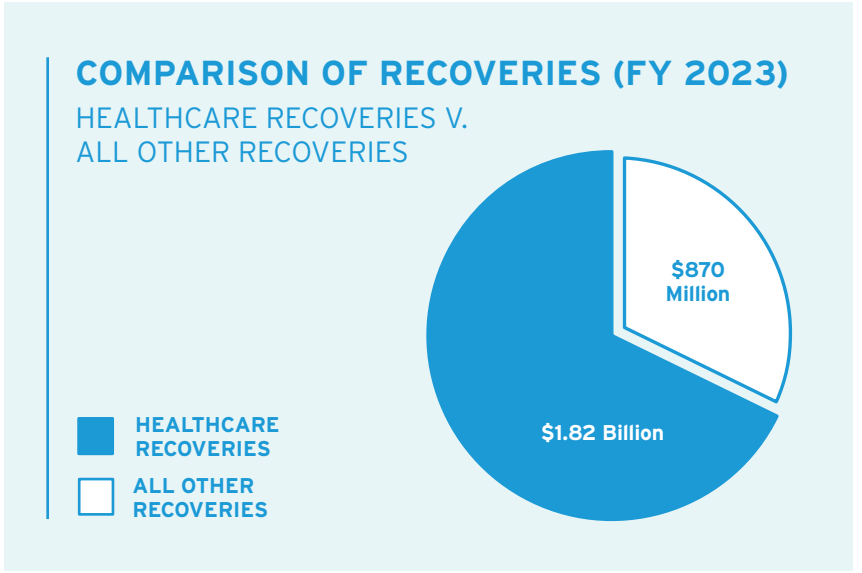
CONTROLLED SUBSTANCES ACT & DRUG DIVERSION

Over the past few years, we have seen a paradigm shift in government enforcement under the Controlled Substances Act (CSA). Although the CSA was enacted over 50 years ago, it did not historically present significant enforcement risk for Drug Enforcement Administration (DEA) registrants like pharmacies and health systems. Often when an individual diverted controlled substances for illicit use, the government partnered with the registrant to prosecute the bad actor. That dynamic has changed.

The CSA establishes a "closed regulatory system making it unlawful to manufacture, distribute, dispense or possess any controlled substance except in a manner authorized by the CSA."[23] The CSA applies to every actor in the controlled substances supply chain, including manufacturers, distributors, pharmacies and practitioners. The CSA and its implementing regulations focus on: (1) maintaining complete and accurate records of all controlled substances transactions; (2) mandatory reporting to the government of all transfers of controlled substances and any theft or significant loss of controlled substances; and (3) ensuring adequate security measures to prevent theft and diversion of controlled substances from their lawful, intended use. When the government discovers CSA compliance issues or diversion, it now demands to know *how* these issues occurred and seeks to hold DEA registrants accountable for alleged violations at their facilities and shortcomings in their controls.

22 https://www.justice.gov/opa/pr/victory-automotive-group-inc-agrees-pay-9-million-settle-false-claims-act-allegations.

23 *Gonzales v. Raich*, 545 U.S. 1, 13 (2005).



Significant Enforcement Results

Continuing a recent trend, the government announced several multi-million dollar settlements with companies alleged to have violated the CSA. These settlements were obtained under the CSA's criminal and civil penalty provisions. The examples discussed in this section are merely exemplary and not exhaustive of the government's enforcement efforts, but they demonstrate that the government is scrutinizing entities throughout the controlled substances supply chain.

In March 2023, People's Pharmacy, Inc. in Colorado agreed to a $3.5 million civil penalty and to forfeit its DEA registration to resolve allegations that it ignored red flags while filling prescriptions for opioids and other drug combinations, which allegedly facilitated the unlawful diversion of those drugs into the community.[24]

In June 2023, Cheshire Medical Center paid $2 million and undertook significant voluntary improvements to resolve allegations that it failed to maintain accurate controlled substances records, including for opioids. The government learned of these issues when Cheshire Medical Center reported that a nurse had stolen fentanyl bags from an automatic dispensing machine. Further audits by Cheshire Medical Center and DEA revealed that the facility was unable to account for hundreds of bags of fentanyl and nearly 18,000 units of other controlled substances. The government also alleged that Cheshire Medical Center failed to regularly review reports to identify possible diversion and to take other steps to prevent and detect diversion.[25]

24 https://www.dea.gov/press-releases/2023/03/27/colorado-pharmacy-and-pharmacist-agree-resolve-allegations-they.

25 https://www.justice.gov/usao-nh/pr/cheshire-medical-center-pay-2-million-settle-allegations-controlled-substances-act.

In August 2023, Clarest LLC, a pharmacy chain that serves long-term care, skilled nursing, assisted living, and rehab facilities in Connecticut and Rhode Island, paid $499,525 and entered into a three-year corrective action plan to settle allegations that it violated the CSA. The government alleged that Clarest distributed controlled substances to unregistered practitioners when it left medications in long-term care facilities' "emergency boxes" and failed to provide all required information on DEA Form 222s (controlled substances order forms).[26]

CSA and FCA Collide

Possible CSA violations may provide an avenue for expanded theories of FCA liability. In 2023, the government intervened in FCA litigation alleging that the defendant defrauded federal healthcare programs by seeking reimbursement for opioids the pharmacy allegedly dispensed, in violation of the CSA. In its complaint, the government alleged that over a five-year period Rite Aid ignored red flags and filled controlled substance prescriptions involving: (1) the combination of an opioid, a benzodiazepine and a muscle relaxant; (2) early fills of fentanyl and oxycodone; and (3) prescriptions from prescribers Rite Aid flagged internally for writing prescriptions with no medically valid purpose.[27] The government contended that in filling these prescriptions, Rite Aid's pharmacists failed to satisfy their corresponding responsibility to ensure the proper dispensing of controlled substances. Because of these alleged CSA violations, the government claimed that Rite Aid falsely certified to federal healthcare programs that the prescriptions it dispensed were valid and that in dispensing the medications it had complied with federal and state law.

Following government intervention and the filing of a motion to dismiss, Rite Aid filed for bankruptcy while its motion to dismiss was pending. As a result, the district court stayed the lawsuit and has not yet ruled on the sufficiency of the government's complaint. But the government's decision to pursue action against Rite Aid raises the question of whether providers can expect to see more FCA lawsuits based on alleged violations of the CSA.

> **Possible CSA violations may provide an avenue for expanded theories of FCA liability.**

26 https://www.justice.gov/usao-ct/pr/health-care-company-and-cheshire-pharmacy-pay-500k-resolve-controlled-substances-act.
27 *U.S. ex rel. White v. Rite Aid Corp.*, No. 1:21-cv-01239 (N.D. Ohio).

COMPLIANCE GUIDANCE

DOJ's Criminal Division continued its recent trend of updating its compliance guidance as set forth in its **Evaluation of Corporate Compliance Programs**.[28] As a refresher, DOJ's June 2020 updated guidance set out the framework on which DOJ has been building ever since. By this point, most healthcare providers should be familiar with the government's expectations as outlined in this guidance. In broad terms, the guidance identifies three fundamental questions regarding corporate compliance programs:

1. Is the compliance program well designed?
2. Is the program applied earnestly and in good faith as evidenced by the fact that it is adequately resourced and empowered to function effectively?
3. Does the compliance program work in practice?

The guidance then proceeds to set forth considerations for prosecutors in evaluating these questions, which healthcare providers can use to evaluate their own compliance programs.

The March 2023 guidance published by DOJ's Criminal Division included a number of additional considerations of which healthcare providers should take note. One of the key components of the guidance involves an evaluation of compensation structures and consequence management. This involves an expectation of transparent communication regarding disciplinary processes and actions, as well as tracking data on disciplinary actions to monitor the effectiveness of compliance programs. The guidance also indicates that companies should consider incentivizing compliance by designing systems that defer compensation tied to standards of conduct combined with efforts to recoup compensation previously awarded to individuals who are deemed to be responsible for corporate wrongdoing.

The government also increasingly expects that companies with robust compliance programs will have effective policies addressing the use of personal devices and third-party messaging platforms. This includes a thorough understanding of the types of communication channels used by company personnel and whether the company has appropriate policies and procedures governing the use of communication platforms and channels. The government has indicated that a company's failure to produce such communications in the context of an investigation may result in an unfavorable resolution for the company.

Finally, the government will consider whether a corporation uses or has used non-disclosure or non-disparagement provisions in compensation agreements, severance agreements or other financial arrangements to inhibit the public disclosure of criminal misconduct by the corporation or its employees.

For its part, the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG) released its own **General Compliance Program Guidance** "as a reference guide for the health care compliance community and other health care stakeholders."[29] Previously published in the Federal Register as compliance program guidance, HHS-OIG announced that current, updated and new compliance program guidance will be maintained on its website

28 https://www.justice.gov/criminal-fraud/page/file/937501/download.
29 https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf.

> **The compliance guidance documents published by both DOJ and HHS-OIG are key references for any healthcare provider. Healthcare providers certainly should expect that the government will take the position that providers are on notice of the government's expectations when it comes to matters of compliance.**

with interactive links to resources. Beginning in 2024, HHS-OIG will publish industry-specific guidance for different types of providers, suppliers and others in the healthcare industry tailored to industry-specific fraud and abuse risk areas and will identify compliance measures that can be taken to reduce such risks.

The compliance guidance documents published by both DOJ and HHS-OIG are key references for any healthcare provider. Healthcare providers certainly should expect that the government will take the position that providers are on notice of the government's expectations when it comes to matters of compliance.

CYBERSECURITY

Two years ago, DOJ launched its **Civil Cyber Fraud Initiative** (CCFI) with a stated goal of holding entities accountable for knowingly misrepresenting cybersecurity practices or knowingly violating obligations to monitor and report cyber incidents to the federal government.

Since that time, the government's enforcement efforts under the CCFI have begun to emerge. Late last year, Verizon agreed to pay $4 million to resolve FCA allegations that it failed to satisfy its contractual cybersecurity obligations in connection with secured network technologies provided to federal agencies.[30] While this conduct may have been viewed previously through the lens of a contractual obligation, that was not the case under the CCFI, and Verizon's failures to satisfy certain security obligations resulted in significant FCA liability.

Healthcare providers should expect to see increased enforcement in this area moving forward. In July 2023, the White House published its **National Cybersecurity Strategy Implementation Plan**, which included an initiative to "Leverage the False Claims Act to improve vendor cybersecurity" under which DOJ will "expand efforts to identify, pursue, and deter knowing failures to comply with cybersecurity requirements in Federal contracts and grants."[31] Later in the year, the Federal Acquisition Regulatory Council proposed new regulations expressly intended to "underscore that compliance with information-sharing and incident-reporting requirements are material to eligibility and payment under Government contracts."[32]

As it relates to the healthcare industry in particular, the **Notice of Proposed Rulemaking for the Cyber Incident Reporting for Critical Infrastructure Act** (CIRCIA) is set for publication in early 2024.[33] Under the CIRCIA, HHS will serve as the designated "Sector Risk Management Agency" for the "Healthcare and Public Health (HPH) Sector," which was identified as one of 16 critical infrastructure sectors covered by CIRCIA. Under CIRCIA, healthcare entities will have new cybersecurity and reporting obligations. If treated similarly to other federal security and reporting obligations, knowing failures to satisfy CIRCIA's requirements could likewise lead to FCA exposure.

30 https://www.justice.gov/opa/pr/cooperating-federal-contractor-resolves-liability-alleged-false-claims-caused-failure-fully.

31 https://www.whitehouse.gov/wp-content/uploads/2023/07/National-Cybersecurity-Strategy-Implementation-Plan-WH.gov_.pdf.

32 https://www.federalregister.gov/documents/2023/10/03/2023-21328/federal-acquisition-regulation-cyber-threat-and-incident-reporting-and-information-sharing.

33 https://www.federalregister.gov/documents/2022/09/12/2022-19550/cyber-incident-reporting-for-critical-infrastructure-act-of-2022-listening-sessions.

NOTEWORTHY SETTLEMENTS

As in recent years, resolutions in healthcare fraud cases accounted for the vast majority of all FCA recoveries in FY 2023. Of the $2.69 billion total in settlements and judgments, recoveries from matters involving the healthcare industry amounted to $1.82 billion (68%). This is the 15th consecutive year that recoveries in federal civil healthcare fraud matters have exceeded $1.5 billion.

Newly filed *qui tam* complaints accounted for the majority of the new civil fraud matters initiated in FY 2023, in line with past years, although the number of government-initiated and data-driven FCA actions continues to rise. Whistleblowers filed 712 *qui tam* lawsuits in FY 2023 and recoveries from these and earlier filed lawsuits accounted for $2.33 billion of the $2.69 billion recovered. Settlements associated with *qui tam* lawsuits where the government intervened or otherwise pursued the allegations comprised more than $1.89 billion of the recoveries from healthcare companies. The **Appendix** to our Healthcare Fraud & Abuse Review contains a detailed breakdown of key settlements from the past year, many of which are referenced within this section of the Review.

HOSPITALS & HEALTH SYSTEMS

Hospitals and health systems resolved a number of notable FCA cases, most of which related to alleged violations of the Stark Law and/or AKS. Financial relationships with physicians continued to account for a significant portion of the recoveries. Common themes in these cases included compensation in excess of fair market value (FMV), compensation structures that varied with referrals and the provision of services to physicians at reduced or no cost. In all, hospitals and health systems paid more than $500 million to resolve FCA allegations based on physician compensation arrangements that violated the Stark Law or AKS.

The largest hospital settlement was announced shortly before the end of the year. Community Health Network, Inc., a nonprofit health system based in Indianapolis, agreed to pay $345 million to resolve allegations that it paid above FMV compensation to a number of employed physicians and it awarded bonuses to physicians that were tied to their referrals, both in violation of the Stark Law, as part of a scheme to recruit physicians for the purpose of capturing their referrals.[34]

34 https://www.justice.gov/usao-sdin/pr/community-health-network-agrees-pay-345-million-settle-alleged-false-claims-act.

Hospitals and health systems also resolved several cases premised on medical necessity allegations, including claims related to the improper performance of "concurrent surgeries"[35] and claims related to the provision of "enhanced services" for Medicaid patients that were contractually not allowed, duplicative of other required services or did not reflect the FMV of the services provided.[36] Other notable hospital settlements involved allegations that urgent care services were billed at a higher rate of service than permitted[37] and that services were provided by unqualified and unlicensed individuals.[38]

LONG-TERM CARE

The majority of settlements in the home health, hospice and skilled nursing facility (SNF) sector involved allegations of medically unnecessary services and medically unnecessary admissions.[39] Those cases included a home health provider that billed for services that were not medically necessary and charged for more time than was actually spent with patients,[40] a hospice provider that billed for care that was not justified by the patients' medical records[41] and a rehabilitation hospital that falsely certified that patients met the applicable criteria for inpatient admission when they did not meet those criteria.[42]

We also saw an uptick in settlements resolving alleged AKS violations related to patient referrals. These arrangements included medical directorships and sublease agreements that constituted inducements for referrals,[43] payments by a nursing home to a supervisor at a local hospital that referred to the facility that were deemed to be in exchange for referrals[44] and the provision of extravagant gifts including golf trips and gift cards to physicians that were intended to induce referrals to the nursing facility.[45]

In the largest long-term care settlement of FY 2023, six nursing facilities, their management company and owner agreed to enter into a $45.6 million consent judgment to resolve allegations that they paid kickbacks to physicians to induce referrals to their facilities.[46] The facilities entered into medical directorship agreements with physicians who agreed in advance to refer a large number of patients to the facilities. The facilities then paid physicians in proportion to their expected referrals and terminated physicians who did not refer an adequate volume. In addition to the consent judgment, the companies entered into a five-year corporate integrity agreement (CIA) that requires an Independent Review Organization's review of their physician relationships.

As in recent years, many of the settlements involving the pharmaceutical and medical device industries involved allegations of AKS violations while others related to alleged violations of industry-specific program regulations.

Another of the year's largest settlements involved the operator of long-term care facilities, which agreed to pay more than $21.6 million to resolve allegations that it billed Medicare for claims that were provided by unqualified or unlicensed individuals, not supported by patients' medical records and not actually performed or performed inadequately.[47] The success of the government's worthless services theory of liability was likely attributable to the particularly egregious circumstances, including services billed as having been performed by physicians who were out of the country at the time and inadequate services that resulted in harm to patients.

PHARMACEUTICAL & DEVICE

As in recent years, many of the settlements involving the pharmaceutical and medical device industries involved allegations of AKS violations while others related to alleged violations of industry-specific program regulations.

Several significant settlements involved violations of specific program requirements. For example, a DME supplier agreed to pay $7 million to resolve allegations that it did not disclose all discounts it received or the actual cost it paid to DME manufacturers when submitting claims for manually priced DME items to Medicaid programs in three states.[48] Another DME provider agreed to pay $5.3 million to resolve allegations that it submitted false claims for non-invasive ventilators when patients were instead prescribed and used BiPAP machines, and continued to bill for equipment after patients no longer needed or were using them.[49] A third

35 https://www.justice.gov/usao-wdpa/pr/james-l-luketich-md-university-pittsburgh-medical-center-and-university-pittsburgh.
36 https://www.justice.gov/usao-cdca/pr/central-coast-county-organized-health-system-three-health-care-providers-agree-pay-68m; https://www.justice.gov/opa/pr/health-care-provider-agrees-pay-5-million-alleged-false-claims-californias-medicaid-program.
37 https://www.justice.gov/usao-cdil/pr/illinois-hospital-agrees-pay-125-million-settle-allegations-billing-error.
38 https://www.justice.gov/usao-sdtx/pr/medical-center-pays-over-21m-settle-alleged-false-claims.
39 *See, e.g.*, https://www.justice.gov/usao-sdoh/pr/home-healthcare-company-pays-9-million-submitting-false-claims-relating-energy; https://www.justice.gov/usao-ut/pr/summit-hospice-pay-over-1m-settle-false-claims-liability; https://www.justice.gov/usao-ndok/pr/united-states-settles-false-claims-allegations-against-evergreen-hospice-llc-48830.
40 https://www.justice.gov/usao-sdoh/pr/home-healthcare-company-pays-9-million-submitting-false-claims-relating-energy.
41 https://www.justice.gov/usao-ut/pr/summit-hospice-pay-over-1m-settle-false-claims-liability.
42 https://www.justice.gov/usao-wdla/pr/united-states-settles-claims-improper-inpatient-rehabilitation-admissions-over-17.
43 https://www.justice.gov/opa/pr/village-home-care-ceo-and-two-doctors-pay-490000-resolve-false-claims-act-allegations-paying.
44 https://www.justice.gov/usao-sdny/pr/us-settles-lawsuit-alleging-bronx-nursing-home-paid-kickbacks-patient-referrals-and.
45 https://www.justice.gov/opa/pr/california-skilled-nursing-facility-and-management-company-agree-pay-3825-million-settle.
46 https://www.justice.gov/opa/pr/california-skilled-nursing-facilities-owner-and-management-company-agree-456-million-consent.
47 https://www.justice.gov/usao-sdtx/pr/medical-center-pays-over-21m-settle-alleged-false-claims.
48 https://www.justice.gov/usao-edky/pr/medical-equipment-company-pays-7-million-resolve-false-claims-act-allegations.
49 https://www.justice.gov/usao-edpa/pr/plymouth-meeting-pa-company-pay-53-million-resolve-false-claims-act-allegations.

COMPARISON OF TOTAL RECOVERIES:

INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (FY 2019-2023)

YEAR	INTERVENED CASES	DECLINED CASES
2019	$1.91 billion	$305.55 million
2020	$1.52 billion	$193.88 million
2020	$1.24 billion	$480.65 million
2022	$803.33 million	$1.19 billion
2023	$1.89 billion	$442.33 million

DME company agreed to pay $29 million to resolve allegations that it overbilled for oxygen equipment by continuing to charge rental payments for the equipment after three years of payments were received, in violation of reimbursement policies.[50] As part of the settlement, the company admitted to a number of lapses in internal controls and entered a five-year CIA with HHS-OIG. Finally, a DME company and its subsidiary agreed to pay over $14.7 million to resolve FCA allegations that they billed for remote cardiac monitoring at a higher level than physicians intended to order or that was medically necessary.[51]

Other settlements involving violations of specific program requirements included a DME distributor and two related companies that agreed to pay more than $500,000 to resolve allegations that they caused providers to submit claims for a device intended to treat migraines without obtaining approval from the U.S. Food and Drug Administration (FDA).[52]

The government continued to pursue cases involving alleged kickbacks stemming from waived co-payments. Two compounding pharmacies and their owner agreed to pay $7.4 million plus potential contingency payments to resolve FCA allegations that they routinely waived patient co-payments without regard to patient need, in addition to adding the antipsychotic drug aripiprazole to compounded topical pain creams without a clinical basis to do so in order to increase reimbursements.[53] Another specialty pharmacy and its CEO agreed to pay $20 million to resolve FCA allegations that they paid kickbacks to patients in the form of waived co-pays without regard to financial need and to physicians in the form of gifts, dinners and free support services.[54] That settlement also included an agreement by a doctor to pay almost $500,000 to resolve allegations that he solicited and accepted remuneration in exchange for referring patients to the pharmacy. Another significant settlement involved a DME manufacturer that agreed to pay $9.75 million to resolve allegations that it provided free implants and surgical instruments to a surgeon for use in surgeries he conducted overseas to induce the surgeon to use its products in surgeries performed in the United States.[55]

LABORATORY & DIAGNOSTIC SERVICES

There were several significant settlements with laboratory and diagnostic providers for unnecessary testing, including standing orders and blanket orders for drug testing that was not medically necessary,[56] and requisition forms that automatically included PCR tests that were not medically necessary when providers ordered URI or UTI panels[57] and medically unnecessary tests that were performed on seniors who also received COVID-19 tests.[58]

The year's largest settlement in this sector involved a cardiac imaging company, which agreed to pay more than $85 million to resolve allegations that it paid referring cardiologists excessive fees to supervise cardiac PET scans.[59] The company allegedly paid cardiologists for supervising scans that were performed when the cardiologists were away from the scanning units or not even on site. As part of that settlement, the company entered into a five-year CIA with HHS-OIG.

Three clinical laboratories settled allegations relating to alleged AKS violations in 2023, with the alleged improper remuneration in the form of payments for referrals of urine drug screens,[60] office space rental agreements that paid inflated office rental payments to referring providers[61] and processing and handling fees paid as an inducement for lab test orders.[62]

Finally, several laboratory and diagnostic service providers settled allegations that they violated program rules, including billing for services that were performed by technicians who did not have the required credentials[63] and overbilling the Department of Defense (DOD) for genetic testing that was performed by a reference lab.[64] One such settlement involved a

50 https://www.justice.gov/usao-edwa/pr/lincare-holdings-agrees-pay-29-million-resolve-claims-overbilling-medicare-oxygen.
51 https://www.justice.gov/opa/pr/biotelemetry-and-lifewatch-pay-more-147-million-resolve-false-claims-act-allegations.
52 https://www.justice.gov/opa/pr/jet-medical-and-related-companies-agree-pay-more-700000-resolve-medical-device-allegations.
53 https://www.justice.gov/opa/pr/two-jacksonville-compounding-pharmacies-and-their-owner-agree-pay-least-74-million-resolve.
54 https://www.justice.gov/usao-edpa/pr/united-states-settles-kickback-allegations-specialty-pharmacy-biotek-remedys-inc-its.
55 https://www.justice.gov/opa/pr/depuy-synthes-inc-agrees-pay-975-million-settle-allegations-concerning-kickbacks-paid.
56 https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and.
57 https://www.justice.gov/usao-edmo/pr/missouri-laboratory-owners-agree-pay-19-million-and-relinquish-7-million-escrow.
58 https://www.justice.gov/opa/pr/lab-billing-company-settles-false-claims-act-allegations-relating-unnecessary-respiratory.
59 https://www.justice.gov/usao-sdtx/pr/cardiac-imaging-company-and-founder-pay-historic-85m-settlement.
60 https://www.justice.gov/usao-wdnc/pr/north-carolina-laboratory-and-owner-agree-pay-more-19-million-resolve-false-claims-0.
61 https://www.justice.gov/usao-sdny/pr/us-settles-false-claims-act-lawsuit-against-cardiologist-and-his-medical-practice.
62 https://www.justice.gov/usao-sc/pr/labcorp-pay-united-states-19-million-settle-allegations-under-false-claims-act.
63 https://www.justice.gov/usao-wdny/pr/cardiac-monitoring-company-settles-fraudulent-billing-allegations.
64 https://www.justice.gov/usao-md/pr/laboratory-corporation-america-agrees-pay-2100000-settle-false-claims-act-allegations.

clinical laboratory that agreed to pay $32.5 million to resolve allegations that it violated Medicare's 14-Day Rule by manipulating its billing practices in multiple ways, including writing off unpaid fees.[65]

INDIVIDUAL PROVIDERS & PHYSICIAN PRACTICE GROUPS

The government continued its focus on individual actors and their roles in healthcare fraud schemes. In the largest settlement of this sort, a vascular surgeon agreed to pay over $43 million to resolve allegations that he billed federal healthcare programs for procedures he did not perform, unbundled procedures and medically unnecessary stent procedures. The physician previously pleaded guilty to related criminal violations in 2022 and was sentenced to 80 months in prison and ordered to pay $19.5 million in restitution.[66]

The government resolved several cases with medical providers in which it alleged that providers misrepresented services rendered in a manner that increased reimbursement or permitted the providers to bill for services that were not reimbursable.[67] Several other settlements involved alleged billing for medically unnecessary services, including medically unnecessary cardiac stents,[68] medically unnecessary neurological procedures[69] and medically unnecessary cataract surgeries.[70]

The government also pursued enforcement actions against individuals for their roles in alleged kickback schemes, including multiple settlements with physicians accused of receiving remuneration from laboratories in exchange for referring patients for testing,[71] a physician who agreed to pay $7.96 million to resolve allegations that he referred business to a compounding pharmacy in exchange for kickbacks[72] and a physician and his wife/administrator who agreed to pay more than $3 million for requesting and receiving kickbacks from a home health agency (HHA) in exchange for referring of Medicare patients.[73] Another physician agreed to pay $1.3 million to resolve allegations that he received kickbacks from Insys Therapeutics disguised as payments for sham speaking events in exchange for ordering medically unnecessary fentanyl prescriptions.[74]

OTHER PROVIDERS

Many other entities and individuals settled FCA allegations related to causing the submission of false claims. In one notable settlement and following similar settlements in prior years, electronic health record (EHR) vendor NextGen Healthcare, Inc., agreed to pay $31 million to resolve allegations that it: (1) falsified the capabilities of certain versions of its software in order to obtain certification under HHS's EHR Incentive Program; and (2) provided unlawful remuneration to its users to induce them to recommend the vendor's software, in violation of the AKS.[75]

Another notable settlement involved a website design company's cybersecurity failures, one of the first settlements of its kind after DOJ's announcement of its new CCFI in 2021. The company and its manager/co-owner agreed to pay nearly $300,000 to resolve allegations that they failed to securely host personal information and properly maintain, patch and update their software systems, contrary to representations in their agreements and invoices with a federally-funded state children's health insurance program. As a result of these alleged cybersecurity failures, more than 500,000 Florida Medicaid applications were hacked.[76]

65 https://www.justice.gov/opa/pr/genomic-health-inc-agrees-pay-325-million-resolve-allegations-relating-submission-false.
66 https://www.justice.gov/opa/pr/michigan-vascular-surgeon-sentenced-80-months-prison-health-care-fraud-conviction-and-agrees.
67 https://www.justice.gov/usao-sdtx/pr/podiatrist-pays-90000-settle-false-billing-allegations; https://www.justice.gov/usao-edny/pr/queens-physician-settles-health-care-fraud-claims-13-million-and-enters-integrity-0; https://events.in.gov/event/attorney_general_todd_rokita_and_team_win_700000_settlement_over_alleged_medicaid_fraud_by_hammond_orthopedic_surgeon; https://www.justice.gov/usao-nj/pr/medical-practice-and-its-owners-pay-1-million-resolve-false-claims-act-allegations; https://www.justice.gov/usao-wdwa/pr/puyallup-washington-wound-treatment-firm-settles-allegations-it-submitted-false-bills.
68 https://www.justice.gov/usao-mdtn/pr/arkansas-cardiologist-agrees-pay-900000-settle-false-claims-act-allegations.
69 https://www.justice.gov/usao-edwa/pr/former-physician-pay-more-11-million-resolve-allegations-he-performed-medically.
70 https://www.justice.gov/usao-ndga/pr/conyers-doctor-pays-1850000-resolve-allegations-she-performed-and-billed-medically.
71 https://www.justice.gov/usao-wdky/pr/owensboro-doctor-pays-931500-resolve-allegations-he-received-kickbacks-laboratory; https://www.justice.gov/opa/pr/hospital-executive-and-three-texas-physicians-pay-over-880000-settle-kickback-allegations.
72 https://www.justice.gov/usao-sdtx/pr/physician-and-pharmacy-settle-claims-unnecessary-medications.
73 https://www.justice.gov/usao-ndil/pr/chicago-doctor-and-his-wife-held-liable-jury-taking-kickbacks-and-causing-false.
74 https://www.reuters.com/legal/government/bankrupt-doctor-settles-avoid-trial-over-insys-opioid-kickbacks-2023-10-13.
75 https://www.justice.gov/opa/pr/electronic-health-records-vendor-nextgen-healthcare-inc-pay-31-million-settle-false-claims.
76 https://www.justice.gov/opa/pr/jelly-bean-communications-design-and-its-manager-settle-false-claims-act-liability.

FALSE CLAIMS ACT UPDATE

The FCA continues to be the federal government's primary civil enforcement tool for pursuing liability against healthcare providers that have allegedly defrauded federal healthcare programs. As in previous years, 2023 saw a number of legal developments involving the FCA that will greatly impact the government's enforcement efforts and the manner in which *qui tam* relators pursue their claims.

ESCOBAR'S "RIGOROUS" MATERIALITY REQUIREMENT

Seven years after the Supreme Court's decision in ***Universal Health Services v. U.S. ex rel. Escobar***, the FCA's "rigorous" and "demanding" materiality element continues to be one of the most frequently litigated issues, including at both the motion to dismiss and summary judgment stages.[77]

Escobar directed courts to focus their assessment of the materiality element on "the likely or actual behavior of the recipient of the alleged misrepresentation." The Supreme Court described the inquiry as "holistic" and identified several "non-exclusive" factors for courts to consider, including: (1) whether the relevant statute, regulatory or contractual requirement is an express condition of payment; (2) whether the alleged violation of the relevant requirement goes to the "essence" of the government's bargain or is instead just "minor" or "insubstantial"; and (3) how the government has responded to similar violations in the past, including whether it consistently pays, or refuses to pay, claims when it has knowledge of noncompliance. Courts have continued to grapple with how to apply these factors.

Not "Too Fact Intensive" to Support Dismissal or Summary Judgment

Although the materiality element involves a fact-specific analysis, the Supreme Court emphasized in *Escobar* that the inquiry is not "too fact intensive" to support the dismissal of an FCA action on a motion to dismiss or at summary judgment. Illustrating that point,

77 579 U.S. 176 (2016).

a number of courts have continued to dismiss FCA cases even at the pleading stage when relators rely only on conclusory allegations of materiality.[78]

In ***U.S. ex rel. Wheeler v. Acadia Healthcare Co.***, for example, the district court dismissed allegations that the defendants had falsely billed for group therapy services by using inaccurate, pre-prepared notes because the relator offered only "general" assertions that the alleged regulatory violations were material and had pleaded materiality on "information and belief."[79] The district court held that such allegations did not clear the "rigorous" hurdle described in *Escobar*. Similarly, in ***U.S. ex rel. Bashir v. The Boeing Co.***, the district court dismissed FCA claims where the complaint "either overlook[ed] or only tangentially address[ed]" the *Escobar* materiality factors and instead offered only "unadorned, conclusory allegation[s]" that the alleged violation of Air Force contractual requirements would have impacted the government's payment decisions.[80]

Even when a relator overcomes the initial pleading hurdle,[81] an FCA action is still subject to dismissal at summary judgment if the relator — who bears the burden of proof — fails to come forward with evidence to support materiality. Consider the district court's decision in ***U.S. ex rel. Hinton v. Integra Lifesciences Holdings Corp.***[82] In that case, a relator alleged that a medical device manufacturer caused the submission of false claims by marketing its device for off-label uses that were not "reasonable and necessary" as required for Medicare reimbursement. Although the district court recognized that violations of the reasonable and necessary requirement may sometimes be material, it nonetheless granted summary judgment for the defendant because the relator failed to introduce any evidence — including any expert testimony — that the specific use of the device at issue was not reasonable and necessary or would have affected the government's payment decision.

Government Knowledge of Allegations Versus Knowledge of Violations

One question that has increasingly divided both trial and appellate courts is whether the government's continued payment of claims is significant to the materiality analysis only if the government has knowledge of actual violations of the relevant regulatory or contractual requirement. Or, rather, is continued payment still relevant to materiality if the government knows only of *allegations* of wrongdoing? As in years past, courts have continued to reach conflicting conclusions on this question.

78 *But see U.S. ex rel. Ellis v. CVS Health Corp.*, 2023 WL 3204015 (E.D. Pa. May 2, 2023) (denying motion to dismiss — despite the relator's failure to plead any specific facts regarding materiality — because the relator was relying on a worthless services theory and it is "self-evident that the government would properly decline to pay" for worthless drugs).

79 2023 WL 6035712 (W.D.N.C. July 27, 2023), report and recommendation adopted, 2023 WL 6060344 (W.D.N.C. Sep. 18, 2023).

80 2023 WL 6377575 (W.D. Wash. Sep. 29, 2023); *see also FDIC v. Fifth Third Bank, N.A.*, 2023 WL 7130553 (2d Cir. Oct. 30, 2023) (affirming dismissal of FCA claims on materiality grounds where the complaint failed to address any of the specific *Escobar* factors with particularity); *U.S. ex rel. Carroll v. Hackensack Meridian Pascack Valley Med. Ctr.*, 2023 WL 8664583 (D.N.J. Dec. 14, 2023) (dismissing FCA claims in part because the complaint did not include any "nonconclusory allegations" that the defendants' alleged misrepresentations affected "the amount Medicare pays").

81 Examples of recent cases where courts held that materiality was plausibly alleged at the pleading stage include *U.S. ex rel. Montenegro v. Roseland Cmty. Hosp. Ass'n*, 2023 WL 8190136 (N.D. Ill. Nov. 27, 2023); *U.S. ex rel. Cooley v. ERMI, LLC*, 2023 WL 3587543 (N.D. Ga. May 22, 2023); and *U.S. ex rel. Taylor v. Healthcare Assocs. of Texas, LLC*, 2023 WL 3294141 (N.D. Tex. May 5, 2023).

82 2023 WL 6793927 (W.D. Mo. Sep. 11, 2023).

One question that has increasingly divided both trial and appellate courts is whether the government's continued payment of claims is significant to the materiality analysis only if the government has knowledge of actual violations of the relevant regulatory or contractual requirement.

In ***U.S. ex rel. Heath v. Wisconsin Bell, Inc.***, the Seventh Circuit reversed a district court's grant of summary judgment for a defendant alleged to have overcharged the government for telecommunications services provided to schools and libraries.[83] While acknowledging that the government had continued to pay the inflated rates even after learning of the relator's allegations, the Seventh Circuit still held that summary judgment as to the materiality element was not warranted because the government lacked "actual knowledge" that the defendant had violated the relevant pricing rules. The Seventh Circuit described the defendant's argument as "seek[ing] to erase the difference between allegations and conclusive proof," and explained that the government's ongoing payment with knowledge of mere *allegations* of wrongdoing could not support summary judgment.

The Fifth Circuit reached a similar conclusion in ***U.S. ex rel. Aldridge v. Corporate Management, Inc.***[84] There, a jury found the defendant liable at trial for defrauding the Medicare program by submitting inflated cost reports. On appeal, the defendant argued that Medicare's payment of the inflated costs while the government's investigation was pending signaled that the alleged violations of the relevant cost rules were not material. Rejecting that argument, the Fifth Circuit reasoned that it was unclear whether Centers for Medicare & Medicaid Services (CMS) was actually "cognizant" of actual fraud, while distinguishing an earlier Tenth Circuit case that had found a lack of materiality in part based on the government's continued payment after it learned of a relator's FCA allegations. Besides, the Fifth Circuit noted, continuing to make payments could not be assumed to be endorsement of the inflated cost reports because there were other good reasons — such as sustaining healthcare access for underserved populations — for the government to continue the flow of funds.

On the other side of the ledger, the district court in ***U.S. ex rel. Jackson v. Ventavia Research Grp., LLC***, granted the defendant's motion to dismiss in large part because the FDA had continued to approve Pfizer's COVID-19 vaccine — which the relator insisted was ineligible for

83 75 F.4th 778 (7th Cir. 2023).

84 78 F.4th 727 (5th Cir. 2023).

DOD funding – even after learning of the relator's allegations.[85] Contrary to the reasoning of the two circuit court decisions just discussed, the district court expressly rejected the argument that the government's knowledge of *alleged* fraud is somehow different from knowledge of *actual* fraud when it comes to analyzing materiality.[86]

Significance of Government Inaction

Even when courts do consider the government's ongoing payment of claims to be relevant to materiality, they often take different approaches when it comes to deciding how much significance to attribute that conduct. Two circuit court decisions from the past year illustrate this tension.

First, in ***U.S. ex rel. Kraemer v. United Dairies, LLP***, the Eighth Circuit affirmed a bench verdict for an FCA defendant almost entirely because the government had regularly paid crop insurance claims in full despite actual knowledge of the defendant's false certifications about how it intended to use the crop at issue.[87] Concluding that the alleged false certifications were, therefore, not material, the Eighth Circuit did not even mention the other *Escobar* materiality factors.

On the other hand, in ***U.S. ex rel. Druding v. Care Alternatives***, the Third Circuit reversed a district court decision that had relied on nearly this same reasoning to grant summary judgment for the defendant. As the Third Circuit described it, the district court had "assigned dispositive weight to a single *Escobar* factor" – namely, the government's inaction after being made aware of the defendant's misconduct. The Third Circuit held that to be a reversible error. Although it agreed that the government's inaction was *some* evidence of materiality, the Third Circuit held that summary judgment was nonetheless inappropriate because other evidence cut the other way – including evidence as to the pervasive nature of the alleged misconduct and the significance of the relevant regulatory requirement.

Materiality Impact of Collaterally Attacking a Relevant Regulatory or Contract Provision

One final and somewhat unique appellate decision on the issue of materiality worth noting is the Fourth Circuit's opinion in ***United States v. Walgreen Co.***[88] In that case, the government alleged that Walgreen Co. (Walgreens) pharmacies defrauded the Virginia Medicaid program by altering records to falsely indicate that patients met certain state-level eligibility criteria for Medicaid coverage of Hepatitis C drugs. The district court dismissed the complaint on materiality grounds, reasoning that the eligibility requirements at issue conflicted with federal law. In the district court's view, that meant that the false statements about those requirements *should not* have affected the state's payment decisions and were therefore not material as a matter of law.

The Fourth Circuit reversed. Without deciding whether the Virginia eligibility criteria conflicted with federal law, the Fourth Circuit held that what matters for materiality purposes is whether the misrepresentations *did* influence the government's payments, not whether they *should have*. Because there was no meaningful dispute on that question, the Fourth Circuit concluded that Walgreens could not avoid liability by collaterally attacking the legality of the eligibility requirements.

DEVELOPMENTS IN PLEADING STANDARDS

Because FCA complaints contain allegations of fraud, they are subject to the heightened pleading standard of Federal Rule of Civil Procedure 9(b), which requires allegations to be pleaded with particularity. In applying Rule 9(b) to FCA complaints, courts typically demand specific allegations of a fraudulent "scheme" carried out by the defendant, but they continue to disagree as to how detailed the allegations must be to connect that scheme to actual claims submitted to the government for payment.

Pleading the Details of a Fraudulent Scheme

All courts agree that to survive a motion to dismiss under Rule 9(b), FCA complaints must first identify the particular details – including the "who, what, when, where, and how" – of the alleged fraudulent scheme. While an FCA complaint need not be exhaustive in that regard, Rule 9(b) requires some level of factual specificity. While a number of cases addressed whether complaints adequately alleged the submission of false claims, very few touched on the initial inquiry–whether the complaint properly pleaded a fraudulent scheme.

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85 2023 WL 2744394 (E.D. Tex. Mar. 31, 2023).
86 The district court's decision in *Jackson* preceded the Fifth Circuit's decision in *Aldridge*, so it remains to be seen whether other Fifth Circuit district courts will feel free to take this same approach.
87 82 F.4th 595 (8th Cir. 2023).
88 78 F.4th 87 (4th Cir. 2023).

In one example, ***U.S. ex rel. Hartley v. Hosp. Auth. of Valdosta and Lowndes Cnty., Ga.***, the relator alleged that a hospital and the treasurer of its board of directors submitted false claims by systematically ignoring applicable regulations.[89] The relator alleged fifteen separate fraudulent schemes, including that the hospital falsified records to support claims, upcoded and violated other billing requirements. After the government declined to intervene, the defendants filed a motion to dismiss, which was granted. Noting the requirement that the relator plead the "who, what, where, when, and how" of fraudulent submission to meet Rule 9(b)'s heightened pleading standard, the district court found that the relator's complaint lacked "essential details, including when [the hospital] made any alleged false submissions, who made the false submissions, the nature of the false submissions, and to whom the false submissions were made." These omissions proved fatal.

Likewise, in ***U.S. ex rel. O'Neill v. Gopalam***, the relator alleged that the defendants operated a scheme to defraud Medicare by running an inpatient psychiatric hospital and outpatient psychiatric services center as a "psych mill," akin to a "pill mill," by prioritizing admissions of Medicare patients and fraudulently extending hospitalizations to boost reimbursement.[90] The district court granted the defendants' motion to dismiss, finding among other things that the relator failed to satisfy Rule 9(b)'s particularity requirement. The district court concluded that the relator's general statements that the defendants violated Medicare statutes and regulations, without pointing to any specific ones or explaining how the defendants' actions violated them, were sweepingly conclusory allegations that failed to satisfy Rule 9(b).

In ***U.S. ex rel. Osinek v. Kaiser Permanente***, the district court concluded that the government had adequately alleged that the defendant submitted false diagnosis codes for patients.[91] The district court had previously dismissed the government's complaint, finding that there were insufficient allegations of a broader scheme to submit inaccurate diagnosis codes, despite the inclusion of several patient examples. The government's amended complaint made detailed allegations regarding a widespread scheme, including that hundreds of thousands of inaccurate diagnoses were uncovered by multiple internal audits and reviews. The district court found that the existence of a "refresh program" to review diagnoses indicated that the inaccurate codes were not an aberration, but an established practice of the company that involved significant pressure on physicians to change diagnosis codes. The government also adequately pleaded knowledge where Kaiser had multiple audits identifying the inaccurate diagnosis codes and warnings from physicians.

In ***U.S. ex rel. Taylor v. Healthcare Associates of Texas, LLC***, the district court found that the relator had adequately pleaded a scheme to submit noncompliant bills for physician services.[92] The district court concluded that the complaint detailed specific ways that the practice submitted claims for uncredentialed providers, "incident to" services that were not actually supervised by the billing physician and billed for unnecessary tests. The district court further held that the relator had adequately pleaded the presentment of false claims where she specified the locations that employed the practices, the practitioners listed on the bills for services, codes used on the bills and individuals knowledgeable of the fraud and claims data.

89 2023 WL 6702483 (M.D. Ga. Oct. 12, 2023).
90 2023 WL 6396659 (M.D. La. Sept. 29, 2023).
91 2023 WL 4054279 (N.D. Cal. June 15, 2023).
92 2023 WL 3294141 (N.D. Tex. May 5, 2023).

In ***U.S. ex rel. Ellis v. CVS Health Corp.***, the district court partially dismissed allegations related to CVS's flash freezing packaging system that allegedly resulted in partial or total loss of the efficacy of certain drugs (*i.e.*, "worthless services").[93] The district court allowed the relator to move forward only on allegations that identified specific drugs whose guides advised that they should not be frozen and that were therefore rendered potentially ineffective. The district court dismissed the more generalized allegations regarding unspecified medications. The district court also dismissed allegations as to subsidiaries of CVS where the relator did not make any specific allegations as to those entities regarding their alleged involvement in the fraud.

In ***U.S. ex rel. Frey v. Health Management Sys., Inc.***, the district court dismissed conspiracy allegations regarding Medicare contractors.[94] The district court found that allegations of contractors collecting and retaining unearned contingency fees for their work for the Medicare program failed to distinguish between the defendants, in support of a conspiracy claim. In addition to lumping the defendants together, the complaint failed to: (1) identify any individuals actually involved in the conduct; (2) specify how the contingency fees were inappropriate; or (3) state whether the company was aware of the alleged wrongdoing.

In ***U.S. ex rel. Williams v. Landmark Hosp. of Athens, LLC***, the district court dismissed allegations that a critical care hospital and pulmonary care clinic performed, or conspired to have performed, fraudulent COVID-19 testing, submitting claims for throat swabs labeled and tested as nasal swabs.[95] The district court held that while the relators sufficiently alleged the defendants knowingly created false lab requisition forms and mislabeled specimens, they failed to adequately state a fraud scheme for purposes or Rule 9(b) and failed to demonstrate the materiality of any false statements.

In ***U.S. ex rel. Robertson v. Millennium Physician Grp., LLC***, the district court dismissed an amended complaint alleging that the defendant physician group engaged in various fraudulent practices to increase Accountable Care Organization (ACO) scores and bonuses, based on the FCA's first-to-file rule and Rule 9(b).[96] While the relator provided "many examples of patient medical records that do not accurately reflect the individual patients' status or the care they received," the complaint failed to link any records to specific improper conduct by specific defendants or plead reliable indicia that any false claims were submitted for payment. The district court also noted the relator's use of the collective "Defendants" throughout rendered the amended complaint insufficient under Rule 9(b).

Multiple cases in 2023 required courts to assess the adequacy of kickback-based fraud allegations under Rule 9(b). For example, in ***U.S. ex rel. Carew v. Senseonics Holdings, Inc.***, the district court dismissed an amended complaint alleging that the defendant paid kickbacks to physicians and patients in the form of speaker fees for sham engagements, travel, meals and procedure-reimbursement arrangements in exchange for use of the defendant's glucose-monitoring product.[97] The district court found that the relators had

93 2023 WL 3204015 (E.D. Pa. May 2, 2023).
94 2023 WL 2563239 (S.D. Tex. Feb. 10, 2023), report and recommendation adopted sub nom. *Frey v. Health Mgmt. Sys., Inc.*, No. 4:21-CV-02024, 2023 WL 2564342 (S.D. Tex. Mar. 17, 2023).
95 2023 WL 3097948 (M.D. Ga. Apr. 26, 2023).
96 2023 WL 2022228 (M.D. Fla. Feb. 15, 2023).
97 2023 WL 2354915 (W.D. Tex. Mar. 3, 2023), report and recommendation adopted sub nom. *U.S. ex rel. Carew v. Senseonic Holdings, Inc.*, 2023 WL 2711637 (W.D. Tex. Mar. 30, 2023).

not pleaded reliable indicia that any speaking events were indeed a sham; that procedure-reimbursement arrangements were above market rates or part of a scheme to induce referrals; or that any other payments were linked to referrals. The district court further noted that the relator relied on "nothing more than the general temporal proximity" of certain claims for payment for the glucose-monitoring product to various unidentified payments to physicians, which is "insufficient to give rise to a strong inference of wrongful conduct and that false claims were actually submitted" to government payors.

In ***U.S. ex rel. Turner v. Dynamic Med. Sys., LLC***, the district court evaluated the relators' second amended complaint alleging false certification and AKS-based FCA claims against a SNF management company and a company that leased mattresses and bedframes to SNFs, concluding that relators still failed to plead with particularity who made a false claim or certification, when or how, in accordance with Rule 9(b).[98] Although the complaint identified "several new names of various officers and employees associated with the defendants, along with their job descriptions," it still failed to address *who* made false statements or omissions. The district court also found allegations that false claims and certifications were submitted "every month" insufficient to describe *when* false claims were submitted, noting unspecified and generic averments of "each" and "every" occurrence, without more, failed to provide adequate notice to the defendants about the specific misconduct to investigate or prepare a defense. Contracts attached to the complaint with execution dates "fail[ed] to further identify when the allegedly fraudulent rates and terms contained within … were actually charged, or when such charges were allegedly submitted to the government."

Likewise, in ***U.S. ex rel. Wilkerson v. RCHP-Florence, LLC***, the district court dismissed allegations that the relator was pressured to improperly admit and retain patients in the hospital's psychiatric unit in violation of Medicare regulations, as well as allegations that the hospital violated the AKS in connection with medical directorship payments.[99] Applying Eleventh Circuit precedent, the district court concluded that the relator failed to plead a sufficient indicia of reliability that any defendant submitted any false claims to federal healthcare programs. The district court also dismissed the relator's claims for violation of the FCA's reverse false claims and conspiracy provisions.

In ***U.S. ex rel. Winnon v. Lozano***, the district court held that the relator had not adequately alleged a kickback scheme.[100] The relator's complaint alleged that the defendant facilities entered into sham medical director agreements and provided meals, alcohol and other gifts to physicians in exchange for referrals. The relator's complaint, however, failed to include specific details regarding what made the agreements a sham – there were no details regarding the rates and volume of referrals, specific patients referred by specific physicians in exchange for remuneration or other reliable indications of fraud.

By contrast, the district court found AKS violations sufficiently pleaded in ***U.S. ex rel. Schroeder v. Medtronic, Inc.***, a case involving allegations of kickbacks and the lack of medical necessity for certain devices used to treat peripheral artery disease.[101] After dismissing a portion of the claims under the public disclosure bar and the statute of limitations, the district court allowed the remainder of the relator's suit to move forward. The district court held that the relator had sufficiently detailed a scheme for billing unnecessary medical procedures involving Medtronic devices and unnecessary off-label use of the devices, where the relator provided sufficient detail about the manner in which Medtronic encouraged physicians to use the devices unnecessarily, the particular physicians who performed the procedures, date ranges for each of the identified healthcare professionals and the particular devices used. In addition, the district court held that the relator had sufficiently pleaded claims based on kickbacks paid to induce purchases of these devices.

98 2023 WL 6927077 (E.D. Cal. Oct. 17, 2023).
99 2023 WL 2730259 (N.D. Ala. Mar. 30, 2023).
100 2023 WL 6065162 (D.D.C. Sept. 18, 2023).
101 2023 WL 5152513 (D. Kan. Aug. 10, 2023).

Courts continued to apply different standards to assess whether FCA complaints contained sufficient allegations that false claims were actually submitted to the government for payment.

Pleading the Submission of False Claims

Courts continued to apply different standards to assess whether FCA complaints contained sufficient allegations that false claims were actually submitted to the government for payment.

Some courts focused on whether the complaint identified specific false claims that were submitted for payment. For instance, in ***U.S. ex rel. Makki v. Rakine***, the relator alleged that a pharmacy and its pharmacists violated the FCA by filling fictitious prescriptions through federal programs and then reselling them on an online market, resulting in two separate reimbursements for the same drug.[102] The district court granted the defendants' motion to dismiss, finding the relator failed to identify any specific false claim submitted to the government, nor the date of any such claim. The district court declined to accept the relator's argument that Rule 9(b) allowed him to survive dismissal so long as he pleaded a fraudulent scheme in detail even without reference to any specific false claims submitted thereunder.

The district court in ***U.S. ex rel. Dustman v. Advocate Health & Hosps. Corp.*** applied a similar rationale in granting the defendants' motion to dismiss.[103] There, the relator alleged that the defendant, who operated an ambulatory surgical center and related corporate entities, along with their outside law firm, violated the FCA by submitting claims for services provided to patients in violation of the Stark Law and AKS. Noting that the Seventh Circuit "has often required representative samples in *qui tam* FCA cases, with few exceptions," the district court reasoned that "the lack of representative claims means there are no facts

102 2023 WL 5762564 (E.D. Mich. Sept. 6, 2023).
103 2023 WL 2799699 (C.D. Ill. Apr. 5, 2023).

connecting the allegedly unlawful referrals to the submission of claims to the government." The relator's allegations regarding the number and dollar value of claims paid to the practice and that related entities made "thousands of unlawful referrals" failed to "take the essential step" of alleging that any patient was improperly referred, and then the practice billed and was paid for services to that patient.

Although most jurisdictions allow for some flexibility in the FCA's presentment requirement, some courts still found that even if the plaintiffs' allegations might support an inference that false claims were submitted, this would not be enough under Rule 9(b). For example, in ***U.S. ex rel. Vito v. Canzoneri***, the district court dismissed the relator's complaint where he failed to allege with sufficient particularity that the defendants' podiatry practice and its owner actually submitted false claims for payment to the government.[104] The relator, a podiatrist and former employee of the practice, essentially alleged that the defendants must have submitted false claims to the government because they were alleged to have: (1) reused leftovers from single-use medication vials taken from a hospital where the podiatrists operated; (2) billed for those reused vials in the practice setting; and (3) treated some patients who were beneficiaries of government healthcare programs. The district court held that this was insufficient to support a "strong inference" that specific claims were submitted to the government because it could "only speculate" about whether the defendants submitted bills to the government for reused vials, or whether those costs were only passed on to patients or private insurers.

District courts in the Fourth Circuit reached similar conclusions under a slightly different test. In ***U.S. ex rel. Embree v. Bharti***, the relator alleged that a hospital and several of its physicians submitted false claims to Medicare and Medicaid by billing for services not performed, upcoding claims and billing for services that were not medically necessary.[105] The defendants filed a motion to dismiss, claiming that the relator had failed to adequately plead the presentment of false claims. The district court noted the two ways a relator can plead presentment in the Fourth Circuit: (1) by alleging with particularity that specific false claims were presented to the government for payment; and (2) by alleging "a pattern of conduct that would necessarily have led to submission of false claims." Under the first approach, the district court found that the relator failed to allege "how, or even whether, the bills for these fraudulent services were presented to Medicare or Medicaid and how or even whether Medicare or Medicaid paid for the services." As to the second approach, while the relator argued it would stretch the imagination for physicians to routinely and falsely chart and code without submitting claims to the government, the district court found that the relator's claims in this respect were inherently speculative and thus failed to meet Rule 9(b)'s heightened standard. As a result, the district court granted the defendants' motion to dismiss.

Applying the same standard, the district court in ***U.S. ex rel. Wheeler v. Acadia Healthcare Co.***, held that a relator's allegations were not sufficient to "allege a pattern of conduct that would necessarily have led to the submission of a false claim to a Government Healthcare Program."[106] The relator alleged that the defendant's substance abuse and behavioral health treatment centers reused form therapy notes to chart and bill for group therapy that was never provided to patients in their opioid treatment program. Although the relator identified several patients who allegedly did not receive group therapy, the district court concluded that the complaint did not "explain which of these individuals were associated with which Government Healthcare Programs" and thus failed to adequately plead the submission of a false claim.

In contrast to the Fourth Circuit's approach, district courts in other circuits continue to hold that the FCA's presentment element can be met when specific allegations of a scheme to submit false claims are paired with "reliable indicia" supporting a strong inference that claims were actually submitted.

In contrast to the Fourth Circuit's approach, district courts in other circuits continue to hold that the FCA's presentment element can be met when specific allegations of a scheme to submit false claims are paired with "reliable indicia" supporting a strong inference that claims were actually submitted. In ***U.S. ex rel. Reach v. Arkansas Heart Hosp., LLC***, the district court denied the defendants' motion to dismiss a complaint alleging that a hospital and several of its physicians: (1) falsified patient charts and documented comorbid conditions that did not exist for the purpose of receiving higher reimbursement from Medicare for valve repair and replacement surgeries; and (2) presented claims to Medicare that were not actually performed.[107] As to the first count, the district court found sufficient allegations of a fraudulent scheme, coupled with reliable indicia leading to a strong inference that claims were actually submitted. Critical to the district court's ruling was the fact that the relator was the CFO of the hospital, had access to billing information and was privy to a meeting about how to increase profits, and data indicating that profits in fact did increase significantly on valve surgeries after the meeting. As to the second count, the district court likewise denied the defendants' motion to dismiss, since the relator alleged a claim submitted for a specific patient on a specific date when the "first assist" listed on the claim was prohibited from participating in surgeries at the time due to a health condition.

Several district courts in the Eleventh Circuit applied the "sufficient indicia of reliability" standard under Rule 9(b). In ***U.S. ex rel. Merritt v. Amedisys, Inc.***, the district court denied a motion to dismiss filed by a HHA and its medical director on presentment grounds.[108] The

104 2023 WL 4082376 (W.D.N.Y. June 20, 2023).
105 2023 WL 6441941 (N.D.W. Va. Sept. 29, 2023).
106 2023 WL 6035712 (W.D.N.C. July 27, 2023), memorandum and recommendation accepted 2023 WL 6060344 (Sept. 18, 2023) (dismissing complaint with prejudice).
107 2023 WL 5432869 (E.D. Ark. Aug. 23, 2023).
108 2023 WL 5436347 (M.D. Ga. Aug. 23, 2023).

relator alleged that the defendants submitted false claims in violation of the FCA by: (1) falsely certifying ineligible patients; (2) billing for services for which a patient did not qualify or that were not actually rendered; (3) compensating the medical director for referrals; and (4) falsifying patient certification forms. The relator alleged a number of examples of specific claims that were submitted in furtherance of the defendants' alleged fraudulent scheme, identifying specific patients, specific dates of service and the basis on which the claims were allegedly false. While the allegations did not contain other important claim details, such as the dates or amounts of charges, the district court found that the relator had alleged facts sufficient to meet the "sufficient indicia of reliability" standard.

Likewise, in ***U.S. ex rel. Rubin v. Sterling Knight Pharm., LLC***, the district court denied the motion to dismiss filed by the defendant pharmaceutical companies and their executives.[109] The relator alleged that the defendants inflated their reported average wholesale price (AWP) of their pharmaceuticals, thereby commanding a premium price from retailers and falsely inflating federal payors' reimbursements. Though no specific false claims submitted by a pharmaceutical retailer were identified in or appended to the complaint, the district court found it sufficient that the relator's allegations derived from personal knowledge gained in his role as chief scientific officer. In that role, he learned how the defendants inflated the AWP, how they would test whether particular pharmaceuticals would "bill out" at inflated rates as intended and how the defendants coached pharmacies and dispensers to maximize reimbursement from inflated pharmaceuticals. The district court highlighted that the relator supplemented these allegations with "specific instances in which the defendants inflated the [AWP] of particular pharmaceuticals, in which the defendants tested whether a drug would 'bill out' at the inflated rate, in which the defendants sold inflated pharmaceuticals to retailers, and in which [one defendant] 'bragged' about the profits extracted from the price-inflation scheme."

Applying the same standard, the district court in ***U.S. ex rel. Chichester-Shepperd v. Millennium Physician Grp., LLC***, granted a motion to dismiss filed by the defendant primary care practice, its CEO, its regional marketing director and a physician.[110] The physician assistant relator alleged that the practice engaged in various forms of upbilling and upcoding, improper referrals and unlicensed practice of medicine, but the district court held that he failed to identify with particularity any false claim and failed to allege any other indicia of reliability that false claims were submitted, since his role as a physician assistant did not include any experience in billing or claim submission.

Similarly, in ***U.S. ex rel. Cook v. Integrated Behavioral Health, Inc.***, the district court dismissed the relators' complaint alleging that numerous individuals, behavioral health providers and nursing homes or assisted living facilities submitted false claims based on underlying violations of the Stark Law and AKS.[111] In addition to holding that the second amended complaint was a prohibited shotgun pleading, the district court held that the relators failed to adequately plead the submission of false claims. Although the relators made allegations about patient names, approximate dates of treatment and approximate dates claims were submitted, this was insufficient in the absence of allegations about the times of treatments, when claims were submitted, account numbers, information about the specific services rendered or the dollar amounts of alleged false claims. Nor did the relators, who are nurses, allege that they had personal knowledge of the defendants' billing practices or otherwise allege any indicia of reliability supporting their assertion that fraudulent claims were submitted. This decision was affirmed by the Eleventh Circuit.[112]

DEVELOPMENTS REGARDING FALSITY

As the statute itself makes clear, plaintiffs in FCA litigation must plead and prove that claims were false in order to prevail. As such, defendants in FCA litigation often challenge the legal viability of theories of falsity advanced by the government or *qui tam* relators. Not surprisingly, courts have continued to issue a number of notable holdings regarding the FCA's falsity element.

Express and Implied False Certification

Claims may trigger FCA liability if they are factually false or legally false. Factually false claims involve billing for goods or services that are incorrectly described or were not provided at all. In addition to liability for submitting "factually false" claims, defendants also may be held liable under the FCA for submitting "legally false" claims that either expressly or impliedly certify compliance with requisite statutes, regulations or contractual provisions. As for implied false certification, the Supreme Court in *Escobar* held that defendants can be liable if: (1) "the claim does not merely request payment, but also makes specific

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109 2023 WL 3190732 (M.D. Fla. Mar. 23, 2023).

110 2023 WL 2022232 (M.D. Fla. Feb. 15, 2023); *see also U.S. ex rel. Issac v. Lockheed Martin*, 2023 WL 3027465 (N.D. Ga. Mar. 23, 2023) (granting motion to dismiss where the relator's personal knowledge as a mechanic was "limited" and he only identified relevant government contracts and provided examples of deficient equipment but failed to allege any specifics regarding claims for payment under those contracts except to speculate that a claim was submitted because payments were made to Lockheed).

111 2023 WL 2617399 (N.D. Ala. Mar. 23, 2023).

112 2023 WL 8841254 (11th Cir. Dec. 21, 2023).

representations about the goods or services provided;" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[113] In 2023, courts continued to analyze the bounds of false certification liability.

In ***U.S. ex rel. Quartararo v. Cath. Health Sys. of Long Island Inc.***, the relator alleged that the defendants diverted federal and state reimbursement funds issued to a nursing home for nursing facility services when their co-owned facilities issued false administrative charges for "utility expenses, payroll expenses, and other ancillary medical and laboratory services that were either not incurred at all or grossly inflated."[114] The relator argued that the defendants' claims were false because they failed to comply with the federal Benefits Conversion Statute, which requires reimbursement dollars be spent only on care for residents.[115] The Second Circuit, however, held that the federal payments at issue constituted reimbursements for past services already provided with no forward-looking conditions as to use of the funds, including a one-time remediation payment from the state of New York. Because these payments all related to past services provided it was not plausible that the defendants diverted the funds to use for an impermissible purpose. Accordingly, the Second Circuit reversed the district court's opinion denying the defendants' motion to dismiss and held that all Benefits Conversion Statute-based claims should be dismissed.

In ***U.S. ex rel. Johnson v. AmeriHealth Ins. Co. of New Jersey***, the Third Circuit held that the defendants' failure to comply with a state regulation limiting co-payments was not a false certification of compliance for federal healthcare reimbursement purposes under health insurance plans listed on New Jersey's federally operated insurance exchange.[116] The Patient Protection and Affordable Care Act (ACA) requires the creation of health insurance exchanges in each state. Any given state can create its own exchange with additional costs and control involved, or forego the expense and control and allow the federal government to operate the exchange in the state on its behalf. The Third Circuit ruled that the ACA clearly distinguishes between state and federally operated exchanges, and because the federal law must be consistent, it determined that it would be illogical for federal exchanges to be subject to a patchwork of varying state law requirements. The Third Circuit explained that the Supreme Court's opinion in ***King v. Burwell*** supports the conclusion that there are meaningful differences between state and federal exchanges.[117] Further, the structure of the ACA necessitates that the provision applies to both federal and state operated exchanges. Ultimately, since New Jersey chose to cede control of its exchange to the federal government to operate on its behalf, the Third Circuit affirmed the district court's determination that a failure to comply with a purely state requirement could not render claims false.

113 579 U.S. at 180.
114 84 F.4th 126 (2d Cir. 2023).
115 The Second Circuit also noted that the use the Benefits Conversion Statute as a basis for a false – certification claim was a matter of first impression in all circuits.
116 2023 WL 3221746 (3d Cir. 2023).
117 576 U.S. 473 (2015). *King* considered the application of federal tax credits to federal and state operated healthcare exchanges. By nature, the tax credit program would not logically operate if it only applied to federally operated exchanges.

Noncompliance with state laws amounted to a plausible submission of false claims in ***U.S. ex rel. Ellsworth Assoc., LLP v. CVS Health Corp.***[118] In that case, the relator alleged that the defendants engaged in an anti-competitive scheme to block Medicare Part D recipients from accessing less expensive drugs. The relator argued that the defendants' noncompliance with state laws regarding substitution of generic pharmaceuticals rendered claims false under an implied and express false certification theory. The district court determined that under the relevant federal regulations, a prescription plan sponsor may only provide prescription drug benefits for those drugs that are dispensed upon a "valid" prescription, which is defined as those that "compl[y] with all applicable state law requirements constituting a valid prescription." As a result, the district court concluded that the plan sponsor is required to attest to all data submitted on reimbursement claims and to certify compliance with state laws.

In ***U.S. ex rel. Bashir v. The Boeing Co.***, the relator alleged that the defendants falsely certified compliance with federal regulations, including national security requirements related to the construction and maintenance of the Air Force One fleet.[119] The district court agreed with the defendants that merely pleading that the defendants' certification of completed work "that it knows was not actually done in accordance with the prime contract," was insufficiently particular to support a claim of an express false certification. The district court, however, determined that the relator adequately pleaded an implied false certification because the defendants made specific representations about the goods provided and the failure to disclose noncompliance with material requirements.

We reported previously on ***U.S. ex rel. Osinek v. Kaiser Permanente***, in which the government intervened in six complaints alleging that members of the Kaiser Permanente consortium violated the FCA through improper use of addenda to add false diagnoses to medical records.[120] As to the FCA's falsity element, the district court held that the government's allegations adequately pleaded factual falsity because the government alleged that patient conditions were contradicted by the medical record and that those conditions, therefore, did not actually exist. Notably, Kaiser itself admitted that "contradictions in medical records *can* serve as *evidence* of a nonexistent diagnosis," and the government pleaded specific examples of clinically inaccurate diagnoses. The government also alleged that these examples were not isolated but representative of systemic and programmatic issues and stemmed from pressure exerted to induce physicians to add unsupported diagnoses.

In ***United States v. Am. Health Found. Inc.***, the government alleged that the defendant failed to comply with the Nursing Home Reform Act (NHRA) and its implementing regulations while knowingly certifying compliance.[121] The government's allegations that the defendant submitted quarterly "assessments" certifying compliance with the NHRA despite falling well short of regulatory requirements were sufficient to plead falsity under an implied false certification theory. The government's allegations were also sufficient to plead factually false statements, as the government cited surveys and sample residents who received federal reimbursement.

118 2023 WL 2467170 (E.D. Pa. Mar. 10, 2023).
119 2023 WL 6377575 (W.D. Wash. Sept. 29, 2023).
120 2023 WL 4054279 (N.D. Cal. June 15, 2023).
121 2023 WL 2743563 (E.D. Pa. Mar. 31, 2023).

> **Under a worthless services theory of FCA liability, a claim for federal reimbursement for a service that lacks any medical value is factually false because the service did not actually occur.**

In ***U.S. ex rel. Ellis v. CVS Health Corp.***, the relator alleged that CVS failed to comply with shipping requirements for pharmaceuticals to which it had certified compliance.[122] The district court concluded that the relator failed to plead falsity under a theory of implied false certification because the relator did not identify any representation about the goods or services provided that would be rendered false by the alleged failure to comply with any specific legal requirements. Moreover, the relator did not identify any expressly false certifications by CVS related to the goods or services provided.

Worthless Services

Under a worthless services theory of FCA liability, a claim for federal reimbursement for a service that lacks any medical value is factually false because the service did not actually occur. Difficult to prove in practice, such worthless services allegations underlie several FCA complaints each year.[123]

In ***U.S. ex rel. Ellis v. CVS Health Corp.***, while the relator failed to adequately plead an express or implied false certification theory of falsity, the district court concluded that the relator did plead a worthless services theory of falsity.[124] As previously noted, the relator alleged that the defendants falsely certified compliance with shipping procedures for various pharmaceuticals. The medication guides for the three pharmaceuticals at issue stated "do not freeze," and CVS's customer service representatives were trained to tell customers to discard medication that appeared to have been frozen. Such targeted allegations raised the issue of whether the pharmaceuticals had medical value or whether they had been rendered useless by flash freezing during shipment. The district court noted that the main issue moving forward was whether the drugs were rendered "worthless" or "less effective" such that they amount to worthless under FCA standards.

122 2023 WL 3204015 (E.D. Pa. May 2, 2023).

123 *See also United States v. Am. Health Found. Inc.*, 2023 WL 2743563 (E.D. Pa. Mar. 31, 2023), which found that the government sufficiently pleaded that the nursing home services were so inadequate and "grossly negligent" that it crossed "the proverbial line in the sand for the purposes of determining when clearly substandard services become worthless."

124 2023 WL 3204015 (E.D. Pa. May 2, 2023).

A contrary conclusion was reached in ***U.S. ex rel. Williams v. Landmark Hosp. of Athens, LLC***.[125] In that case, the district court held that the relator's allegations that the defendants mislabeled and misidentified laboratory specimens constituted general negligence and were insufficient to support a worthless services theory of falsity in connection with an alleged fraudulent COVID-19 testing scheme.

DEVELOPMENTS REGARDING KNOWLEDGE AND SCIENTER

In order to prevail on FCA claims, a *qui tam* relator or the government must plead and prove that the defendant acted with one of three mental states: (1) actual knowledge; (2) deliberate ignorance; or (3) reckless disregard of the truth or falsity of the information. As discussed, the Supreme Court in ***U.S. ex rel. Schutte v. SuperValu Inc.*** clarified that the FCA's scienter element focuses on "what the defendant thought when submitting the false claim" – meaning whether the defendant subjectively knew that its claims were false. Case law will continue to develop in the coming years, but several courts have already considered the FCA's scienter element following *Schutte*. Initial results suggest that courts likely will reach varying outcomes as they grapple with the FCA's scienter element and that it will remain a hotly litigated issue in post-*Schutte* FCA litigation.

As we reported in last year's Review, FCA defendants had obtained significant victories on the issue of scienter where courts applied the objective standard from the Supreme Court's opinion in *Safeco*. Those cases included *Schutte* as well as ***U.S. ex rel. Proctor v. Safeway, Inc.***, in the Seventh Circuit, ***U.S. ex rel. Sheldon v. Allergan Sales, LLC***, in the Fourth Circuit and ***Olhausen v. Arriva Medical, LLC***, in the Eleventh Circuit.[126] The relators in

> **In order to prevail on FCA claims, a *qui tam* relator or the government must plead and prove that the defendant acted with one of three mental states:**
>
> 1. **actual knowledge;**
> 2. **deliberate ignorance; or**
> 3. **reckless disregard of the truth or falsity of the information.**

125 2023 WL 3097948 (M.D. Ga. Apr. 26, 2023).

126 *Schutte*, 9 F.4th 455 (7th Cir. 2021); *Proctor*, 30 F.4th 649 (7th Cir. 2022); *Olhausen*, 2022 WL 1203023 (Apr. 22, 2022); *Sheldon*, 24 F.4th 340 (4th Cir. 2022); *Sheldon*, 49 F.4th 873 (4th Cir. 2022) (*en banc*).

each of these cases petitioned the Supreme Court for review of the FCA's scienter standard. With the Supreme Court's decision in *Schutte* in June 2023, the defendants' victories in these cases were vacated and the cases remanded back to their respective lower courts for further proceedings.[127] In two of these cases, the parties have fully briefed dispositive motions following remand, which highlight how the plaintiffs and the defendants (and DOJ through a Statement of Interest filing) strongly disagree as to how *Schutte* should be applied moving foward.[128] We expect that decisions on these motions will be issued in 2024.

Beyond those cases, courts issued other important scienter decisions, as well. In ***U.S. ex rel. Heath v. Wisconsin Bell, Inc.***, the Seventh Circuit held that knowing about a regulation and yet not having a system in place to monitor compliance with that regulation is enough to create a reasonable inference that a defendant was "conscious of a substantial and unjustifiable risk that [its] claims [were] false, but submit[ted] the claims anyway" – (*i.e.,* the "reckless disregard" standard under *Schutte*).[129] There, the relator alleged that a telecommunication provider submitted false claims to the government by pricing its customers who were eligible for federal subsidies (primarily schools and libraries) the same as its customers who were not eligible for federal subsidies, in violation of the Federal Communications Commission's (FCC) "lowest-corresponding-price rule." Relying on the Supreme Court's opinion in *Schutte*, the Seventh Circuit reversed a district court's order granting summary judgment for the defendant on scienter because the defendant admitted that it was aware of the rule, but still did not implement any methods or programs to make sure its contracts with eligible schools and libraries complied with the rule. Indeed, as the Seventh Circuit noted, the defendant continued to violate the rule even after it finally implemented procedures to attempt to comply with the rule and after its parent company settled a DOJ and FCC investigation regarding similar issues in a different state.

Conversely, in ***U.S. ex rel. Kraemer v. United Dairies, LLP***, the Eighth Circuit affirmed summary judgment in favor of the defendant where a relator alleged that several dairy farms were falsely certifying to the Federal Crop Insurance Corporation (FCIC) that the grain corn they were planting and insuring complied with federal regulations.[130] While the Eighth Circuit primarily based its holding on materiality grounds, it also observed that the defendant dairy farms did not have "a culpable mind" to defraud the government. The Eighth Circuit observed that the FCIC's insurance program was "to say the least, complex" and that "overwhelming" testimony demonstrated that the type of grain corn defendants had been planting could be insured by the FCIC.

In ***U.S. ex rel. Edalati v. Sabharwal***, the district court addressed what it described as the "inverse" factual scenario of *Schutte* – where the defendant violated a relatively unambiguous regulation but subjectively believed that his claims were proper – in denying *a relator's* motion for summary judgment on the issue of scienter.[131] There, the relator moved for partial summary judgment because the defendant had reviewed the regulation at issue, was aware of all of the underlying facts that did not satisfy the regulatory requirements, failed to seek any clarification or guidance on the significance of those facts and proceeded to bill CMS anyway. Because evidence in the record demonstrated that the defendant subjectively believed claims billed to Medicare were proper, the district court ruled that it was a question of fact whether or not the defendant knowingly submitted false claims.

Several district courts have evaluated scienter arguments at the pleading stage and found the allegations sufficient to survive a motion to dismiss. In ***U.S. ex rel. Louderback v. Sunovion Pharmaceuticals, Inc.***, a defendant moved to dismiss a relator's *qui tam* complaint because the defendant had posted a "Part B Agreement" (an agreement that, according to the relator, violated the AKS) to its website.[132] While the district court granted the defendant's motion to dismiss on causation grounds, the district court rejected the defendant's scienter argument because, at best, posting the agreement on its website "for all to see" showed that a hypothetical person might have concluded that the agreement fell into an AKS safe harbor, which would not be dispositive of scienter.

Similarly, in ***U.S. ex rel. Miller v. Reckitt Benckiser Grp. PLC***, the relator alleged that a drug manufacturer structured its contract with a pharmacy benefit manager (PBM) so that it could evade CMS's "best price" regulations while still offering significant rebates to the PBM.[133] Despite the defendants' argument that they attempted to comply with an unambiguous regulation (and thus did not have scienter), the district court found that the relator pleaded scienter by alleging that the defendants ensured that the parts of the negotiation were discussed under the table, that the PBM helped structure the contract to avoid setting a new "best price," and that the defendants used these contracts to submit "best price" reports to CMS.

Another notable development can be found in the district court's opinion in ***U.S. ex rel. Patzer v. Sikorsky Aircraft Corp.***, where summary judgment was denied as to scienter because there was evidence in the record that a compliance employee had repeatedly warned executives that they were negotiating an arrangement that would amount to cost-plus-a-percentage-of-cost (CPPC) contracting, which is illegal in government contracting.[134] The district court noted that while the lack of any response to the employee's concerns could show a lack of actual knowledge, the record evidence could be enough for a reasonable juror to conclude that the defendants either ignored or gave no serious consideration to the concerns and, as a result, acted with reckless disregard as to whether they were violating the ban on CPPC contracting.

And, in ***United States v. Regeneron Pharmaceuticals, Inc.***, the district court reached a similar conclusion, denying summary judgment because certain defendant employees believed they were engaging in conduct that would violate the FCA.[135] As the district court put it, "the relevant scienter is not limited to that of the CEO (who, of course, may well have been deceived by his employees); if a single employee of [defendant] had the requisite knowledge and intent, that is sufficient."

127 *U.S. ex rel. Schutte v. SuperValu, Inc.*, No. 11-cv-03290 (C.D. Ill.); *U.S. ex rel. Proctor v. Safeway, Inc.*, No. 11-cv-03406 (C.D. Ill.); *Sheldon v. Forest Laboratories, LLC*, No. 14-cv-02535 (D. Md.); *Olhausen v. Arriva Medical*, LLC, No. 19-cv-20190 (S.D. Fla.).
128 *Schutte*, No. 11-cv-03290 (C.D. Ill.); *Sheldon*, No. 14-cv-02535 (D. Md.).
129 75 F.4th 778 (7th Cir. 2023) (quoting *Schutte*, 143 S. Ct. at 1401).
130 82 F.4th 595 (8th Cir. 2023), *reh'g denied*, 2023 WL 7015733 (8th Cir. Oct. 25, 2023).
131 2023 WL 5334621 (D. Kan. Aug. 18, 2023).
132 2023 WL 8188879 (D. Minn. Nov. 27, 2023).
133 2023 WL 6849436 (W.D. Va. Oct. 17, 2023).
134 2023 WL 6883637 (E.D. Wis. Oct. 17, 2023).
135 2023 WL 7016900 (D. Mass. Oct. 25, 2023).

As with the other FCA liability provisions, allegations of reverse false claims are subject to the pleading requirements of Rule 9(b) and are often considered at the motion to dismiss stage.

REVERSE FALSE CLAIMS

Under 31 U.S.C. § 3729(a)(1)(G), a defendant may have liability under the FCA when it: (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. As such, § 3729(a)(1)(G) is known as the FCA's "reverse false claim" provision because liability results from a party avoiding payment of money due to the government as opposed to submitting a false claim to the government.

Analysis of the FCA's reverse false claim provision often focuses on its relationship to traditional FCA violations. Courts typically 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.[136]

As with the other FCA liability provisions, allegations of reverse false claims are subject to the pleading requirements of Rule 9(b) and are often considered at the motion to dismiss stage. When a plaintiff fails to plead the presentment of false claims with sufficient particularity, district courts have little difficulty in dismissing allegations purporting to assert violations of the FCA reserve false claim provision. In ***U.S. ex rel. Hartley v. Hosp. Auth. of Valdosta & Lowndes Cnty., Ga.***, the district court dismissed the relator's reverse false claim allegations because of the relator's failure to plead that the defendant hospital falsely submitted any claims for payment to the government, in relation to an alleged wide-ranging scheme.[137] Likewise, in ***U.S. ex rel. PCTLS, LLC v. Northwestern Memorial Healthcare***, the district court granted the defendant hospital's motion to dismiss allegations that it had violated the FCA's reverse false claim provision in connection with the alleged waiving or discounting of patient co-payments in violation of the AKS.[138] The district court explained that the relator's claims failed because the relator failed to plead any false claims that needed to be repaid.[139]

In considering reverse false claim violations, district courts often must evaluate whether certain alleged conduct amounts to an "obligation." In ***U.S. ex rel. Wheeler v. Acadia Healthcare Co.***, the relator alleged that the defendants failed to implement and follow provisions of a CIA with HHS-OIG, which the relator asserted triggered the stipulated penalty provisions of the CIA.[140] The district court determined that the contingent nature of the CIA's stipulated penalty provisions amounted to contingent exposure and did not constitute an "obligation" under the FCA. While the district court noted that courts are split on this particular question, it ultimately concluded that the majority position that stipulated penalty provisions do not amount to an obligation was the more persuasive approach.[141]

The district court reached a similar conclusion in ***U.S. ex rel. Ellsworth Assoc., LLP v. CVS Health Corp.***, where the relator alleged that CVS knowingly violated Federal Trade Commission firewall requirements and refused to pay fines that might be due as a result of a violation of those requirements.[142] The district court explained that reverse false claim violations could not be based on a "future discretionary act" and that regulatory fines and penalties are not considered "obligations" because they are "contingent on the Government's prosecutorial discretion."

PUBLIC DISCLOSURE BAR

The FCA's "public disclosure bar" is designed to deter opportunistic *qui tam* relators from filing parasitic lawsuits substantially based on information previously disclosed to the public. A relator's claim can survive the public disclosure bar, however, if the relator qualifies as an "original source" of the FCA allegations.[143]

The public disclosure bar provides a strong defense for a defendant facing allegations of fraud when those allegations are already in the public domain. Where a defendant asserts the public disclosure bar as a defense, the district court must determine whether: (1) a public disclosure previously occurred; (2) that disclosure was substantially similar to the relator's allegations; and, if so, (3) the relator is nevertheless an "original source" of the FCA allegations.

136 *See U.S. ex rel. Wheeler v. Acadia Healthcare Co.*, 2023 WL 6035712 (W.D.N.C. July 27, 2023) ("[A] relator cannot properly allege a reverse false claim that is premised on the same conduct as claims under Section 3729(a)(1)(A) and (a)(1)(B)." (quotation marks and citation omitted)).

137 2023 WL 6702483 (M.D. Ga. Oct. 12, 2023).

138 2023 WL 6388328 (N.D. Ill. Sept. 29, 2023).

139 *See also U.S. ex rel. Merritt v. Amedisys, Inc.*, 2023 WL 5436347 (M.D. Ga. Aug. 23, 2023) (denying the defendant's motion to dismiss concerning the FCA's reverse false claim provision concerning alleged false certifications for home healthcare services for which patients were not eligible).

140 2023 WL 6035712 (W.D.N.C. July 27, 2023).

141 *See also U.S. ex rel. Rubin v. Sterling Knight Pharm., LLC*, 2023 WL 3190732 (M.D. Fla. Mar. 23, 2023) (rejecting reverse false claim allegations based on allegedly inflated average wholesale price because the relator failed to identify a specific "obligation" to the United States preceding the allegedly fraudulent conduct).

142 2023 WL 2467170 (E.D. Pa. Mar. 10, 2023).

143 31 U.S.C. § 3730(e)(4).

A relator's claim can survive the public disclosure bar, however, if the relator qualifies as an "original source" of the FCA allegations.

When is the Public Disclosure Bar Jurisdictional or Non-Jurisdictional?

Enacted in 2010, the ACA resulted in numerous changes to the FCA, one of which was district courts' authority to dismiss cases pursuant to the public disclosure bar. While the FCA previously stated that "[n]o court shall have *jurisdiction* over an action...,"[144] the ACA's revised language provides that "[a] court *shall dismiss* an action, unless opposed by the government...."[145] Since that statutory modification, most courts have held that the post-ACA public disclosure bar serves as an affirmative defense rather than as a limit to subject-matter jurisdiction.[146]

Courts have applied the public disclosure bar differently, however, when some of a relator's *qui tam* allegations pre-date the ACA and others post-date the ACA. In ***Foster v. PHH Mortgage***, the district court ruled that if any of the alleged fraudulent activity occurred before the ACA's enactment on March 23, 2010, then the entire alleged scheme is subject to the pre-ACA jurisdictional public disclosure bar.[147] There, a relator alleged that a mortgage lender defrauded the government by refusing to grant borrowers' requests for forbearance and, instead, foreclosed on government-guaranteed mortgages. Although the relator argued that his pre-ACA factual allegations were merely background information and that all of the actual FCA violations occurred after the ACA was enacted, the district court reasoned that the jurisdictional nature of the public disclosure bar turns on "whether any of the conduct related to the alleged violation took place *before* Congress's amendment in March 23, 2010." Because some of the factual allegations – even if background information – occurred before the jurisdictional dividing line, the district court ruled that the pre-ACA public disclosure bar applied to the entirety of the relator's claims.

What is a "Public Disclosure"?

By statute, the public disclosure bar only applies to allegations that were publicly disclosed: "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media."[148] While that standard may seem straightforward, courts continue to grapple with what disclosures fit into those specified categories.

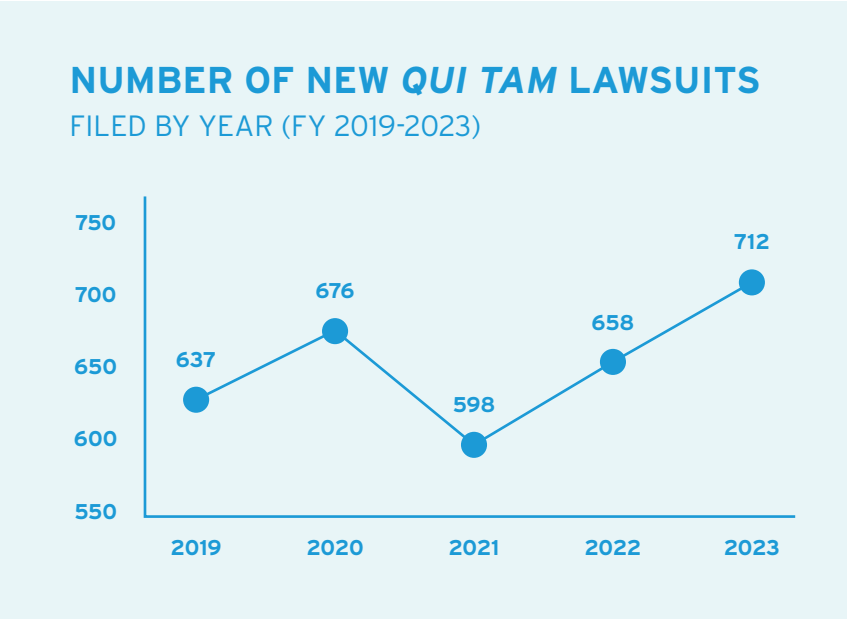
In ***U.S. ex rel. Silbersher v. Valeant Pharm Int'l, Inc.***, the Ninth Circuit addressed a novel disclosure and held that an inter partes review (IPR) of a patent was not a public disclosure.[149] The relator alleged that a drug manufacturer fraudulently obtained several patents so it could charge an artificially high price for certain drugs even though the patents had been called into question by: (1) earlier patent prosecutions describing similar drugs and related enforcement actions; (2) an IPR proceeding dealing with whether the patents were valid at all; (3) two published medical studies that undermined the manufacturer's discovery; and (4) a *Law360* article that covered challenges to the patents. While the Ninth Circuit held that the previous patent prosecutions were clearly public disclosures and assumed without deciding that the *Law360* article and published medical studies were disclosures, it held that the IPR was not a public disclosure because the government was not a party to the proceeding. The Ninth Circuit also noted that the IPR's function was to adjudicate a dispute between the manufacturer and a competitor seeking to invalidate the patent – not to conduct a government fact-finding process or investigation.

Courts also addressed what sources of information can qualify as part of "the news media." On one hand, in ***U.S. ex rel. Kuriyan v. Molina Healthcare of New Mexico, Inc.***, the district court held that "news media" should be defined broadly to include "newsworthy" information that is readily available to the public.[150] As a result, the district court held that a report found on the New Mexico Legislature's website qualified as a public disclosure because the website was intended to disseminate legislative affairs information to the public. On the other hand, some courts have been hesitant to characterize any and all information that is publicly available on the internet as a public disclosure. For instance, in ***U.S. ex rel. Louderback v. Sunovion Pharmaceuticals, Inc.***, the district court held that the public disclosure bar did not apply where the defendant provided the court with a screenshot from its website.[151] The district court reasoned that any definition of the term "news media" should be tethered to the actual definition of: (1) "news," which it observed to be "a report of recent events," "material reported in a newspaper or news periodical or on a newscast," and "matter that is newsworthy;" and (2) "media," which (according to the court) implied "agencies of mass communication." As a result, the defendant's customer-directed communications, which were the functional equivalent of a "terms of use" document, were not public disclosures.

When are Allegations "Substantially the Same" as a Disclosure?

For a prior public disclosure to preclude a relator's allegations, the public disclosure also must be "substantially the same" as the allegations in the *qui tam* complaint. In ***U.S. ex rel. Silbersher v. Valeant Pharm. Int'l, Inc.***, the Ninth Circuit reversed a district court's order granting a motion to dismiss, holding that prior disclosures were not "substantially

144 31 U.S.C. § 3730(e)(4)(A) (2009) (emphasis supplied).
145 31 U.S.C. § 3730(e)(4)(A) (2010) (emphasis supplied).
146 *See U.S. ex rel. Louderback v. Sunovion Pharm., Inc.*, 2023 WL 8188879 (D. Minn. Nov. 27, 2023) ("The federal courts of appeals that have confronted the issue have unanimously held that the 2010 amendments transformed the public disclosure bar from a jurisdictional bar to an affirmative defense."); *U.S. ex rel. Kuriyan v. Molina Healthcare of N.M., Inc.*, 2023 WL 5526373 (D.N.M. Aug. 28, 2023) (same).
147 2023 WL 4312899 (N.D. Ill. May 30, 2023).
148 31 U.S.C. § 3730(e)(4)(A).
149 76 F.4th 843 (9th Cir. 2023).
150 2023 WL 5526373 (D.N.M. Aug. 28, 2023); *see also U.S. ex rel. Berkley v. Ocean State, LLC*, 2023 WL 3203641 (D.R.I. May, 2 2023) (holding that a press release published to a website lacking editorial judgment was a public disclosure because it was intended to disseminate information to the public at large).
151 2023 WL 8188879 (D. Minn. Nov. 27, 2023).



the same" as fraud allegations where the prior disclosures contained only pieces of the puzzle but did not show the whole picture of the fraud.[152] The relator alleged that a drug manufacturer withheld material information in order to fraudulently obtain a patent and charge the government artificially high prices for drugs. The drug manufacturer argued that the relator's claims were barred because several prior disclosures disclosed that the patent should be invalidated for obviousness. The Ninth Circuit disagreed, finding that none of the prior disclosures triggered the public disclosure bar because they did not disclose the patent was fraudulently obtained and, as a result, the relator still had to "fill[] the gaps by putting together the material elements of the allegedly fraudulent scheme."

In addition to requiring the entirety of the alleged fraudulent scheme to be disclosed, prior disclosures only trigger the public disclosure bar if the disclosures "set the government squarely on the trail of a specific and identifiable defendant's participation in the fraud."[153] In ***U.S. ex rel. Piacentile v. U.S. Oncology, Inc.***, the Second Circuit held that a defendant need not be named specifically in the prior disclosure in order to be included within the disclosure. There, an oncology practice moved to dismiss a relator's *qui tam* complaint because three complaints previously disclosed the kickback scheme at issue. Although none of the complaints identified the oncology practice by name, the Second Circuit affirmed the district court's order granting dismissal because the previous complaints each described the practice's involvement in the scheme by implication, which sufficiently put the government on notice that the oncology practice was involved in the kickback scheme.

152 76 F.4th 843 (9th Cir. 2023).
153 2023 WL 2661579 (2d Cir. Mar. 28, 2023).

The Fifth Circuit reached a similar conclusion in ***U.S. ex rel. Vaughn v. Harris County Hospital Dist.***, holding that the public disclosure bar was triggered where news media previously reported that federal officials were investigating the same fraudulent scheme that the relator alleged in his complaint.[154] Because the government clearly was aware of the alleged fraud, the fact that the prior disclosures did not detail the exact manner that the defendants perpetrated the fraudulent scheme was irrelevant.

Yet, in ***U.S. ex rel. Berkley v. Ocean State, LLC***, the district court denied a motion to dismiss on public disclosure grounds because the prior disclosure did not name the defendants and, as a result, the relator had to "ferret out" the defendants' alleged role in defrauding the government through his own investigation, demonstrating that the prior disclosure did not put the government on notice of the potential fraud.[155] And, in ***U.S. ex rel. Carson v. Select Rehab., Inc.***, the district court denied a motion to dismiss where a rehabilitative service provider argued that the public disclosure bar applied because news articles and government reports previously disclosed the relator's allegations.[156] The district court disagreed and found that, although the relator's allegations were similar to the reports and news articles, the prior disclosures only described a general industry problem and therefore fell short of accusing the provider of any actual fraudulent activity.

When is a Relator an Original Source?

Even if a prior public disclosure was substantially similar to a relator's allegations, a relator may still proceed if he or she qualifies as an "original source." An "original source" is an individual who either: (1) voluntarily disclosed the information to the government before the relevant public disclosure; or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and voluntarily provided that information to the government before filing his or her complaint.

Most courts agree that simply adding additional details regarding an alleged scheme does not qualify a relator as an original source. In ***U.S. ex rel. Vaughn v. Harris County Hospital Dist.***, the Fifth Circuit affirmed dismissal under the public disclosure bar of a *qui tam* lawsuit alleging that private hospitals violated the FCA by submitting private expenses to be matched by federal Medicaid dollars.[157] The relator, an administrator of the program in Texas who handled these partnerships, argued he was an original source despite years of news media coverage of the allegations. Despite being an insider, the Fifth Circuit found that he did not "materially add" to the public allegations where the defendants were sufficiently identified by the news media, the public disclosures themselves indicated that the defendants had sufficient knowledge of the conduct and any specifics that the relator provided were just variations on the publicly disclosed allegations.

154 2023 WL 8649876 (5th Cir. Dec. 14, 2023).
155 2023 WL 3203641 (D.R.I. May, 2 2023).
156 2023 WL 5339605 (E.D. Pa. Aug. 18, 2023); *see also U.S. ex rel. Ellsworth Assocs., LLP v. CVS Health Corp.*, 2023 WL 2467170 (E.D. Pa. Mar. 10, 2023) (holding that a public disclosure was not substantially similar where it would only suggest that the government "had some general suspicion" of wrongdoing and not that the government "was aware of the underlying and specific fraudulent allegations in th[e] case").
157 2023 WL 8649876 (5th Cir. Dec. 14, 2023).

An "original source" is an individual who either:

1. **voluntarily disclosed the information to the government before the relevant public disclosure; or**
2. **"has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" and voluntarily provided that information to the government before filing his or her complaint.**

Similarly, the district court in ***U.S. ex rel. Winnon v. Lozano*** dismissed the action, in part, because it determined that simply enumerating additional defendants or locations where the fraud was perpetrated was insufficient to "materially add" to already publicly disclosed allegations regarding therapy services at certain SNFs where the government had investigated and settled similar allegations in a public lawsuit.[158] The relator there also failed to state whether she provided the information she claimed qualified her as an original source to the government.

In addition, taking publicly disclosed data and information and applying "specialized knowledge or expertise" is insufficient to qualify a relator as an original source. In ***U.S. ex rel. Silbersher v. Allergan, Inc.***, the district court on remand from the Ninth Circuit determined that an individual who gained his knowledge from patent prosecutions of various pharmaceutical companies was not an original source.[159] The district court held that a relator who derives his knowledge of the alleged fraud by applying specialized expertise to the publicly disclosed facts cannot claim to have "independent" knowledge under the original source exception. The district court determined that the relator instead must bring some set of "historical facts" beyond any "specialized expertise the relator brought to bear in order to discern those facts."

By contrast, a relator may qualify as an original source when he or she provides sufficient details that alert the government to fraud that is distinct from what was already disclosed publicly. In ***U.S. ex rel. Rubin v. Sterling Knight Pharm., LLC***, the district court found that a relator could move forward with a suit, despite an earlier filed action, where he provided personal knowledge of the corporate entities at issue, a conspiracy to cultivate a network of independent pharmacies and dispensing physicians to purchase inflated pharmaceuticals, manipulation of the average wholesale price reported for those pharmaceuticals and the specific pharmaceuticals that were at issue.[160] The previously filed complaint alleged a related fraud by pharmaceutical purchasers and did not implicate the manufacturers or include the detail provided by the relator.

At least one court analyzed the original source issue in the context of a corporate entity relator formed for the purpose of litigation. In ***U.S. ex rel. 3729, LLC v. Express Scripts Holding Co.***, the district court analyzed whether the relator, a limited liability company formed for the purpose of the FCA litigation, qualified as an original source under either the pre-ACA or post-ACA version of the FCA.[161] The district court dismissed the pre-ACA claims, holding that the newly formed relator could not have had "direct knowledge" of the information collected by its principals from before its formation. The removal of the "direct knowledge" requirement in the post-ACA statute allowed the litigation entity to proceed on its post-ACA allegations, but the district court found that it still did not "materially add" to the extensive public disclosures made in the news media.

FIRST-TO-FILE BAR

The FCA's first-to-file bar prevents any person or entity other than the government from "interven[ing] or bring[ing] a related action based on the facts underlying the pending action."[162] The provision prevents *qui tam* actions relying on the same essential facts the government has already obtained regarding the alleged fraud based upon a previously filed *qui tam* action.

The first-to-file bar prohibits bringing subsequent "related action[s]" under the FCA. It is not always clear, however, how "related" claims must be to invoke the bar. Since a subsequent claim is unlikely to restate the facts and allegations as a prior action verbatim, courts must diligently compare the claims to determine if they include the same essential elements of fraud. In ***U.S. ex rel. Mosley v. Walgreen Co.***, the district court applied the "material elements test" used by the Eleventh Circuit for assessing whether the first-to-file bar applied.[163] This test compares complaints side-by-side and determines whether the later-filed complaint alleges a fraudulent scheme the government already should be equipped to investigate based on the first complaint. In applying the test, the district court determined that both complaints alleged the same type of nationwide fraud connected to coupons and discounts for Medicare Part D drugs. The district court held that the prior complaint should have put the government on notice of the scope and nature of the allegations and dismissed the second-filed action under the first-to-file bar.[164]

158 2023 WL 6065161 (D.D.C. Sept. 18, 2023); *see also Foster v. PHH Mortg.*, 2023 WL 4312899 (N.D. Ill. May 30, 2023) (granting a motion to dismiss where the relators' complaints regarding mortgage fraud post-dated the thoroughly covered public mortgage crisis by at least a decade and did not add any information that would assist the government in identifying new fraudulent conduct).

159 2023 WL 2593777 (N.D. Cal. Mar. 20, 2023).

160 2023 WL 3190732 (M.D. Fla. Mar. 23, 2023), appeal dismissed sub nom. *Rubin v. Sterling Knight Pharm., LLC*, 2023 WL 4743747 (11th Cir. July 7, 2023).

161 2023 WL 4056042 (S.D. Cal. June 16, 2023).

162 31 U.S.C. § 3730(b)(5).

163 2023 WL 5029112 (S.D. Fla. Aug. 8, 2023).

164 The district court in *United States v. Millennium Physician Grp., LLC*, similarly compared the complaints side-by-side under the material elements test and found that while there were differences between the complaints at issue, there were a "myriad" of essential facts in common, holding that the complaints were "related" under the first-to-file bar. The second-filed complaint was dismissed. 2023 WL 2022228 (M.D. Fla. Feb. 15, 2023).

There remains a circuit split regarding whether the first-to-file bar is jurisdictional. Currently, the Fourth, Fifth, Sixth, Ninth, Tenth and Eleventh Circuits have held that the first-to-file bar is jurisdictional, despite potentially contrary suggestions by the Supreme Court, while the D.C., First, Second and Third Circuits have held it is not jurisdictional.

In ***U.S. ex rel. Mullen v. Cardinal Health, Inc.***, the district court dismissed a second complaint that shared the "essential facts" as a previously filed complaint.[165] The district court determined that the relator's complaint alleged the same fraudulent scheme and relied on similar underlying facts as a previously filed pending complaint. Both involved aggressive marketing practices by the defendant for the specialty pharmaceutical distribution market for physicians. Because the initial complaint provided the government with the essential facts to investigate the allegations, the district court concluded that the first-to-file bar prevented the action from proceeding.

Finally, there remains a circuit split regarding whether the first-to-file bar is jurisdictional. Currently, the Fourth, Fifth, Sixth, Ninth, Tenth and Eleventh Circuits have held that the first-to-file bar is jurisdictional, despite potentially contrary suggestions by the Supreme Court, while the D.C., First, Second and Third Circuits have held it is not jurisdictional.

STATUTE OF LIMITATIONS

The statute of limitations under the FCA can significantly limit or even require the dismissal of claims. Under 31 U.S.C. § 3731(b), an action asserting an FCA claim 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 2019, the Supreme Court held that both limitation periods apply to a declined *qui tam* action.[166] When the government declines to intervene, a relator may proceed with an action filed more than six years after the FCA violation occurs if the action is filed within three years of when the relevant government official, not the relator, should have known the material facts.

165 2023 WL 5807370 (D. Mass. Sept. 7, 2023).
166 *Cochise Consultancy v. U.S. ex rel. Hunt*, 139 S. Ct. 1507 (2019).

In ***U.S. ex rel. Schroeder v. Medtronic, Inc.***, the district court considered a motion to dismiss a relator's FCA claims against a device manufacturer, hospital and radiology physician group.[167] The physician group argued that certain claims were barred by the FCA's six-year statute of limitations, looking back from the date the relator filed an amended complaint naming the group. The relator argued for a ten-year statutory of limitations. The district court ultimately found that the six-year statute of limitations applied because the relator's initial disclosures that it provided to the government included physicians in the radiological group and sufficiently put the government on notice of the potential fraud. Since this disclosure was made more than three years prior to adding the physician group as a defendant, the district court determined that the government knew or should have known of facts material to the relator's FCA claims against the defendant and dismissed claims over six years as time-barred.

The inquiry to determine whether the government knew or should have known the relevant material facts is not limited to the initial disclosures made by the relator. In ***U.S. ex rel. La Frontera Ctr., Inc. v. United Behavioral Health, Inc.***, the district court considered a motion to dismiss a relator's fraudulent inducement claim based on a contract to process healthcare claims. Several months after the parties entered into the contract at issue, the defendant was subject to public hearings and fined for failure to process Medicaid claims.[168] The government should have known about the facts material to the claim given the public investigation, sanctions and news releases. The district court held that the relator had either three years after the government was put on notice or the six year statute of limitations within which to file suit. Because he did not, the complaint was dismissed as time-barred.

Courts have also emphasized that the FCA's statute of limitations applies to separate claims, but not separate theories of the same claim. In ***United States v. Wagoner***, the government alleged that a medical center and its providers fraudulently coded urine drug screen tests.[169] The government later amended its complaint to allege that the defendants also ordered urine drug screen tests that were not medically necessary. The defendant moved to dismiss, arguing that the statute of limitations should bar the new claims. The district court denied the defendant's motion, finding that the allegations were different theories underpinning the same legal claims and the same cause of action.

DISCOVERY DEVELOPMENTS

In litigated FCA cases, key questions of the scope of discovery and whether particular privileges apply to certain categories of communications are often hotly litigated. Discovery disputes regarding whether communications between *qui tam* relators and the government continue to be litigated both in intervened and declined FCA lawsuits. Other issues including the proper scope of discovery requests in FCA cases have also been considered by courts.

167 2023 WL 5152513 (D. Kan. Aug. 10, 2023).
168 2023 WL 1817380 (D.N.M. Feb. 8, 2023).
169 2023 WL 1795906 (N.D. Ind. Feb. 7, 2023), *reconsideration denied*, 2023 WL 5030763 (N.D. Ind. Aug. 8, 2023).

The government and relators often take an aggressive approach regarding the scope of applicable privileges and in challenging the adequacy of a defendant's discovery responses in FCA litigation because the burdens associated with discovery are typically most heavily borne by the defendants. Courts have traditionally adopted a deferential approach regarding the scope of discovery and application of privilege where the government or the relator is the requesting party. More recently, however, there has been an increased willingness to scrutinize these issues more closely.

For example, in ***U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.***, the First Circuit affirmed the district court's dismissal of the relators' claims based on the use of protected information, in direct violation of the district court's earlier orders.[170] In that case, the relators alleged that the defendants engaged in a fraudulent scheme to sell hip replacement devices. Prior to filing a *qui tam* lawsuit, the relators served as expert witnesses in multidistrict litigation involving the DePuy devices, and as such were subject to multiple protective orders regarding the confidential DePuy product design. The district court previously ruled that the relators were required to base their FCA claims on non-confidential information; nonetheless, the relators used the manufacturer's confidential information in drafting their second amended complaint. As a result, the district court dismissed relators' claims and the First Circuit affirmed, concluding that when the "noncompliant litigant has manifested a disregard for orders of the court and been suitably forewarned of the consequences of continued intransigence, a trial judge need not first exhaust milder sanctions before resorting to dismissal of the litigant's action or claim."

Government Related Discovery Requests

In ***U.S. ex rel. Liebman v. Methodist Le Bonheur Healthcare***, the relators alleged that the defendant hospital system unlawfully paid an oncology practice in exchange for patient referrals, in violation of the AKS.[171] The district court granted the government's motion for late intervention one month prior to the initial discovery deadline, based in large part on assurances by the government that there would be minimal additional discovery required. A number of significant discovery disputes nevertheless followed. For example, the magistrate judge ruled that the government's stipulation that it would not rely on certain documents requested by the defendants failed to satisfy its discovery obligations. As such, the government was required to produce all non-privileged responsive documents and the defendants were entitled to a Rule 30(b)(6) deposition of government officials about the steps taken to search for and identify responsive documents if the response is not satisfactory. The magistrate judge also ruled that the government's failure to comply with prior discovery orders was not substantially justified and permitted the defendants to file a motion for sanctions. As to the defendant's discovery obligations, the district court affirmed the magistrate judge's ruling that the defendant did not waive privilege concerning documents and communications with employees of consulting firms retained by the defendant to provide FMV opinions regarding the compensation between the hospital and practice. The government sought to compel the production of such documents, arguing that the defendant should not be allowed to produce and rely on the opinions as a "sword," and then "shield" the underlying communications as privileged. After an *in camera* review, the district court rejected the government's arguments and concluded that the defendant's intent to rely on the FMV opinions did not waive the asserted privileges.

We previously reported on ***U.S. ex rel. Fischer v. Cmty. Health Network, Inc.***, where the government intervened with respect to alleged Stark Law violations.[172] Nearly a decade after the filing of the initial *qui tam* lawsuit, the defendants raised an advice of counsel defense and the government challenged the adequacy of privilege logs produced by the defendants. In considering this issue, the district court held that the defendants' privilege logs did not adequately describe the legal advice to support the assertion of the protections of the attorney work-product doctrine and granted the government's request for a more detailed privilege log. The district court noted that certain entries had no reference to seeking or requesting legal advice, such as, "Communication with In-House counsel regarding physician contracts and/or compensation" and "Attachment to Communication with In-House counsel regarding physician contracts and/or compensation." Because the defendants had specified "seeking legal advice" or "requesting legal advice" on some, but not all, of the entries, the district court reasoned that the absence of those words must carry weight. Further, the district court was unpersuaded by the defendants' use of a third party to conduct privilege review reasoning that the privilege log must be able to stand on its own. Accordingly, the government had good reason to challenge the sufficiency of the so-called "barebones entries" and the defendants were ordered to supplement their privilege log. The district court concluded by cautioning that the failure to produce an adequate privilege log, where appropriate, could result in a waiver of privilege.

In a separate order in that same case, the defendants were also required to provide more detailed responses to the government's requests to identify every physician who received a service line financial performance bonus and describe how the bonus was calculated.[173] The district court agreed with the government that the defendants' interrogatory responses were deficient, quoting examples that it found to include vague assertions and company jargon. Additionally, the district court found sanctions appropriate as to the defendants' failure to provide a narrative response describing the criteria and calculation of the bonus after multiple requests, nine discovery conferences over two years and a violation of the district court's prior discovery order.

The defense sought to compel production of communications between the relator and journalists in addition to communications between counsel for the relator and counsel for the U.S. Senate Committee on Veterans' Affairs in ***U.S. ex rel. Schroeder v. Medtronic, Inc.***[174] Despite the relator's claims that all relevant documents had been produced, the defendant argued that relevant documents were clearly withheld by the relator based on the defense's review of the privilege log and certain redacted documents in the initial production. The district court ordered the relator to produce all responsive communications. Further, communications between the relator's counsel and general counsel for the Senate Committee were not protected by attorney-client or common interest privilege because the relator provided no evidence to show that the relator was seeking legal advice or that any

170 69 F.4th 1 (1st Cir. 2023).
171 2023 WL 3400486 (M.D. Tenn. May 10, 2023).
172 2023 WL 3151847 (S.D. Ind. Apr. 28, 2023), *report and recommendation adopted sub nom. U.S. ex rel. Fischer v. Cmty. Health Network, Inc.*, 2023 WL 4577673 (S.D. Ind. June 27, 2023).
173 2023 WL 3114211 (S.D. Ind. Apr. 27, 2023).
174 2023 WL 4864983 (D. Kan. July 31, 2023).

information was shared in confidence. The district court also found that a general shared desire for one party to prevail in litigation does not alone constitute a common legal interest justifying the application of the common interest doctrine to protect the materials shared with a non-party to the litigation, such as the Senate Committee. Rather, it determined that a community of interest exists where different persons or entities have an identical, not similar, legal interest with respect to the subject matter of a communication between an attorney and a client concerning legal advice.

The district court ruled that the relator's FCA disclosure statement to the government was protected in ***U.S. ex rel. Everest Principals, LLC v. Abbott Labs., Inc.***[175] The district court noted that the disclosure statement was prepared in anticipation of litigation and at least protected as work product. Noting the circuit split as to whether such documents are solely protected as work product, opinion product or a combination of the two, the district court found it unnecessary to analyze the distinction here where the defendants failed to show substantial need and undue hardship. The district court also concluded that the relator's communications with the government were protected as work product.

In ***Franchitti on behalf of United States v. Cognizant Tech. Sols. Corp.***, the defendants sought to compel the government as a non-party to produce documents and communications between the government and the relator, and between DOJ and other government entities.[176] The government objected to the requests as overly broad, unduly burdensome and precluded by various privileges and public policy. The district court concluded that applicable privileges protected documents and communications between DOJ and the relator. The district court, however, rejected the government's objections to producing documents and communications between DOJ and other governmental entities because such documents could bear on the government's knowledge of the underlying conduct and go directly to the FCA's materiality element. The district court concluded that the request specifically targeted non-privileged, relevant interagency communications about the lawsuit, reasoning that the defendants "cannot more precisely itemize the records" without additional information from the government.

Discovery disputes followed the government's intervention in ***U.S. ex rel. Integra Med Analytics LLC v. Laufer***, in which it was alleged that SNFs billed for medically unnecessary services by keeping residents for longer than necessary and providing higher levels of rehabilitation therapy than reasonable or necessary.[177] The defendants requested that the government identify which of the 152 individuals in its initial disclosures the government interviewed and provide "a summary of the information provided by each" interviewee after the government intervened. The government argued that such information should be protected by the work-product and law enforcement privileges, but offered to identify the individuals referenced in the complaint. While the district court determined that the interviewee names were protected as work-product, the district court concluded that the defendants showed a substantial need and undue hardship justifying limited disclosure. As a result, the government was ordered to identify the interviewees on which it intended to rely upon at trial as well as the individuals referenced in the complaint. Government interview summaries, however, were determined to be protected work-product.

Scope of Discovery

The defendants in ***U.S. ex rel. Everest Principals, LLC v. Abbott Labs., Inc.***, described earlier, sought a protective order to limit the geographic and temporal scope of the relator's FCA discovery.[178] While the district court allowed discovery nationwide, it did limit the time period for discovery. The district court determined that the allegations in the complaint were sufficient to justify nationwide discovery because the relator provided details of national training, sales tracking and compensation directed at implementing the alleged fraudulent practices and identified specific circumstances demonstrating the same in several geographic regions, even though the relator worked only in a specific geographic area.

In ***Watkins v. Lincare, Inc.***, the plaintiff alleged that the defendant respiratory therapy and services provider retaliated against her after she reported the defendant's instances of patient harm and fraudulent billing.[179] The defendant terminated the plaintiff in January 2021 and in June 2021 reached a settlement with the government related to such conduct resulting in reimbursement payments to the federal government and patient account adjustments of over $500,000. The plaintiff sought to compel the production of any prior FCA allegations against the defendant in addition to any allegations of fraudulent billing practices since her termination to demonstrate that the defendant had engaged in a pattern of defrauding the federal government, covering it up and retaliating against employees who report it. The district court found the relator's request for prior FCA allegations relevant to establish her good faith belief that the defendant had violated the FCA and specifically the FCA's intent element. Moreover, the district court concluded that such complaints could help the relator identify other whistleblowers who were fired to demonstrate that the defendant's stated reason for firing her was pretextual. The district court, however, limited the discovery to the type of fraudulent billing that the plaintiff had reported, as well as to the geographic region in which she worked.

In ***U.S. ex rel. Long v. Janssen Biotech, Inc.***, the relator alleged that the defendant pharmaceutical company unlawfully provided free business advisory services to physicians who prescribed its medications.[180] The relator sought discovery regarding communications between the defendant and the government, including information provided or disclosed to DOJ, whether the defendant ever sought an Advisory Opinion from HHS-OIG and any communications with CMS. The magistrate judge concluded that the information sought by the relator was "relevant and discoverable," particularly as to the FCA's materiality element.

175 2023 WL 8040762 (S.D. Cal. Nov. 20, 2023).
176 2023 WL 2759075 (D.N.J. Apr. 3, 2023).
177 2023 WL 3203912 (S.D.N.Y. May 2, 2023).
178 2023 WL 6612471 (S.D. Cal. Oct. 10, 2023).
179 2023 WL 6129517 (S.D.W. Va. Sept. 19, 2023).
180 2023 WL 2429358 (D. Mass. Mar. 9, 2023).

Although the risk of such substantial damages may often cause FCA defendants to settle claims prior to trial, this year, several cases resulted in jury verdicts and substantial damage awards against defendants.

DAMAGES

Should a defendant be held liable under the FCA, the damages available to the government or a relator can be extensive. In addition to statutory civil penalties for each violation, under 31 U.S.C. § 3729(a)(1), the defendants can also be held liable for up to three times treble damages "which the Government sustains because of the act of that person." Although the risk of such substantial damages may often cause FCA defendants to settle claims prior to trial, this year, several cases resulted in jury verdicts and substantial damage awards against defendants.

In ***U.S. ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.***, the relators alleged that the defendant falsely billed Medicare for services it did not perform when it billed for vascular ultrasounds before physicians had the opportunity to interpret the associated studies and sign the final reports.[181] At the conclusion of a jury trial, the jury determined that the defendant had submitted 7,380 false claims, resulting in $2.7 million in damages to the government, which were then trebled to nearly $8.2 million. In its renewed motion for judgment as a matter of law, the defendant argued that the government suffered no damages because the government would have eventually paid for all of the services at some point when the reports were finalized. The district court rejected this argument, noting that even if the services were eventually provided, the defendant still harmed the government by prematurely billing for the services and denying the government the "time value of money." However, the district court agreed that since the defendant did ultimately provide the services in question, the jury's damages award must be set aside for an interest-based model that determined the interest accrued on each claim between the day the false claim was paid and the date of the jury verdict when it was determined to be false. The district court also rejected the defendant's claim that the relator's request for $21.8 million in damages was a violation of the Eighth Amendment's Excessive Fines Clause, as the requested penalty was still only a third of the statutorily available fines and the defendant's scheme had caused significant harm to the government and the public through its fraud scheme.

In ***U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp.***, the government alleged that the defendants violated the FCA when various ophthalmologists sought reimbursement for procedures using the defendants' ophthalmologic devices without disclosing that the defendants had provided the ophthalmologists kickbacks in the form of meals, tickets for sporting events and other items of value.[182] After a two-month trial, the jury found that the defendants had caused the ophthalmologist to submit 64,575 false claims resulting in more than $43 million in damages. After the trial ended, the government sought a judgment of more than $489 million based on the trebling of the damages combined with more than $358 million in statutory penalties. Prior to the district court entering judgment, the defendants asked the district court to reject the proposed judgment amount, arguing that the jury instructions were incorrect, the amount of damages violated the Fifth and Eighth Amendments and the amount did not take into account settlements with other entities. The district court, however, declined to address these arguments and simply noted that the only reason the judgment was not entered immediately upon the rendering of the verdict was to allow the parties to determine the proper penalty calculation. Since the defendant did not dispute the mathematical calculation used to treble the damages in the jury's verdict or the applicable penalties, the district court entered a judgment of more than $487 million after the parties agreed to take into account $2.4 million in settlements with other entities. The defendants' motion for judgment as a matter of law, in which the defendants reiterated their arguments regarding the district court's improper instruction on damages and the allegedly excessive penalties, remains pending before the district court as of publication.[183]

Finally, following a jury verdict against Eli Lilly concerning FCA violations related to the failure to pay Medicaid drug rebates resulting in $61 million in damages, the district court considered the FCA's trebling and statutory penalty provisions in ***U.S. ex rel. Streck v. Takeda Pharm. Am., Inc.***[184] The district court ultimately ruled that Eli Lilly owed over $183 million in treble damages and $9.8 million in civil penalties. Eli Lilly has since appealed the district court's trial rulings to the Seventh Circuit, where briefing has been completed, but oral argument has not been set.

181 649 F. Supp. 3d 404 (W.D. Tex. 2023).

182 2023 WL 3412775 (D. Minn. May 12, 2023).

183 Defendant Paul Ehlen, who largely controlled the corporate defendant Cameron-Ehlen Group, Inc., died in a plane crash a little more than a month after the judgment was entered. The government requested that the district court substitute the executor of Mr. Ehlen's estate as defendant. On October 11, 2023, the district court ruled that the executor could be substituted as a defendant because FCA cases are "action[s] for damages . . . commenced by or on behalf of the United States," and under 28 U.S.C. § 2404 these claims "shall not abate on the death of a defendant but shall survive and be enforceable against his estate as well as against surviving defendants." The district court noted that even though the penalties in the case, which far outweighed the actual or even treble damages available, were not "damages" under 28 U.S.C. § 2404 because the underlying claim did seek remedial relief in the form of damages suffered by the government, the entire "action" would survive the death of the defendant, to include both remedial and punitive relief against the estate of the deceased defendant. 2023 WL 6619744, at *1 (D. Minn. Oct. 11, 2023).

184 2023 WL 3320281 (N.D. Ill. May 9, 2023).

ISSUES INVOLVING RELATORS

Following the FCA's Filing Requirements

The FCA requires *qui tam* relators to file FCA lawsuits under seal in order to allow the government an opportunity to investigate the allegations and determine whether to intervene in the lawsuit.[185] Where a relator fails to follow this procedural requirement, such a failure can jeopardize a relator's ability to pursue the claims asserted in their complaint. Where the government declines to intervene and the relator's *qui tam* lawsuit is unsealed, a relator's decision to file an amended complaint can implicate this procedural requirement if the amended complaint includes new claims or theories of liability that were not included in the original *qui tam* lawsuit, if the amended complaint is not filed under seal.

In ***U.S. ex rel. Williams v. Landmark Hosp. of Athens, LLC***, the district court considered claims asserted in a relator's amended complaint that had not been asserted in the original complaint in the context of the FCA's seal requirement.[186] The relator's original complaint asserted FCA violations premised on a worthless services theory of liability associated with COVID-19 testing; while the relator's amended complaint added FCA claims concerning fraud associated with provider relief funds and payments associated with medications, lab charges, therapy imaging and medical equipment unrelated to COVID-19. The district court noted a divergence of views by courts when an "amended complaint endeavors to add new FCA claims not previously presented to the Government for investigation," with some courts not requiring the relator to file such an amendment under seal. The district court ultimately rejected that view and concluded that newly alleged claims included in an amended complaint must be filed under seal to allow the government to consider those claims. As a result, the relator failed to follow the FCA's filing requirements and the newly-asserted claims were dismissed without prejudice.

> **The FCA requires *qui tam* relators to file FCA lawsuits under seal in order to allow the government an opportunity to investigate the allegations and determine whether to intervene in the lawsuit.**

185 31 U.S.C. § 3730(b)(2).
186 2023 WL 3097948 (M.D. Ga. Apr. 26, 2023).

> **The first element of an FCA retaliation claim requires that the plaintiff be engaged in a 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.**

Retaliation

The FCA protects whistleblowers from adverse employment actions related to their efforts to report violations of the statute.[187] To establish a prima facie claim under the FCA'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.[188] When the employee has met this burden, the burden shifts to the employer to provide a legitimate, non-retaliatory reason for the termination, which the employee can rebut by showing it was pre-textual.[189]

Protected Activity and the Underlying Fraud

The first element of an FCA retaliation claim requires that the plaintiff be engaged in a 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.[190]

Defendants often obtain dismissal or summary judgment because of a plaintiff's failure to plead or prove protected activities. In ***U.S. ex rel. Rose v. Select Rehab., LLC***, however, the district court denied a motion to dismiss, finding that the plaintiff, an occupational therapist, had alleged sufficient facts to state a claim for retaliation against the defendant employer.[191] To support the requirement of pleading a protected activity, the plaintiff alleged that she was terminated for complaining that patients were receiving unnecessary therapy services and for

187 31 U.S.C. § 3730(h).
188 At least one district court decision reinforced that an individual supervisor is not an "employer" within the meaning of the FCA. *See Brunelle v. PeaceHealth*, 2023 WL 121436 (W.D. Wash. Jan. 6, 2023) (granting dismissal because the FCA does not authorize retaliation claims against individual supervisors).
189 *See, e.g.*, *Toledo v. HCA Healthcare, Inc.*, 2021 WL 4990821 (S.D. Tex. Oct. 27, 2021).
190 31 U.S.C. § 3730(h)(1).
191 2023 WL 2816835 (E.D. Pa. Apr. 6, 2023).

recording — and refusing to cross out — a discharge note in a patient's medical record, which she had made to prevent an FCA violation. The district court concluded that the plaintiff successfully alleged protected activity, as her reports had a sufficient nexus to the FCA.

Several cases highlighted that internal reports of regulatory noncompliance do not always constitute FCA protected activities. To constitute protected activity, an employee's internal complaint must protest the submission of a false or potentially false claim to the federal government. The district court in ***Ruffolo v. Halifax Health, Inc.***, underscored this point in granting summary judgment to the defendant nursing services provider on a retaliation claim brought by the plaintiff operations manager.[192] The plaintiff alleged that she was terminated after reporting that the patient coordinators were making changes to case management data without consent from nurses. The district court found that the plaintiff's report did not protest the submission of false or potentially false claims to the federal government, as the plaintiff did not know whether the defendant had submitted or was going to submit any false claim, nor whether the changes to case management data impacted any government-reimbursed accounts.

Similarly, in ***U.S. ex rel. Jackson v. Ventavia Research Grp., LLC***, where the plaintiff claimed she was retaliated against for reporting concerns about the defendant's clinical trials of the COVID-19 vaccine, the district court granted dismissal, explaining that "internal complaints about patient safety, or protocol and regulatory violations, are not the same thing as complaining about defrauding the Government."[193] Likewise, the district court dismissed the retaliation claim in ***U.S. ex rel. Lokosky v. Acclarent, Inc.***, where the plaintiff, a sales representative for the defendant, alleged that she was terminated in retaliation for raising internal complaints regarding the off-label marketing of products sold by the defendant.[194] Because the plaintiff "never once raised the issue of false claims" in her internal complaints, the district court found that the plaintiff had not engaged in activities protected by the FCA.

In contrast to the foregoing cases, the district court in ***Vanderlan v. Jackson HMA, LLC***, denied a motion to dismiss, finding that the plaintiff's internal reports protested the submission of false claims.[195] The plaintiff alleged that he was terminated for repeatedly informing the defendant medical center of its unlawful "patient dumping" in violation of the Emergency Medical Treatment and Labor Act. Because the defendant had certified its compliance with the law when seeking Medicare and Medicaid reimbursement, the district court found that the plaintiff had plausibly linked his whistleblowing activities to the FCA.

In several circuits, courts consider whether an employee in the plaintiff's position would have an objectively reasonable basis for believing that their employer was committing fraud against the government. For example, in ***Clark-Kutscher v. SSM Health Care Corp.***, the district court granted summary judgment to the defendant hospital where the plaintiff refused to document non-billable patient interactions through consultation and progress notes, as she believed that drafting her notes in billable format as directed would be "illegal" and constitute "Medicare fraud."[196] The district court found the plaintiff's belief unreasonable, as a reasonable nurse would not have believed that the hospital had asked them to commit fraud simply by requiring that all services be recorded in billable format.

The district court in ***Gilbert v. Ctrs. for Advanced Orthopaedics, LLC***, granted dismissal where the plaintiff, a member of the defendant's physicians federation, twice alerted the defendant that its profit-sharing arrangement violated the Stark Law.[197] The district court found that the plaintiff failed to allege an objectively reasonable belief that the alleged violation resulted in the submission of any false or fraudulent claims to the federal government. And, in ***U.S. ex rel. Hartley v. Hosp. Auth. of Valdosta & Lowndes Cnty., Ga.***, the district court dismissed a retaliation claim where the relator alleged that she was terminated for informing a doctor that it was illegal to alter a diagnostic code in order to refile a claim.[198] Because the plaintiff's complaint contained no allegation that any of the defendant medical center's physicians had submitted a claim for payment to the federal government, let alone a claim based on a falsified diagnosis, the plaintiff's allegations were insufficient to establish an objectively reasonable belief that the defendant was submitting false claims.

Employer Notice

The second question in assessing FCA retaliation claims is whether an employer had knowledge that the plaintiff-employee tried to stop a potential FCA violation before taking adverse action. Courts consider whether someone with decision-making authority had notice of the protected activity, whether the employee framed their concerns as potentially fraudulent or illegal conduct and whether the employee's protected activity occurred outside the scope of the employee's regular duties.

In ***U.S. ex rel. Toledo v. HCA Holdings, Inc.***, a prospective payment system coordinator at an inpatient hospital claimed that she raised concerns of alleged fraud to various employees at the hospital.[199] The district court denied the coordinator's motion for partial summary judgment for her retaliation claim and granted the defendant's motion for summary judgment. The Fifth Circuit affirmed and explained that notice was not sufficient, noting that: (1) the concerns were framed as mistakes or possible computer glitches; (2) the relevant decision-makers were unaware of these communications; and (3) the majority, if not all, of the communications related to the coordinator's job duties.

Although courts consider whether the employee framed the concerns as fraudulent or illegal, an employee typically does not need to explicitly connect the alleged fraud to the FCA. In ***U.S. ex rel. Barrick v. Parker-Migliorini International, LLC***, the Tenth Circuit affirmed the district court's denial of a motion for judgment as a matter of law following a jury verdict in favor of the employee.[200] Prior to filing a *qui tam* action, the employee brought concerns regarding possible illegal activity to the company's CFO on at least three occasions. The employer argued that it did not have notice of the protected activity because the employee failed to convey a connection between the alleged fraud and the

192 2023 WL 5516022 (M.D. Fla. July 26, 2023).
193 2023 WL 2744394 (E.D. Tex. Mar. 31, 2023), *appeal dismissed,* 2023 WL 7318489 (5th Cir. Sept. 27, 2023).
194 2023 WL 3457903 (D. Mass. May 10, 2023).
195 2023 WL 3485264 (S.D. Miss. May 16, 2023).
196 2023 WL 5832143 (S.D. Ill. Sept. 8, 2023).
197 2023 WL 4409199 (D. Md. July 7, 2023).
198 2023 WL 6702483 (M.D. Ga. Oct. 12, 2023).
199 2023 WL 2823899 (5th Cir. Apr. 7, 2023).
200 79 F.4th 1262 (10th Cir. 2023).

FCA. The Tenth Circuit clarified that the employee did not need to "say magic words such as 'FCA violation' or 'fraudulent report to the government to avoid payment'" to put the company on notice.

Employees asserting retaliation claims often satisfy the notice requirement by reporting fraud or unlawful activity to a supervisor, but some district courts apply a heightened standard. In ***U.S. ex rel. Robertson v. Millennium Physician Grp., LLC***, a physician at a large primary care practice raised concerns regarding alleged false diagnoses and fraudulent testing policies to management, including at staff meetings and with a billing employee.[201] The physician asserted FCA retaliation claims against the practice, several related companies, executive and administrative officers, and physician employees. The district court granted the defendants' motion to dismiss, reasoning that even if the physician's activities constituted protected activity, it was unclear whether the decision-makers in the practice, which had over 200 healthcare providers and 1,000 home health professionals, were actually aware of the concerns.[202]

Some district courts also hold employees with compliance-related responsibilities to heightened notice standards. To show that the employer had notice under this heightened standard, the protected activity must go beyond the employee's regular scope of duties. In ***Slagh v. Joseph House, Inc.***, a clinical director reported several instances of alleged fraudulent billing to the company's program director and executive director.[203] The company filed a motion to dismiss the retaliation claim, arguing in part that the clinical director had a heightened obligation to provide notice because her job duties included ensuring compliance. The district court denied the motion to dismiss and determined that the clinical director's reports, which were more specific than simply reporting unethical behavior and went beyond her scope of duties, provided the requisite notice to the company.

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.

As a starting point, adverse employment action that takes place prior to a plaintiff's protected activity cannot be the basis of an FCA retaliation claim. In ***Del Signore v. Nokia of Am. Corp.***, the district court granted summary judgment in favor of a telecommunications company that terminated an employee for legitimate, non-retaliatory reasons, considering any adverse actions that predated protected activity only as background evidence, not as adverse actions that might form an element of his retaliation claims.[204] The district court ultimately found that no reasonable jury could rule in the plaintiff's favor when the plaintiff refused to cooperate with the defendants in obtaining evidence that he was medically able to return to work after a short-term disability period.

An FCA retaliation plaintiff must show a causal connection between an adverse employment action and the protected activity.

In order to avoid summary judgment on an FCA retaliation claim, a plaintiff must provide either direct evidence of retaliation or must create an inference of retaliation under the *McDonnell-Douglas* burden-shifting framework. In ***U.S. ex rel. Hinton v. Integra Lifesciences Holdings Corp.***, the defendant prevailed on summary judgment because the plaintiff employee failed to provide sufficient evidence that her protected activities caused her termination. Direct evidence was lacking, as human resources terminated the plaintiff before learning of internal complaints she made regarding the off-label marketing of the defendant's products.[205] The plaintiff also failed to provide indirect evidence of retaliation under the *McDonnell-Douglas* framework, as there was evidence that she was terminated for creating a hostile work environment, and not solely for protected activities.

In ***Carroll v. Idemia Identity & Sec. USA LLC***, the district court granted summary judgment in favor of a biometrics company where the plaintiff failed to establish a causal nexus between his alleged protected activities and any adverse employment action.[206] The district court noted that it was part of the job of a management-level employee to resolve noncompliance, so making only internal complaints of such noncompliance was insufficient to support a claim of retaliation.

In the absence of direct evidence of causation, close temporal proximity between protected activity and an adverse employment action may give rise to an inference of causation. For example, in ***Oldham v. Centra Health, Inc.***, the district court denied summary judgment when the adverse action occurred just 25 minutes after an employee emailed the board of directors complaining of Medicare fraud and just four days after his first complaint to the government.[207] In ***Villamizar v. Senior Care Pharmacy Servs., Inc.***, the district court denied summary judgment and found a causal link between a plaintiff's complaint and subsequent termination a few weeks later, concluding that "a reasonable juror could infer that plaintiff's complaint triggered his subsequent discharge."[208]

Temporal proximity between the protected activity and the subsequent adverse employment action may not be sufficient alone to show causation. For example, in ***Lord v. Univ. of Miami***, the district court denied a motion for judgment as a matter of law when the adverse employment action happened on the same day an employer held a meeting about the

201 2023 WL 2022228 (M.D. Fla. Feb. 15, 2023).
202 *See also U.S. ex rel. O'Neill v. Gopalam*, 2023 WL 6396659 (M.D. La. Sept. 29, 2023) (finding notice where a nurse reported alleged fraudulent practices to a behavioral hospital's CEO).
203 2023 WL 2867318 (S.D. Ohio Apr. 10, 2023).
204 2023 WL 3292570 (N.D. Ill. May 5, 2023).
205 2023 WL 6793927 (W.D. Mo. Sept. 11, 2023).
206 2023 WL 8115042 (M.D. Tenn. Nov. 22, 2023).
207 2023 WL 3899084 (W.D. Va. June 8, 2023).
208 2023 WL 3619450 (E.D. Cal. May 24, 2023).

allegations of fraud that were the subject of the plaintiff's protected activity.[209] The district court held a reasonable jury could find the defendant did not terminate the plaintiff as a result of his protected activity because "making the two decisions in one day is not unreasonable," and there was sufficient evidence for the jury to look past the temporal proximity and to refuse to infer causation. On the other hand, in ***Hall v. Abington Mem'l Hosp.***, the district court found unpersuasive an argument that a nine-month gap between the plaintiff's initial complaints and their termination was too broad for the two events to be causally linked.[210]

In ***Mason v. Health Mgmt. Assocs., LLC***, the district court clarified that the date to use in analyzing temporal causation is when the employer decided to terminate the employee, not the actual termination date.[211] "To do otherwise would permit employers to escape liability by simply waiting to issue the final retaliatory termination decision. This loophole would gut the statute's protections for whistleblowers." The district court denied summary judgment because there was sufficient evidence that a jury could find that there was no break in the temporal nexus between the plaintiff's protected activity and the adverse employment action.

Regarding the standard that courts will use in resolving retaliation claims, a circuit split remains in place whether courts apply a "but-for" causation standard. In ***Hennessey v. Mid-Michigan Ear, Nose and Throat P.C.***, a district court within the Sixth Circuit declined to apply the "but-for" standard even though a Sixth Circuit concurring opinion had cited the "but-for" standard (as articulated by the Third Circuit) with approval.[212] Explaining that the Sixth Circuit "ha[d] yet to explicitly apply a 'but-for' causation standard to the FCA anti-retaliation provision in a majority opinion," the district court instead applied the "motivating factor" test for causation. By contrast, in *Hall*, the district court used the "but-for" test for causation, following the Third Circuit precedent.

Finally, in ***Glasper v. St. James Wellness Rehab & Villas, LLC***, the district court granted a defendant's motion to dismiss the plaintiff's complaint when the plaintiff did not provide sufficient facts under the standard pleading requirements to support a plausible inference that the defendant retaliated against her because of her protected activity.[213] Because the timing of the alleged retaliation was unclear, the district court stated that the plaintiff "did not include enough facts to get the picture of what happened." In other words, the plaintiff did not answer the "who, what, when, where, why, and how" needed to plausibly allege a claim under the FCA.

209 2023 WL 354276 (S.D. Fla. Jan. 23, 2023).
210 2023 WL 6216526 (E.D. Pa. Sept. 25, 2023).
211 2023 WL 5284827 (W.D.N.C. Aug. 16, 2023).
212 2023 WL 4676875 (W.D. Mich. July 21, 2023).
213 2023 WL 5830684 (N.D. Ill. Sept. 8, 2023).

ATTORNEYS' FEES

The FCA allows for an award of reasonable attorneys' fees and costs to a *qui tam* relator under 31 U.S.C. § 3730(d)(1) from the proceeds of an action or settlement concerning FCA claims. Except in limited circumstances, there typically is little dispute about the threshold question of whether the relator is entitled to fees where there has been an award of damages under the FCA or a settlement of FCA claims stemming from a relator's *qui tam* complaint. More often, courts are called upon to examine arguments from the defendants that the fees sought by the relator are not "reasonable" as the FCA requires.

In ***U.S. ex rel. Zappala v. Steward Health Care Sys. LLC***, the defendants argued that the relators' fee request was unreasonable because the settlement reflected limited success relative to the overall claims and allegations in the *qui tam* complaint and asserted that the relators should be awarded just 12.5% (or one-eighth) of the fees, costs and expenses sought, which corresponded to the one intervened claim of the eight asserted.[214] The district court agreed with the defendants, concluding that there was no indication from the relators' counsel as to what work was performed on what claims, and no indication that the intervened claim required any more work than any of the declined claims. As a result, the relators were awarded just 12.5% of their requested fees, costs and expenses.

Perhaps less commonly considered, the FCA also permits a defendant to recover its reasonable attorneys' fees, expenses and costs "if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment."[215]

In ***U.S. ex rel. Jehl v. GGNSC Southaven, LLC***, the defendant sought an award of fees under this FCA provision after identifying for the district court several undisputed facts that the defendant believed showed that the FCA claims were frivolous and vexatious including: (1) the relator's failure to check easily accessible public information that would have undermined his claims; (2) asserting a theory of liability rejected by his own expert; and (3) continuing to pursue his claims after learning that CMS guidelines clearly and unambiguously rejected his theory of liability. Based on these facts, the district court concluded that the relator's lawsuit "was patently and demonstrably frivolous because an application of plain language of public federal law…and application of easily obtainable public facts lead to the inexorable conclusion that relator's action is groundless."

214 2023 WL 6626547 (D. Mass. Oct. 11, 2023). Courts also evaluated more traditional challenges to relators' claims for attorneys' fees, costs and expenses, such as the reasonableness of the hourly rate sought or the work that was performed. *See, e.g., U.S. ex rel. Habana Hosp. Pharmacy, Inc.*, 2023 WL 5611906 (S.D. Fla. Aug. 7, 2023); *United States v. Allergan, Inc.*, 2023 WL 4754637 (C.D. Cal. July 24, 2023).
215 31 U.S.C. § 3730(d)(4).

STARK LAW/ ANTI-KICKBACK STATUTE

Use of the AKS and Stark Law to establish FCA violations across healthcare industry sectors has remained a staple of the government's enforcement efforts and a common theory of liability in relators' *qui tam* lawsuits. As a result, courts have continued to issue noteworthy decisions tackling causation under the AKS and exploring other AKS and Stark Law issues.

REMUNERATION AND CAUSATION UNDER THE AKS

Continuing a recent trend, courts have wrestled with the appropriate causation standard in FCA cases premised on AKS violations under 42 U.S.C. § 1320a-7b(g), which provides that claims "resulting from" an AKS violation are "false or fraudulent" for FCA purposes. As noted, a circuit split has emerged and cases have highlighted the two main causation analyses: "but-for" causation and a less demanding "causal connection" test. Courts also have considered the proper definition of "remuneration" under the AKS.

The Sixth Circuit considered both of these issues in ***U.S. ex rel. Martin v. Hathaway***, and ultimately agreed with the district court that the relator's claim lacked both the elements of remuneration and causation.[216] The case was filed by an ophthalmologist who alleged that the defendant hospital rescinded its offer of employment to her after another ophthalmologist threatened to take his referrals away from the hospital if it hired the relator and promised to continue, and even increase, his referrals to the hospital if it did not. The lawsuit alleged that the hospital's decision not to fire the relator in return for the other ophthalmologist's promise to continue referring patients violated the AKS, resulting in FCA violations for later claims tied to the other ophthalmologist's referrals.

The Sixth Circuit first considered whether "remuneration" under the AKS covers "just payments and other transfers of value or any act that may be valuable to another." It decided on the narrower approach after surveying the statutory scheme, OIG guidance and other appeals courts' interpretations, finding that most definitions of remuneration involve some type of payment or transfer of financial value. As a result, the court

216 6 F.4th 1043 (6th Cir. 2023).

The government has continued to stress that improper financial arrangements between hospitals and physicians can compromise medical judgment and threaten the integrity of federal healthcare programs.

found the allegations insufficient to plead an AKS violation because the hospital's decision not to hire the relator did not entail a payment or transfer of value to the other ophthalmologist, even if it may have benefited him.

The Sixth Circuit next addressed causation and following the Eighth Circuit's approach, adopted the "but-for" causation standard – that is, the FCA plaintiff must prove that the claim for reimbursement would not have occurred without the alleged remuneration.[217] The Sixth Circuit concluded that "the ordinary meaning of 'resulting from' is but-for causation," and that legislative history did not "overcome the ordinary meaning of the text" where criminal penalties are at stake. It cautioned that "reading causation too loosely" would mean that "much of the workaday practice of medicine might fall within an expansive interpretation of the Anti-Kickback Statute."

Defendants facing FCA liability premised on alleged AKS violations undoubtedly will continue to push for a narrower interpretation of these key AKS elements.[218]

HOSPITAL/PHYSICIAN KICKBACK SCHEMES

The government has continued to stress that improper financial arrangements between hospitals and physicians can compromise medical judgment and threaten the integrity of federal healthcare programs. As such, the government and *qui tam* relators – especially physician relators and former hospital executives – have continued to pursue FCA cases premised on allegations of improper inducements to referring providers by hospitals and health systems including excessive compensation, free services in the form of hospital-employed nurse practitioners and physician assistants and other above FMV business transactions that run afoul of the AKS and/or Stark Law. Because AKS and Stark Law violations may taint large numbers of claims stemming from the alleged improper arrangements, these cases often result in significant FCA settlements.

In March 2023, Covenant Healthcare System, along with two physicians, agreed to pay over $69 million to resolve FCA allegations that Covenant had improper financial relationships with referring physicians.[219] Covenant allegedly: (1) entered into contracts with physicians to serve as medical directors which did not satisfy any exceptions to the Stark Law or the AKS; (2) employed a physician whose financial relationship did not satisfy any exception to the Stark Law; (3) forgave rental payments from a physician who rented office space; and (4) permitted an investment group owned by Covenant-employed physicians to secure an equipment lease through non-arm's-length negotiations.

In May 2023, Massachusetts Eye and Ear agreed to pay more than $5 million to resolve allegations that certain of its physician compensation models, involving 44 physicians, violated the Stark Law.[220] The hospital allegedly paid its affiliated physician group a percentage of the hospital's operating margin from certain outpatient departments (*i.e.*, facility fees). The physician group, in turn, paid a portion of those pooled funds as bonuses to certain of its employed physicians, typically allocating the pool based on the employed physicians' personally performed services or hours worked. The hospital also paid the group 100% of the profits from macular injections and then allocated the profits to physicians based on their personally performed injections. The government contended that the payments to the physician group, which then were used to pay the employed physicians of the group, created a financial relationship with the physicians employed by the group practice that did not meet an applicable Stark Law exception.

In May 2023, Detroit Medical Center, along with its former and current corporate parents, agreed to pay approximately $29.7 million to settle FCA claims brought by a former employed physician based on alleged AKS violations.[221] The government alleged that the health system provided the services of hospital-employed midlevel practitioners at no cost or below FMV to physicians to induce them to refer additional patients to the health system. The government further alleged that the physicians were selected based on the volume of their referrals to the health system.

In June 2023, St. Francis Health System, along with certain of its affiliates, agreed to pay $36.5 million to resolve allegations that it violated the FCA, the Stark Law and the AKS by making payments to orthopedic surgeons that were tied to the volume or value of referrals.[222] The settlement resolved allegations that St. Francis caused the submission of false claims as a result of an unlawful financial relationship between St. Francis and Piedmont Orthopedic Associates (POA), whereby POA's compensation was tied to the volume or value of the practice's referrals to St. Francis. The relator alleged that the hospital feared competition from POA and sought to convince surgeons from

217 *See U.S. ex rel. Cairns v. D.S. Medical LLC*, 42 F.4th 828 (8th Cir. 2022).

218 Two recent district court opinions covered more fully in Pharmaceutical and Medical Device Developments (pgs. 44-46) highlight this trend. In those cases, the district courts within the same judicial district reached opposite conclusions on the appropriate causation elements. The opinions in both of those cases have been certified for interlocutory appeal to the First Circuit and will be decided later this year. No matter the standard applied by the First Circuit, parties will continue to ask for the Supreme Court to weigh in on this deepening split among the circuits.

219 https://www.justice.gov/usao-edmi/pr/covenant-healthcare-system-and-physicians-pay-over-69-million-resolve-false-claims-act.

220 https://www.justice.gov/d9/2023-05/us_v._massachusetts_eye_and_ear_-_settlement_agreement.pdf.

221 https://www.justice.gov/opa/pr/detroit-medical-center-vanguard-health-systems-and-tenet-healthcare-corporation-agree-pay.

222 https://www.justice.gov/usao-sc/pr/st-francis-pay-united-states-365-million-settle-allegations-under-false-claims-act.

the group to become employees of the hospital by paying them excessive compensation, including an annual bonus. The complaint alleged that numerous physicians received compensation in excess of the 90th percentile even though collections for their services were in the bottom quartile.

In December 2023, ChristianaCare Health System agreed to pay $42.5 million to resolve FCA allegations premised on AKS and Stark Law violations.[223] The lawsuit, brought by a former chief compliance officer, alleged that the hospital system provided independent neonatologists and surgeons with improper remuneration in the form of the services of hospital-employed midlevel providers in exchange for referrals to the system.

Finally, in December 2023, Community Health Network agreed to pay $345 million and enter into a five-year CIA with HHS-OIG to resolve alleged FCA violations premised on Stark Law violations.[224] The government alleged that beginning in 2008 and 2009, senior management embarked on an illegal scheme to recruit physicians for employment to capture their lucrative downstream referrals. The government alleged that the health system paid above FMV compensation to certain employed physicians and that it awarded bonuses to physicians that were tied to the volume or value of their referrals. The government also alleged that, although the health system hired a valuation firm to analyze whether compensation was consistent with FMV, it knowingly provided the valuation firm with false compensation figures so the valuation firm would issue a favorable opinion.

Beyond those settlements, the government has intervened in FCA lawsuits and litigated FCA claims premised on alleged AKS and Stark Law violations involving physicians and hospitals. In December 2023, in ***U.S. ex rel. Nocie v. Steward Health System***, the government intervened and filed a complaint against Steward and certain of its subsidiaries, alleging that the defendants violated the Stark Law and the FCA.[225] The complaint alleged that between January 2013 and March 2022, Steward Medical Group paid a cardiac surgeon above FMV and tied his compensation to the volume or value of his referrals. The government alleged that the medical group paid the surgeon nearly $5 million in incentive compensation that was calculated based on the number of cases he referred to the hospital.

Compensation arrangements between physicians and their group practices also continued to be the subject of FCA claims. For example, in ***U.S. ex rel. Goldberg v. Sacramento Heart & Vascular Med. Assocs.*** (SHVMA), the relator, a former practice administrator, alleged that SHVMA and its director, Dr. Philip Bach, paid primary care physician employees of SHVMA bonuses based on their referral of patients for various diagnostic services provided by the defendants in violation of both federal and state law.[226] The relator also alleged that the defendants engaged in upcoding. The district court denied the defendants' motion to dismiss, which argued that the alleged bonuses

223 https://www.justice.gov/usao-de/pr/christianacare-pays-425-million-resolve-health-care-fraud-allegations-0.

224 https://www.justice.gov/usao-sdin/pr/community-health-network-agrees-pay-345-million-settle-alleged-false-claims-act.

225 U.S. ex rel. Nocie v. Steward Health System, No. 1:18-cv-11160 (D. Mass); see also https://www.justice.gov/usao-ma/pr/united-states-files-complaint-against-st-elizabeths-medical-center-steward-medical-group.

226 2023 WL 5435890 (E.D. Cal. Aug. 23, 2023).

Compensation arrangements between physicians and their group practices also continued to be the subject of FCA claims.

fell within a safe harbor for payments to bona fide employees. Despite the fact that the complaint referred to the primary care physicians at issue as "employees," the district court held that this was insufficient on its own to establish that a "common law" employment relationship existed, which would be required to raise the safe harbor as an affirmative defense.

OTHER INDUCEMENTS TO REFERRAL SOURCES

In ***U.S. ex rel. Carter v. Emergency Staffing Solutions, Inc.*** (ESS), the district court denied a motion to dismiss FCA claims filed by a former hospital administrator against a medical management and physician staffing company.[227] ESS supplied hospitals with emergency room and hospitalist physicians and promoted its business as being able to increase hospital revenue through increased inpatient admissions. According to the relator, ESS and its alleged "sister" company, Hospital Care Consultants (HCC), violated the Stark Law and AKS by paying staffed physicians a per-patient amount for each referral to inpatient care and continued to reward hospitalists for certain performed tasks (*e.g.*, $25-$75 per round, $50 per transfer or discharge). ESS-contracted physicians allegedly accounted for a vastly disproportionate number of inpatient referrals and received total compensation far above FMV for their services. ESS also allegedly independently billed and retained all "professional fee" billings for services provided by its physicians. The district court held that the relator had adequately pleaded violations of the FCA, AKS and Stark Law.

As noted earlier, in ***U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp.***, a district court entered a $487 million judgment against Precision Lens and its owner for violations of the AKS and FCA following a jury verdict against the defendants.[228] The government alleged that Precision Lens, a distributor of intraocular lenses and other surgical products, offered and provided ophthalmic surgeons "exorbitant entertainment and high-end travel and accommodations," including private jet flights, Broadway musicals, luxury fishing trips, skiing vacations and sporting events.

227 2023 WL 2754347 (N.D. Tex. Mar. 31, 2023).

228 2023 WL 3412775 (D. Minn. May 12, 2023); see also https://www.justice.gov/usao-mn/pr/court-enters-487-million-judgment-against-precision-lens-and-owner-paul-ehlen-paying.

Marketing and the waiver of patient co-payments continue to be an important focus of regulatory scrutiny. In June 2023, DOJ announced a $7.4 settlement with Smart Pharmacy, Inc. and related parties to resolve allegations that Smart Pharmacy waived patient co-payments for pain cream prescriptions that were improperly supplemented with a drug used to treat various psychological conditions.[229] In September 2023, the government settled FCA claims based on AKS allegations with BioTek reMEDys Inc., its CEO and a physician for $20 million.[230] In this intervened case, the government alleged that the parties waived co-pays for high-cost specialty drugs and infusion services to induce referrals and paid kickbacks to physicians in exchange for referring patients to BioTek including meals, tickets, gifts and free practice management and clinical support services.

Defendants had some success in fending off AKS-based FCA claims. In ***U.S. ex rel. Hart v. McKesson Corp.***, the relator, a former business development executive, alleged that McKesson Corporation and its affiliate entities violated the AKS when it offered high-volume oncology practices free access to two business management tools, the "Margin Analyzer and the Regimen Profiler," which were geared towards increasing the practices' profitability with respect to prescribing certain medications.[231] The relator further alleged that claims for reimbursement submitted by these practices were tainted by the kickback scheme and thus violated the FCA. In dismissing the relator's FCA claims, the district court reiterated that a bare allegation that a certain activity is unlawful, even if that allegation was made known to the defendant, is not sufficient to impute knowledge of its unlawfulness for the purposes of the AKS. The district court noted that even if a relator were to discuss his or her belief that certain activity is unethical or wrongful with another employee, that too would be insufficient to show that their employer knew of the unlawfulness of their conduct. Rather, the requisite scienter must consist of an intentional violation of a "known legal duty." The district court explained that general knowledge of an arrangement is likewise insufficient to show that one knew the arrangement was illegal. In sum, the district court concluded that "rais[ing] generalized compliance concerns to [an] immediate [] supervisor via instant messenger during a training . . . will not do to allege that McKesson was knowingly violating the law."

LABORATORY ENFORCEMENT UNDER THE AKS AND STARK LAW

A decade-long series of laboratory-related FCA lawsuits also came to a close, with the latest development involving allegations against laboratory entities Health Diagnostic Laboratory, Inc. (HDL) and Singulex, Inc. (Singulex). In April 2015, both HDL and Singulex reached settlements with the government to resolve allegations that they had paid sham specimen fees to physicians in exchange for referrals for blood panel testing.[232]

229 https://www.justice.gov/opa/pr/two-jacksonville-compounding-pharmacies-and-their-owner-agree-pay-least-74-million-resolve.
230 https://www.justice.gov/opa/pr/united-states-settles-kickback-allegations-biotek-remedys-inc-chaitanya-gadde-and-dr-david.
231 2023 WL 2663528 (S.D.N.Y. Mar. 28, 2023).
232 See, e.g., https://www.justice.gov/opa/pr/two-cardiovascular-disease-testing-laboratories-pay-485-million-settle-claims-paying.

Allegations of AKS violations also targeted technology providers for possible FCA liability. This expansion of government enforcement tools against technology providers is a harbinger of the government's response to future issues stemming from cybersecurity, artificial intelligence and algorithmic fraud.

Other government enforcement actions have followed. In February 2023, Labcorp agreed to a $19 million settlement agreement to resolve claims that it had provided free "processing services" (including blood draws or blood processing services) to physicians who referred patients to HDL/Singulex, in exchange for those physicians' referrals to Labcorp for additional or duplicative testing.[233] The government also alleged that Labcorp had knowledge that these physicians were receiving kickbacks from HDL/Singulex in exchange for such referrals.

OTHER STARK LAW AND AKS CASES

Allegations of AKS violations also targeted technology providers for possible FCA liability. This expansion of government enforcement tools against technology providers is a harbinger of the government's response to future issues stemming from cybersecurity, artificial intelligence and algorithmic fraud.

In July 2023, NextGen Healthcare, Inc., an EHR vendor, entered into a settlement agreement for $31 million to resolve allegations that it misrepresented the capabilities of certain versions of its EHR software and provided unlawful remuneration to its users to induce them to recommend NextGen's software.[234] The government alleged that NextGen violated the AKS by knowingly giving credits, often worth as much as $10,000, to current customers whose recommendation of NextGen's EHR software led to a new sale. The government also alleged other remuneration, including tickets to sporting events and entertainment, was provided to induce referrals.

233 https://www.justice.gov/usao-sc/pr/labcorp-pay-united-states-19-million-settle-allegations-under-false-claims-act.
234 https://www.justice.gov/opa/pr/electronic-health-records-vendor-nextgen-healthcare-inc-pay-31-million-settle-false-claims.

The year also included a challenge to a government interpretation of a key Stark Law exception. In ***Community Oncology Alliance v. Becerra***, the plaintiff challenged CMS's publication of a September 2021 frequently asked questions (FAQ) document that restricts the delivery of medications, including chemotherapy, to patients in their homes.[235] The FAQ provides that items are not considered to be "furnished" for purposes of the "location requirement" of the Stark Law's in-office ancillary services exception if a patient receives an item by mail outside the physician's office, as they would not have been dispensed to the patient in the office. Community Oncology Alliance has claimed that the government issued a rule under the guise of being a FAQ in violation of federal rulemaking requirements and that the change has, "in one fell swoop, placed a nationwide and indefinite freeze on the furnishing of cancer medications dispensed by physicians (or physician-owned pharmacies) to their patients via delivery, causing substantial and irreparable harm to oncologists and their patients alike." In December 2023, the district court denied Community Oncology Alliance's request for preliminary injunction and declined to temporarily block CMS from enforcing the FAQ, concluding that Community Oncology Alliance is unlikely to succeed in the case since the FAQ is not inconsistent with the Stark Law.

235 *Community Oncology Alliance v. Becerra*, No. 1:23-cv-02168-CJN (D.D.C).

MANAGED CARE/ MEDICARE ADVANTAGE

For more than twenty years, Medicare-eligible beneficiaries have had the option to enroll in Medicare Advantage (MA) and predecessor plans in lieu of traditional Medicare. Privately-owned Medicare Advantage Organizations (MAOs) contract with CMS to administer the Medicare benefit under Medicare Part C. MAOs receive premium funding from CMS, which includes 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 their medical history, demographic and other considerations. The risk score and corresponding capitation payment amount are intended to reflect the anticipated cost to manage a beneficiary's care, relative to other beneficiaries.

In recent years, the popularity of the MA program has increased significantly. In 2023, 48% of eligible Medicare beneficiaries (or 31.6 million individuals) elected to enroll in a MA plan. Payments made by CMS to MA plans amount to over $454 billion annually. In 2024, MA enrollment is projected to increase to over 50% of all Medicare-eligible beneficiaries (or 33.8 million individuals). As the percentage of Medicare-eligible beneficiaries electing to enroll in MA plans and corresponding government payments continues trending upward, regulators have responded with increased scrutiny, with enforcement focusing on on risk-adjustment coding, marketing practices, prior authorization and utilization management and – most recently – the use of artificial intelligence (AI).

MAOs and their downstream entities have faced increased scrutiny by CMS, HHS-OIG and the legislative branch, which has resulted in a less favorable regulatory and economic environment for Medicare Part C. For example, CMS has: (1) reduced the 2024 base rate paid to MAOs by 1.1%; (2) begun phasing in a new risk-adjustment model that excludes payment for 2,000 diagnoses under the capitated model; and (3) announced more restrictive criteria for Star Ratings quality bonuses. Likewise, HHS-OIG announced its intention to roll out nationwide auditing of what it perceives to be high-risk diagnosis codes. The industry also saw changes and proposals from CMS to strengthen regulatory limitations on and oversight of MA marketing activities and related compensation to agents, brokers and field marketing organizations, as well as prior authorization and utilization management functions, among other updates. After the issuance of the risk adjustment data validation (RADV) audit final rule, which became effective April 3, 2023, RADV audit findings are expected to be extrapolated for payment years 2018 and beyond with no fee-for-service adjuster, posing significant potential financial impact to MAOs and further heightening the importance of accurate coding.

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FCA ENFORCEMENT RESULTS

In 2023, there were two settlements by MAOs and one settlement by a primary care physician practice resolving allegations of FCA violations related to risk-adjustment practices.

Complete Physician Services, a primary care physician practice in Philadelphia, and two physicians agreed to pay $1.5 million plus interest to resolve FCA allegations related to purported misrepresentation of the severity of illness and services rendered, in part, to MA beneficiaries.[236] The government alleged that these misrepresentations resulted in unsupported diagnoses, including morbid obesity diagnoses for patients with a BMI under 35 and unsupported chronic obstructive pulmonary disease diagnoses, which led to increased reimbursement from MA plans. In entering the settlement, DOJ emphasized its commitment to investigate all potential fraud allegations related to Medicare Part C, including against physician practices.

Martin's Point Health Care Inc., a managed care plan operating in Maine and New Hampshire, entered into a $22.485 million settlement to resolve FCA allegations that the company submitted inaccurate diagnosis codes for its MA plan participants to increase Medicare reimbursements.[237] The government alleged that the MA plan initiated retrospective chart reviews to identify and submit additional diagnosis codes to Medicare, many of which were unsupported by patient medical records. This settlement highlights the continued scrutiny of one-way retrospective chart reviews as an area of MA enforcement, which have previously been the subject of OIG reports and multiple *qui tam* cases.

Finally, The Cigna Group (Cigna) agreed to pay more than $172 million to resolve one *qui tam* matter in Tennessee and separate government allegations of FCA violations in Pennsylvania including: (1) submitting false and invalid diagnosis codes for MA enrollees resulting from a retrospective chart review program and knowingly submitting and/or failing to withdraw inaccurate diagnosis codes for morbid obesity (PA matter); and (2) reporting and falsely certifying diagnosis codes to CMS based only on in-home assessments of MA beneficiaries without reliable diagnostic testing or imaging to support the data and/or treatment of the conditions.[238] In connection with this settlement, Cigna also entered into a five-year CIA with HHS-OIG, which requires independent oversight of the company's compliance program, annual auditing of risk-adjustment data and reporting to OIG, among other considerations.

CRIMINAL ENFORCEMENT

In October 2023, DOJ announced that it would decline to prosecute HealthSun Health Plans, Inc., a subsidiary of Elevance Health, for alleged risk-adjustment fraud.[239] Despite the declination, HealthSun agreed to repay $53 million to CMS, which was determined to have been the illicit gain from the alleged fraud scheme, commonly known as "declination with disgorgement." DOJ considered other factors as part of this settlement, including HealthSun's voluntary disclosure and proactive cooperation during the government's investigation. The declination marked the first known use of DOJ Criminal Division's Voluntary Self-Disclosure and Corporate Enforcement Policy, outside of the Foreign Corrupt Practices Act (FCPA). This outcome underscores DOJ's commitment to promoting corporate self-disclosure amidst the growing enforcement involving MAOs.

Notably, DOJ's declination came one day after HealthSun's former director of Medicare risk adjustment analytics was indicted with respect to allegations that the director and her unnamed co-conspirator knowingly submitted unsupported risk-adjusting diagnosis codes that were not diagnosed by the treating provider, but added afterwards into the EHR. That criminal action remains pending.

PENDING LITIGATION

Litigation of FCA matters involving MA plans remains on-going in a number of important cases.

In ***U.S. ex rel. Osinek v. Kaiser Permanente***, the government intervened in six *qui tam* complaints, alleging that members of the Kaiser Permanente consortium violated the FCA through improper use of addenda to medical records.[240] The government alleges that between 2009 and 2018, Kaiser added approximately 500,000 diagnoses via addenda to medical records that were unsupported in the beneficiary's original medical

236 https://www.justice.gov/usao-edpa/pr/primary-care-physicians-pay-15-million-resolve-false-claims-act-liability-submitting.
237 https://www.justice.gov/opa/pr/martins-point-health-care-inc-pay-22485000-resolve-false-claims-act-allegations.
238 https://www.justice.gov/usao-edpa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations.
239 https://www.justice.gov/opa/pr/former-executive-medicare-advantage-organization-charged-multimillion-dollar-medicare-fraud.
240 No. 3:13-cv-03891 (N.D. Cal.).

records, resulting in payments from CMS "in the range of $1 billion." After previously granting part of Kaiser's motion to dismiss the government's original complaint-in-intervention, the district court denied Kaiser's motion to dismiss the first amended complaint, concluding that the government had adequately pleaded a factual falsity theory of liability and that Kaiser acted with the requisite level of intent to state viable FCA claims at the pleading stage.[241]

In ***U.S. ex rel. Ross v. Indep. Health Corp.***, the defendants are alleged to have improperly collected and retained overpayments from CMS, in violation of the FCA. The defendant DxID LLC, a vendor of risk-adjustment services to MA plans, offered two services that captured diagnosis codes for the defendant Independent Health Association, Inc.: (1) a retrospective chart review program, which allegedly included mining of MA enrollees' medical records for risk-adjusting conditions that predated the encounter; and (2) an addenda process whereby medical providers were allegedly "nudged" to retroactively add unsupported diagnoses to medical records, sometimes months after the encounter in question. On January 3, 2023, the district court denied, in part, the defendants' motion to dismiss, finding that the government sufficiently alleged its claim that the defendants violated legal obligations under federal regulations. Furthermore, the district court found "no support" for the defendants' interpretation of the ICD-10 guidelines as non-binding, sub-regulatory guidance.[242]

Finally, we are monitoring consumer class action litigation concerning AI use, which includes separate suits filed by the same plaintiffs' law firms against Cigna, UnitedHealth Group and Humana.[243] The plaintiffs in these cases generally allege that insurers have used AI to automatically deny claims based on predictive algorithms and seek injunctive relief, which would essentially require insurers to stop using generative AI tools. This litigation bears continued watching as it progresses.

241 2023 WL 4054279 (N.D. Cal. Jun. 15, 2023).
242 2023 WL 24055 (W.D.N.Y. Jan. 3, 2023).
243 *Kisting-Leung v. Cigna Corp.*, 2:23-cv-01477 (E.D. Cal.); *Estate of Lokken v. UnitedHealth Group, Inc.*, No. 0:23-cv-03514 (D. Minn.); *Barrows v. Humana, Inc.*, No. 3:23-cv-00654 (W.D. Ky.).

PHARMACEUTICAL & MEDICAL DEVICE DEVELOPMENTS

Government regulators continued to monitor the activities of pharmaceutical and medical device manufacturers with heightened scrutiny.

PATIENT ASSISTANCE PROGRAMS

The intersection between patient assistance programs (PAPs) or other charitable funds and the AKS continued to define much of the enforcement and regulatory activity involving the pharmaceutical industry. PAPs provide financial assistance or free drug products to low income individuals who otherwise could not afford their prescriptions and are most often sponsored or funded by pharmaceutical manufacturers. When those manufacturers directly or indirectly subsidize cost-sharing obligations for their own products, however, those manufacturers risk potential AKS violations. Indeed, it has long been the case that the government has viewed improperly structured donations to PAPs to violate the AKS if they are made with the intent to induce Medicare-funded referrals or purchases of particular drugs.[244]

As discussed, Pfizer received a negative HHS-OIG Advisory Opinion when proposing a co-pay assistance program for patients prescribed Pfizer's own drugs based on the conclusion that such programs generate remuneration that could induce patients to utilize their drugs. Litigation seeking to upend that negative administrative outcome by advancing a narrower interpretation of the AKS elements has largely been unsuccessful.

A number of FCA lawsuits remain pending in which alleged AKS violations concerning co-pay assistance programs are at issue. Litigation remains pending against two pharmaceutical manufacturers challenging the manufacturers' contributions to charitable funds that raise key AKS issues that undoubtedly will deepen a circuit split concerning the AKS element of causation. District court opinions reached exactly the opposite conclusion as to how causation should be interpreted and both cases have been certified for interlocutory appeal to the First Circuit.

244 https://oig.hhs.gov/documents/special-advisory-bulletins/880/2005PAPSpecialAdvisoryBulletin.pdf.

Unlike in recent years, there were no blockbuster FCA settlements announced in 2023 involving the pharmaceutical or device industry. The absence of such settlements does not suggest any sort of slowing of the government's FCA enforcement efforts in this area; rather, as in prior years, it likely reflects where certain FCA cases or investigations stand relative to their conclusion.

In ***United States v. Teva Pharmaceuticals USA, Inc.***, the government filed FCA litigation against Teva, alleging that Teva caused the submission of false claims stemming from illegal co-pay subsidies in connection with the sale of its multiple sclerosis drug.[245] Teva donated over $350 million to charitable funds to cover the co-payment obligations of patients in need of its drug, while at the same time significantly increasing the wholesale acquisition cost of its drug. The government alleged that Teva made the donations with the intent of inducing Medicare-reimbursed claims, which resulted in significant revenue for Teva. In ruling on cross motions for summary judgment, the district court denied Teva's motion, concluding that the government had gathered sufficient evidence to establish the elements of causation and scienter. At the same time, the district court granted the government's motion for summary judgment as to the elements of materiality and causation and determined that the measure of damages would be the entirety of the government's payments for the claims resulting from the illegal kickbacks. As to the element of causation, the district court concluded that the government "need not prove 'but for' causation." Quoting a prior First Circuit opinion, the district court concluded that the government must only show "a sufficient causal connection between an AKS violation and a claim submitted to the federal government."

Another district court within the First Circuit reached the opposite conclusion on the question of what should be required to plead and prove causation in ***United States v. Regeneron Pharmaceuticals, Inc.***[246] As with the case involving Teva, the government filed an FCA lawsuit against Regeneron alleging its donations to a patient assistance foundation violated the AKS. Regeneron manufactures a drug that treats neovascular age-related macular degeneration (AMD). Since 2014, it has been the sole manufacturer donor with respect to a particular patient assistance foundation that provides co-pay assistance to patients suffering from AMD who are prescribed AMD drugs. Patients, however, were not provided any information from the charitable foundation regarding the source of the assistance they received. In ruling on cross motions for summary judgment on the issue of causation (*i.e.*, whether the government could show that Regeneron's donations resulted in false claims), the district court adopted the framework for evaluating causation articulated by the Sixth Circuit in ***U.S. ex rel. Martin v. Hathaway*** and held that the government must establish "but-for" causation. Nonetheless, the district court denied both parties' motions for summary judgment as to causation.

The First Circuit will hear interlocutory appeal concerning these cases in the first part of 2024.

OTHER FCA LITIGATION & SETTLEMENTS

Historically, high-dollar FCA settlements involving the pharmaceutical and device sectors of the healthcare industry typically account for significant portions of the overall FCA settlement totals touted by DOJ. For example, in September 2022, DOJ announced that the pharmaceutical company Biogen, Inc. agreed to pay $900 million to settle FCA allegations that it paid illegal kickbacks to its largest prescribers to induce those prescribers to prescribe certain of the company's drugs.

Unlike in recent years, there were no blockbuster FCA settlements announced in 2023 involving the pharmaceutical or device industry. The absence of such settlements does not suggest any sort of slowing of the government's FCA enforcement efforts in this area; rather, as in prior years, it likely reflects where certain FCA cases or investigations stand relative to their conclusion.

The settlements that were reached reflect a continued focus on drug pricing and AKS-related issues. As one example, drug maker Nostrum Laboratories Inc. and its CEO agreed to pay up to $50 million to settle FCA allegations that the company underpaid rebates owed under the Medicaid Drug Rebate Program.[247] As part of the settlement, Nostrum admitted that it incorrectly characterized a relaunched version of one of its drugs as a reformulation and substantially raised the price of the drug without paying higher rebates through the Medicaid Drug Rebate Program. Nostrum argued that, because its product was a "new drug," it should not have to pay the rebates based on the prior version's applicable price. As a result, the government contended that Nostrum and its CEO knowingly failed to pay the required rebate amounts owed for its drug. The settlement reached by Nostrum and its CEO was based on their financial condition.

Medical device manufacturer DePuy Synthes, Inc., agreed to pay $9.75 million to resolve state and federal FCA allegations that certain former sales representatives gave a Massachusetts surgeon more than $100,000 worth of free DePuy implants and instruments, including cages, rods, screws, plates and surgical instrumentation, that the

245 2023 WL 4565105 (D. Mass. July 14, 2023).
246 2023 WL 7016900 (D. Mass. Oct. 25, 2023).

247 https://www.justice.gov/usao-ma/pr/drugmaker-nostrum-and-ceo-agree-pay-50-million-resolve-claims-underpaying-rebates-owed.

surgeon used to perform surgeries overseas for patients who were not federal healthcare beneficiaries.[248] The settlement resulted from the filing of a *qui tam* lawsuit by a former DePuy sales representative.

Pharmaceutical company Ultragenyx Pharmaceutical Inc. agreed to pay $6 million to resolve FCA allegations that it violated the AKS and caused false claims to be submitted to Medicare and Medicaid by paying for genetic tests, including an additional fee to receive test results for marketing purposes.[249] The United States contended that Ultragenyx violated the AKS by paying kickbacks: (1) to beneficiaries in the form of free genetic tests to induce their purchase of Medicare or Medicaid-reimbursed drugs manufactured by Ultragenyx; and (2) to the laboratory for the test results in order to induce the referral to Ultragenyx of healthcare providers to whom Ultragenyx could market their drugs. The company admitted and accepted responsibility for certain facts included in the settlement.

CRIMINAL ENFORCEMENT

The government has continued to pursue a number of significant criminal enforcement matters involving DME-related fraud schemes. For example, the government secured a guilty plea and three-year prison sentence against the owner of a DME company for his role in defrauding government healthcare programs of more than $11 million for medically unnecessary ventilators, tracheotomy supplies and feeding tubes.[250] The owner directed the forgery of medical records, physician notes and provider signatures in response to audits and record requests to cover up the scheme and personally obtained over $3.4 million in proceeds, which he used to pay for personal vehicles, personal chef services, events and entertainment. In another case, a Florida woman was sentenced to 20 years in prison for her role in a scheme to defraud Medicare by submitting over $192 million in claims for unnecessary genetic tests and DME.[251] The defendant signed thousands of orders for medically unnecessary orthotic braces and genetic testing for Medicare beneficiaries who were never examined or treated. This fraud scheme was part of a larger telemarketing scheme in which telemarketing companies would contact Medicare beneficiaries to convince them to accept orthotic braces and genetic tests and would then send pre-filled orders for these products to the defendant, who would fraudulently sign the orders.

Pharmaceutical-related fraud also remained a criminal enforcement priority. For example, the government announced charges against ten defendants in association with the submission of over $370 million in fraudulent claims submitted in connection with prescription drugs.[252] These charges were brought against the owner and a corporate officer of a pharmaceutical wholesale distribution company, who were charged for their role in an alleged $150 million fraud scheme related to the company's purchase and diversion of prescription HIV medication that resulted in the marketing and reselling of that medication by falsely representing that the company acquired it through legitimate channels. The defendants allegedly purchased the diverted medication at a substantial discount from individuals who obtained the drugs primarily through illegal "buyback" schemes in which they paid HIV patients cash for their expensive HIV medication and repackaged those pills for resale. In a related case, a convicted defendant was sentenced to fifteen years in prison for illegally acquiring large quantities of prescription drugs from patients for whom the drugs had been prescribed but not yet consumed. As part of this scheme, the defendant repackaged the drugs, sold them to wholesale companies and used his share of the proceeds to purchase luxury goods, including a Lamborghini, a Mercedes and three boats.

248 https://www.justice.gov/opa/pr/depuy-synthes-inc-agrees-pay-975-million-settle-allegations-concerning-kickbacks-paid.
249 https://www.justice.gov/opa/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce.
250 https://www.justice.gov/opa/pr/man-sentenced-114m-medicare-and-medicaid-fraud-scheme.
251 https://www.justice.gov/opa/pr/nurse-practitioner-sentenced-192m-medicare-fraud-scheme.
252 https://www.justice.gov/opa/pr/national-enforcement-action-results-78-individuals-charged-25b-health-care-fraud.

APPENDIX
2023 NOTABLE SETTLEMENTS

HOSPITALS & HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/27/2023	University of Pittsburgh Medical Center; University of Pittsburgh Physicians; Dr. James L. Luketich	Surgeon, university hospital and physician group agreed to pay $8.5 million to resolve allegations that the hospital billed for concurrent surgeries performed by Dr. Luketich in violation of Medicare's teaching physician rules.[1]	**$8.5 million**
2/28/2023	Wake Forest University Baptist Medical Center	Health system agreed to pay $754,585 to resolve allegations that it billed Medicare for therapy services at an affiliated SNF that were not supported by the medical record.[2]	**$754,585**
3/3/2023	Lakeland Regional Medical Center	Health system agreed to pay $4 million to resolve allegations that it made improper, non-bona fide donations to a county government to improperly fund the state's share of Medicaid payments to the health system.[3]	**$4 million**
3/7/2023	Penn State Health	Health system agreed to pay over $1.25 million to resolve self-disclosed FCA allegations that it submitted claims to Medicare for evaluation & management (E&M) services on the same date that infusion services were provided, in violation of Medicare rules and regulations.[4]	**$1.25 million**
3/20/2023	Luminis Health Doctors Community Medical Center, Inc. (DCMC); Diagnostic Imaging Associates, LLC (DIA)	Hospital and a radiology imaging provider agreed to pay over $2 million to resolve allegations that DIA billed Medicare and Medicaid under its assigned number for services provided to cancer patients, including technical services actually rendered by DCMC's outpatient screening facilities, then paid a portion of the global fee to DCMC. DCMC was not independently enrolled with the programs and thus was ineligible to directly bill and receive reimbursement.[5]	**$2 million +**
3/21/2023	University of Iowa	University agreed to pay $16,444 and implement a mandatory training program for physicians to resolve allegations that its academic medical center billed Medicare for x-ray interpretations conducted by residents when payment regulations require interpretations be reviewed or performed by a physician other than a resident in order to be eligible for payment.[6]	**$16,444**

1 https://www.justice.gov/usao-wdpa/pr/james-l-luketich-md-university-pittsburgh-medical-center-and-university-pittsburgh.
2 https://www.justice.gov/usao-mdnc/pr/wfbmc-agrees-pay-us-754585-following-documentation-issues-relating-therapy-services.
3 https://www.justice.gov/opa/pr/florida-s-lakeland-regional-medical-center-agrees-pay-4-million-settle-common-law-allegations.
4 https://www.justice.gov/usao-mdpa/pr/penn-state-health-agrees-pay-125266228-settle-voluntary-disclosure-related-milton-s.
5 https://www.justice.gov/usao-md/pr/acute-care-hospital-and-radiology-imaging-practice-pay-more-2-million-resolve-false.
6 https://www.justice.gov/usao-ndia/pr/university-iowa-agrees-training-payment-16444-resolve-united-states-allegations.

HOSPITALS & HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/29/2023	Covenant Healthcare System; Dr. Mark Adams; Dr. Asim Yunus	Hospital system agreed to pay over $69 million to resolve allegations that it participated in improper financial relationships with eight referring physicians and a physician-owned investment group, resulting in claims tainted by AKS and Stark Law violations being submitted to various government programs. Two of the eight physicians, neurosurgeon Dr. Adams and electrophysiologist Dr. Yunus, agreed to pay $406,551 and $345,987, respectively, to resolve allegations related to their relationships with Covenant.[7]	**$69.75 million**
4/17/2023	Meharry Medical College	Medical college agreed to pay $100,749 to resolve allegations that it submitted false claims for certain physician services performed by unsupervised residents, in violation of Medicare billing rules.[8]	**$100,749**
4/17/2023	Sibley Hospital; Johns Hopkins Health System	Hospital and parent health system agreed to pay $5 million to resolve self-disclosed FCA allegations that from 2008 through 2011 the hospital billed Medicare for services referred by 10 cardiologists who were receiving compensation that exceeded the FMV of their services, in violation of the Stark Law.[9]	**$5 million**
4/28/2023	Northwest Arkansas Hospitals, LLC	Hospital agreed to pay over $1 million to resolve allegations that it submitted claims to Arkansas Medicaid for hospitalizations when underlying documentation did not support or justify the medical necessity of the same.[10]	**$1.11 million**
5/9/2023	Yale New Haven Health Services Corp.; Northeast Medical Group, Inc.	Hospital and physician group agreed to pay $560,718 to resolve allegations that they submitted claims for E&M services billed by physicians when the services should have been billed by midlevel providers, resulting in 10-15% higher reimbursement to the hospital.[11]	**$560,718**
5/12/2023	St. Elizabeth's Hospital of the Hospital Sisters Health System	Hospital agreed to pay $12.5 million to resolve allegations that it submitted claims for urgent care services billed at a higher rate of service.[12]	**$12.5 million**
5/18/2023	Brookdale Hospital Medical Center	Nonprofit hospital agreed to pay $300,000 to resolve allegations that it defrauded the federally-funded Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) by: (1) causing ineligible persons to be qualified for WIC benefits; (2) falsifying time sheets for work purportedly performed by breastfeeding peer counselors; and (3) falsifying budget records to inflate the hospital's purported requirements for WIC funds.[13]	**$300,000**

7 https://www.justice.gov/usao-edmi/pr/covenant-healthcare-system-and-physicians-pay-over-69-million-resolve-false-claims-act.
8 https://www.justice.gov/usao-mdtn/pr/meharry-medical-college-agrees-settle-false-claims-act-allegations.
9 https://www.justice.gov/opa/pr/sibley-hospital-and-johns-hopkins-health-system-settle-allegations-improper-compensation.
10 https://arkansasag.gov/news_releases/attorney-general-griffin-announces-settlement-with-northwest-arkansas-hospitals-llc.
11 https://www.justice.gov/usao-ct/pr/hospital-owner-and-hospitalist-group-agree-pay-560k-settle-false-claims-act-allegations.
12 https://www.justice.gov/usao-cdil/pr/illinois-hospital-agrees-pay-125-million-settle-allegations-billing-error.
13 https://www.justice.gov/usao-edny/pr/brookdale-hospital-agrees-civil-settlement-resolve-allegations-former-employees.

HOSPITALS & HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/31/2023	VHS of Michigan Inc. d/b/a The Detroit Medical Center Inc. (DMC); Vanguard Health Systems Inc.; Tenet Healthcare Corporation	Hospital and its current and former owners agreed to pay over $29 million to resolve allegations that they provided kickbacks to 13 physicians in the form of DMC-employed midlevel practitioner services at no cost or below FMV to induce referrals to DMC's affiliated facilities, in violation of the AKS.[14]	**$29.74 million**
6/15/2023	St. Francis Physician Services, Inc.; St. Francis Hospital; Bon Secours St. Francis Health System, Inc.	Nonprofit health system agreed to pay $36.5 million to resolve allegations that it violated the Stark Law and AKS through an unlawful contractual payment structure with an orthopedic practice whereby St. Francis made bonus payments tied to the volume or value of the practice's referrals to the hospital.[15]	**$36.5 million**
6/29/2023	CenCal Health; Cottage Health System; Sansum Clinic; Community Health Centers of the Central Coast	County organized health system along with three affiliated healthcare providers agreed to pay a total of $68 million (detailed below) to resolve allegations that they caused the submission of false claims for "enhanced services" to Adult Expansion Medi-Cal members that were contractually not allowed, duplicative of other required services or otherwise ineligible for payment.[16] • CenCal Health - $49.5 million • Cottage Health System - $10 million • Sansum Clinic - $5 million • Community Health Centers of the Central Coast - $3.5 million	**$68 million**
7/26/2023	Edward W. Sparrow Hospital Association d/b/a Sparrow Medical Group; Sparrow Care Network; Sparrow Health System	Health system agreed to pay $671,310 to resolve allegations that it improperly billed mid-level provider services under physicians' names when applicable "incident to" billing provisions were not met, thus resulting in inflated reimbursement.[17]	**$671,310**
8/30/2023	Lompoc Valley Medical Center	Health system agreed to pay $5 million to resolve allegations that it submitted or caused the submission of false claims for "enhanced services" to Adult Expansion Medi-Cal members that were contractually not allowed, duplicative of other required services or otherwise ineligible for payment. Seven additional providers reached separate settlements in the same case.[18]	**$5 million**

14 https://www.justice.gov/opa/pr/detroit-medical-center-vanguard-health-systems-and-tenet-healthcare-corporation-agree-pay.
15 https://www.justice.gov/usao-sc/pr/st-francis-pay-united-states-365-million-settle-allegations-under-false-claims-act.
16 https://www.justice.gov/usao-cdca/pr/central-coast-county-organized-health-system-three-health-care-providers-agree-pay-68m.
17 https://www.justice.gov/usao-wdmi/pr/2023_0726_Sparrow.
18 https://www.justice.gov/opa/pr/health-care-provider-agrees-pay-5-million-alleged-false-claims-californias-medicaid-program.

HOSPITALS & HEALTH SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/26/2023	Putnam Community Medical Center of North Florida	Medical center agreed to pay $1 million to resolve allegations that it submitted claims to Medicare and TRICARE for services performed at its now-closed sleep center without adequate physician supervision.[19]	**$1 million**
11/28/2023	Appalachian Regional Healthcare, Inc.; Dr. Padubidri Chandrashekar	Hospital system and employed cardiologist agreed to pay over $3 million to resolve self-disclosed FCA allegations that they submitted or caused the submission of false claims to Medicare and Kentucky Medicaid for: (1) medically unnecessary diagnostic catheterizations; (2) improperly billed services performed prior to the unnecessary catheterizations; (3) related hospital admissions that did not meet admission requirements; and (4) related ambulance transfers.[20]	**$3.03 million +**
12/19/2023	Community Health Network Inc. (CHN)	Health system agreed to pay $345 million to resolve allegations that it submitted claims to Medicare for services unlawfully referred by employed physicians it was paying in violation of the Stark Law. The settlement resolves allegations that the hospital: (1) engaged in an illegal scheme to recruit specialists with above FMV compensation to capture lucrative downstream referrals; (2) knowingly provided an external valuation firm with false compensation figures in order to receive favorable FMV opinions; and (3) structured bonus payments to account for physician referrals to the hospital. As part of the resolution, CHN entered into a five-year CIA with HHS-OIG.[21]	**$345 million**
12/20/2023	Doctor's Hospital 1997 L.P. d/b/a United Memorial Medical Center LLC	Company that formerly operated hospitals agreed to pay $2 million, along with additional contingent payments, to resolve allegations that it: (1) double-billed the government for COVID-19 tests that were also billed to other government programs; and (2) fraudulently claimed excessive cost outlier payments then concealed and improperly avoided its obligation to reimburse any excessive outlier payments received.[22]	**$2 million**

19 https://www.justice.gov/usao-mdfl/pr/putnam-community-medical-center-north-florida-agrees-pay-one-million-dollars-settle.
20 https://www.justice.gov/usao-edky/pr/eastern-kentucky-hospital-system-and-cardiologist-agree-collectively-pay-more-3.
21 https://www.justice.gov/opa/pr/indiana-health-network-agrees-pay-345-million-settle-alleged-false-claims-act-violations.
22 https://www.justice.gov/opa/pr/united-memorial-medical-center-pay-2-million-plus-additional-contingent-payments-allegedly.

HOSPICE & HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/7/2023	United Energy Workers Healthcare, Corp.	Home healthcare provider and related entities agreed to pay $9 million to resolve allegations that they submitted false claims to the U.S. Department of Labor for services provided to beneficiaries of the Energy Employees Occupational Illness Compensation Program Act. The alleged FCA violations included: (1) billing for case management services not provided; (2) billing for more time than was actually spent with patients; (3) providing and billing for non-covered services; and (4) providing services without required licensures.[23]	**$9 million**
3/3/2023	Summit Hospice	Hospice provider agreed to pay $1,045,944 to resolve allegations that it submitted claims to Medicare and Medicaid for hospice services provided to patients whose records lacked documentation of eligibility for those services.[24]	**$1.05 million**
4/19/2023	1st Adult & Pediatrics Healthcare Services	Pediatric home health and personal care services provider agreed to pay $3 million to resolve allegations that it submitted claims to Virginia Medicaid for in-home healthcare services for patients who were actually hospitalized at the time the services were billed, and that it billed for home health services that were not actually provided. The United States and the Commonwealth of Virginia intervened in the action and obtained default prior to settlement.[25]	**$3 million**
5/23/2023	Village Home Care LLC; Joy Rodak; Dr. Kuchakulla Reddy; Dr. Vishnu Reddy	Home health provider and its owner-CEO agreed to pay $225,000 and $105,000, respectively, based on their financial abilities to pay, to resolve allegations that they paid kickbacks to two physicians in the form of sham medical director or sublease agreements in exchange for patient referrals. The two physicians also agreed to pay $100,000 and $61,943 to resolve related allegations that they accepted kickbacks in exchange for referrals.[26]	**$491,943**
6/29/2023	Evergreen Hospice, LLC	Hospice company agreed to pay over $48,000 to resolve allegations that it submitted claims to Medicare for hospice services provided to beneficiaries who did not qualify for hospice services for terminally ill patients.[27]	**$48,830**

23 https://www.justice.gov/usao-sdoh/pr/home-healthcare-company-pays-9-million-submitting-false-claims-relating-energy.
24 https://www.justice.gov/usao-ut/pr/summit-hospice-pay-over-1m-settle-false-claims-liability.
25 https://www.justice.gov/usao-wdva/pr/1st-adult-pediatrics-healthcare-pay-3-million-settle-false-claims-act-allegations.
26 https://www.justice.gov/opa/pr/village-home-care-ceo-and-two-doctors-pay-490000-resolve-false-claims-act-allegations-paying.
27 https://www.justice.gov/usao-ndok/pr/united-states-settles-false-claims-allegations-against-evergreen-hospice-llc-48830.

SKILLED NURSING FACILITIES & NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/22/2023	Cornerstone Healthcare Group Holding Inc.; CHG Hospital Medical Center LLC d/b/a Cornerstone Hospital Medical Center	Long-term acute care facility and its operator agreed to pay $21,637,512 to resolve allegations that they submitted claims to Medicare for services that were: (1) provided by unqualified and unlicensed students; (2) provided while treating physicians were out of the country but billed as if rendered by those physicians; (3) not supported by patients' diagnoses or medical records; and (4) not actually rendered or were worthless.[28]	**$21.63 million +**
2/27/2023	Saratoga Center for Care, LLC; Saratoga Care and Rehabilitation Center, LLC; 149 Ballston Ave., LLC; Ballston Two, LLC; Leon Melohn; Alan "Ari" Schwartz; Jeffrey Vegh; Jack Jaffa	SNF, its landlord and related entities and individuals agreed to pay $7,168,000 to resolve allegations that they submitted or caused to be submitted to the New York Medicaid program claims for worthless services, and that the physical condition of the facility deteriorated so much that it violated federal and state regulations. The facility ceased to operate after the government's investigation and the settling parties agreed to voluntary exclusion from federal healthcare programs for periods ranging from 10-20 years.[29]	**$7.17 million +**
4/24/2023	Lafayette Physical Rehabilitation Hospital; Acadiana Management Group, LLC; Dr. Carolyn Smith	Rehabilitation hospital and its management company agreed to pay $1.2 million, and an admitting physician agreed to pay $575,000 to resolve allegations that they submitted claims to Medicare for medically unnecessary inpatient rehabilitation treatment.[30]	**$1.77 million**
5/17/2023	Morris Park Nursing Home; Tzodik Weinberg a/k/a Justin Weinberg; Maier Arm	SNF agreed to pay $2.85 million and two related individuals agreed to pay $495,000 and $115,000 each to resolve allegations that they engaged in two schemes to increase the number of original Medicare enrollees at the SNF: (1) SNF and its administrator made cash payments to a hospital discharge planning supervisor for patient referrals; and (2) SNF, the administrator and another individual switched residents from Medicare Advantage plans to higher-reimbursing original Medicare, with the administrator and other individual splitting a $1,000 payment per disenrollment. The United States filed and settled the complaint, and the settlement with the SNF took into account its prior voluntary self-disclosure of facts related to the changes made to residents' insurance coverage.[31]	**$3.46 million**
6/23/2023	Alta Vista Healthcare & Wellness Centre, LLC; Rockport Healthcare Services	SNF and its management company agreed to pay $3.825 million to resolve allegations that they gave extravagant gifts and payments for purported medical director services to referring physicians, in violation of AKS. The settlement amount was negotiated based on the companies' ability to pay. As part of the resolution, the companies entered into a five-year CIA with HHS-OIG.[32]	**$3.82 million +**

28 https://www.justice.gov/usao-sdtx/pr/medical-center-pays-over-21m-settle-alleged-false-claims.
29 https://www.justice.gov/opa/pr/landlord-and-former-operators-upstate-new-york-nursing-home-pay-7168000-resolve-false-claims.
30 https://www.justice.gov/usao-wdla/pr/united-states-settles-claims-improper-inpatient-rehabilitation-admissions-over-17.
31 https://www.justice.gov/usao-sdny/pr/us-settles-lawsuit-alleging-bronx-nursing-home-paid-kickbacks-patient-referrals-and.
32 https://www.justice.gov/usao-cdca/pr/inland-empire-skilled-nursing-facility-and-management-company-agree-pay-38m-settle.

SKILLED NURSING FACILITIES & NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/12/2023	Diversicare Healthcare Services, LLC; Kellie S. Lemons; Charles M. James	Long-term care and rehabilitation services company and two occupational therapy assistants agreed to pay $1,377,696 to resolve allegations that they submitted claims to Medicare for services that were not provided.[33]	**$1.37 million +**
8/31/2023	Watermark Retirement Communities LLC	Senior living community operator agreed to pay $4.25 million to resolve allegations that it solicited and received kickbacks from a HHA operator through the purchase of two of Watermark's HHAs, in violation of the AKS. The HHA operator resolved related allegations in 2021. [34]	**$4.25 million**
9/20/2023	ResCare	Community living care company agreed to pay $576,111.43 to resolve allegations it submitted false claims to Medicaid for services that: (1) were not supported by documentation; (2) were not allowed; or (3) exceeded Medicaid allowances. As part of the settlement, the company will implement a new EHR system for West Virginia locations.[35]	**$576,000 +**
11/15/2023	Prema Thekkek; Paksn Inc.; Kayal Inc. d/b/a Bay Point Healthcare Center; Nadhi Inc. d/b/a Gateway Care & Rehabilitation Center; Oakrheem Inc. d/b/a Hayward Convalescent Hospital; Bayview Care Inc. d/b/a Hilltop Care and Rehabilitation Center; Aakash Inc. d/b/a Park Central Care & Rehabilitation Center; Nasaky Inc. d/b/a Yuba Skilled Nursing Center	Six SNFs, their owner and the owner's management company agreed to pay over $45 million to resolve allegations that they paid kickbacks in the form of sham medical directorship payments to physicians to induce patient referrals, in violation of the AKS. As part of the resolution, the parties entered into a five-year CIA with HHS-OIG.[36]	**$45.64 million +**

33 https://www.justice.gov/usao-mdal/pr/diversicare-and-two-occupational-therapy-assistants-pay-over-13-million-resolve-false.
34 https://www.justice.gov/opa/pr/watermark-retirement-communities-pay-425-million-allegedly-receiving-kickback-violation.
35 https://www.thecentersquare.com/west_virginia/article_306b4bae-57c3-11ee-a545-db9a77d9079c.html.
36 https://www.justice.gov/opa/pr/california-skilled-nursing-facilities-owner-and-management-company-agree-456-million-consent.

PHARMACEUTICAL & DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/4/2023	Jet Medical Inc.; Medical Components Inc.; Martech Medical Products Inc.	Medical device distributor and two related companies agreed to pay $545,133 to resolve allegations they caused providers to submit claims for a device intended to treat migraines without obtaining approval from the FDA or conducting an investigational study to determine the device's safety and efficacy. The medical distributor also entered into a deferred prosecution agreement and agreed to pay $200,000 to resolve criminal allegations stemming from its distribution of the device.[37]	**$545,133 (civil)** **$200,00 (criminal)**
1/20/2023	DePuy Synthes, Inc.	Medical device manufacturer agreed to pay $9.75 million to resolve state and federal FCA allegations that it paid kickbacks in the form of free implants and surgical instruments to a surgeon for use in surgeries he conducted overseas to induce the surgeon to use its products in surgeries performed in the United States, in violation of the AKS.[38]	**$9.75 million**
2/1/2023	Joint Active Systems, Inc.	Medical device manufacturer agreed to pay $500,000 to resolve state and federal FCA allegations that it arranged for providers to bill North Carolina Medicaid for its range-of-motion devices because the company did not meet the requirements to bill North Carolina Medicaid directly and/or lacked credentials necessary to do so. In exchange, the providers retained a portion of the reimbursements.[39]	**$500,000**
3/1/2023	United Seating and Mobility, LLC, d/b/a Numotion	DME supplier agreed to pay $7 million to resolve allegations that it did not disclose all discounts it received or the actual cost it paid to DME manufacturers when submitting claims for manually priced DME items to Medicaid programs in three states. As a result, the company received higher reimbursements than it was entitled to receive. As part of the settlement, the manufacturer entered into a five-year CIA with HHS-OIG.[40]	**$7 million**
4/12/2023	Danco Laboratories, LLC	Pharmaceutical distributor agreed to pay $765,000 to resolve allegations that it failed to mark imported pharmaceutical products with the appropriate country of origin, avoiding the marking duties it owed for those imports.[41]	**$765,000**
4/21/2023	AdaptHealth LLC, f/k/a QMES, LLC	DME provider agreed to pay $5.3 million to resolve allegations that it submitted false claims for non-invasive ventilators when patients were instead prescribed and used BiPAP machines, for which federal payors reimburse suppliers thousands of dollars less per year. The company also allegedly continued to bill for equipment after patients no longer needed or were using them and double-billed for some ventilator rentals.[42]	**$5.3 million**

37 https://www.justice.gov/opa/pr/jet-medical-and-related-companies-agree-pay-more-700000-resolve-medical-device-allegations.
38 https://www.justice.gov/opa/pr/depuy-synthes-inc-agrees-pay-975-million-settle-allegations-concerning-kickbacks-paid.
39 https://www.justice.gov/usao-ednc/pr/illinois-medical-device-manufacturer-agrees-pay-500000-resolve-allegedly-fraudulent.
40 https://www.justice.gov/usao-edky/pr/medical-equipment-company-pays-7-million-resolve-false-claims-act-allegations.
41 https://www.justice.gov/opa/pr/pharmaceutical-distributer-agrees-pay-765000-resolve-false-claims-act-allegations-relating.
42 https://www.justice.gov/usao-edpa/pr/plymouth-meeting-pa-company-pay-53-million-resolve-false-claims-act-allegations.

PHARMACEUTICAL & DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/17/2023	Zoll Medical Corporation	Medical device supplier agreed to pay $400,000 to resolve allegations that it sold electrocardiogram (ECG) cables to federal government purchasers that were manufactured in China, in violation of the Trade Agreements Act of 1979, which restricts the procurement of goods under certain government contracts to purchases from specific designated countries. The company settled the allegations as common law claims, an alternate remedy under the FCA.[43]	**$400,000**
8/28/2023	Lincare Holdings, Inc.	DME provider agreed to pay $29 million to resolve allegations that it overbilled for oxygen equipment by continuing to charge rental payments for the equipment after three years of payments were received, in violation of reimbursement policies. As part of the settlement, the company admitted to a number of lapses in internal controls and entered a five-year CIA with HHS-OIG.[44]	**$29 million**
10/17/2023	Oxygen Plus, Inc.	DME provider agreed to pay $200,000 to resolve allegations that it continued to bill for non-invasive ventilators even after patients no longer needed the devices or were no longer using them.[45]	**$200,000**
10/23/2023	Star Medical Supply, Inc.	Medical supply company agreed to pay $932,000 to resolve state FCA allegations that it billed for medical supplies, including incontinence supplies, that were not requested or used by beneficiaries and that in some instances were not supported by a valid order.[46]	**$932,000**
10/30/2023	Nostrum Laboratories Inc.; Dr. Nirmal Mulye	Laboratory and its founder and CEO agreed to pay up to $50 million, based on financial contingencies, to resolve allegations that they knowingly failed to pay the required rebate amounts owed for an antibiotic it acquired, as required by the Medicaid Drug Rebate Program and as invoiced by State Medicaid programs.[47]	**$3.83 million (guaranteed)** **$46.18 million (contingent)**
12/18/2023	BioTelemetry Inc.; LifeWatch Services Inc.	Medical device company and its subsidiary agreed to pay over $14.7 million to resolve allegations that they billed for remote cardiac monitoring at a higher level than physicians intended to order or that was medically necessary by causing clinic staff to enroll patients in telemetry, even when physicians had ordered a less expensive service.[48]	**$14.73 million**

43 https://www.justice.gov/usao-ri/pr/us-resolves-civil-claims-against-medical-device-manufacturer-falsely-claiming-chinese.
44 https://www.justice.gov/usao-edwa/pr/lincare-holdings-agrees-pay-29-million-resolve-claims-overbilling-medicare-oxygen.
45 https://www.justice.gov/usao-edky/pr/floyd-county-company-agrees-pay-200000-resolve-allegations-fraudulent-billing.
46 https://www.marylandattorneygeneral.gov/press/2023/102323a.pdf.
47 https://www.justice.gov/opa/pr/drugmaker-nostrum-and-its-ceo-agree-pay-50-million-settle-false-claims-act-claims.
48 https://www.justice.gov/opa/pr/biotelemetry-and-lifewatch-pay-more-147-million-resolve-false-claims-act-allegations.

PHARMACEUTICAL & DEVICE

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
12/21/2023	Ultragenyx Pharmaceutical Inc.	Pharmaceutical company agreed to pay $6 million to resolve allegations that it violated the AKS by entering into an arrangement with a genetic testing lab whereby the lab provided genetic tests at no cost to patients or their healthcare providers and provided the results of those tests to the pharmaceutical company for use in marketing its drug.[49]	**$6 million**
12/22/2023	Philips RS North America LLC f/k/a Philips Respironics, Inc.	DME manufacturer agreed to pay more than $2.4 million to resolve allegations that it provided sleep labs with free masks used to treat and diagnose sleep-related respiratory disorders to induce the labs' physicians to prescribe its products.[50]	**$2.47 million**

49 https://www.justice.gov/opa/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce.
50 https://www.justice.gov/usao-sdca/pr/phillips-respironics-pays-24-million-allegedly-giving-kickbacks.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/27/2023	Walgreen Co.	Pharmacy operator agreed to pay $7 million to resolve allegations that a former pharmacist and store manager falsified the required prior authorization requests and clinical records for a Hepatitis C medication. The pharmacy allegedly knowingly retained the resulting overpayments after the conduct was discovered.[51]	**$7 million**
2/6/2023	OraPharma, Inc.	Specialty pharmacy agreed to pay $100,000 to resolve allegations that it employed account managers who, in some instances, worked as dental hygienists in dental offices in their assigned sales territories. Thus, the government contended the account managers may have received incentive compensation that was tied to prescriptions they recommended, in violation of the AKS.[52]	**$100,000**
2/7/2023	The Pill Club	Online pharmacy operator agreed to pay $15 million to resolve state FCA allegations that it billed for counseling services it had not provided and dispensed costly contraceptive products that customers did not ask for.[53]	**$15 million**
4/7/2023	MedCare Clinic & Pharmacy, LLC	Pharmacy agreed to pay $213,677 to resolve allegations that it billed federal healthcare programs for medications that were never dispensed to beneficiaries. The government alleged that inventory records showed the pharmacy did not purchase enough of these medications to fill all of the prescriptions for which it billed.[54]	**$213,677**
6/15/2023	Smart Pharmacy, Inc.; SP2, LLC; Gregory Balotin	Two compounding pharmacies and their owner agreed to pay $7.4 million plus potential contingency payments to resolve allegations that they violated the FCA by: (1) adding the antipsychotic drug aripiprazole to compounded topical pain creams without a clinical basis to do so in order to increase reimbursements; and (2) routinely waiving patient co-payments without regard to patient need. The settlement amount was based on the defendants' ability to pay. As part of the settlement, the owner entered into a three-year integrity agreement (IA) with HHS-OIG.[55]	**$7.4 million**

51 https://www.justice.gov/usao-edtn/pr/walgreen-co-pays-7-million-settle-allegations-under-false-claims-act.
52 https://www.justice.gov/usao-ma/pr/orapharma-inc-agrees-pay-100000-resolve-allegations-false-claims-act-violations.
53 https://oag.ca.gov/news/press-releases/attorney-general-bonta-announces-15-million-settlement-against-silicon-valley.
54 https://www.justice.gov/opa/pr/north-carolina-pharmacy-agrees-resolve-false-claims-act-allegations.
55 https://www.justice.gov/opa/pr/two-jacksonville-compounding-pharmacies-and-their-owner-agree-pay-least-74-million-resolve.

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/1/2023	Future Pharmacy, Inc.; JJ Pharmacy, Inc.; Arthur Kilimnik; Alexander Ferman; Mikhail Ferman; Leonard Kilimnik; Aleksey Orlov	Two pharmacies and their owners agreed to pay over $3.5 million to resolve allegations that they billed Medicare for prescription medications that were not actually dispensed. The two pharmacies agreed to be excluded from federal healthcare programs for five years, surrender their DEA Registrations and terminate operations. The settlement also resolved claims against a minority owner of the two pharmacies, who allegedly violated the CSA by failing to maintain required records and allowed another individual to order controlled substances under this name.[56]	**$3.5 million +**
9/20/2023	LASR Enterprises	Pharmacy agreed to pay $925,000 to resolve state FCA allegations that it submitted claims for drugs it over-dispensed or dispensed without a valid prescription.[57]	**$925,000**
9/30/2023	BioTek reMEDys, Inc.; Chaitanya Gadde; Dr. David Tabby	Specialty pharmacy and its CEO agreed to pay $20 million to resolve allegations that they paid kickbacks to: (1) patients in the form of waived copays without regard to financial need; and (2) physicians in the form of gifts, dinners and free support services. As part of the settlement, a doctor agreed to pay $480,000 to resolve allegations that he solicited and accepted remuneration in exchange for referring patients to the pharmacy. The settlements were based on all parties' ability to pay.[58]	**$20.48 million**
11/16/2023	4 Corners Pharmacy	Pharmacy agreed to pay $800,000 to resolve allegations that it billed the Department of Labor for a compound supplement that either was not ordered by a licensed healthcare provider or was never delivered to beneficiaries.[59]	**$800,000**

56 https://www.justice.gov/usao-edpa/pr/northeast-philadelphia-pharmacies-and-their-owners-agree-pay-over-35-million-resolve.
57 https://oag.ca.gov/news/press-releases/attorney-general-bonta-announces-925000-settlement-palm-springs-pharmacy.
58 https://www.justice.gov/usao-edpa/pr/united-states-settles-kickback-allegations-specialty-pharmacy-biotek-remedys-inc-its.
59 https://www.justice.gov/usao-mdfl/pr/4-corners-pharmacy-agrees-pay-800000-resolve-claims-false-billing.

LABORATORY, PATHOLOGY, RADIOLOGY & DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/3/2023	Beyond Reps, Inc. d/b/a IronRod Health and Cardiac Monitoring Services	Provider of remote cardiac monitoring services agreed to pay $673,200 to resolve allegations that it billed for services performed by technicians lacking required credentials and misrepresented that it performed services in New York State to receive higher Medicare reimbursements.[60]	**$673,200**
2/7/2023	Laboratory Corporation of America	Laboratory company agreed to pay $19 million—in a settlement reached on the eve of trial in a declined *qui tam* action (*U.S. ex rel. Lutz v. Lab. Corp. of Am. Holdings* (D.S.C.))—to resolve allegations that it provided phlebotomy services to patients of providers it knew were receiving process and handling fees from two other clinical laboratories to induce patient referrals to their laboratories. The other two laboratories previously entered settlements for a combined $48.5 million.[61]	**$19 million**
3/27/2023	Laboratory Corporation of America	Laboratory company agreed to pay $2.1 million to resolve allegations that it inappropriately billed the DOD for genetic testing performed by a reference lab under a DOD contract, as a result of double and/or triple billing, overcharging and billing in the absence of appropriate documentation.[62]	**$2.1 million**
3/30/2023	GlycoMark, Inc.	Diabetes blood test distributor agreed to pay $195,000 to resolve allegations that it encouraged customers to submit claims for one of its diabetes management tests after the test was no longer approved for Medicare and Medicaid reimbursement by encouraging labs to continue billing for the test using a blood sugar test-related CPT code, and printing and distributing marketing materials that stated "reimbursed by Medicare" with that CPT code.[63]	**$195,000**
4/4/2023	Genotox Laboratories Ltd.	Laboratory agreed to pay at least $5.9 million plus additional contingent amounts to resolve allegations that it: (1) billed for drug tests that were not covered and/or were unreasonable or unnecessary, after offering providers "custom profiles" to pre-select the tests for the providers to order; and (2) paid kickbacks to independent contractor sales representatives and marketing firms to arrange for or recommend the ordering of its laboratory testing, in violation of the AKS. The company also entered into a five-year CIA with HHS-OIG and separately entered into an 18-month deferred prosecution agreement to resolve related criminal allegations.[64]	**$5.9 million**

60 https://www.justice.gov/usao-wdny/pr/cardiac-monitoring-company-settles-fraudulent-billing-allegations.
61 https://www.justice.gov/usao-sc/pr/labcorp-pay-united-states-19-million-settle-allegations-under-false-claims-act.
62 https://www.justice.gov/usao-md/pr/laboratory-corporation-america-agrees-pay-2100000-settle-false-claims-act-allegations.
63 https://www.justice.gov/usao-edpa/pr/diabetes-blood-test-distributor-glycomark-agrees-pay-195000-settle-false-claims-act.
64 https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and.

LABORATORY, PATHOLOGY, RADIOLOGY & DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/9/2023	Blue Waters Assessment and Testing Services, LLC; VerraLab JA, LLC d/b/a BioTap Medical; David Waters	Two laboratory companies and one of their owners agreed to pay over $1.74 million to resolve allegations that they billed for urine drug tests that were collected and performed to satisfy a court order and not for purposes of medical diagnosis or treatment, as required for billing Medicaid and Medicare.[65]	**$1.74 million +**
6/16/2023	VitalAxis Inc.	Billing company for diagnostic laboratories agreed to pay over $300,000 to resolve allegations that it submitted false claims to Medicare for medically unnecessary respiratory pathogen panels run on seniors who received COVID-19 tests. In connection with the settlement, the company received cooperation credit with the government for performing and disclosing the results of an internal investigation, disclosing facts and material not known to the government but relevant to its investigation, providing information relevant to the potential misconduct of other individuals and entities and admitting liability. The settlement also evidenced that the government has an ongoing investigation of an undisclosed laboratory and physician involved in the alleged scheme.[66]	**$300,479**
7/31/2023	Thyroid Specialty Laboratory Inc. d/b/a TEN Healthcare; 3890 Management LLC; TEN Marketing	Clinical testing laboratory and related entities agreed to pay $1.9 million and relinquish approximately $7 million held in escrow after CMS suspended payments to the lab, to resolve allegations that the lab billed for: (1) upper respiratory infection and urinary tract infection polymerase chain reaction panels that were medically unnecessary; and (2) therapeutic drug assays and specimen validity testing that it had already billed for using CPT codes that incorporated these tests. The company allegedly continued to submit these claims despite being subject to a Medicaid audit in 2017 and an overpayment in 2019 for the same billing practices. As part of the settlement, the company entered into a five-year CIA with HHS-OIG.[67]	**$8.9 million**
8/1/2023	BestCare Laboratory Services LLC; Karim A. Maghareh	Now-defunct clinical laboratory and its owner agreed to pay an additional $5.7 million to settle an outstanding 2018 FCA judgment relating to allegations that the company billed Medicare for inaccurate travel allowance reimbursements for lab technicians.[68]	**$5.7 million**
8/4/2023	Aspirar Medical Lab, LLC; Pick Chay	Laboratory and its owner agreed to pay over $1.95 million to resolve allegations that they billed for urine drug tests that were medically unnecessary and were tainted by illegal kickbacks between the company and a referring entity (BPolloni Consulting, LLC), in violation of the AKS. The CEO of BPolloni previously pleaded guilty to related criminal charges.[69]	**$1.95 million +**

65 https://www.justice.gov/usao-edky/pr/drug-testing-companies-agree-collectively-pay-17-million-resolve-false-claims-act.
66 https://www.justice.gov/opa/pr/lab-billing-company-settles-false-claims-act-allegations-relating-unnecessary-respiratory.
67 https://www.justice.gov/usao-edmo/pr/missouri-laboratory-owners-agree-pay-19-million-and-relinquish-7-million-escrow.
68 https://www.justice.gov/opa/pr/clinical-laboratory-and-its-owner-agree-pay-additional-57-million-resolve-outstanding.
69 https://www.justice.gov/usao-wdnc/pr/north-carolina-laboratory-and-owner-agree-pay-more-19-million-resolve-false-claims-0.

LABORATORY, PATHOLOGY, RADIOLOGY & DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/18/2023	H&D Sonography LLC	Sonography company agreed to pay $95,000 to resolve allegations that it offered remuneration to referring physicians in the form of office rental payments that were commercially unreasonable to induce diagnostic testing, in violation of the AKS. The company also entered into a three-year deferred prosecution agreement to resolve related criminal charges.[70]	**$95,000**
9/18/2023	Gramercy Cardiac Diagnostic Services P.C.; Dr. Klaus Peter Rentrop	Cardiac diagnostic imaging practice and its cardiologist owner agreed to pay over $6.5 million to resolve allegations that they paid referring physicians and their practices millions of dollars in kickbacks through inflated rental payments and referral fees to induce referrals for diagnostic tests and procedures, in violation of the AKS and Stark Law. As part of the settlement, the cardiologist: (1) agreed to a consent judgment of more than $64 million, which may be enforced if the settlement payments are not made; (2) relinquished ownership and control of his practice and paid a portion of the sale proceeds to the United States; (3) was indefinitely barred from working for any entity billing federal healthcare programs; and (4) entered into a five-year voluntary exclusion agreement with HHS-OIG.[71]	**$6.5 million +**
9/26/2023	Exact Sciences	Company that provides at-home colon cancer-screening tests agreed to pay $13.75 million—in a settlement reached on the eve of trial in a declined *qui tam* action (*U.S. ex rel. Rosen v. Exact Sciences* (M.D. Fla.))—to resolve allegations that they offered gift cards to prescribed patients in exchange for their samples for testing, in violation of the AKS.[72]	**$13.75 million**
10/2/2023	Genomic Health, Inc.	Clinical diagnostic company agreed to pay $32.5 million to resolve allegations that it violated Medicare's 14-Day Rule in multiple ways, including: (1) submitting separate claims for its cancer tests within 14-days of a patient's inpatient discharge or outpatient procedure that should have been covered by the hospital's diagnosis-related group payment or billed to the hospital, respectively; (2) conspiring with hospitals and physicians to manipulate the ordering of its cancer tests to avoid the 14-Day Rule; and (3) failing to send timely invoices to hospitals for laboratory services falling within the 14-Day Rule and instead writing off the unpaid fees, in violation of the AKS.[73]	**$32.5 million**

70 https://www.justice.gov/usao-nj/pr/morris-county-sonography-company-enters-deferred-prosecution-agreement-agrees-pay-95000.
71 https://www.justice.gov/usao-sdny/pr/us-settles-false-claims-act-lawsuit-against-cardiologist-and-his-medical-practice.
72 https://compliancecosmos.org/gift-cards-are-heart-fca-settlement-1375m-oig-approved-similar-arrangement#footnotes.
73 https://www.justice.gov/opa/pr/genomic-health-inc-agrees-pay-325-million-resolve-allegations-relating-submission-false.

LABORATORY, PATHOLOGY, RADIOLOGY & DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/10/2023	Cardiac Imaging Inc.; Sam Kancherlapalli	Imaging company and founder/owner/CEO agreed to pay $75 million, plus additional amounts based on future revenues, and its owner-CEO agreed to pay over $10.48 million to resolve allegations that they violated the AKS and Stark Law by: (1) paying above FMV fees to referring cardiologists to supervise PET scans; and (2) compensating cardiologists for services not provided. The company relied on a consultant's FMV analysis that, the government contended, the company knew relied on fundamental inaccuracies about the services referring physicians provided and that the consultant ultimately withdrew from its engagement. As part of the settlement, both parties entered into a five-year CIA with HHS-OIG.[74]	**$85.48 million +**
10/17/2023	Exagen Inc.	Diagnostic testing provider agreed to pay $653,143 to resolve allegations that it entered into specimen processing agreements with referring physicians and then billed for tests it performed after receiving orders from referring physicians to whom it paid the specimen processing fees, in violation of the AKS.[75]	**$653,143**
11/2/2023	Genesis Reference Laboratories LLC	Clinical laboratory agreed to pay over $1.19 million to resolve allegations that it paid illegal kickbacks in exchange for testing referrals from providers, in violation of the AKS. The laboratory allegedly used marketing companies that utilized Management Services Organizations (MSOs) to disguise the kickbacks to providers.[76]	**$1.19 million +**

74 https://www.justice.gov/usao-sdtx/pr/cardiac-imaging-company-and-founder-pay-historic-85m-settlement.
75 https://www.justice.gov/usao-ma/pr/exagen-inc-agrees-pay-653143-resolve-allegations-kickback-violations.
76 https://www.justice.gov/usao-nj/pr/florida-laboratory-agrees-pay-over-11-million-settle-kickback-allegations.

BEHAVIORAL HEALTH & SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
2/2/2023	Community Mental Health Affiliates, Inc.	Behavioral health provider agreed to pay $384,322 to resolve allegations that it submitted claims for Medicaid Rehabilitation Option services while failing to document at least 40 hours of services per month as required.[77]	**$384,322**
2/10/2023	ABA Programming Inc. d/b/a Applied Behavior Center for Autism; Sherry Michael	Autism therapy provider and its owner agreed to pay $2 million to resolve allegations that they submitted claims to TRICARE and the Indiana Medicaid program for services that were: (1) upcoded, concurrent or duplicated; (2) not covered by TRICARE; and (3) already paid by another third-party.[78]	**$2 million**
2/13/2023	Northeast Health Services, LLC; Robert A. Conway; Wallace W. Varonko	Mental health services provider and its former owners agreed to pay $940,000 to resolve allegations that they caused the submission of claims to MassHealth for services provided by clinicians who were not properly supervised.[79]	**$940,000**
2/24/2023	Great Circle	Nonprofit behavioral health organization agreed to pay $1.866 million to resolve allegations that it submitted claims certifying that it provided enhanced levels of staffing for particular children resulting in additional payments, when that enhanced staffing or supervision was not provided. The company also entered into a related non-prosecution agreement.[80]	**$1.86 million +**
3/3/2023	Psychiatric Solutions P.C.; Longview Psychiatric Center PLLC; Longview Psychiatric Center LP; Dr. Ashok Jain	Psychiatric companies and their owner agreed to pay $3 million to resolve allegations that they submitted claims to Medicare for Transcranial Magnetic Stimulation procedures that were: (1) worthless or not performed; (2) not medically necessary; or (3) not overseen by a physician.[81]	**$3 million**
4/18/2023	K-Assist, LLC; Kelly Stutzman	Behavioral health practice and its owner agreed to pay $234,064 to resolve allegations that they submitted claims to Medicaid for psychotherapy services that they falsely represented were delivered by a licensed provider when an unlicensed individual rendered the services. In a separate state criminal proceeding, the owner pleaded nolo contendere to health insurance fraud and agreed to pay $63,764.23 in restitution and be subject to a three-year suspended jail sentence and five-year conditional discharge.[82]	**$234,064**

77 https://www.justice.gov/usao-ct/pr/behavioral-health-provider-pays-384k-settle-allegations-it-overbilled-connecticut.
78 https://www.justice.gov/usao-sdin/pr/us-attorneys-office-recovers-2-million-autism-therapy-provider-alleged-false.
79 https://www.mass.gov/news/former-owners-of-taunton-based-mental-health-centers-to-pay-940000-to-masshealth-in-settlement.
80 https://www.justice.gov/usao-edmo/pr/missouri-nonprofit-admits-false-statements-about-care-foster-youth-agrees-pay-18.
81 https://www.justice.gov/usao-sdtx/pr/psychiatrist-settles-claims-unnecessary-brain-stimulation-treatments.
82 https://www.justice.gov/usao-ct/pr/connecticut-behavioral-health-clinician-group-pays-234k-settle-false-claims-allegations.

BEHAVIORAL HEALTH & SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/17/2023	Compassionate Counseling Services, LLC	Behavioral health provider agreed to pay $150,000 to resolve allegations that it caused the submission of claims to Medicaid for Diagnostic Assessments: (1) without proper documentation, signatures and dates; and (2) for subsequent services for which it was unable to support medical necessity.[83]	**$150,000**
7/7/2023	Health Connect America	Behavioral health provider agreed to pay $4,611,375 to resolve allegations that it submitted claims to Medicaid for services that were not provided within two of its programs. The settlement also resolved FCA allegations that the company submitted claims for a third program where services were provided by non-credentialed or improperly trained mental health professionals but were billed using the identity of a properly-trained and credentialed provider. As part of the settlement, which also resolved potential criminal liability, the company agreed to a five-year period of increased compliance and oversight.[84]	**$4.61 million +**
9/11/2023	Mile High Psychiatry LLC; Michael K. Chism, II	Psychiatry practice and its owner agreed to pay $1.9 million to resolve allegations that they improperly double-billed Medicare and Medicaid for both E&M services and psychotherapy services provided in the same patient visit.[85]	**$1.9 million**
9/29/2023	Connex Family Services, LLC; Bianca Riddle	Behavioral health provider and its owner agreed to pay $918,000, and up to $2,053,387 more if the company is sold within five years, to resolve allegations that they submitted claims to Medicaid and TRICARE for applied behavioral analysis services that were not provided. As part of the settlement, they entered into a three-year IA with HHS-OIG.[86]	**$918,000 (guaranteed)** **$2.05 million + (contingent)**
9/29/2023	Edgewater Systems for Balanced Living, Inc.	Mental health provider agreed to pay $1.25 million to resolve pre-suit FCA allegations that it billed the Indiana Medicaid program for mental health counseling sessions in the absence of a required Individualized Integrated Care Plan. The provider knew of the requirement based on prior negative audits.[87]	**$1.25 million**

83 https://www.justice.gov/usao-mdnc/pr/false-claims-act-settlement-reached-rockingham-health-care-provider.
84 https://www.justice.gov/usao-wdva/pr/health-connect-america-fined-over-46-million-improper-billing-practices.
85 https://www.justice.gov/usao-co/pr/colorado-psychiatry-practice-and-owner-agree-pay-19-million-settle-allegations-0.
86 https://www.justice.gov/usao-edva/pr/behavioral-services-healthcare-provider-and-its-owner-settle-false-claims-act.
87 https://www.justice.gov/usao-ndin/pr/settlement-125-million-edgewater-systems-balanced-living-inc-fraudulently-billing.

BEHAVIORAL HEALTH & SUBSTANCE ABUSE TREATMENT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/5/2023	Luminosity Behavioral Health Services, Inc.	Mental health provider agreed to pay $700,000 to resolve allegations that it falsely billed MassHealth for higher levels of services than actually provided and using an additional code that was not applicable to the services provided. As part of the settlement, the company agreed to implement a three-year independent compliance monitoring program.[88]	**$700,000**
10/17/2023	Ubuntu Autism Consultants, LLC; Autism Behavioral Links, Inc.; Ian Gatheca; Autism Resources and Therapy Center; Mary Wangari	Two applied behavioral analysis providers and their owners agreed to collectively pay more than $2.5 million to resolve allegations that they submitted false claims to MassHealth for: (1) services that were not rendered; (2) services that were not properly documented; (3) failing to provide acceptable supervision of paraprofessionals; and/or (4) services provided by individuals without the appropriate credentials for the service in question. As part of the resolution, all parties have agreed to a three-year independent compliance monitoring program at their own expense.[89]	**$2.52 million +**

88 https://www.mass.gov/news/brockton-based-mental-health-provider-agrees-to-700000-settlement-to-resolve-masshealth-fraud-allegations.
89 https://www.mass.gov/news/ag-campbell-announces-more-than-25-million-in-fraud-settlements-with-two-autism-services-providers.

MANAGED CARE & HEALTH PLANS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
Various	Centene Corporation	Pharmacy benefits manager entered into settlements with multiple states to resolve allegations related to its subsidiaries overcharging for pharmacy benefits management services and failing to pass on retail discounts to state Medicaid programs. Resolutions in 2023 include: • Indiana: $66.5 million[90] • California: $215.4 million[91]	**$281.9 million**
7/31/2023	Martin's Point Health Care Inc.	MA plan operator agreed to pay over $22 million to resolve allegations that it submitted false diagnosis codes not supported by patients' medical records for its MA plan enrollees in order to increase reimbursement.[92]	**$22.48 million +**
9/30/2023	The Cigna Group	MA plan owner/operator agreed to pay over $172 million to resolve allegations that it submitted false diagnosis codes not supported by patients' medical records for its MA plan enrollees in order to increase reimbursement, including diagnoses of serious and complex conditions based solely on cursory in-home assessments by providers who did not perform necessary diagnostic testing and imaging. As part of the settlement, Cigna entered into a five-year CIA with HHS-OIG.[93]	**$172.29 million +**

90 https://events.in.gov/event/attorney_general_todd_rokita_wins_665_million_settlement_with_major_healthcare_company_following_allegations_of_overcharging.
91 https://oag.ca.gov/news/press-releases/attorney-general-bonta-announces-215-million-settlement-against-healthcare.
92 https://www.justice.gov/opa/pr/martins-point-health-care-inc-pay-22485000-resolve-false-claims-act-allegations.
93 https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/12/2023	Mitias Orthopedics, PLLC; Dr. Hanna "Johnny" Mitias; Champion Orthopedics	Orthopedic practice, its owner and a subsidiary agreed to pay more than $1.87 million to resolve allegations that they billed Medicare and Medicaid for a brand-name product used in knee injections but instead used an inexpensive compounded agent for the injections.[94]	**$1.87 million +**
2/10/2023	Southeastern Medical Center	Orthopedic surgery practice agreed to pay $700,000 to resolve allegations that it billed Medicaid for spinal manipulation under Anesthesia (CPT code 22505) when it was not providing spinal manipulation under general anesthesia as required and when documentation for many patients did not support that spinal manipulations was occurring at all. The government noted that its investigation of the practice began when it identified the practice as a "substantial outlier across all Medicaid providers" for billing this CPT code.[95]	**$700,000**
2/13/2023	Florida Cardiology, P.A.; Various physicians	Cardiology practice and ten affiliated physicians agreed to pay $2 million to resolve multiple allegations of false billing. Two physicians allegedly caused the practice to bill for more intravascular stents than were actually used in patient procedures. One physician allegedly billed for procedures that were not performed by himself or, in some instances, by any qualified practitioner. All ten physicians submitted claims for services and procedures that allegedly were performed at times they were not in the United States.[96]	**$2 million**
2/27/2023	Nashville Acupuncture Clinic, PLLC	Acupuncture clinic agreed to pay $300,000 to resolve allegations that it billed the Department of Veterans Affairs for services which were not authorized, not coded appropriately or not supported by the medical record.[97]	**$300,000**
3/20/2023	Dr. Mark A. Ellis; Ellis Pain Center; Patsy Allen	Pain medicine specialist, his practice and his practice manager agreed to pay $5 million to resolve allegations that they billed Medicare for urine drug tests that were not actually conducted and could not have been conducted on the practice's analyzer. They also allegedly billed Medicare for urine drug tests and diagnostic tests that were not medically necessary.[98]	**$5 million**
3/20/2023	Ismat Farhan; USA Medical Transport	Ambulance company and its owner agreed to pay $862,500 to resolve allegations that they billed Medicaid for medical transport services that were not adequately or correctly documented or were never provided.[99]	**$862,500**

94 https://www.justice.gov/usao-ndms/pr/mitias-pay-187-million-settle-false-claims-act-allegations-medicare-and-medicaid.
95 https://events.in.gov/event/attorney_general_todd_rokita_and_team_win_700000_settlement_over_alleged_medicaid_fraud_by_hammond_orthopedic_surgeon.
96 https://www.justice.gov/usao-mdfl/pr/florida-cardiology-pa-and-10-physicians-agree-pay-2-million-settle-false-claims-act.
97 https://www.justice.gov/usao-mdtn/pr/nashville-acupuncture-clinic-agrees-pay-300000-resolve-false-claims-act-allegations.
98 https://www.justice.gov/usao-mdga/pr/athens-georgia-pain-medicine-owner-practice-manager-agree-5-million-settlement.
99 https://ag.ny.gov/press-release/2023/attorney-general-james-secures-more-860000-capital-region-medical-transportation.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/22/2023	Dr. Sonjay Fonn; Deborah Seeger; Midwest Neurosurgeons, LLC; DS Medical, LLC	Neurosurgeon, his fiancée and their companies agreed to pay $825,000 to resolve allegations that they received kickbacks from spinal implant companies in exchange for use of the companies' products by the neurosurgeon. The settlement was reached in this government-intervened FCA lawsuit on the eve of trial, less than a year after the Eighth Circuit's opinion on AKS causation in this case (*U.S. ex rel. Cairns v. DS Medical, LLC*).[100]	**$825,000**
3/23/2023	Arlington Ophthalmology Association, P.L.L.C. d/b/a Kleiman Evangelista Eye Centers	Ophthalmology provider group agreed to pay over $2.9 million to resolve allegations that it improperly induced referrals of patients who were candidates for cataract surgery, through various forms of remuneration paid to optometrists who co-managed patient care with the provider group, in violation of the AKS.[101]	**$2.9 million +**
4/20/2023	Dr. Paul S. Koch	Ophthalmologist and former owner of a chain of ophthalmology practices agreed to pay over $1.16 million to resolve allegations that he paid kickbacks to optometrists who referred patients to him and his practice for laser-assisted cataract surgeries, in violation of the AKS.[102]	**$1.16 million +**
4/28/2023	Dr. Joel Aronowitz; Daniel Aronowitz; Dr. Joel A. Aronowitz, M.D.; Tower Multi-Specialty Medical Group; Tower Wound Care Center of Santa Monica, Inc.; Tower Outpatient Surgery Center, Inc.; Tower Medical Billing Solutions	Plastic surgeon, along with his son, medical practices and billing company, agreed to pay $23.9 million to resolve allegations that they: (1) falsified the place of service code on skin grafts to maximize reimbursement; and (2) failed to properly dispose of unused portions of single-use skin graft materials and instead used them in subsequent procedures involving different Medicare and Medicaid beneficiaries which resulted in double billing. As part of the settlement, the surgeon and Tower Multi-Specialty Medical Group agreed to a voluntary exclusion from federal healthcare programs for 15 years. The son agreed to be excluded for three years.[103]	**$23.9 million**
4/28/2023	Dr. Fadi El-Atat; Dr. Sarah Abdul-Sater; FA CV Consultants P.C.	Two doctors and their medical practice agreed to pay $1 million to resolve allegations that they billed for medically unnecessary balance tests, pulmonary function tests, allergy tests, automatic nervous tests and cardiology ultrasound tests performed on Medicare and Medicaid beneficiaries.[104]	**$1 million**
5/8/2023	United Wound Healing P.S.	Wound care services provider agreed to pay $292,132 to resolve allegations that it submitted claims for E&M services provided on the same day as another medical procedure which is generally prohibited by Medicare, except in limited circumstances not applicable here.[105]	**$292,132**

100 https://www.justice.gov/opa/pr/justice-department-settles-lawsuit-against-neurosurgeon-and-his-fianc-e-alleging-receipt.
101 https://www.justice.gov/usao-edtx/pr/ophthalmology-practice-agrees-pay-over-29-million-settle-kickback-allegations.
102 https://www.justice.gov/usao-ri/pr/former-owner-ri-ophthalmology-chain-pay-11m-settlement-false-claims-inquiry-united-states.
103 https://www.justice.gov/opa/pr/beverly-hills-plastic-surgeon-agrees-pay-nearly-24-million-settle-false-claims-act.
104 https://www.justice.gov/usao-nj/pr/medical-practice-and-its-owners-pay-1-million-resolve-false-claims-act-allegations.
105 https://www.justice.gov/usao-wdwa/pr/puyallup-washington-wound-treatment-firm-settles-allegations-it-submitted-false-bills.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/11/2023	Familia Dental	Dental practice agreed to pay $300,000 to resolve allegations that it submitted false claims for services that were medically unnecessary.[106]	**$300,000**
5/23/2023	Elite Medical Spine & Musculoskeletal Center PLLC; Dr. Derek Lado	Specialty spine and musculoskeletal practice and its doctor agreed to pay $135,871 to resolve allegations that, after the government seized many packages of foreign and non-FDA-approved Botox in route to the practice and warned the practice about it, the doctor knowingly used the unapproved Botox to treat Medicare beneficiaries and then billed for the services.[107]	**$135,871**
5/24/2023	Corebella Health, LLC; Marcos de Escobar	Medical and wellness provider and its naturopath-owner agreed to pay almost $400,000 to resolve allegations that they submitted false claims and received overpayments as a result of billing for: (1) physician services when the services were provided by nurse practitioners and did not meet "incident-to" billing requirements; (2) more units than were actually prepared for allergy immunotherapy; and (3) E&M services on the same day as a procedure using Modifier 25, when, in fact, no significant, separately identifiable E&M services were provided.[108]	**$399,440**
5/24/2023	Massachusetts Eye and Ear Infirmary; Massachusetts Eye and Ear Associates, Inc.; Foundation of the Massachusetts Eye and Ear Infirmary, Inc.	Group of specialty eye and ear practices agreed to pay over $5.7 million to resolve allegations that seven of their physician compensation plans, which involved a total of 44 doctors, were in violation of the Stark Law. Mass General Brigham, which acquired the practices after the compensation plans began, voluntarily terminated the compensation plans and disclosed the issue to the government in connection the government's investigation into related allegations. [109]	**$5.7 million +**
5/25/2023	Complete Physician Services; Dr. Kenneth Wiseman; Dr. Steven Schmidt	Primary care practice and two physicians agreed to pay $1.5 million to resolve allegations that they caused the submission of false claims to Medicare Part C by submitting morbid obesity diagnosis codes to Part C where diagnosis lacked medical support in that the patients had a BMI under 35 and by submitting COPD diagnoses which were not supported medically or by appropriate documentation. The government also alleged that the practice and physicians caused the submission of false claims to Medicare Part B for inflated E&M billing and "incident-to" billing when the physician was out of the country.[110]	**$1.5 million**

106 https://www.justice.gov/usao-cdil/pr/federal-and-state-authorities-reach-settlement-familia-dental-over-healthcare-fraud.
107 https://www.justice.gov/usao-wdmi/pr/2023_0523_Derek_Lado.
108 https://www.justice.gov/usao-ct/pr/connecticut-naturopath-and-practice-pay-400k-settle-false-claims-improper-billing.
109 https://www.justice.gov/usao-ma/pr/massachusetts-eye-and-ear-agrees-pay-over-57-million-resolve-false-claims-act.
110 https://www.justice.gov/usao-edpa/pr/primary-care-physicians-pay-15-million-resolve-false-claims-act-liability-submitting.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/30/2023	Dr. James Ellner; Georgia Pain Management, P.C.; Samson Pain Center, P.C	Pain management center and its doctor, along with an ambulatory surgical center, agreed to pay $625,000 to resolve allegations that they: (1) improperly used Modifier 25 to unbundle and bill routine E&M services that were not separately billable from other minor surgical procedures performed on the same day; and (2) entered into an arrangement with a reference lab in which the lab paid the salary of an individual who functioned as a free employee for the pain management center, in exchange for the doctor's referral of urine drug tests, in violation of the AKS. The government further contended that many of the referred urine drug tests were medically unnecessary.[111]	**$625,000**
6/13/2023	Carolina Heart and Leg Center, P.A.; Dr. Hari Saini	Physician and his cardiology practice agreed to pay more than $5.01 million to resolve allegations that they systematically overstated the stenosis percentage to justify performing medically unnecessary atherectomy procedures. The government noted that the settlement was reached "after six years of discovery and litigation, and with trial looming" in an intervened lawsuit.[112]	**$5.01 million +**
6/20/2023	CRH Healthcare, LLC; Peachtree Immediate Care FP, LLC	Two urgent care chains agreed to pay $1.6 million to resolve allegations that they improperly upcoded E&M claims for the testing and treatment of patients who were suspected of COVID-19 exposure.[113]	**$1.6 million**
6/30/2023	Alamo City Pain Consultants LLC, d/b/a The Institute for Functional Health	Medical practice agreed to pay $357,913 to resolve allegations that it submitted false claims for implanted neuro-simulators when a P-Stim device had actually been used.[114]	**$357,913**
6/30/2023	Psych Dimensions Inc.; Lambert & Moore Enterprises Inc.	Two medical practices agreed to pay $155,254 to resolve allegations that they submitted false claims for implanted neuro-simulators when a P-Stim device had actually been used.[115]	**$155,254**
7/11/2023	Lags Spine & Sportscare Medical Centers Inc.; Dr. Francis P. Lagattuta	Spine and sports care medical practice and its owner and medical director agreed to pay more than $11.38 million to resolve allegations that they billed for medically unnecessary skin biopsies, spinal cord stimulation surgeries and definitive urine drug testing which were medically unnecessary. As part of the settlement, the owner and medical director agreed to be excluded from federal healthcare programs for five years.[116]	**$11.38 million +**

111 https://www.justice.gov/usao-ndga/pr/woodstock-pain-management-doctor-and-clinics-pay-625000-resolve-false-claims-act.
112 https://www.justice.gov/usao-ednc/pr/fayetteville-cardiologist-agrees-pay-over-5-million-resolve-allegedly-false-medicare.
113 https://www.justice.gov/usao-ndga/pr/georgia-urgent-care-chain-agrees-pay-1600000-resolve-false-claim-act-allegations.
114 https://www.justice.gov/usao-wdtx/pr/two-texas-medical-practices-pay-more-500000-resolve-false-claims-act-liability.
115 https://www.justice.gov/usao-wdtx/pr/two-texas-medical-practices-pay-more-500000-resolve-false-claims-act-liability.
116 https://www.justice.gov/usao-edca/pr/california-doctor-and-medical-practice-agree-pay-114-million-resolve-false-claims-act.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
7/13/2023	Skin Cancer & Cosmetic Dermatology Center, P.C.; Dr. John Y. Chung	Dermatologist and his practice agreed to pay $6.6 million to resolve allegations that they: (1) billed for Mohs procedures as if both the surgical and pathology portions of the procedures were performed by the dermatologist when at least one portion was actually performed by others; and (2) regularly billed for multiple procedures, performed on the same patient on the same day, in a manner that improperly evaded Medicare's "multiple procedure reduction rule." As part of the settlement, the parties entered into an IA with HHS-OIG.[117]	**$6.6 million**
7/20/2023	Dr. Imran Chishti; C Care LLC; Dr. Shamim Justin Badiyan; Psych Care Consultants LLC	Two physicians and two medical practices agreed to pay $525,610 to resolve allegations that they received payments from MSOs in exchange for the doctors' referrals for laboratory tests to multiple laboratory companies, in violation of the AKS.[118]	**$525,610**
7/21/2023	John A. Greager, II; Cancer Therapy Associates, S.C.	Doctor and his surgical center agreed to pay over $750,000 to resolve allegations they billed for multiple mole removals on the same day and made it appear that the procedures were performed on multiple dates, in order to receive increased reimbursement from Medicare and the Federal Employees Health Benefits Plan. The doctor was also criminally prosecuted and received a 6-month prison sentence plus a fine of $1 million.[119]	**$757,879**
7/27/2023	Advanced Health Partners, Inc., f/k/a Medicom Management Services, Inc.; Medexcel USA, Inc.; Medexcel Emergency Physician Services of Yonkers, PLLC; Tri-State Emergency Physicians, PLLC	Emergency physician groups and management companies agreed to pay $475,000 to resolve allegations that they caused the submission of false claims that included NPIs of physicians who often were no longer employed by the physician groups or did not supervise or perform the services in the submitted claims.[120]	**$475,000**
8/7/2023	Evoke Neuroscience, Inc.; Dr. David Hagedorn	Neuroscience company agreed to pay $225,000, and its co-founder/CEO agreed to pay $220,000, to resolve allegations that they caused false claims to be submitted to Medicare for a "brain health" device by promoting six false billing codes to providers.[121]	**$445,000**

117 https://www.justice.gov/usao-edtn/pr/dermatologist-agrees-pay-66-million-settle-allegations-fraudulent-billing-practices.
118 https://www.justice.gov/usao-nj/pr/texas-and-missouri-physicians-and-medical-practice-agree-pay-over-525000-settle-kickback.
119 https://www.justice.gov/usao-ndil/pr/suburban-chicago-doctor-and-his-surgical-center-pay-more-750000-settle-false-claims.
120 https://www.justice.gov/usao-sdny/pr/us-settles-lawsuit-alleging-medical-staffing-and-services-companies-defrauded-medicare.
121 https://www.justice.gov/usao-edpa/pr/neuroscience-company-and-co-founderceo-pay-445000-resolve-false-claims-act-allegations.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/24/2023	Dr. Rajendra Bothra; The Pain Center USA, PLLC; Interventional Pain Center, PLLC	Interventional pain management specialist and his two medical entities agreed to pay $6.5 million to resolve allegations that they submitted false claims for: (1) medically unnecessary presumptive and definitive urine drug tests; (2) additional laboratory charges that were not separately billable with the urine drug tests; (3) medically unnecessary moderate sedation services that were often performed along with interventional pain management procedures that did not require these services; and (4) back braces that were medically unnecessary or otherwise ineligible for reimbursement.[122]	**$6.5 million**
9/12/2023	Frederick Oncology and Hematology Associates, P.C.	Former medical practice agreed to pay $850,949 to resolve allegations that it: (1) billed E&M services using a code modifier that is only appropriate when there is a separate and distinct E&M service on the same day as a procedure or other service being performed on a patient, when such separate and distinct E&M service had not been performed; and (2) submitted claims using a physician's billing number, when a non-physician provider actually treated the patient in the physician's temporary absence.[123]	**$850,949**
9/13/2023	Oliver Street Dermatology Management LLC	Company that manages and operates dermatology practices and pathology laboratories agreed to pay nearly $8.9 million to resolve allegations, which the company voluntarily self-disclosed to DOJ, that former senior managers had offered or agreed to increase the purchase price of certain acquired dermatology practices, in exchange for an agreement by the acquired practice's provider to refer services to company-affiliated entities after the acquisition, in violation of the Stark Law and AKS.[124]	**$8.89 million +**
9/21/2023	Dr. Gregory Stynowick; Pain Management Medical Center LLC; Dr. Chad Shelton; Dr. Michael Boedefeld; Pro Pain LLC	Three doctors and their pain management practices agreed to pay $653,796 to resolve allegations that they received payments from MSOs in exchange for the doctors' referrals for laboratory tests to multiple laboratory companies, in violation of the AKS.[125]	**$653,796**
9/29/2023	Dr. Moustafa Moustafa; South Carolina Nephrology and Hypertension Center Inc.	Doctor and his medical practice agreed to pay over $585,000 to resolve allegations that they received various forms of remuneration to induce the referral of patients for laboratory testing, in violation of the AKS.[126]	**$585,540**

122 https://www.justice.gov/usao-edmi/pr/michigan-doctor-pay-65-million-resolve-false-claims-act-allegations.
123 https://www.justice.gov/usao-md/pr/frederick-medical-practice-pays-united-states-more-850000-resolve-claims-it.
124 https://www.justice.gov/usao-ndtx/pr/dermatology-management-company-pay-89-million-resolve-self-reported-false-claims-act.
125 https://www.justice.gov/opa/pr/missouri-physicians-and-pain-management-practices-agree-pay-over-650000-settle-kickback.
126 https://www.justice.gov/usao-nj/pr/south-carolina-doctor-and-nephrology-practice-agree-pay-more-585000-settle-laboratory.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/2/2023	Dr. Michael Sawaf; Premier Dental Group PLLC of Knoxville, f/k/a Orthodontic Designs by Michael Sawaf, PLLC	Dental group and its doctor have agreed to pay $985,541 to resolve allegations that they caused the submissions of false claims to TennCare by: (1) upcoding claims for dental services; and (2) identifying credentialed dentists as the rendering provider for services that were actually rendered by uncredentialed dentists who were ineligible to bill TennCare.[127]	**$985,541**
10/17/2023	IPC Hospitalists of Michigan, Inc.; Inpatient Consultants of Michigan, P.C.; IPC Healthcare f/k/a IPC The Hospitalist Company; Team Health Holdings, Inc.	Hospitalist groups agreed to pay more than $4.38 million to resolve allegations that they: (1) upcoded specific CPT codes which usually report complex E&M services; (2) allowed hospitalists to bill for an impossible amount of inpatient procedures and services in a single day; and (3) submitted claims for procedures and services performed by the same provider on the same day and billed to the Medicare and Medicaid programs for beneficiaries located in Michigan and Indiana, when no services were actually rendered to Michigan-based beneficiaries.[128]	**$4.38 million +**
10/18/2023	Jena Medical Group, LLC; Benjamin Weiss; Moishe Hoffman; Dr. Jason Schultz	Medical group, its principals and physician agreed to pay over $1.72 million to resolve allegations that they billed for radiofrequency ablations that were not medically necessary and/or performed by an unqualified technician. The government alleged that patients were led to believe the unqualified technician was a doctor who could perform their procedures, and that the medical group washed and allowed the re-use of single-use catheters.[129]	**$1.72 million +**
10/23/2023	DaVita Healthcare Partners, Inc.; Bay Ridge Sunset Park Dialysis Center, Inc.; Midwood Chayim Aruchim Dialysis Associates, Inc.; New York Artificial Kidney Center, Inc.; The Rogosin Institute; Nephrology Foundation of Brooklyn; Terence Cardinal Cooke Health Care Center; New York Renal Associates, Inc.; Dialysis Clinic, Inc.	Several dialysis providers and management companies agreed to pay over $9.59 million to resolve allegations that they caused retail pharmacies to submit claims to Medicaid for certain injectable drugs administered during dialysis treatment, when Medicaid had already paid for those drugs as part of the payments the dialysis providers received for dialysis treatment.[130]	**$9.59 million +**
10/23/2023	Affinity Acupuncture, LLC	Acupuncture provider agreed to pay $250,000 to resolve allegations that it submitted false claims to the U.S. Department of Veterans Affairs for procedures that: (1) were not authorized; (2) lacked supporting documentation; or (3) were not allowed as originally coded.[131]	**$250,000**

127 https://www.justice.gov/usao-edtn/pr/dental-provider-and-associated-individuals-agree-resolve-allegations-improper-billing.
128 https://www.justice.gov/usao-edmi/pr/hospitalist-companies-agree-pay-nearly-44-million-settle-false-claims-act-allegations.
129 https://www.justice.gov/usao-mdfl/pr/jena-medical-group-llc-its-principals-and-physician-agree-pay-over-17-million-settle.
130 https://www.justice.gov/usao-edny/pr/dialysis-providers-settle-civil-fraud-claims-more-95-million.
131 https://www.justice.gov/usao-mdtn/pr/affinity-acupuncture-agrees-pay-250000-resolve-false-claims-act-allegations.

SPECIALTY CARE & OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
11/6/2023	Atlanta Medical and Aesthetic Center, Inc. d/b/a AIM Medical Center; Dr. Saima Syed; Rehan Syed	Medical practice, physician and practice employee agreed to pay $225,000 to resolve allegations that they submitted false claims for office visits by upcoding certain visits to make them appear more complex or lengthy, and by indicating that the physician had personally performed certain services, when she was travelling out of the country at the time the services were provided.[132]	**$225,000**
11/29/2023	Innovative Sleep Centers PLLC; Innovative Sleep Centers, Inc.	Two sleep centers agreed to pay $644,562 to resolve allegations that they submitted false claims for: (1) E&M services under the name of the center's medical director when a lower provider actually performed the services; (2) office visits under the name of the medical director when the services were performed by other employees who were not qualified to do so; and (3) sleep studies performed by technologists who lacked the requisite credentials.[133]	**$644,562**
12/4/2023	Med First Immediate Care & Family Practice, P.A.	Medical practice agreed to pay $1.45 million to resolve allegations that it submitted false claims for: (1) medically unnecessary presumptive and definitive urine drug testing at one of its clinics, as both tests were performed at nearly every patient office visit for patients on opioid therapy and were repeated without individualized determinations of need; and (2) E&M services at a higher level than was actually provided.[134]	**$1.45 million**
12/19/2023	Dr. Wendell Heidinger; Optimal Health of Southern Oregon, LLC	Doctor and his practice agreed to pay $115,000 to resolve allegations that they submitted claims coded as "E&M" when frequency specific microcurrent (FSM) treatments, which are investigational treatments Medicare does not cover, were primarily performed.[135]	**$115,000**
12/21/2023	Total Access Urgent Care	Urgent care practice agreed to pay over $9.15 million to settle allegations that it submitted false claims to Medicare, TRICARE and a federal COVID-19 uninsured program for: (1) office visits performed by a physician when a non-physician practitioner had actually performed them; (2) upcoded office visits; and (3) COVID-19 testing using improper billing codes, the latter of which the practice voluntarily disclosed to the government during its investigation. The settlement also resolved the practice's separate self-disclosure to CMS that bonuses paid to certain physicians it employed were based in part on the volume or value of their referrals, in violation of the Stark Law and AKS.[136]	**$9.15 million +**

132 https://www.justice.gov/usao-ndga/pr/snellville-doctor-pays-225000-resolve-allegations-improper-billing.
133 https://www.justice.gov/usao-wdwa/pr/sleep-disorder-medical-practice-clinics-california-and-washington-resolves-allegations.
134 https://www.justice.gov/usao-mdnc/pr/med-first-agrees-pay-1450000-resolve-health-care-fraud-allegations-south-carolina.
135 https://www.justice.gov/usao-or/pr/grants-pass-physician-and-affiliated-medical-practice-agree-pay-115000-settle-health.
136 https://www.justice.gov/usao-edmo/pr/united-states-reaches-91-million-civil-settlement-total-access-urgent-care-over-false.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/3/2023	Dr. Amr El-Khashab	Podiatrist agreed to pay $90,000 to resolve allegations that he and his prior podiatrist-employer billed Medicare for the surgical implantation of neurostimulator devices when patients actually received devices for electro-acupuncture, which does not require surgical implantation. In 2022, the government settled with the podiatrist's employer for related allegations.[137]	**$90,000**
1/4/2023	Dr. Kishor Vora	Physician agreed to pay more than $900,000 to resolve allegations that he referred patients to a laboratory for genetic tests, including medically unnecessary and unreasonable tests, in exchange for payments from the laboratory, in violation of the AKS.[138]	**$931,500**
1/5/2023	Dr. Jeffrey G. Tauth	Cardiologist agreed to pay $900,000 to resolve allegations that he inserted medically unnecessary cardiac stents into Medicare patients. As part of the resolution, the physician and his practice entered into a three-year IA with HHS-OIG.[139]	**$900,000**
1/9/2023	Dr. Aarti D. Pandya; Aarti D. Pandya, M.D. P.C.	Physician and her practice agreed to pay approximately $1.85 million to resolve allegations that they billed for: (1) medically unnecessary cataract surgeries and diagnostic tests, which, in some cases, caused patient injury; (2) incomplete tests or tests of worthless value; and (3) office visits that did not provide the level of service claimed. As part of the settlement, the physician and her practice entered into a five-year IA and conditional exclusion release.[140]	**$1.85 million**
3/13/2023	Dr. Kathy Cornelius	Physician agreed to pay $500,000 to resolve allegations that she referred Medicare patients for medically unnecessary genetic tests, including tests based on brief telemedicine consultations that failed to establish legitimate medical justification.[141]	**$500,000**
3/20/2023	Dr. Steven A. St. Lucia	Former orthotic and prosthetic surgeon agreed to pay $42,000 to resolve allegations that he caused the submission of false claims to Medicare by circumventing the effects of his medical license revocation and exclusion from federal healthcare programs. Following his exclusion in 2000, the surgeon opened a medical supply company and falsified the Medicare enrollment application by concealing his license revocation and exclusion. After CMS denied the company's enrollment, the physician transferred ownership of the company to a new owner but continued working for the company, including ordering services for Medicare patients and billing in the name of another provider. The surgeon pleaded guilty to related state criminal charges, was sentenced to prison and was ordered to pay approximately $400,000 in restitution.[142]	**$42,000 (civil)** **$400,000 (criminal)**

137 https://www.justice.gov/usao-sdtx/pr/podiatrist-pays-90000-settle-false-billing-allegations.
138 https://www.justice.gov/usao-wdky/pr/owensboro-doctor-pays-931500-resolve-allegations-he-received-kickbacks-laboratory.
139 https://www.justice.gov/usao-mdtn/pr/arkansas-cardiologist-agrees-pay-900000-settle-false-claims-act-allegations.
140 https://www.justice.gov/usao-ndga/pr/conyers-doctor-pays-1850000-resolve-allegations-she-performed-and-billed-medically.
141 https://www.justice.gov/usao-de/pr/united-states-settles-claims-genetics-testing-fraud.
142 https://www.justice.gov/usao-ndny/pr/former-niskayuna-surgeon-pay-42000-defrauding-medicare; https://ig.ny.gov/news/ig-investigation-secures-nearly-400000-restitution-health-care-fraud-scheme-3.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/30/2023	Gisele Nguyen	Pharmacist agreed to pay more than $3.93 million to resolve allegations that she fraudulently billed claims to the Medicare Part D Program for medications that were never dispensed to beneficiaries.[143]	**$3.93 million +**
4/24/2023	Dr. Ajay Kumar Aggarwal; Medley Compounding Pharmacy LLC	Physician and a compounding pharmacy owned and operated by the physician and his wife agreed to pay more than $7.96 million to resolve allegations that: (1) they submitted false claims to the federal Workers' Compensation Program for expensive and medically unnecessary pain creams, gels and patches using pre-printed prescription pads; and (2) the physician received kickbacks for referring business to the pharmacy, in violation of the AKS.[144]	**$7.96 million +**
4/24/2023	Dr. Jason A. Dreyer	Former neurosurgeon agreed to pay over $1.17 million to resolve allegations that he performed medically unnecessary neurosurgery procedures that were billed to federal healthcare programs. As part of the settlement, the physician agreed to enter into an exclusion agreement with HHS-OIG for at least nine years. The settlement followed a $22.69 million settlement in 2022 with the neurosurgeon's former hospital employer for similar conduct, where the hospital admitted that it permitted the neurosurgeon to resign without reporting him.[145]	**$1.17 million +**
5/5/2023	Dr. Evelyn Llewellyn	Psychologist agreed to pay $658,294 to resolve allegations that she submitted claims to Medicare and Medicaid for psychology services that were not provided. Her husband, who was responsible for submitting claims to payors, pleaded guilty to health care fraud.[146]	**$658,294**
5/11/2023	Dr. Gary S. Winn	Former medical director and owner of a family medical practice agreed to pay $330,607 to resolve allegations that he submitted false claims to Medicare and Medicaid for services that were not provided or were not medically reasonable or necessary, including osteopathic manipulation treatment services, E&M services, tobacco use cessation counseling visits, outpatient visits and patient drug testing services.[147]	**$330,607**
5/16/2023	Dr. Ndudi Aniemeka; Obiageli Aniemeka	Physician and his wife/clinic administrator agreed to pay a more than $3 million judgment to resolve allegations that they requested and received kickbacks from a home health agency in exchange for the physician's referrals of Medicare patients, in violation of the AKS.[148]	**$3.01 million +**

143 https://www.justice.gov/opa/pr/california-pharmacist-agrees-settle-allegations-fraud.
144 https://www.justice.gov/usao-sdtx/pr/physician-and-pharmacy-settle-claims-unnecessary-medications.
145 https://www.justice.gov/usao-edwa/pr/former-physician-pay-more-11-million-resolve-allegations-he-performed-medically.
146 https://www.justice.gov/usao-ct/pr/connecticut-psychologist-pays-658k-settle-allegations-she-received-payments-medicare-and.
147 https://www.justice.gov/usao-me/pr/arundel-resident-agrees-pay-over-330000-settle-allegations-false-claims-act-violations.
148 https://www.justice.gov/usao-ndil/pr/chicago-doctor-and-his-wife-held-liable-jury-taking-kickbacks-and-causing-false.

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
5/25/2023	Dr. Vasso Godiali	Vascular surgeon agreed to pay up to $43.42 million to resolve allegations that he defrauded federal healthcare programs by: (1) submitting claims for vascular stents and thrombectomies he did not perform; (2) billing for multiple vascular stents in the same blood vessel and arterial thrombectomies and preparing materially inaccurate medical records to justify the billings and each procedure's medical necessity; and (3) improperly using Modifier 59 to "unbundle" services that should have been billed together. The physician previously pleaded guilty to related criminal violations in 2022, was sentenced to 80 months in prison and was ordered to pay $19.5 million in restitution.[149]	**$43.42 million (civil)** **$19.5 million (criminal)**
7/24/2023	Dr. Rakesh Kansal	Cardiovascular physician agreed to pay $310,000 to resolve allegations that he submitted claims for patients he referred for cardiovascular stress tests to a testing facility where he had an ownership interest, in violation of the Stark Law.[150]	**$310,000**
9/21/2023	Dr. Arun Arora	Physician agreed to pay $1.3 million to resolve allegations that he billed Medicare for critical care services to residents of nursing homes when he actually provided routine care. The physician also entered into a separate three-year IA with HHS-OIG as part of the resolution.[151]	**$1.3 million**
10/13/2023	Dr. Edward Lubin	Pain management physician agreed to pay $1.5 million to resolve allegations that he received kickbacks from Insys Therapeutics—disguised as payments for sham speaking events—in exchange for ordering fentanyl prescriptions that were medically unnecessary. The settlement occurred after the doctor filed Chapter 11 bankruptcy and on the eve of trial.[152]	**$1.5 million**
12/4/2023	Peggy Borgfeld; Dr. Linh Nguyen; Dr. Thuy Nguyen; Dr. Heriberto Salinas	Three physicians agreed to collectively pay over $550,000 and a hospital executive agreed to pay $325,000, plus additional contingency payments, to resolve allegations that they were involved in an illegal remuneration scheme, in violation of the AKS. The government alleged that the physicians received payments from two MSOs in exchange for the physicians' referrals for laboratory tests to a hospital and two laboratory companies, in violation of the AKS. The government alleged that the hospital executive knew that the hospital paid commissions to recruiters who used the MSOs to pay kickbacks to the physicians, and despite that knowledge, signed false certifications in Medicare cost reports about the hospital's compliance with the AKS.[153]	**$880,199**

149 https://www.justice.gov/opa/pr/michigan-vascular-surgeon-sentenced-80-months-prison-health-care-fraud-conviction-and-agrees.
150 https://www.justice.gov/usao-ndin/pr/settlement-rakesh-kansal-md-violations-stark-law-regarding-physician-self-referrals.
151 https://www.justice.gov/usao-edny/pr/queens-physician-settles-health-care-fraud-claims-13-million-and-enters-integrity-0.
152 https://www.reuters.com/legal/government/bankrupt-doctor-settles-avoid-trial-over-insys-opioid-kickbacks-2023-10-13.
153 https://www.justice.gov/opa/pr/hospital-executive-and-three-texas-physicians-pay-over-880000-settle-kickback-allegations.

OTHER

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
1/13/2023	Amvik Solutions, LLC	Medical billing company agreed to pay $153,300 to resolve allegations that it submitted claims for applied behavioral analysis services that identified the incorrect rendering provider, resulting in the payment of claims that would otherwise not have been paid.[154]	**$153,300**
3/14/2023	Jelly Bean Communications Design LLC; Jeremy Spinks	Website design company and its manager/co-owner/sole employee agreed to pay $293,771 to resolve allegations that they failed to securely host personal information and properly maintain, patch and update their software systems, contrary to representations made in a contract, agreements and invoices with a federally-funded state children's health insurance program. As a result of these alleged cybersecurity failures, more than 500,000 Florida Medicaid applications were hacked.[155]	**$293,771**
4/25/2023	Good Shepherd Catholic School, Inc.	Nonprofit, private school agreed to pay $354,000 to resolve allegations that it submitted claims to TRICARE for applied behavioral analysis therapy furnished to autistic students in a group setting rather than one-on-one as required.[156]	**$354,000**
6/16/2023	Capital Technology Information Services, Inc.	Healthcare information technology company agreed to pay more than $1.71 million to resolve allegations that it billed the National Institutes of Health (NIH) for unallowable costs and personal expenses, non-contract-related work and work that was not actually performed. The costs were allegedly falsely represented as being incurred in support of the company's performance of its grant and contract with the NIH.[157]	**$1.71 million +**
7/14/2023	NextGen Healthcare, Inc.	EHR vendor agreed to pay $31 million to resolve allegations that it: (1) falsified the capabilities of certain versions of its software to obtain certification under HHS's EHR Incentive Program; and (2) provided unlawful remuneration to its users to induce them to recommend the vendor's software, in violation of the AKS.[158]	**$31 million**
9/18/2023	Franceene McKinney	Medical information technology and coding consultant agreed to pay $30,000 to resolve allegations that she aided healthcare professionals in using a billing code designed for the surgical implantation of neurostimulator electrodes when, instead, the patients received devices for electro-acupuncture that did not require surgical implantation. The consultant and her company agreed to a three-year exclusion from participating in federal healthcare programs.[159]	**$30,000**

154 https://www.justice.gov/usao-ct/pr/alabama-medical-billing-company-pays-153k-resolve-false-claims-allegations.
155 https://www.justice.gov/opa/pr/jelly-bean-communications-design-and-its-manager-settle-false-claims-act-liability.
156 https://www.justice.gov/usao-wdok/pr/private-oklahoma-city-school-pays-354000-settle-allegations-submitting-false-claims.
157 https://www.justice.gov/usao-md/pr/health-care-information-technology-contractor-agrees-pay-more-17-million-resolve-false.
158 https://www.justice.gov/opa/pr/electronic-health-records-vendor-nextgen-healthcare-inc-pay-31-million-settle-false-claims.
159 https://www.justice.gov/usao-sdtx/pr/ohio-coding-consultant-agrees-settle-allegations-regarding-neurostimulator-devices.

CONTROLLED SUBSTANCES ACT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
3/3/2023	Dr. Howard Silcoff	Medical practice and its physician-owner agreed to pay $70,377 to resolve CSA and FCA allegations that they prescribed controlled substances to a certain patient in excessive quantities for more than a decade, outside the course of professional practice.[160]	**$70,377**
3/27/2023	People's Pharmacy, Inc.; Mahnaz Abharian	Pharmacy and its owner-pharmacist agreed to pay $3.5 million to resolve CSA allegations that they unlawfully dispensed controlled substances, including opioids and drug combinations, despite red flags that the prescriptions were not issued for legitimate medical purposes. As part of the resolution, the pharmacy agreed to permanently forgo holding a pharmacy license or DEA registration and the owner-pharmacist agreed to not dispense any controlled substances in the future.[161]	**$3.5 million**
3/28/2023	Catherine Devaney McKay	Former CEO of mental health and addiction treatment centers agreed to pay $300,000 to resolve CSA allegations that the company and its executives failed to keep proper records of its controlled substances when they were transferred between its facilities. This settlement resolves the government's claims against the CEO for her individual role in the violations.[162]	**$300,000**
6/12/2023	Stevens Pharmacy, Inc.; Steven W. Gough	Pharmacy and its owner agreed to pay $275,000 to resolve CSA allegations that they dispensed controlled substances based on invalid prescriptions and failed to maintain accurate inventories of certain controlled substances. The pharmacy surrendered its DEA registration and the owner agreed to notify DEA if he engages in the practice of pharmacy and to submit to warrantless inspections by DEA for three years if he operates a pharmacy practice at any location.[163]	**$275,000**
6/21/2023	Cheshire Medical Center	Medical center agreed to pay $2 million to resolve CSA allegations that it failed to keep adequate records of controlled substances, including opioids, resulting in thousands of missing controlled substance units. As part of the settlement, the medical center agreed to additional security and recordkeeping measures.[164]	**$2 million**

160 https://www.justice.gov/usao-ndny/pr/tompkins-county-medical-practice-pays-70377-resolve-false-claims-act-and-controlled.
161 https://www.dea.gov/press-releases/2023/03/27/colorado-pharmacy-and-pharmacist-agree-resolve-allegations-they.
162 https://www.justice.gov/usao-de/pr/former-connections-ceo-pays-300000-resolve-alleged-violations-federal-controlled.
163 https://www.justice.gov/usao-mdla/pr/port-allen-pharmacy-and-pharmacist-pay-275000-resolve-federal-civil-lawsuit-under.
164 https://www.justice.gov/usao-nh/pr/cheshire-medical-center-pay-2-million-settle-allegations-controlled-substances-act.

CONTROLLED SUBSTANCES ACT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
6/23/2023	CVS	Pharmacy agreed to pay $70,000 to resolve CSA allegations that pharmacists filled forged prescriptions and ignored red flags that the prescriptions were fraudulent. The settlement resulted from two criminal investigations into individuals who filled forged prescriptions at multiple locations of the pharmacy.[165]	**$70,000**
7/7/2023	Dr. Jennifer Burkitt	Dentist agreed to pay $150,000 to resolve CSA allegations that her practice failed to: (1) uphold effective controls against diversion; (2) keep complete and proper records; and (3) retain accurate forms and inventories.[166]	**$150,000**
7/31/2023	Christian & Missionary Alliance Foundation, Inc.	Nonprofit foundation agreed to pay $250,000 to resolve CSA allegations that it failed to: (1) conduct the required biennial inventories; (2) maintain records of controlled substances it acquired; and (3) notify the DEA of a theft or loss within one business day. The organization relinquished its DEA registration prior to the settlement.[167]	**$250,000**
8/1/2023	Tick Klock Drug	Pharmacy agreed to pay a $20,000 penalty to resolve CSA allegations that it failed to exercise its corresponding responsibility by filling prescriptions despite the presence of red flags and failing to keep proper records of certain controlled substances. As part of the settlement, the pharmacy entered into a Memorandum of Agreement (MOA) with the DEA under which it is required to conduct regular inventory audits and provide employee training.[168]	**$20,000**
8/4/2023	Woodfield Distribution, LLC; Adam Runsdorf	Drug wholesaler and its owner agreed to pay $2.475 million to resolve CSA allegations that they failed to account for and falsified documentation of millions of dosage units of controlled substances and failed to notify the DEA of stolen controlled substances. As part of the settlement, the parties surrendered their DEA registrations. A separate criminal investigation also resulted in the owner and a related company pleading guilty to trafficking counterfeit drugs, conspiracy and money laundering conspiracy.[169]	**$2.48 million**

165 https://www.justice.gov/usao-nh/pr/cvs-pay-70000-resolve-allegations-it-filled-fake-prescriptions.
166 https://www.justice.gov/usao-ndok/pr/dentist-agrees-pay-150000-penalties-alleged-controlled-substances-violations.
167 https://www.justice.gov/usao-mdfl/pr/christian-missionary-alliance-foundation-inc-agrees-pay-250000-resolve-alleged.
168 https://www.justice.gov/usao-edwa/pr/colfax-pharmacy-tick-klock-drug-agrees-pay-20000-penalty-and-implement-corrective.
169 https://www.justice.gov/usao-sdfl/pr/adam-runsdorf-and-woodfield-distribution-llc-agree-pay-2475-million-resolve.

CONTROLLED SUBSTANCES ACT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
8/25/2023	Dr. William D. Stratford Jr.	Doctor operating multiple clinics agreed to pay $85,000 to resolve CSA allegations that he did not maintain the required DEA registration at all locations and failed to maintain distribution or administration records for ketamine as required by DEA. As part of the settlement, the doctor agreed to restrictions on his prescribing authority and will be required to attend CSA training.[170]	**$85,000**
8/29/2023	Clarest, LLC d/b/a Clarest Health; ProCare LTC; New England LTC; ProCare LTC Pharmacy of Connecticut LLC	Pharmacy that services long-term care facilities and its parent companies agreed to pay $499,525 to resolve allegations that they violated the CSA by: (1) distributing controlled substances to non-registered practitioners; (2) failing to properly record DEA Form 222s; and (3) failing to reject order forms that were not properly prepared. As part of the settlement, the companies agreed to enter into a three-year DEA Corrective Action Plan.[171]	**$499,525**
8/30/2023	Jang Boo Chi M.D. P.C.; Dr. Jang Boo Chi	Medical practice and its physician-owner agreed to pay $135,000 to resolve CSA allegations of supplying prescriptions outside the usual course of practice, for non-legitimate purposes and in combinations which were dangerous to patients. As part of the settlement, the doctor surrendered his DEA registration and will not be able to seek renewal for a minimum of 15 years.[172]	**$135,000**
8/31/2023	Dr. Marina (aka Marianna) Abrams	Naturopathic physician agreed to pay $65,000 to resolve allegations that she wrote prescriptions outside the scope of what a naturopathic physician can provide and without a DEA registration in the state where she was practicing. The naturopath also entered into a four-year MOA with DEA.[173]	**$65,000**
9/29/2023	Ferry County Hospital District	Hospital district agreed to pay a $15,000 CSA penalty for failing to exercise corresponding responsibility at a pharmacy it owned. As part of the settlement, the company entered into a MOA with the DEA.[174]	**$15,000**

170 https://www.justice.gov/usao-mt/pr/missoula-doctor-settles-alleged-controlled-substances-act-recordkeeping-violations-85000.
171 https://www.justice.gov/usao-ct/pr/health-care-company-and-cheshire-pharmacy-pay-500k-resolve-controlled-substances-act.
172 https://www.justice.gov/usao-ndny/pr/former-auburn-physician-pays-135000-and-forfeits-dea-registration-overprescribing.
173 https://www.justice.gov/usao-wdwa/pr/doj-and-dea-settle-claims-naturopath-improperly-prescribed-scheduled-drugs.
174 https://www.justice.gov/usao-edwa/pr/ferry-county-hospital-district-agrees-pay-15000-penalty-and-implement-corrective.

CONTROLLED SUBSTANCES ACT

DATE	ENTITY	FCA ALLEGATIONS	AMOUNT
10/4/2023	Rx Express of Panama City	Pharmacy agreed to pay $60,000 to resolve CSA allegations that it filled controlled substance prescriptions that were outside the course of normal practice, including in high dosages and high quantities. As part of the settlement, the pharmacy agreed to enter a two-year compliance monitoring agreement with DEA.[175]	**$60,000**
10/11/2023	Zarzamora Healthcare LLC d/b/a Rite-Away Pharmacy & Medical Supply #2; Jitendra Chaudhary	Pharmacy and its pharmacist-owner agreed, as part of a consent judgment, to pay $275,000 to resolve CSA allegations of improper dispensing of controlled substances including opioids. The parties are also permanently enjoined from dispensing certain opioid prescriptions, including combination opioid and benzodiazepine prescriptions.[176]	**$275,000**
11/6/2023	Droguería Betances LLC	District court entered a consent decree requiring a pharmaceutical distributor to pay $12 million to resolve CSA allegations that it failed to: (1) report hundreds of suspicious opioid orders to DEA; (2) maintain accurate records of orders and shipments; and (3) submit required reports of its distribution transactions to DEA. The consent decree also requires the company to implement widespread improvements in its compliance program.[177]	**$12 million**
12/6/2023	Fountain Hill Pharmacy	Pharmacy agreed to pay $165,000 to resolve CSA allegations that it failed to maintain complete and accurate records required for controlled substances did not conduct a biennial inventory as required. As part of the settlement, the pharmacy is subject to monitoring requirements related to reporting, dispensing and prescribing and is for responsible for conducting additional training on DEA regulations.[178]	**$165,000**

175 https://www.justice.gov/usao-ndfl/pr/pharmacy-agrees-60000-settlement-relating-controlled-substances-act-claims.
176 https://www.justice.gov/opa/pr/federal-court-orders-san-antonio-area-pharmacy-and-pharmacist-pay-275000-civil-penalty-case.
177 https://www.justice.gov/opa/pr/federal-court-orders-puerto-rico-pharmaceutical-distributor-pay-12-million-connection.
178 https://www.justice.gov/usao-edpa/pr/philadelphia-pharmacy-pays-165000-resolve-allegations-failing-maintain-proper.

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 Law School and Belmont University College of Law.

For more information, please visit our website at **www.bassberry.com/healthcare-fraud**.

Our Healthcare Fraud & Abuse Resource Center provides a central location for healthcare leaders to access tools and information, including:

- An innovative, searchable database featuring nearly 1,900 significant FCA settlements from the last decade.
- Content from our Inside the False Claims Act blog.
- Current and past editions of the Healthcare Fraud & Abuse Annual Review.
- A video library with presentations from conferences and webinars highlighting the latest compliance and enforcement developments.

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

Ranked 4th Largest Healthcare Law Firm in the U.S. (2023)

Healthcare & Healthcare Government Investigations and Fraud Attorneys Recognized (2023)

Named Healthcare Practice Group of the Year (2020)

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Angie Bergman represents healthcare providers and companies facing claims of fraud, government investigations and Medicare administrative appeals. She represents a broad range of clients in all sectors of the healthcare industry including hospitals, long-term care facilities, ambulatory surgery centers, home health and hospice providers.

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Kristin Bohl blends her experience as a healthcare attorney in private practice and government service with first-hand knowledge of care delivery as a registered nurse. Kristin advises hospitals, health systems and other provider organizations on compliance and regulatory issues and fraud and abuse matters, with a focus on the wide range of Medicare payment models. Before she entered private practice, Kristin was the Technical Advisor in the Division of Technical Payment Policy at CMS. She was part of a team that developed the CMS Voluntary Self-Referral Disclosure Protocol and provided technical assistance in the creation of Stark Law waivers for ACO models and other payment initiatives of the Center for Medicare and Medicaid Innovation within CMS.

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Taylor Chenery concentrates 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 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 and compliance assessments for healthcare companies and providers, advising them on compliance-related issues. He also routinely represents healthcare clients defending claims denials in Medicare and Medicaid claims audits.

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Matt Curley is co-chair of the Bass, Berry & Sims Healthcare Fraud & Abuse Task Force and represents clients in connection with internal and governmental investigations and related civil and criminal proceedings, particularly involving matters of fraud and abuse within the healthcare industry. Matt has considerable experience in litigating matters under the FCA and in representing clients in actions and investigations brought by government regulators, including DOJ, HHS-OIG and various state agencies. 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 and has taught Healthcare Fraud & Abuse there for more than a decade.

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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.

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Lindsey Brown Fetzer is chair of the firm's multi-disciplinary Managed Care Practice Group and has a deep understanding of the managed care industry and partners with her clients to provide strategic guidance and solutions in this ever-evolving area. She has extensive experience working with healthcare plans, risk-bearing provider groups, and vendors in litigation, investigations, and compliance counseling matters. She represents clients in connection with government and internal investigations and litigation involving alleged violations of the FCA, AKS, FCPA and other criminal and civil regulations.

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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.

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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.

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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.

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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 Stark Law and HHS-OIG disclosure protocols.

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Brian Irving represents businesses and individuals in government investigations and enforcement actions, focusing on healthcare fraud and controlled substances enforcement and diversion. Brian's clients span a variety of industries, including healthcare, pharmacy and government contracting. Brian is the editor of the firm's Inside the False Claims Act blog and the co-chair of the firm's Controlled Substances Enforcement & Diversion Practice.

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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.

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Travis Lloyd focuses on complex healthcare regulatory matters. He represents a broad range of healthcare industry clients, including hospitals and health systems, ambulatory surgery centers, post-acute providers, behavioral health providers and physician practices, as well as their strategic partners. A substantial portion of Travis's practice involves advising clients on fraud and abuse issues, including those that relate to AKS and the Stark Law. His experience includes guiding healthcare providers through thorny compliance issues, obtaining advisory opinions, managing internal compliance reviews and investigations, and making voluntary disclosures to government entities.

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Bill Mathias is a healthcare regulatory attorney with a focus on fraud and abuse and Stark Law issues. He works with healthcare organizations to structure complex business arrangements, including joint ventures and strategic transactions, to manage risk while meeting their business objectives. Bill is a recognized leader on the federal AKS, the Stark Physician Self-Referral Law, EKRA and the federal Civil Monetary Penalty (CMP) regulations. He regularly assists with government investigations and defending FCA lawsuits and other enforcement actions.

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Jennifer Michael draws on her experience as the former Chief of the Industry Guidance Branch at HHS-OIG 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 AKS, the federal CMP law and other state and federal fraud and abuse laws and navigate government investigations under the federal 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.

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Lisa Rivera is chair of the firm's Compliance & Government Investigations Practice Group and 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 & Abuse and Litigation at Belmont University College of Law.

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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. She has successfully litigated and resolved matters for a variety of global, national and regional clients, including hospitals and health systems, health insurers, life sciences companies, hospice and home health providers, behavioral health providers and physician groups.

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Danielle Sloane helps national 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, joint ventures, compliance reviews, self-disclosures and voluntary repayments.

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

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