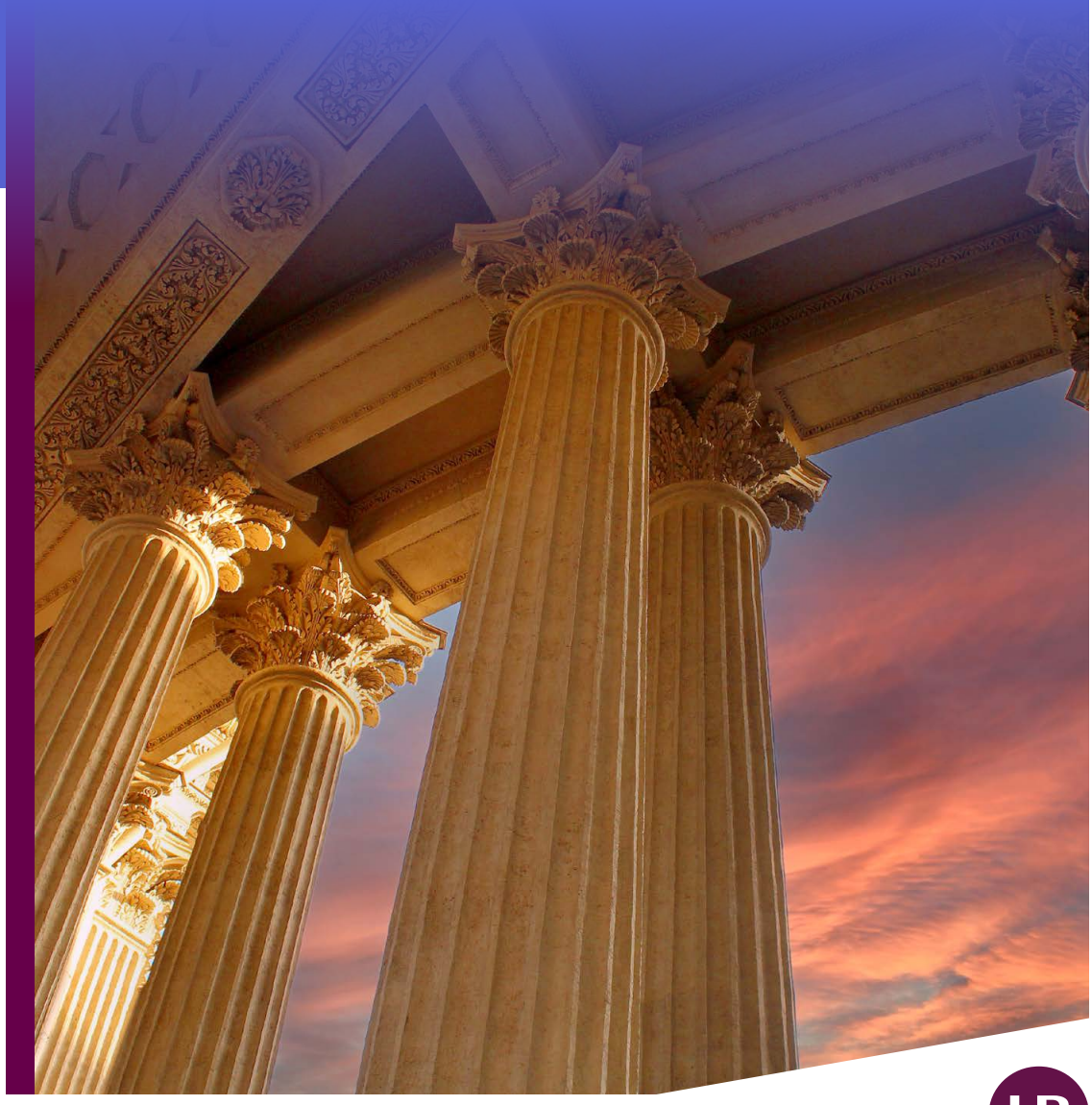
HAYNES BOONE

False Claims Act

2021 Year in Review



Clients and Friends,

In 2021, the COVID-19 pandemic continued to cast a pall over the nation's economic and healthcare landscapes. New laws were passed and several existing laws were renewed or extended to provide trillions of dollars of additional government funding to affected businesses and individuals. In the midst of this, the government maintained its focus on possible fraud associated with government funds, including violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA").

This Review highlights key developments from 2021 related to the FCA, including:

- The recovery by the government of more than $5.6 billion in settlements and judgments in FCA cases in 2021
- The government prioritizing the detection, investigation, and prosecution of fraud related to COVID-19 relief programs and cybersecurity by several means, including the FCA
- The government returning to earlier standards regarding individual accountability and reliance on sub-regulatory guidance
- Continued judicial efforts to interpret the elements of an FCA claim, including "materiality," after the U.S. Supreme Court's landmark decision in *Escobar*
- Significant judicial decisions regarding the types of allegations sufficient to satisfy Rule 9(b)'s heightened pleading standard, what constitutes an original source for purposes of the public disclosure bar, and whether the FCA imposes an objective scienter standard, among many other issues

In 2021, Haynes Boone's Healthcare and Life Sciences Practice represented healthcare providers, defense contractors, and individuals in FCA investigations and lawsuits. We successfully resolved matters before lawsuits were filed, negotiated favorable settlements at all stages, and defended our clients in active litigation and appeals. We also advised many healthcare providers and contractors regarding FCA compliance and other related issues.

If you have any questions about the issues covered in this Review, please let us know. We look forward to working with our friends and clients in 2022.

Stacy Brainin, Bill Morrison, Taryn McDonald, and Neil Issar

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Meet the Authors

STACY BRAININ has extensive experience in white collar criminal defense and government investigations, including representation of companies and individuals in both criminal and civil matters. Her practice also includes complex business litigation with an emphasis in healthcare and professional liability matters. She has defended cases alleging civil and criminal business fraud in state and federal courts throughout the country. Stacy represents and advises healthcare providers in civil and criminal disputes with state and federal government agencies. She is experienced in handling internal investigations and routinely advises clients regarding difficult compliance and disclosure issues. Stacy has served as adjunct professor at the University of Texas School of Law from 2009-2019.

BILL MORRISON is a partner and co-chair of the firm's Healthcare and Life Sciences Practice Group. Prior to Haynes and Boone, he served as Vice President and Assistant General Counsel of Tenet Healthcare, where he oversaw civil and criminal investigations involving FCA matters, class actions, and other high-level disputes. As a private practice lawyer, he has represented national healthcare providers in connection with federal grand jury subpoenas and with Civil Investigative Demands regarding potential FCA violations.

NICK BUNCH is a partner in Haynes Boone's White Collar and Government Investigations practices. Nick is an experienced trial lawyer, appellate advocate, and former federal prosecutor, who brings an insider's perspective on how the government investigates and prosecutes white-collar criminal and civil matters. Nick gained that unique insider's perspective over nearly 11 years at the U.S. Attorney's Office for the Northern District of Texas where he served as an Assistant United States Attorney, Deputy Criminal Chief, and Deputy Section Chief, investigating, prosecuting, and supervising healthcare, corruption, national security, cybercrime, and economic crime offenses.

ANDREW GUTHRIE is a partner who focuses his practice on appeals and critical trial court briefing across an array of subject matters, including the False Claims Act, business disputes, bankruptcy, energy, products liability, and intellectual property. Prior to joining the firm, Andrew clerked for the Honorable Don R. Willett of the Texas Supreme Court (now a Judge on the United States Court of Appeals for the Fifth Circuit).

JENNIFER KREICK advises and counsels health industry clients, such as health systems, providers, suppliers, investors, pharmaceutical manufacturers and biotech companies, and managed care organizations, on how best to meet their business goals and manage and address the increasingly complex regulatory and compliance environment in the healthcare industry. Jennifer helps clients structure and negotiate complex transactions and strategic business partnerships, and navigate the challenges and regulatory framework unique to the healthcare system.

NEIL ISSAR focuses his practice on healthcare litigation, securities enforcement defense, and government investigations, with particular expertise in fraud and abuse laws (including the False Claims Act, the AntiKickback Statute, and the Stark Law), navigation of regulatory and compliance issues involving the healthcare industry, representing securities market participants before the SEC, and defending and pursuing antitrust claims. Neil has been recognized in "Ones to Watch" by Best Lawyers in America.

TARYN McDONALD is an associate in the firm's Government Enforcement and Litigation Practice Group. Her practice focuses on False Claims Act *qui tam* litigation, healthcare litigation, and internal investigations. Taryn has experience assisting clients under government investigation for potential violations of the Stark Law, the False Claims Act, and the Anti-Kickback Statute. Prior to attending law school, Taryn worked for the Texas Office of Attorney General.

TAMMIE BANKO is an associate in the Litigation Practice group in the Dallas office of Haynes Boone. Her practice focuses on securities litigation, government investigations, and white collar defense.

BEN BRECKLER is an associate in the Litigation Practice group in the Dallas office of Haynes Boone. His practice focuses on government investigations, securities litigation, white collar defense, and antitrust.

WES DUTTON is an associate in the Litigation Practice Group in the Dallas office of Haynes and Boone. Wes has been recognized in "Ones to Watch" by Best Lawyers in America.

DALEY EPSTEIN focuses her practice on complex commercial litigation, intellectual property litigation, and government investigations. Daley's experience includes representing organizations and individuals under investigation by the SEC. She also has particular experience defending and pursuing claims relating to partnership and private equity disputes, trademark infringement, copyright infringement, and breaches of technology agreements.

WILSON MILLER is an associate in the Litigation Practice Group in Haynes Boone's Dallas office. His practice focuses on complex litigation related to franchising, contracts, and intellectual property.

2021: A Look Back at the Numbers

The False Claims Act broadly prohibits anyone from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment if the claim will be paid directly or indirectly by the federal government. 31 U.S.C. § 3729(a)(1)(A). It also broadly prohibits anyone from knowingly making, using, or causing to be made or used, a false record or statement that is material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B).

The FCA is the government's main enforcement tool for fighting fraud, with over $5.6 billion recovered in settlements and judgments during fiscal year 2021.[1] This represents the second largest annual total in False Claims Act history, and the largest since 2014. Total recoveries since 1986—the year Congress significantly strengthened the FCA—now exceed $70 billion.

DOJ further reported:

- Of the $5.6 billion recovered, over $5 billion came from the healthcare industry.
- Relators (a.k.a. whistleblowers) filed 598 new "*qui tam*" actions in 2021.
- Of the $5.6 billion recovered, nearly $1.6 billion related to cases filed by private whistleblowers, with whistleblowers receiving over $237 million for their share of the rewards.

Notable Settlements

The cases resolved in 2021 included many notable settlements and recoveries. The year's largest recoveries reflected DOJ's traditional focus on violations of the Anti-Kickback Statute ("AKS") and the Stark Law, which can render a claim "false or fraudulent" and therefore form the basis for an FCA action. For example:

- Three generic pharmaceutical manufacturers agreed to pay a combined $447.2 million to settle alleged violations of the FCA and AKS related to price-fixing of generic drugs.[2] The companies allegedly conspired to raise prices on generic drugs such as anti-inflammatory medications to treat pain and arthritis, various creams and ointments, and drugs used to treat hypertension and high cholesterol, which purportedly caused a spike in those prices for federal healthcare programs.

  All three companies also paid criminal penalties to resolve criminal charges with DOJ's Antitrust Division based on the same conduct. The civil settlements are separate—and in addition to—these criminal penalties.

- A mail-order diabetic testing supply company—once the nation's largest Medicare supplier in that space—and its parent company agreed to pay $160 million to settle alleged violations of the FCA and AKS resulting from purported kickbacks.[3]

  The company allegedly paid kickbacks (with the parent's approval) to Medicare beneficiaries by providing them with free glucometers—even though they were ineligible to receive glucometers or were deceased—and waiving copayments for

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

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

3 Release available at https://www.justice.gov/opa/pr/mail-order-diabetic-testing-supplier-and-parent-company-agree-pay-160-million-resolve-alleged

other diabetic testing supplies if Medicare denied payment. In fact, Medicare typically denied payment because the beneficiaries were not yet entitled to these supplies.

Notably, company founders had previously paid $1 million to resolve allegations of their participation in the kickback scheme.

- In September, the government obtained a $140 million default judgment for violations of the Stark Law and AKS by a suite of five healthcare and pain management companies owned or operated by a single chiropractor, which allegedly provided kickbacks to other providers to induce referrals of urine drug tests.[4] The default judgment, which was the second in this matter, resolved claims brought by whistleblowers who were former employees of pain management clinics owned by the chiropractor.

  The government also alleged that two of the entities—a substance abuse counseling clinic and a urine drug testing lab—billed for needless urine tests.

DOJ also announced the first few civil settlements involving allegations of fraud against the Paycheck Protection Program ("PPP"), a loan program for small businesses impacted by the COVID-19 pandemic:

- In January 2021, an internet retail company, its debtor in bankruptcy, and its president agreed to pay $100,000 to settle allegations that they violated the FCA by making false statements to federally insured banks—including that the company was not in bankruptcy—in order to influence those banks to approve, and the Small Business Administration to guarantee, a PPP loan of $350,000.[5]
- In October, a Florida-based duct cleaning company agreed to pay $30,000 to settle allegations that it violated the FCA by obtaining more than one PPP loan in CY 2020, which rendered false the company's earlier certification that it had not received duplicative PPP funds.[6]

In addition, there were several notable settlements involving military defense manufacturers:

- An Illinois-based manufacturer of military vehicles agreed to pay $50 million to resolve allegations that it fabricated fraudulent commercial sales invoices to induce the U.S. Marine Corps to enter into a contract modification with inflated prices.[7] The contract was for the manufacture of a suspension system used in armored vehicles designed to withstand improvised explosive device attacks and ambushes.
- A Washington-based subsidiary of the Boeing Company agreed to pay $25 million to settle allegations that it knowingly submitted materially false cost and pricing data for contracts with the U.S. Special Operations Command and the Department of the Navy to supply and operate unmanned aerial vehicles ("UAVs").[8] The company allegedly acquired seven non-competitively-bid contracts by falsely claiming it would use new materials to make the UAVs, but actually used less expensive recycled, refurbished, reconditioned, or reconfigured materials.

Finally, DOJ announced its second-ever settlement based on alleged violations of the "Open Payments Program," formerly known as the "Physician Payments Sunshine Act." Under the Open Payments Program, medical product manufacturers and group purchasing organizations must disclose to the Centers for Medicare

4 Release available at https://www.justice.gov/opa/pr/united-states-obtains-140-million-false-claims-act-judgments-against-south-carolina-pain

5 Release available at https://www.justice.gov/usao-edca/pr/eastern-district-california-obtains-nation-s-first-civil-settlement-fraud-cares-act

6 Release available at https://www.justice.gov/opa/pr/covid-19-task-force-nets-florida-duct-cleaning-company-settles-false-claims-act-allegations

7 Release available at https://www.justice.gov/opa/pr/navistar-defense-agrees-pay-50-million-resolve-false-claims-act-allegations-involving

8 Release available at https://www.justice.gov/opa/pr/insitu-inc-pay-25-million-settle-false-claims-act-case-alleging-knowing-overcharges-unmanned

& Medicaid Services ("CMS") certain payments or transfers of value to providers or teaching hospitals because financial relationships between providers and companies can create conflicts of interest and constitute "kickbacks." So, if a company fails to report such payments to CMS, the company may face liability for violations of both the AKS and the Open Payments Program.

Violations of the Open Payments Program have been rarely enforced, but in March 2019, the U.S. Senate Finance Committee asked the U.S. Department of Health and Human Services Office of Inspector General ("OIG") and CMS to investigate Open Payments Program non-compliance.

In May 2021, a French medical device manufacturer and its American affiliate agreed to pay $2 million to settle such claims—$1 million to settle whistleblower allegations that the companies violated the FCA and AKS when they entertained U.S.-based physicians at a 2013 conference in France, and a separate $1 million to settle allegations that the companies violated the Open Payments Program by not reporting the entertainment expenses to CMS.[9]

As this is only the second settlement since the Senate Committee's March 2019 request, it remains to be seen whether DOJ will make the Open Payments Program a continued focus of enforcement.

Legislative and Enforcement Update

1. AS EXPECTED, DOJ IS CRACKING DOWN ON COVID-RELATED FRAUD.

Acting Assistant Attorney General Brian Boynton gave a speech in February in which he identified COVID-19-related fraud as a top enforcement priority.[10] He explained:

> The circumstances of the current pandemic may be novel, but the inevitable fraud schemes it will produce will in many cases resemble misconduct that the False Claims Act has long been used to address. These schemes will likely include false representations regarding eligibility, misuse of program funds, and false certifications pertaining to loan forgiveness.

In May, DOJ announced the formation of a COVID-19 Fraud Enforcement Task Force, to be organized and led by Deputy Attorney General Lisa Monaco.[11] Attorney General Merrick Garland directed the Task Force "to marshal the resources of the Department of Justice in partnership with agencies across government to enhance enforcement efforts against COVID-19 related fraud."

As discussed above, DOJ announced the first few civil settlements involving allegations of fraud against the Paycheck Protection Program, and in September, DOJ charged five defendants for alleged fraud related to the Provider Relief Fund.[12] The defendants allegedly did not have an operational medical practice. Instead, they used money already received from the Provider Relief Fund for personal purposes instead of running a medical practice as required.

We expect fraud related to COVID-19 relief program funds will remain a focus of government enforcement in the near future.

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

10 Remarks available at https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar

11 Release available at https://www.justice.gov/opa/pr/attorney-general-announces-task-force-combat-covid-19-fraud

12 Release available at https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion

2. THE BIDEN ADMINISTRATION HAS IDENTIFIED CORPORATE CORRUPTION, INCLUDING INDIVIDUAL ACCOUNTABILITY, AS A NATIONAL PRIORITY.

Under the Obama administration, DOJ's total FCA recoveries hit all-time highs, totaling over $5 billion in 2012, $6.1 billion in 2014, and $4.9 billion in 2016. In contrast, the four years of the Trump administration were marked by deregulation and decreased corporate crime enforcement, resulting in total FCA recoveries averaging under $3 billion annually.

As discussed in last year's Review, the COVID-19 pandemic spurred the rapid injection of trillions of dollars of government funds into the economy. In 2021, new laws were passed and several laws from the preceding year were renewed or extended to provide even more funding. As a result, the Biden administration has repeatedly emphasized its focus on fraud and corporate corruption involving new sources of government funds.

For example, in June the White House issued a memorandum establishing the fight against corruption, including holding corrupt individuals accountable, as a core national security interest.[13] In December, the White House issued an official strategy document that expanded on the memorandum and outlined five "mutually reinforcing pillars" for fighting corruption.[14] The strategy included "mak[ing] it harder to hide the proceeds of ill-gotten wealth in opaque corporate structures, reduc[ing] the ability of individuals involved in corrupt acts to launder funds through anonymous purchases of U.S. real estate, and bolster[ing] asset recovery and seizure activities."

3. THE "MONACO MEMO" SIMILARLY IDENTIFIED CORPORATE CRIME AND INDIVIDUAL ACCOUNTABILITY AS DOJ PRIORITIES.

DOJ first announced an increased focus on individual accountability in corporate investigations in the 2015 "Yates Memo." In late 2018, however, DOJ reduced the level of disclosure required by companies under criminal investigation. Companies were no longer expected to identify *all employees* involved in the conduct regardless of culpability. Rather, they could identify only individuals who were *substantially involved* in or responsible for the conduct.

On October 28, 2021, Deputy Attorney General Lisa Monaco issued a memorandum (the "Monaco Memo"), which revised DOJ's corporate criminal enforcement policies and practices and explained that "[f]ighting corporate crime is a top priority of the Department of Justice."[15] In particular, the Monaco Memo instructs prosecutors to:

- Consider a corporation's *full history* of misconduct rather than only prior instances of similar misconduct;
- Require corporations to provide all relevant facts about *all individuals* responsible for misconduct in order to award any cooperation credit; and
- Favor the imposition of a monitor where there is a demonstrated need for, and clear benefit to be derived from, a monitorship.

DOJ Criminal Division Chief Kenneth Polite described the Monaco Memo as a "return to the Yates memo" standard—that is, cooperation credit again requires disclosure of information about "all individuals involved" rather than only individuals "substantially involved."[16] Polite also explained that there would be "significant scrutiny" of companies under government investigation—"both from an individual perspective as well as from a corporate perspective."

13 Memorandum available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/06/03/memorandum-on-establishing-the-fight-against-corruption-as-a-core-united-states-national-security-interest/

14 Document available at https://www.whitehouse.gov/wp-content/uploads/2021/12/United-States-Strategy-on-Countering-Corruption.pdf

15 Memorandum available at https://www.justice.gov/dag/page/file/1445106/download

16 Remarks available at https://www.law360.com/whitecollar/articles/1447069/new-doj-crime-chief-talks-carrot-and-stick-enforcement

4. THE "GARLAND MEMO" ALLOWS DOJ TO ONCE AGAIN RELY ON SUB-REGULATORY GUIDANCE TO SUPPORT FCA ENFORCEMENT ACTIONS.

Generally speaking, federal agencies must comply with the procedural requirements of the Administrative Procedure Act ("APA") to develop and issue regulations. But agencies can also issue statements of agency policy or interpretive guidance that are not subject to APA requirements. These are called "sub-regulatory guidance" and can take the form of policy statements, opinion letters, or manuals. While sub-regulatory guidance is not binding, it can be important in providing direction and insight into complex regulations—particularly in the highly regulated healthcare industry.

Before 2017, DOJ and relators routinely relied on sub-regulatory guidance as a basis for alleging violations of the FCA. But the Trump Administration moved to limit this practice. First, Attorney General Jeff Sessions issued a memorandum (the "Sessions Memo") prohibiting DOJ from issuing or utilizing its own non-binding guidance to create binding standards by which DOJ would determine compliance with existing regulatory or statutory requirements.[17]

In January 2018, Associate Attorney General Rachel Brand issued a memorandum (the "Brand Memo") that expanded on the Sessions Memo by restricting the use of any agency's sub-regulatory guidance in affirmative civil enforcement ("ACE") cases brought by DOJ, including FCA cases.[18] The Brand Memo prohibited any agency statement of general applicability and future effect that is designed to advise parties about legal rights and obligations from being used to create binding requirements that did not already exist by statute or regulation. The Brand Memo was particularly beneficial for healthcare defendants due to the widespread use of guidance documents by regulatory agencies like CMS, OIG, and the Food and Drug Administration ("FDA").

The practical effect of the Brand Memo was that sub-regulatory guidance could only establish *voluntary* standards, and non-compliance with those standards would not necessarily result in an enforcement action or FCA violation. A year after the Brand Memo was issued, however, DOJ clarified that sub-regulatory guidance and knowledge thereof could be used to as evidence of (1) scienter, notice, knowledge, and mens rea; (2) professional or industry standards or practices and duties, customs, or practices for government agencies; (3) scientific or technical processes; (4) a party's compliance with guidance; and (5) legal or factual context.

On July 1, 2021, Attorney General Merrick Garland issued a memorandum (the "Garland Memo") that rescinded both the Sessions Memo and the Brand Memo.[19] While sub-regulatory guidance still cannot form the basis for an enforcement action, it "may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements." The Garland Memo also explains that DOJ attorneys "are free to cite or rely on" sub-regulatory guidance "as appropriate" if it is relevant to claims or defenses in litigation.

The Garland Memo means DOJ has regained its pre-2017 flexibility to rely on sub-regulatory guidance. As a result, DOJ may rely more heavily on OIG advisory opinions, CMS manuals, Medicare policy statements, and the like in FCA actions. DOJ may also rely on the large volume of sub-regulatory guidance issued over the past year by agencies administering COVID-19 relief fund programs to combat fraud related to those programs.

5. THE BIDEN ADMINISTRATION IS FOCUSING ON CYBERSECURITY, AND A NEW DOJ INITIATIVE WILL UTILIZE THE FCA TO TARGET CYBERSECURITY FRAUD.

Cyberattacks have been increasing in frequency over the past few years, with many targeting critical infrastructure. For example, in late 2019 and early 2020, more than 18,000 customers of SolarWinds, a Tulsa-based company that provides system monitoring software, inadvertently

17 Memorandum available at https://www.justice.gov/opa/press-release/file/1012271/download
18 Memorandum available at https://www.justice.gov/file/1028756/download
19 Memorandum available at https://www.justice.gov/opa/page/file/1408606/download

installed software updates from SolarWinds that had been infected with malicious code. This allowed hackers to access all of those customers' systems.

In May 2021, the Colonial Pipeline, the largest pipeline system for carrying refined oil products in the country, suffered a ransomware cyberattack that impacted computerized equipment managing the pipeline. The pipeline was shut down for six days, resulting in fuel shortages across several states.

In response to those cyberattacks and others, the Biden administration issued Executive Order 14028 on May 12, 2021.[20] The executive order outlined several actions to address the cybersecurity of government agencies, agencies' suppliers, and the private sector, including requiring IT service providers to share cybersecurity incident information that could impact government networks and establishing baseline security standards for development of software sold to the government. The executive order also directed the federal government to secure cloud services and zero-trust architecture, and mandated deployment of multifactor authentication and encryption within a specific time period.

Relatedly, on October 6, 2021, DOJ launched a Civil Cyber-Fraud Initiative to pursue government contractors that knowingly misrepresent their cybersecurity safeguards or fail to monitor and report cybersecurity incidents.[21]

Led by the Fraud Section of the DOJ Civil Division's Commercial Litigation Branch, the initiative will utilize the FCA to identify, pursue, and deter cybersecurity vulnerabilities and incidents that arise with government contracts and that put sensitive information and critical government systems at risk. In particular, the initiative aims to bring FCA claims against contractors that knowingly provide deficient cybersecurity products or services, misrepresent their cybersecurity practices or safeguards, or violate obligations to monitor and report cybersecurity incidents and breaches.

Deputy Attorney General Lisa Monaco also stated that government contractors and grant recipients "entrusted to work on sensitive government systems" who "fail to follow required cybersecurity standards" will be subject to "very hefty fines" under the initiative.

In addition, Acting Assistant Attorney General Brian Boynton discussed the initiative and explained that certain cybersecurity failures are "prime candidates" for potential FCA enforcement and that the FCA was a "natural fit" for pursuing knowing failures to comply with cybersecurity standards in particular.[22] Thus, it appears FCA enforcement will play a key role in DOJ's continuing efforts to promote cybersecurity and protect federal funds from cybersecurity fraud.

6. PRIVATE EQUITY FIRMS INVESTING IN OR OWNING HEALTHCARE COMPANIES CONTINUE TO FACE THE RISK OF FCA LIABILITY.

Generally, an investment or ownership interest in a company does not expose the investor or owner to liability for acts undertaken by the company. But as private equity ownership of hospitals and physician practices has steadily increased over the past decade, private equity owners in the healthcare industry—especially those that manage their portfolio companies—are more often being named as defendants in FCA cases. This trend continued in 2021.

In July, DOJ announced that a Texas-based electroencephalography testing company agreed to $13.5 million to resolve allegations that it submitted false claims that resulted from kickbacks to referring physicians or that sought payment for work not performed or for which only a lower level of reimbursement was justified.[23]

20 Executive order available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/05/12/executive-order-on-improving-the-nations-cybersecurity/

21 Announcement available at https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative

22 Remarks available at https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-cybersecurity-and

23 Release available at https://www.justice.gov/opa/pr/eeg-testing-and-private-investment-companies-pay-153-million-resolve-

A Texas-based private investment company that had an agreement to manage the testing company also paid a separate $1.8 million for allegedly discovering the kickbacks through due diligence prior to investing but then doing nothing. DOJ alleged this meant the investment company effectively caused the submission of false claims by allowing the kickbacks to continue once it entered into the management agreement.

Similarly, in October, a private equity firm and two former executives of a mental health center owned by the firm agreed to pay $25 million to settle a relator's allegations that they caused fraudulent claims to be submitted to Massachusetts' Medicaid program.[24] The relator alleged that the mental health center was providing mental health services by unlicensed, unqualified, and improperly supervised mental health counselors. It also alleged that the private equity firm and executives knew of those issues but failed to adopt recommendations to bring the mental health center into compliance.

Prior to settling, the private equity firm and executives moved to dismiss the relator's claims. But the federal district court in Massachusetts held that there was sufficient evidence to create a factual question concerning whether the firm knew of the compliance issues. *See United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*, 2021 WL 2003016, at *18 (D. Mass. May 19, 2021). Specifically, the court highlighted evidence that the mental health center's chief clinical officer had shared reports about supervision issues with the private equity firm's employees, as well as the firm's knowledge of the procedures of billing the federal government.

These cases serve as a reminder that (1) FCA liability may apply to any person or entity that "causes" a false claim to be submitted, and not just to those that submit claims themselves; and (2) private equity firms considering investment in or ownership of companies that receive government funds should be particularly conscientious about FCA compliance when conducting due diligence.

7. THE PROPOSED FALSE CLAIMS AMENDMENTS ACT OF 2021 WOULD INCREASE THE BURDEN ON FCA DEFENDANTS.

In July, a bipartisan group of senators led by Senator Chuck Grassley introduced a bill entitled the False Claims Amendment Acts of 2021 (S.B. 2428). The bill sought to amend the FCA to make dismissals more difficult for defendants to obtain, especially those based on materiality. In October and November, the bill was debated by members of the Senate Judiciary Committee, and a streamlined, committee-approved bill was reported to the Senate on November 16, 2021.[25]

The latest version of the bill proposes to change the evidentiary burden of proof for materiality. As discussed in Section D.5, the U.S. Supreme Court's 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar* held that a misrepresentation or non-compliance that renders a claim false or fraudulent only violates the FCA if it is "material" to the government's payment decision. *Escobar* and subsequent court decisions hold that government inaction and/or continued payment of claims after learning about an alleged misrepresentation or fraud is strong evidence of non-materiality.

The bill would amend the FCA, however, by clarifying that for purposes of materiality, "the decision of the Government to forego a refund or to pay a claim despite actual knowledge of fraud or falsity ***shall not be considered dispositive*** if other reasons exist for the decision of the Government with respect to such refund or payment." According to Senator Grassley, this change would "clarify misinterpretations created by the *Escobar* court, by clarifying what should already be common sense."[26]

The bill would also amend the FCA by clarifying the standard for government dismissal of a *qui tam* action pursuant to 31 U.S.C. § 3730(c)(2)(A). Specifically, the

kickback-and-false

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

25 Text of the bill available at https://www.congress.gov/bill/117th-congress/senate-bill/2428/text

26 Remarks available at https://www.judiciary.senate.gov/meetings/10/21/2021/executive-business-meeting

bill would eliminate a circuit split by codifying the two-part "rational relation" standard first outlined by the Ninth Circuit in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998) (since adopted by the Third and Tenth Circuits, as discussed in last year's Review and in Section D.1.a).

Under that standard, the government must hold a hearing prior to dismissal and identify (1) a "valid government purpose" to be served by the dismissal, and (2) a "rational relation between dismissal and accomplishment of the purpose." *Id.* at 1145. According to Senator Grassley, it is "just common sense" that "[i]f there are serious allegations of fraud against the government, the Attorney General should have to state the legitimate reasons for deciding not to pursue them in court."[27] If the government satisfies the two-part test, the burden switches to the relator "to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *Id.*

Further, the bill would clarify that the FCA's existing anti-retaliation provision applies to current *or former* employees (i.e., post-employment retaliation).

The bill is currently on the Senate's legislative calendar for business. If enacted, it may lead to higher discovery costs as parties seek to determine whether "other reasons exist[ed] for the decision of the Government" to continue to pay claims after knowledge of fraud. The bill would also remove the government's "unfettered right" to dismiss an action under 31 U.S.C. § 3730(c)(2)(A) without explanation. Both of these effects would, in turn, likely lead to fewer early dismissals of FCA actions.

8. DOJ MADE ITS ANNUAL INFLATION ADJUSTMENT TO THE CIVIL MONETARY PENALTY AMOUNTS.

While the FCA states that a person who violates the statute is liable "for a civil penalty of not less than $5,000 and not more than $10,000," the penalty amounts are adjusted annually for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990.

On December 13, 2021, DOJ announced its final rule increasing the civil monetary penalty amounts that can be assessed for violations of the FCA to a minimum of $11,803 per false claim and a maximum of $23,607.

Significant Judicial Decisions

1. GOVERNMENT DISMISSAL OF A *QUI TAM* ACTION

A. A three-way circuit split on the standard of review for government motions to dismiss remains in place.

Under the FCA, private citizens with knowledge of alleged fraudulent practices (i.e., whistleblowers or relators) may file and litigate FCA cases on behalf of the government. Such cases are called "*qui tam*" actions. When a *qui tam* action is filed, the government generally has three options:

1) Intervene in the litigation and take over the case;

2) Decline intervention and allow the relator to litigate the case on its own; or

3) Move for dismissal of the case over the objections of the relator.

To exercise the third option, the FCA requires the government to notify the relator that it is filing a motion to dismiss, and the court must provide the relator an opportunity for a hearing on the motion. 31 U.S.C. § 3730(c)(2)(A). But the FCA is silent as to whether the government must formally intervene before filing a

27 Remarks available at https://www.grassley.senate.gov/news/news-releases/grassley-celebrating-whistleblower-appreciation-day

motion to dismiss, and it does not outline the standard that the government must meet for a court to grant its motion to dismiss.

As discussed in last year's Review, a three-way circuit split has developed regarding the standard the government must meet to obtain dismissal over the objections of the relator:

1) The Ninth and Tenth Circuits use a two-part "rational relation" standard, under which the government must identify (1) a "valid government purpose" to be served by the dismissal, and (2) a "rational relation between dismissal and accomplishment of the purpose." *Sequoia Orange*, 151 F.3d at 1145. This is the standard Senator Grassley's proposed bill would codify (discussed in Section C.7).

2) The D.C. Circuit uses a more deferential standard, under which courts do not review the grounds for the government's motion to dismiss and instead view the FCA as giving the government an "unfettered right" to dismiss an action. *Swift v. United States*, 318 F.3d 250, 252–53 (D.C. Cir. 2003).

3) The Seventh Circuit applies the Federal Rules of Civil Procedure as it would to any party, allowing the government to rely on Rule 41(a)(1)(A)(i) to "dismiss an action without a court order" by serving a notice of dismissal any time "before the opposing party serves either an answer or a motion for summary judgment." *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 839 (7th Cir. 2020). The Seventh Circuit conceded that this approach "lies much nearer" to the deferential "unfettered right" standard than the stricter "rational relation" standard. *Id.* at 840.

In June 2021, the U.S. Supreme Court declined to review the Seventh Circuit's decision. *CIMZNHCA, LLC v. United States*, 141 S. Ct. 2878 (2021). The Court also previously denied certiorari in a D.C. Circuit case in which the relator urged the Court to address the circuit split and adopt the "rational relation" standard. *See United States ex rel. Schneider v. JPMorgan Chase Bank, Nat'l Ass'n*, 140 S. Ct. 2660 (2020). So, the three-way circuit split remains in place.

B. The Third and Eleventh Circuits followed the Seventh Circuit's approach on the standard of review, but diverged on whether the government must intervene prior to dismissal.

In October, the Third Circuit followed the Seventh Circuit's approach in relying on the Federal Rules of Civil Procedure to review government motions to dismiss, rather than adopting either one of the "rational relation" or "unfettered right" standards. But all three take slightly different views on the need for government intervention in seeking dismissal.

The Seventh Circuit in *CIMZNHCA* largely disregarded the fact that the government had not intervened in the case before seeking dismissal because it construed DOJ's motion as one "both to intervene and then to dismiss." 970 F.3d at 840.

In *Polansky v. Executive Health Resources Inc.*, the Third Circuit clarified that "the Government must intervene before it can move to dismiss, but it can seek leave to intervene at any point in the litigation upon a showing of good cause." 17 F.4th 376, 385 (3d Cir. 2021). Once the government has intervened, the Third Circuit held it can move to automatically dismiss the case pursuant to Rule 41(a)(1)(A)(i) by serving a notice of dismissal any time "before the opposing party serves either an answer or a motion for summary judgment."

The Third Circuit explained that since Congress clearly intended the FCA to establish "civil" proceedings—that is, lawsuits brought in accordance with the Federal Rules of Civil Procedure—there was "no reason for these standards to apply with less force in a *qui tam* action than they do in any other civil action." *Id.* at 389.

In December, the Eleventh Circuit agreed with the Third and Seventh Circuits' rules-based approach by holding that "[o]nce the Government has placed its motion before the Court, it must exercise its executive authority in accordance with the Federal Rules of Civil Procedure." *United States v. Republic of Honduras*, 2021 WL 6143686, at *3 (11th Cir. Dec. 30, 2021).

But the Eleventh Circuit declined to impose a good-cause intervention requirement. The court cited an earlier decision in explaining that intervention is only

required when the government intends to actually proceed with the litigation—not when the government is only stepping in for the purpose of ending the case. *See id.* at *2 (citing *United States v. Everglades College, Inc.*, 855 F.3d 1279, 1285 (11th Cir. 2019)). The Eleventh Circuit viewed the notice and hearing requirements of 31 U.S.C. § 3730(c)(2)(A) as sufficient since, "[a]fter all, it is the Government's claim and the Government's damages" and "[t]he decision to dismiss the case for the Government's damages lies within the prosecutorial discretion of the Executive Branch." *Id.*

2. THE PUBLIC DISCLOSURE BAR AND ORIGINAL SOURCE EXCEPTION

The FCA's public disclosure bar prohibits *qui tam* suits if "substantially the same allegations or transactions" of fraud as alleged in the suit were previously disclosed (1) in a federal proceeding in which the government or its agent was a party; (2) in a federal report, hearing audit, or investigation; or (3) in the news media—*unless* the relator has sufficient knowledge of the fraud to qualify as an "original source." 31 U.S.C. § 3730(e)(4).

For a relator's case to survive the public disclosure bar, the relator must show that (1) the public disclosure bar does not apply; or if it does, that (2) the relator is an "original source." This defense is a common source of litigation, as courts attempt to strike the congressionally intended balance between discouraging parasitic lawsuits and properly incentivizing true whistleblowers.

A. The public disclosure bar applies only if there has been a disclosure outside of the government.

In November, the Second Circuit joined nine other courts of appeals in holding that the public disclosure bar applies only if there has been a disclosure outside of the government. *See United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 123 (2d Cir. 2021). In *Foreman*, the only relevant disclosures were reports disclosed only to defense-related government entities. All of the reports were designated as confidential and for official use only and were not disclosed to innocent government employees.

In other words, the reports were not disclosed to the public and all government employees who received the reports had an obligation to keep them confidential. The court held that those circumstances did not implicate the public disclosure bar.

B. Recent Fifth Circuit and Ninth Circuit opinions applied the pre-2010 public disclosure bar to affirm dismissal of FCA actions.

The public disclosure bar was amended by the Affordable Care Act ("ACA") in 2010. The pre-ACA public disclosure bar applied only where the subsequent action was "*based upon* the public disclosure of allegations or transactions," rather than the amended bar's requirement that the subsequent action raise "*substantially the same* allegations or transactions" as the public disclosure. The pre-ACA public disclosure bar also required that an original source have "direct and independent knowledge" of the information forming the basis of the allegations.

Due to the lengthy nature of many FCA suits, courts continue to grapple with cases implicating the pre-ACA version of the public disclosure bar years after the ACA was enacted. For example, the Fifth Circuit held last year that a relator's lawsuit against the acquiror of a prior FCA defendant was "based on" the prior FCA lawsuit under the pre-ACA bar where it relied on the "same contracts" and "same scheme." *United States ex rel. Schweizer v. Canon, Inc.*, 9 F.4th 269, 276 (5th Cir. 2021).

In *Schweizer*, the relator alleged that Océ North America (1) overcharged the government for the same products it sold to non-government customers, and (2) sold the government non-compliant products manufactured in China and other countries. The government eventually intervened in and settled the case with Océ, and Océ was subsequently acquired by Canon, Inc. Three years after the settlement, the relator filed a second FCA action against Canon, alleging that Canon had been continuing Océ's fraud by violating the same government contracts at issue in the first action.

The district court dismissed the second action, and the Fifth Circuit affirmed, based on the public disclosure bar. The Fifth Circuit ruled that the second action was "based upon" the first action because it involved "the same fraudulent scheme," an identical contract, and

the "complaint against Canon draws largely, if not exclusively, from [the] complaint against Océ." *Id.* The court rejected the relator's argument that her suit against Canon "expose[d] a different wrongful scheme" because Canon purportedly "restarted" Océ's scheme after Canon acquired it. *Id.* at 277.

The Ninth Circuit also recently explained that under the pre-ACA public disclosure bar, "a relator must show that he had firsthand knowledge of the alleged fraud, and that he obtained this knowledge through his own labor unmediated by anything else." *Solis v. Millennium Pharm., Inc.*, 852 F. App'x 298, 300 (9th Cir. 2021).

In *Solis*, the court ultimately held that the relator did not qualify as an original source because he was unable "to identify any instances of false claims for reimbursement [which made] his allegations inadequate to show direct knowledge." *Id.*

C. The Sixth Circuit issued two opinions interpreting post-2010 original source exception.

The post-ACA public disclosure bar lowered the standard such that a relator qualifies as an "original source" if he or she "has knowledge that is independent of and *materially adds* to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B) (emphasis added). Case law discussing the "materially adds" language of the post-ACA public disclosure bar is relatively limited. But the Sixth Circuit tackled the phrase in two recent opinions.

In *United States ex rel. Maur v. Hage-Korban*, the Sixth Circuit opined that "[m]ateriality in this setting requires the claimant to show he had information of such a nature that knowledge of the item would affect a person's decision-making, is significant, or is essential." 981 F.3d 516, 527 (6th Cir. 2020). In other words, "the relator must bring something to the table that would add value for the government." *Id.*

In *Maur*, the Sixth Circuit affirmed dismissal because the relator "merely provid[ed] additional instances of the same type of fraud" and therefore offered no information that would affect the "government's decision-making." 981 F.3d at 529. In fact, the publicly disclosed agreement and the relator's complaint "were levied against the same actor for the same type of fraud" and alleged that the same "unnecessary cardiac and stent procedures" were performed at the same hospitals. *Id.* at 526. Because the public disclosures already "set the government on the trail of the alleged fraud," the relator's only contribution of additional defendants did *not* materially add to the previously disclosed allegations. *Id.* at 528.

In another case, the Sixth Circuit rejected a relator's claim on similar grounds because the relator merely offered specific examples of the already publicly disclosed underlying conduct, and therefore "proffered no information to change the government's thinking or decision-making with respect to the alleged fraud." *United States ex rel. Rahimi v. Rite Aid Corp.*, 3 F.4th 813, 831–32 (6th Cir. 2021).

3. THE FIRST-TO-FILE BAR

The FCA's first-to-file bar provides that "no person other than the government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). Generally speaking, the rule prohibits an individual from bringing a *qui tam* action if there is already another pending action alleging the same essential elements of fraud.

In 2021, the Fifth Circuit affirmed a dismissal under the FCA's first-to-file bar. *See Capshaw v. White*, 854 F. App'x 610, 611–12 (5th Cir. 2021), *pet. for cert. docketed*, No. 21-626 (U.S. Oct. 29, 2021). There, the initial relator brought claims under the FCA, AKS, and the Stark Law, alleging that the defendants "knowingly set up a system of kickbacks and illegal referrals." *Id.* at 611. Months later, secondary-relators filed a similar action against the same defendants under the same statutes as well as the analogous Texas statutes. *Id.*

Despite the additional state law claims and some additional factual details, the district court dismissed the claims, holding that the new additions "allege the same material or essential elements of fraud" from the original complaint and would have been discovered by a government investigation into the original claims. *Capshaw v. White*, 2017 WL 3841611, at *4 (N.D. Tex. Jan. 23, 2017). The Fifth Circuit adopted the district court's reasoning in determining that the "add[itional]

factual details" and "analog[ous]" Texas claims were not sufficient to render the second action "unrelated" to the first action. *Capshaw*, 854 F. App'x at 612.

4. THE HEIGHTENED PLEADING STANDARD OF RULE 9(B)

The submission of a false or fraudulent claim to the government is essential to an FCA violation. Because it involves fraud, any FCA allegation must satisfy the heightened pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure. That is, a party "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

A. The circuit split on what is required to satisfy Rule 9(b) in FCA actions remains.

Although courts generally agree that a relator must plead the "who, what, when, where, and how" of the alleged fraud, the manner in which courts have applied the Rule 9(b) pleading standard and the types of allegations considered sufficient to satisfy Rule 9(b) in FCA cases continue to vary significantly.

As discussed in previous Reviews, some circuits, including the Fourth, Sixth, and Eleventh Circuits, favor—and in some cases require—detailed allegations of a specific, representative false claim that was actually submitted to the government. Other circuits take a less stringent approach, requiring particular details of a scheme to submit false claims to the government *plus* indicia of reliability that false claims were actually submitted—without requiring allegations of a specific false claim.

The U.S. Supreme Court has yet to agree to hear a case that will resolve this circuit split. So, lower courts continued to provide varying guidance in 2021 on what is required under Rule 9(b). But the U.S. Supreme Court recently called for the views of the Solicitor General in a case raising this issue, so it is possible this circuit split may be addressed in 2022. *See Johnson v. Bethany Hospice*, 2022 WL 145173 (U.S. Jan. 18, 2022).

B. Recent Sixth Circuit and Eleventh Circuit opinions reaffirm their requirement for allegations of a specific false claim.

The Sixth Circuit reiterated that it "has imposed a clear and unequivocal requirement that a relator allege specific false claims when pleading a violation of the [False Claims] Act." *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192, 196 (6th Cir. 2021). Therefore, "under Rule 9(b), the identification of at least one false claim with specificity is an indispensable element of a complaint that alleges a False Claims Act violation." *Id.*

The Eleventh Circuit similarly held that dismissal was warranted where there was "no way right now for the Court based on the allegations before it to identify a specific instance in which federal funds were used to pay a fraudulent claim." *Startley Gen. Contractors, Inc. v. Water Works Bd. of the City of Birmingham*, 857 F. App'x 540, 545 (11th Cir. 2021).

In *Startley*, the relator provided allegations of improper billing practices and claimed to have "access to an insider formerly employed with [the defendant] with firsthand knowledge of a fraudulent scheme involving billing practices, underbidding, bribery, and kickbacks." *Id.* at 541. But the district court held, and the Eleventh Circuit affirmed, that this still meant the relator "needed specific allegations that a fraudulent claim was submitted to the federal government or to an entity administering federal funds." *Id.* at 541–42.

In another case, the Eleventh Circuit rejected relators' argument that knowledge of and access to defendant's billing practices, combined with data showing that the defendant billed Medicare for their patients, constituted indicia of reliability to support their claim that the defendant submitted false claims. *See Estate of Helmly v. Bethany Hospice & Palliative Care of Coastal Ga., LLC*, 853 F. App'x 496, 501 (11th Cir. 2021), *pet. for cert. docketed*, No. 21-462 (U.S. Sept. 27, 2021).

The court explained that "relators cannot rely on mathematical probability to conclude that [a defendant] surely must have submitted a false claim at some point" and that "numerical probability is not an indicium of reliability." *Id.* at 502. Since the relators' complaint "fail[ed] to identify even a single, concrete example of a false claim submitted to the government," the relators failed to plead a false claim with the particularity required by Rule 9(b).

C. The Seventh Circuit requires allegations sufficient to provide an inference that false claims were submitted.

Two recent Seventh Circuit opinions discussed the types of allegations sufficient to satisfy the less stringent Rule 9(b) standard. In *United States ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, the relator alleged that a provider who contracted with Illinois' Medicaid program to provide skilled nursing facility ("SNF") services and subcontracted the provision of SNF services continued to bill Medicaid after the subcontract was terminated and the provider was not providing any services at all. 17 F.4th 732, 736 (7th Cir. 2021). The relator also alleged that the provider fraudulently induced the state to enter into contract renewals by misrepresenting that it would continue to provide SNF services despite not intending to do so. *Id.* at 741.

The district court dismissed the complaint because there were no details in the relator's allegations about the contract-renewal negotiations between the provider and the state. *Id.* But the Seventh Circuit reversed, finding that the relator "provided numerous details indicating when, where, how, and to whom allegedly false representations were made" as well as "precise allegations about the beneficiaries, the time period, the mechanism for the fraud, and the financial consequences." *Id.* These "detailed allegations support[ed] a strong inference that [the defendant] was making false claims." *Id.* at 740. The relator could not be faulted "for not having [contract renewal] information that exists only in [the defendant's] files." *Id.* at 741.

Similarly, in *United States ex rel. Mamalakis v. Anesthetix Management LLC*, the relator alleged that his former employer's anesthesiologists "upcoded" bills submitted to Medicare and Medicaid—that is, billed using the higher-paying code for "medically directed" services when the services actually provided only qualified for payment at a lower rate for "medically supervised" services. 20 F.4th 295, 297 (7th Cir. 2021). The relator provided 10 specific examples of procedures billed with the wrong code, with "[e]ach example identif[ying] the procedure in question, the anesthesiologist involved, and the specific ways in which he or she did not perform the services required to bill at the medical-direction rate." *Id.* at 300.

The district court dismissed the relator's claims after concluding that the examples "failed to provide adequately particularized factual support for the allegation that the anesthesiologists fraudulently billed at the medical-direction rate." *Id.* But the Seventh Circuit reversed, explaining that the relator was not required to identify specific false invoices or claims—especially since the relator lacked access to the defendant's billing records. *Id.* at 301. The appellate court held that the 10 specific examples were detailed enough for the court to "plausibly infer that at least on these occasions, [the defendant] presented false claims to the government." *Id.* at 303.

D. Statistics can help but are not enough alone.

Statistics may be useful in establishing a fraudulent scheme with some indicia of reliability, but they are not a substitute for particularized allegations.

As discussed in last year's Review, the Fifth Circuit previously held that relator Integra Med Analytics, a forensic data analysis company, could not rely on statistics alone to establish "particular details of a scheme to defraud Medicare." *See United States ex rel. Integra Med Analytics LLC v. Baylor Scott and White Health*, 816 F. App'x 892, 900 (5th Cir. 2020) (per curiam), *cert. denied*, 141 S. Ct. 905 (2020).

In that case, Integra Med Analytics analyzed inpatient claims data for a six-year period, compared them to national averages for other hospitals, and relied on statements from a medical coder that formerly worked for the defendant-hospital to allege that the defendant engaged in "upcoding" to increase its Medicare reimbursement. But the Fifth Circuit deemed this insufficient since there was "a legal and 'obvious alternative explanation' for the statistical data presented": that the defendant was simply ahead of most healthcare providers in following new guidelines from CMS regarding use of secondary diagnosis codes that could lead to increased reimbursement. *Id.* at 898.

In March 2021, the Ninth Circuit came to the same conclusion in another case brought by Integra Med

Analytics. In *Integra Med Analytics LLC v. Providence Health & Services*, the relator similarly relied "primarily on a statistical analysis of Medicare-claims data that demonstrated [the defendant] submitted proportionally more claims with higher-paying diagnosis codes than comparable institutions." 854 F. App'x 840, 841 (9th Cir. 2021) (mem.).

Like the Fifth Circuit, the Ninth Circuit rejected the statistics-only approach because Integra Med Analytics failed to "rule out an obvious alternative explanation, that [defendant] . . . was simply ahead of others in its industry" due to its use of "specifically hired consultants to improve its Medicare billing." *Id.* at 844.

Both the Fifth Circuit and Ninth Circuit pointed out that their conclusions did not categorically preclude statistical data from being used to support FCA allegations, but such data must be "paired with particular details of a false claim" to satisfy Rule 9(b). *Id.* at 845 n.5; *Integra Med Analytics*, 816 F. App'x at 898.

E. Group pleading is likely insufficient.

Despite the lenient standard used in some circuits, group pleading is unlikely to pass muster in any court. For example, in *Smith v. Peters*, the Ninth Circuit dismissed an FCA complaint that "lump[ed] together all of the defendants and assert[ed] that everyone did everything, even though the various defendants held different positions . . . and thus cannot plausibly have all had the exact same role in the fraud." 849 F. App'x 713, 714 (9th Cir. 2021).

5. *ESCOBAR* AND MATERIALITY

The FCA imposes liability where a person "knowingly makes, uses, or causes to be made or used, a false record or statement ***material*** to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B) (emphasis added). The statute defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

The U.S. Supreme Court construed the materiality requirement to mean that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision." *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016). *Escobar* reasoned that this requirement, like scienter, must be "rigorous" to ensure that the FCA does not become "a vehicle for punishing garden-variety breaches of contract or regulatory violations" or "minor or insubstantial" non-compliance with government contracts. *Id.* at 192, 194.

Since *Escobar*, numerous district and appellate courts have attempted to interpret what is and is not "material." Some of the key decisions issued in 2021 are summarized below.

A. The materiality analysis remains a "holistic" examination of several non-dispositive factors—even evidence of government inaction is not enough to dismiss an FCA action by itself.

Escobar explained that the materiality inquiry may be influenced by non-exclusive factors such as whether the alleged non-compliance goes to the "essence of the bargain," whether the non-compliance is significant (as opposed to "minor or insubstantial"), and whether the government has taken action in response to similar, known violations (e.g., consistently refusing to pay claims in similar circumstances or continuing to pay in full despite actual knowledge of the alleged violation). *See* 136 S. Ct. at 194–95. As a result, many courts have viewed the materiality analysis as a "holistic," "totality-of-the-circumstances" examination where no one factor is determinative.

For example, in *United States ex rel. Bibby v. Mortgage Investors Corp.*, the relators alleged that the defendant violated the FCA by falsely certifying to the U.S. Department of Veterans Affairs ("VA") that it was charging permissible fees for mortgages to veterans eligible for the VA's Interest Rate Reduction Refinance Loans ("IRRRL"), thereby inducing the VA to insure non-compliant loan and improperly assume the risk of default. *See* 987 F.3d 1340, 1343–44 (11th Cir. 2021), *cert. denied*, 141 S. Ct. 2632 (2021).

The district court granted the defendant's motion for summary judgment for insufficient evidence of materiality. On appeal, the Eleventh Circuit reviewed

several indicators of materiality—namely, (1) whether the requirement at issue was a condition of payment, (2) whether the misrepresentation was essential to the bargain, (3) the government's actions based on its actual knowledge of violations, and (4) the requirement's centrality within the regulatory scheme. *See id.* at 1347–52.

Like many other courts, the Eleventh Circuit described the materiality test as "holistic, with no single element—including the government's knowledge and its enforcement action—being dispositive." *Id.* at 1352; *see also United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 110 (2d Cir. 2021) ("No one factor is dispositive, and our inquiry is holistic.").

Thus, the Eleventh Circuit weighed factors that suggested immateriality (such as the VA continuing to insure the defendant's loans after learning of the alleged violations) against factors that suggested materiality (such as the fee-related requirement being a condition to payment and essential to the IRRRL program and the VA conducting additional audits and ordering the defendant to refund improper fees for specific loans). The court ultimately concluded there was genuine issue of material fact and reversed summary judgment.

Other recent appellate decisions similarly support the notion that allegations or evidence of government inaction upon learning of a defendant's misrepresentations or non-compliance do not indicate immateriality on their own.

For example, in *United States ex rel. Prose v. Molina Healthcare of Illinois, Inc.* (discussed in Section D.4.c), the Seventh Circuit reversed dismissal and explained that "[m]any things could explain the government's continued contracting with [the defendant]" and "[l]ater exploration will be needed before anyone can say what the government did and did not know about [the defendant]'s provision of SNF services." 17 F.4th at 744.

Likewise, in *United States ex rel. Cimino v. International Business Machines Corp.*, the D.C. Circuit reversed dismissal and explained that "[i]t is also plausible that the IRS could have later learned of [the defendant's] fraud and continued to pay for the licenses for any number of reasons that do not render [the defendant's] fraud immaterial," including because "the IRS may have felt obligated to pay until it received a legal determination that it was relieved of the agreement's terms." 3 F.4th 412, 423 (D.C. Cir. 2021).

B. Materiality encompasses both the decision to award a contract and the decision to make payments under the contract.

While *Escobar* addressed materiality only in the context of false certification claims, courts have also applied *Escobar*'s principles to claims under a fraudulent inducement theory.

The Second Circuit recently addressed this theory in a case involving a government program setting aside contract benefits for companies considered to be "service-disabled veteran-owned small businesses" ("SDVOSBs"). In *United States v. Strock*, the government alleged that a non-veteran defendant recruited a service-disabled veteran to head a business that procured millions of dollars in government contracts reserved for SDVOSBs, but in reality the veteran's ownership was a front for the non-veteran defendant to funnel the government contract work to his own company. 982 F.3d 51, 56 (2d Cir. 2020).

The district court dismissed the government's complaint, concluding that the government had not adequately pleaded that the alleged misrepresentation—that the defendant's business qualified as an SDVOSB—was material to the government's decision to make payments under the awarded contracts.

But the Second Circuit vacated the dismissal, explaining that *Escobar*'s instruction that a misrepresentation must be material to the government's "payment decision" should be construed broadly to encompass "both the decision to award contracts in the first instance and the decision to ultimately pay claims under these contracts." *Id.* at 60. The fact that there was no express provision in any government contract requiring compliance with SDVOSB eligibility conditions was not dispositive of materiality. Instead, the Second Circuit held that the government satisfied the materiality requirement by alleging that:

1) SDVOSB status was a necessary precondition for awarding contracts in the first place;

2) In most cases, it carefully screened contractors for SDVOSB eligibility prior to awarding contracts; and

3) The defendant's non-compliance was "substantial from the very inception of its contracts with the government through their completion" because misrepresenting SDVOSB status undercuts the SDVOSB program's express congressional purpose by diverting contracts and benefits intended for service-disabled veterans to an ineligible company.

See id. at 62–65.

C. A district court accepted a novel argument that non-compliance with a requirement that contravenes federal law does not establish materiality.

One district court recently accepted a novel argument that the government cannot use an FCA claim to enforce legally unenforceable payment criteria. In *United States v. Walgreen Co.*, the government alleged that a Walgreens clinical pharmacy manager made false statements in hepatitis C drug preauthorization submissions to Virginia Medicaid. 2021 WL 5760307, at *1 (W.D. Va. Dec. 3, 2021). The state of Virginia had put preauthorization requirements in place because the drugs were expensive and Virginia Medicaid had a limited budget.

Walgreens pointed to a November 2015 CMS letter, which advised state Medicaid programs that they had to comply with the requirements of Section 1927(d)(1) and (d)(2) of the Social Security Act when excluding coverage of Hepatitis C drugs. The referenced statutory provisions provide that a covered drug may only be excluded for specific reasons related to the drug's clinically meaningful therapeutic advantage over other drugs in the formulary. Cost alone is not an acceptable rationale for excluding or restricting access to a medically necessary drug.

While the CMS letter "was merely agency guidance and does not have the effect of law," the district court held that "it does present a compelling interpretation of the applicable statute." *Id.* at *10. As such, the court found that Virginia Medicaid's preauthorization requirements based on drug cost violated the Social Security Act. Walgreens argued, and the court agreed, that this meant Virginia Medicaid was legally obligated to pay the claims at issue and that any false statements related to preauthorization requirements deemed illegal and unenforceable could not be material to the payment decision. As a result, the court dismissed the FCA claims requiring materiality.

6. SCIENTER

The FCA "is not intended to punish honest mistakes or incorrect claims submitted through mere negligence." *United States ex rel. Skibo v. Greer Labs., Inc.*, 841 F. App'x 527, 531 (4th Cir. 2021) (citation omitted). Rather, FCA liability requires that a defendant acted "knowingly." *See* 31 U.S.C. § 3729(a)(1). The terms "knowing" and "knowingly" are defined by the FCA to "mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

A. The FCA imposes an objective scienter standard such that a defendant does not act knowingly if it had an objectively reasonable, albeit incorrect, understanding of the law.

In August, the Seventh Circuit joined several other circuits in holding that an FCA defendant does not act "knowingly" if it acts under an incorrect interpretation of the statute or regulation at issue so long as the interpretation was objectively reasonable and did not conflict with any authoritative guidance.

In *United States ex rel. Schutte v. SuperValu, Inc.*, the relators alleged that the defendants, which operated a grocery store chain and more than 800 in-store pharmacies, knowingly reported retail cash prices as their pharmacies' "usual and customary" drug prices for purposes of seeking reimbursement from Medicare Part D and Medicaid, rather than the lower prices charged to customers under its discount program. 9 F.4th 455, 459 (7th Cir. 2021).

The district court granted summary judgment in favor of the defendants because their understanding of the "usual and customary price," even if incorrect, was objectively reasonable based upon the governing regulations and case law at the time. The district court applied the U.S. Supreme Court's decision in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), which dealt with scienter under the Fair Credit Reporting Act ("FCRA").

The Seventh Circuit affirmed, joining the Third, Eighth, Ninth, and D.C. Circuits in adapting *Safeco*'s construction of the terms "knowing" and "reckless disregard" under the FCRA to the FCA. 9 F.4th at 465. Specifically, the court held that a defendant who acts "under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it." *Id.* at 464 (citing Safeco, 551 U.S. at 70). Thus, "a defendant's subjective intent does not matter for its scienter analysis—the inquiry is an objective one." *Id.* at 470.

Applying the *Safeco* standard, the Seventh Circuit concluded that the defendants' interpretation of "usual and customary price" under the relevant Medicaid regulations was objectively reasonable. The court also concluded there was no sufficiently specific "authoritative guidance"—either circuit court precedent or guidance from the relevant agency—on the issue to render the defendants' interpretation objectively unreasonable. Taken together, these conclusions meant that the relator failed to create a genuine issue of material fact as to whether the defendants "knowingly" inflated their prices in claims for Medicare and Medicaid reimbursement. *Id.* at 468.

The Seventh Circuit's decision in *Schutte* is a reminder that since *Escobar*, scienter, like materiality, is a "rigorous" requirement that is strictly enforced and that acts as a hurdle for the government and relators alike—particularly in cases where defendants may have had a reasonable, if incorrect, interpretation of the statutes or regulations at issue. *See Skibo*, 841 F. App'x at 531 (affirming summary judgment for lack of scienter where the defendant acted in accordance with industry practice and the common understanding of the regulatory requirements at issue).

7. FALSITY

As the name implies, the FCA only imposes liability for "false claims"— that is, for presenting a false or fraudulent claim or making a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)–(B). A defendant may also be liable under the FCA for a "reverse false claim" if it makes or uses a false record or statement for the purpose of avoiding or decreasing an "obligation" owed to the United States. See 31 U.S.C. § 3729(a)(1)(G).

The terms "false" and "fraudulent" are not defined in the FCA, so the governing standards have been developed through caselaw. Courts provided additional guidance in 2021.

A. The circuit split on whether an "objective falsehood" is necessary to establish falsity remains.

As discussed in last year's Review, a circuit split exists as to whether an "objective falsehood" is necessary to establish falsity, especially in cases where clinical judgment is the basis for the alleged fraud.

In 2019, the Eleventh Circuit in *United States v. AseraCare, Inc.* considered whether Medicare claims can be deemed false if there is a disagreement between medical experts as to the accuracy of the information contained in the claim. *See* 938 F.3d 1278, 1281 (11th Cir. 2019). The Eleventh Circuit held that: "(1) the FCA's falsity element requires proof of an objective falsehood; and (2) that a mere difference of opinion between physicians, without more, is not enough to show falsity." *Id.* at 1290–91.

The Eleventh Circuit reaffirmed its objective falsehood requirement in an unpublished opinion issued in 2021. *See Bell v. Cross*, 2021 WL 5544685, at *2 (11th Cir. Nov. 26, 2021) (per curiam) (unpublished) ("[I]n order for a clinical judgment to be 'false' in the context of the FCA, it must be *objectively* false, meaning that it 'contains a flaw that can be demonstrated through verifiable facts.'") (emphasis in original) (citing *AseraCare*, 938 F.3d at 1297).

In 2020, two appellate courts rejected the Eleventh Circuit's *AseraCare* holding. First, the Third Circuit

rejected an objective falsehood requirement, finding that a subjective dispute among physician experts about the certification of patients for hospice care was sufficient evidence of falsity to defeat summary judgment. *See United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 95, 100 (3d Cir. 2020) (concluding that "the common-law definition of fraud permits a finding that subjective opinions may be considered false and that medical opinions can be false and are not shielded from scrutiny").

Two weeks later, the Ninth Circuit held that "the FCA does not require a plaintiff to plead an 'objective falsehood'" and a physician's Medicare certification that inpatient hospitalization is medically necessary can be false or fraudulent "for the same reasons as an opinion can be false or fraudulent," such as if the medical necessity opinion is not honestly held or if it implies the existence of facts that do not exist. *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1119 (9th Cir. 2020).

Notably, the Ninth Circuit did not characterize its holding as "directly" contrary to the Eleventh Circuit's holding in *AseraCare*. Rather, the Ninth Circuit viewed *AseraCare* as focusing only on *reasonable* disagreement between medical experts *with no other evidence* to prove falsity. So, the Ninth Circuit did not view its own conclusion that some subjective statements—including medical opinions—could be false as contradicting *AseraCare*.

Indeed, the Ninth Circuit pointed to dicta in *AseraCare* identifying certain medical opinions that even the Eleventh Circuit would consider to be false. *See AseraCare*, 938 F.3d at 1302 ("[T]he parties agree that an opinion can be considered objectively false if the speaker does not actually hold that opinion" or simply "rubber-stamp[s] whatever file was put in front of him," if the opinion is "based on information that the physician knew, or had reason to know, was incorrect," or if "no reasonable physician" would agree with the doctor's opinion, "based on the evidence[.]").

In 2021, the U.S. Supreme Court declined to review the Third Circuit and Ninth Circuit opinions, allowing the circuit split to continue. *See Care Alternatives v. United States*, 141 S. Ct. 1371 (2021); *RollinsNelson LTC Corp. v. United States ex rel. Winters*, 141 S. Ct. 1380 (2021). But the Ninth Circuit's comments about the Eleventh Circuit's ruling suggest the split may not be as deep as it initially appeared.

8. RETALIATION AGAINST WHISTLEBLOWERS

To protect whistleblowers, the FCA has an anti-retaliation provision that imposes liability on an employer if an employee is "discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop one or more violations of this subchapter." 31 U.S.C. § 3730(h)(1).

A. In the absence of direct evidence of retaliation, most courts continue to use a three-step framework to assess FCA retaliation claims.

Circuits courts have generally held that when there is no direct evidence of retaliation, an FCA retaliation claim must be analyzed by a three-step framework that follows the burden-shifting framework of *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802–03 (1973):

1) *First*, an employee must prove that:
   a) She engaged in a protected activity;
   b) Her employer knew about these acts; and
   c) She suffered adverse action because of these acts.

2) *Second*, if the employee proves these three elements, the burden of proof shifts to the employer to provide a legitimate, non-retaliatory explanation for its allegedly retaliatory action.

3) *Third*, the burden then shifts back to the employee to demonstrate that the employer's explanation is pretextual and the employer's action was therefore discriminatory or retaliatory.

See, e.g., El-Khali v. Usen, 2021 WL 4621828, at *3 (6th Cir. Oct. 7, 2021).

To qualify as "protected activity" under the first step, the law requires: (1) acts in furtherance of an FCA

action, or (2) other "efforts to stop" one or more FCA violations, "even if those efforts do not lead to a lawsuit or the 'distinct possibility' of a lawsuit." *See Hickman v. Spirit of Athens, Alabama, Inc.*, 985 F.3d 1284, 1288 (11th Cir. 2021) (citing *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 95–98 (2d Cir. 2017)).

B. The alleged misconduct must involve false claims or representations made to the government

To qualify for the FCA's protections, employees must show, at the very least, that they had a "reasonable belief" that they were reporting fraud that involved false claims to the federal government. *Hickman*, 985 F.3d at 1289. At a minimum, whistleblowers are required to show that the alleged misconduct had "something to do with the False Claims Act—or at least that a reasonable person might have thought so." *Id.*

In *Hickman*, for example, the Eleventh Circuit concluded that plaintiffs could not show a "reasonable belief" that an FCA violation had occurred when they knew that the funds at issue came to the defendant automatically by operation of law, not based on representations made or claims submitted to the government. *Id.*

Further, the conduct complained of must be false or fraudulent; allegations of regulatory violations are not enough. *See Skibo on behalf of United States v. Greer Labs., Inc.*, 841 F. App'x 527, 534 (4th Cir. 2021) (holding that "the fatal flaw in Appellants' claim is that they never allege that they raised an issue of *false or fraudulent* conduct beyond a regulatory violation that would constitute an FCA violation").

C. An adverse action must be a company act resulting in a change in employment status.

The Sixth Circuit recently held that an "adverse action" under the first step must be a "significant change in employment status" and "requires an official act of the enterprise, a company act." *El-Khali v. Usen*, 2021 WL 4621828, at *5 (6th Cir. Oct. 7, 2021). In *El-Khali*, a medical executive committee recommended that the relator's staff privileges to work at a medical center not be renewed. The Sixth Circuit concluded that the recommendation was not an adverse employment action for purposes of establishing an FCA retaliation claim because it was "advisory only," was a decision made by a committee rather than the medical center's governing body, and did not itself result in any tangible, material change in the relator's employment status.

D. Courts are split on whether the anti-retaliation provision applies to former employees with post-termination claims.

Courts are split as to whether former employees can assert post-termination retaliation claims. *See United States ex rel. Felten v. William Beaumont Hosp.*, 993 F.3d 428, 430 (6th Cir. 2021), *pet. for cert. docketed*, No. 21-443 (U.S., Sept. 22, 2021); *Potts v. Center for Excellence in Higher Education, Inc.*, 908 F.3d 610 (10th Cir. 2018). At issue is the word "employee" in the FCA's anti-retaliation provision and the scope of prohibited employer conduct. Specifically, courts disagree on whether the term "employee" in 31 U.S.C. § 3730(h)(1) includes someone who is no longer an employee when the alleged retaliation takes place.

In March, the Sixth Circuit reviewed this question as an issue of first impression in that circuit. *Felten*, 993 F.3d at 430. Finding the language of the text ambiguous, the court adopted the Supreme Court's approach in *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340–41 (1997), which "provides guidelines for determining when a statute's meaning is not plain in the context of protections for employees and what to do in the face of ambiguity." *Felten*, 993 F.3d at 431.

The Court concluded that, under the *Robinson* analysis, former employees are protected under the anti-retaliation provision because (1) the word "employee" has no "temporal qualifier"; (2) the dictionary definition of the word could cover former employees; and (3) other aspects of the FCA's statutory framework support a reading that the FCA covers former employees, such as § 3730(h)(2) listing reinstatement as a possible relief available to employees subject to retaliation—"after all, only someone who has lost a job can be reinstated." *Id.* at 433.

This decision splits from the Tenth Circuit in *Potts*, which also applied the *Robinson* test, but "conclude[d]

that the False Claims Act's anti-retaliation provision *unambiguously excludes* relief for retaliatory acts occurring after the employee has left employment." *Potts*, 908 F.3d at 618 (emphasis added).

9. RECOVERY, DAMAGES, AND FEES

A. The Eleventh Circuit held that monetary awards in a non-intervened qui tam *action are subject to the Eighth Amendment's prohibition on excessive fines.*

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. CONST., AMEND. 8. The U.S. Supreme Court has held that "[t]he Excessive Fines Clause limits the government's power to extract payments, whether in cash or in kind, as punishment for some offense." *Austin v. United States*, 509 U.S. 602, 609–10 (1993) (internal quotation marks omitted). So, the Eighth Amendment's proscription on excessive fines typically applies to cases brought by the government, not to civil disputes between private parties.

As a matter of first impression, the Eleventh Circuit recently held that FCA monetary awards are "fines" and that the Eighth Amendment applies even to non-intervened FCA *qui tam* actions. *See Yates v. Pinellas Hematology & Oncology, P.A.*, 2021 WL 6133175, at *12 (11th Cir. Dec. 29, 2021). FCA monetary awards are "fines" because they are, at least in part, statutorily-mandated "punishment" for the defendant's conduct. *Id.* And though the government is not a party in non-intervened cases, *qui tam* actions are nonetheless lawsuits brought "in the name of the government" as a "stand-in" and a partial assignee of the government's damages claim. *Id.* at *14; 31 U.S.C. § 3730(b)(1). The court also pointed to the government's "substantial control" over *qui tam* actions even when it does not intervene.

The Eleventh Circuit ultimately concluded that the monetary award imposed in *Yates*—a total of $1.18 million, composed of treble damages on a roughly $750 actual damages award and a statutory penalty of $5,500 per claim for 214 claims—did not violate the Eighth Amendment's prohibition on excessive fines because treble damages are mandated by the FCA, the court imposed the lowest possible statutory penalty, the defendant was in the class of defendants at whom the FCA was principally directed, and the harm caused by the defendant was considerable. 2021 WL 6133175, at *18–19.

B. The D.C. Circuit limited the scope of the FCA's alternate remedy provision to legal claims that a relator could pursue under the FCA.

The FCA includes an "alternate remedy" provision that allows a relator to recover under the statute even when the government elects to pursue certain allegations through an administrative or other proceeding as an alternative to an FCA action. 31 U.S.C. § 3730(c)(5). This ensures a relator is not excluded from any recovery after assuming the risk and responsibility of the *qui tam* action if the government elects not to intervene.

The relator "shall have the same rights in such proceeding as such person would have had if the action had continued under this section [of the FCA]." *Id.* This includes the relator's entitlement to a 15–30% share of the proceeds or settlement of the claim. 31 U.S.C. § 3730(d)(1).

Courts have interpreted the alternate remedy provision narrowly in terms of both timing and substance. For example, the Second and Fifth Circuits previously held that the alternate remedy provision required a pending *qui tam* action in which the government could intervene, which means that a relator is not entitled to a share of any proceeds if the government pursued an alternate remedy prior to the relator filing suit or after the relator voluntarily dismissed its *qui tam* action. *See United States v. L-3 Commc'ns EOTech, Inc.*, 921 F.3d 11, 23–26, (2d Cir. 2019); *United States ex rel. Babalola v. Sharma*, 746 F.3d 157, 162 (5th Cir. 2014).

In addition, the Eighth Circuit previously explained that:

> [A] relator seeking recovery must establish that "there exists [an] overlap between Relator's allegations and the conduct discussed in the settlement agreement." A relator is not entitled to a share of the proceeds derived from a non-overlapping

> claim that the government could have added in the original action but instead pursues in an alternate proceeding.

Rille v. PricewaterhouseCoopers LLP, 803 F.3d 368, 373 (8th Cir. 2015).

In July, the D.C. Circuit joined the trend of narrowly interpreting the alternate remedy provision. In *United States ex rel. Kennedy v. Novo A/S*, the relator alleged that a pharmaceutical manufacturer caused the submission of false claims when it instructed sales representatives to minimize warnings from the FDA that the drug created an unknown risk of contracting cancer. 5 F.4th 47, 51 (D.C. Cir. 2021).

The government intervened and reached a $46.5 million settlement. Days later, the government filed a separate action in the same court under the Food, Drug, and Cosmetic Act ("FDCA"). A settlement was also reached in that case. The relator requested a share of both settlements. The district court granted relator's request for a portion of the FCA settlement but denied her request to receive a share of the FDCA settlement.

On review, the D.C. Circuit held that "regardless of the government's decision to intervene in the False Claims Act litigation, the FDCA settlement was not an 'alternate remedy' because it did not involve the type of claim covered by the False Claims Act." *Id.* at 54. In other words, "[i]f the alternate proceeding seeks recompense for some other type of claim that the relator could not have brought, then the proceeding is not covered by subsection 3730(c)(5) because it is not 'alternate' to the False Claims Act *qui tam* remedy. It is a different legal claim altogether, arising beyond the False Claims Act's borders." *Id.* at 56. The fact that the FDCA case was based on the same underlying facts as the FCA case did not matter.

C. Lower courts within the D.C. Circuit disagree on the proper method for calculating damages offsets.

Though not often litigated, district courts are split on the issue of whether damages offsets should be calculated according to (a) the *pro tanto* approach; or (b) the *pro rata* or "proportionate share" approach. The *pro tanto* approach reduces a non-settling defendant's liability by the actual amount paid by a settling defendant. In contrast, the *pro rata* approach reduces a non-settling defendant's liability by the settling defendants' share of the fault.

This issue is currently pending before the D.C. Circuit on interlocutory appeal. *See United States v. Honeywell Int'l Inc.*, 2021 WL 2493382, at *1 (D.D.C. June 18, 2021). In that case, Honeywell argued that it was entitled to summary judgment based on a *pro tanto* offset, or a "dollar-for-dollar reduction" of its damages, because the amount the government received through settlements with other defendants was greater than the amount of Honeywell's alleged FCA statutory damages liability.

The court denied summary judgment, holding that that the "proportionate share" approach to calculating damages offsets applies in an FCA case involving multiple alleged joint tortfeasors, and the fact finder would therefore need to calculate Honeywell's proportionate share of common damages before applying any offsets. *Id.* at *8.

Interestingly, another judge of the same district court previously applied the *pro tanto* approach. *See Miller v. Holzmann*, 563 F. Supp. 2d 54 (D.D.C. 2008). As a result, the court in *Honeywell* recognized that "there are conflicting decisions by district court judges, including within this district," creating an intra-circuit split. *Honeywell*, 2021 WL 2493382, at *6.

D. Attorneys' fees and costs must be reasonable.

Although the FCA provides that a prevailing relator's attorneys' fees and costs "shall be awarded against the defendant", the lodestar method governs whether such fees are reasonable. *See* 31 U.S.C. § 3730(d)(1); *Zediker v. OrthoGeorgia*, 857 F. App'x 600, 600 (11th Cir. Aug. 17, 2021) (per curiam) (affirming a reduced fee award supported by a "well-reasoned 32-page opinion" explaining that the government reached a settlement on three "relatively minor" claims and that most of relator's 158-page complaint contained allegations that were "not substantiated by other evidence, were not valuable enough to be worthy of pursuit, were not legally viable, or were factually impossible in light of the actual claims submitted by the Defendants").

10. OTHER NOTABLE DECISIONS

A. Contrary to other circuits, the Ninth Circuit allows FCA claims to proceed on a "fraud-on-the-FDA" theory.

At least three circuits have cautioned against allowing FCA claims to encroach upon the FDA's regulatory regime. But last year, the Ninth Circuit allowed an FCA claim brought on a "fraud-on-the-FDA" theory.

The First, Third, and Fourth Circuits previously urged caution about the reach of the FCA when a relator's evidence in support of a fraud-on-the-FDA theory failed to satisfy the elements of an FCA claim. First, in 2014, the Fourth Circuit rejected a relator's allegation that a pharmaceutical service provider's non-compliance with FDA regulations amounted to a false statement or fraudulent course of conduct under relevant Medicare and Medicaid statutes. *See United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700–02 (4th Cir. 2014).

The court expressed concern that a theory of liability tied only to regulatory non-compliance would encourage use of the FCA as a sweeping mechanism to enforce regulatory compliance and "short-circuit the very remedial process the Government has established to address non-compliance with those regulations." *Id.* at 702 (quoting *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 310 (3d Cir. 2011)).

Then, in *D'Agostino v. ev3, Inc.*, the First Circuit held that a relator could not establish a causal link between a medical device manufacturer's misrepresentation and the FDA's approval of a device without proof of subsequent FDA action withdrawing such approval. 845 F.3d 1, 3, 7–10 (1st Cir. 2016). The court warned that allowing juries in *qui tam* actions to find causation when the FDA itself has not acted would deter applications for FDA approval, swamp the FDA with unnecessary data, and undercut the FDA's responsibility to monitor fraud. *Id.* at 8–9.

Finally, the Third Circuit held in 2017 that reporting deficiencies identified by a relator were not material under *Escobar*. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489–90 (3d Cir. 2017). Because the FDA and other government actors either deemed the violations insubstantial or would do so if made aware of the violations, the court characterized the relator's effort to enforce regulations through the FCA as inappropriate. *Id.* at 490 ("After all, the False Claims Act is not 'a blunt instrument to enforce compliance with all . . . regulations.'") (quoting *Wilkins*, 659 F.3d at 307).

In April 2021, however, the Ninth Circuit reversed in part a district court's dismissal of FCA claims brought on a fraud-on-the-FDA theory. In *Dan Abrams Co. v. Medtronic Inc.*, the relator alleged that Medtronic fraudulently obtained FDA clearance for several devices used in spinal fusion surgeries, unlawfully marketed them for both off-label and contraindicated uses, and illegally compensated physicians to use them—thereby causing those physicians to submit false claims to Medicare. See 850 F. App'x 508, 508 (9th Cir. 2021).

The Ninth Circuit explained that the government's decision to pay for medical devices is based on FDA approval or clearance and compliance with other pertinent regulations—not a device's use. *Id.* at 509. The court held that devices that can only be used in a contraindicated manner would not have received FDA clearance if not for Medtronic's misrepresentations to the FDA. In other words, "Medtronic's alleged fraud went 'to the very essence of the bargain'" of FDA certification. *Id.* at 511.

The Ninth Circuit expressly rejected Medtronic's argument "that the FCA is not the proper vehicle to bring a fraud-on-the-FDA claim," and refused to follow the First, Third, and Fourth Circuits' previous opinions "caution[ing] against allowing claims under the False Claims Act to wade into the FDA's regulatory regime." *Id.*

B. The Third Circuit held that FERA retroactivity turned on pendency of an FCA lawsuit, not the underlying claim or conduct.

As mentioned in Sections D.5 and D.7, the FCA prohibits anyone from "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). But before 2009, the language of the provision differed in that it prohibited anyone from

"knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement to get a false or fraudulent claim *paid or approved by the Government*."

In 2008, the U.S. Supreme Court interpreted this provision to require proof that the defendant's purpose in making or using a false record or statement was to specifically defraud the government. See *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 668–72 & n.2 (2008).

To "clarify and correct [this] erroneous interpretation of the [FCA]," Congress passed the Fraud Enforcement and Recovery Act of 2009 ("FERA"), which, among other things, changed § 3729(a)(1)(B)'s language to its current form so that it could not be read as requiring specific intent to defraud the government.

Recognizing that there may be disputes about how to apply FERA's changes to conduct that pre-dated FERA's date of enactment, Congress designated FERA's changes to that provision as taking effect as if enacted on June 7, 2008—almost one year prior to its actual enactment—and "apply[ing] to all ***claims*** under the False Claims Act . . . pending on or after that date."

Although courts agree that the amendment has retroactive effect, a circuit split exists regarding the meaning of the term "claims." The question is whether it refers to demands for payment submitted after June 7, 2008 or conduct that occurred after that date, or to lawsuits initiated on or after that date (regardless of when the underlying conduct occurred).

In 2021, the Third Circuit joined the Second, Sixth, and Seventh Circuits in concluding that Congress used the term "claims" to mean lawsuits. *See United States ex rel. International Brotherhood of Electrical Workers Local Union No. 98 v. Farfield Co.*, 5 F.4th 315, 331 (3d Cir. 2021). The Third Circuit explained that this interpretation made contextual sense and reflected the fact that the FCA typically used "claims" synonymously with the term "cases" unless preceded by the words "false" or "fraudulent." So, the Third Circuit held that the revised FCA language applied to "relevant conduct, ***whenever occurring***, that was subject to a lawsuit pending on or after" June 7, 2008.

In so holding, the court broke with the Fifth, Ninth, and Eleventh Circuits, which have held that "claims" refers only to actual requests or demands for payment that were pending on or after June 7, 2008. *See id.* at 330–31.

Table of Authorities

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STATUTES & OTHER AUTHORITIES

Contact Us

STACY BRAININ
Partner | General Counsel
stacy.brainin@haynesboone.com
+1 214.651.5584

BILL MORRISON
Partner
bill.morrison@haynesboone.com
+1 214.651.5018

NICK BUNCH
Partner
nick.bunch@haynesboone.com
+1 214.651.5537

ANDREW GUTHRIE
Partner
andrew.guthrie@haynesboone.com
+1 214.651.5821

JENNIFER KREICK
Partner
jennifer.kreick@haynesboone.com
+1 214.651.5492

NEIL ISSAR
Associate
neil.issar@haynesboone.com
+1 214.651.5281

TARYN McDONALD
Associate
taryn.mcdonald@haynesboone.com
+1 214.651.5646

TAMMIE BANKO
Associate
tammie.banko@haynesboone.com
+1 214.651.5397

BEN BRECKLER
Associate
benjamin.breckler@haynesboone.com
+1 214.651.5263

WES DUTTON
Associate
wes.dutton@haynesboone.com
+1 214.651.5520

DALEY EPSTEIN
Associate
daley.epstein@haynesboone.com
+1 214.651.5625

WILSON MILLER
Associate
wilson.miller@haynesboone.com
+1 214.651.5484

HAYNES BOONE

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Dallas - North
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