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False Claims Act

2020 Year in Review

Clients and Friends,

In 2020, the COVID-19 pandemic caused dramatic shifts in the nation's economic landscape. One thing that did not change was the government's focus on fraud and violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA"). In fact, that focus only increased with the enactment of several new laws providing trillions of dollars in government funding to affected business and individuals.

This Review highlights those and several other key developments from 2020, including:

- The recovery by the government of more than \$2.2 billion in settlements and judgments in FCA cases in 2020.
- The government prioritizing the detection, investigation, and prosecution of fraud related to or arising from the COVID-19 pandemic.
- Judicial efforts to determine the correct standard of review when the government moves to dismiss FCA cases brought by relators.
- Continued judicial efforts to interpret the elements of an FCA claim, including "materiality," after the Supreme Court's landmark decision in *Escobar*.
- Significant judicial decisions regarding the meaning of falsity (including whether subjective differences in clinical judgments can render a claim false), the public disclosure bar and its original source exception, and pleading requirements for FCA cases, among other issues.

In 2020, Haynes and Boone 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. 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 2021.

Stacy Brainin, Bill Morrison, and Chris Rogers

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The COVID-19 Pandemic

1. THE FEDERAL GOVERNMENT PROVIDED SEVERAL NEW SOURCES OF FUNDING.

The COVID-19 pandemic caused unprecedented disruption to all facets of our lives. In response to the economic impact of the pandemic, the federal government took several steps to provide funding to affected businesses and individuals. Unfortunately, more funding from the government means more potential for fraud.

On March 6, 2020, Congress enacted the Coronavirus Preparedness and Response Supplemental Appropriations Act, which provided \$8.3 billion in emergency funding for federal agencies to respond to the COVID-19 outbreak, with a focus on vaccine research and development. Twelve days later, Congress enacted the Families First Coronavirus Response Act, which provided \$104 billion in paid sick leave and unemployment benefits for workers and families.

Congress later passed the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), a \$2.2 trillion economic stimulus package that included:

- \$300 billion in cash payments to individual Americans;
- \$260 billion in increased unemployment benefits;
- \$349 billion in initial funding for the Paycheck Protection Program (“PPP”), which provided forgivable loans to small businesses;
- \$500 billion in aid for larger businesses;

- \$339.8 billion to state and local governments; and
- \$100 billion in a “Provider Relief Fund” for healthcare providers and hospitals on the front lines of the coronavirus response.

The CARES Act was amended on April 24, 2020 with the enactment of the Paycheck Protection Program and Health Care Enhancement (“PPP/HCE”) Act, which provided an additional \$310 billion in PPP funding and an additional \$75 billion for the Provider Relief Fund.

Most recently, Congress passed the Consolidated Appropriations Act of 2021 to provide another \$900 billion in COVID-19 stimulus relief, including, among other things, \$284 billion in PPP loans, \$166 billion for a second cash payment to individual Americans, \$325 billion for small businesses, and \$69 billion for vaccines, testing, and healthcare providers.

2. THE NEW FUNDING ONLY HEIGHTENED THE GOVERNMENT’S CONTINUING EMPHASIS ON FRAUD ENFORCEMENT.

As noted above, any rapid injection of trillions of dollars into the economy creates a very high risk for misuse of federal funds. In addition, Deputy Attorney General Jeffrey Rosen explained that the government saw “a disconcerting increase in reports of false, misleading, or unfair commercial practices . . . as bad actors use the pandemic to exploit American consumers.”¹ Such practices include “bad actors selling fake testing kits, cures, so-called ‘immunity’ pills, and fake promises of personal protective equipment,” as well as “exploiters [] using robocalls, social

media, and other mechanisms to offer fake services like free coronavirus testing in order to obtain credit card numbers and personally identifiable information.”

As a result, the Department of Justice (“DOJ”) and government officials have repeatedly emphasized during the COVID-19 pandemic that they will continue cracking down on fraud. For example, on March 16, 2020, then-Attorney General William Barr issued a memorandum directing all U.S. Attorneys to “prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic.”

In a follow-up memorandum, Rosen directed each U.S. Attorney to appoint a Coronavirus Fraud Coordinator to serve as legal counsel for their federal judicial district on matters relating to COVID-19, direct the prosecution of COVID-19-related crimes, and conduct outreach and awareness. Rosen later stated that “[c]oronavirus-related wrongdoing will continue to be a DOJ priority for the foreseeable future.”²

In addition, Treasury Secretary Steven Mnuchin stated that companies receiving more than \$2 million in federal funding during the pandemic will face close scrutiny. And Barr issued a press release urging the public to report suspected fraud schemes related to COVID-19, including providers “fraudulently bill[ing]” for tests and procedures.³ These efforts resulted in the National Center for Disaster Fraud receiving more than 74,000 calls and emails and the FBI’s Internet Crime Complaint Center receiving more than 20,000 tips for suspicious coronavirus-related websites or social media postings.⁴

As to the FCA specifically, Acting Assistant Attorney General Ethan Davis explained that DOJ’s Civil Division “will make it a priority to use the False Claims Act to combat fraud in the Paycheck Protection Program” and “other assistance programs created by the CARES Act.” Similarly, Deputy Assistant Attorney General Michael Granston expected the FCA to “play a central role in the Department’s pursuit of

COVID-19 related fraud,” with particular focus on “false representations regarding eligibility, misuse of program funds, and false certifications pertaining to loan forgiveness.”⁵

3. THE CARES ACT INCLUDES SEVERAL MEASURES TO FIGHT FRAUD.

The CARES Act itself recognizes the potential for fraud in the programs it establishes and includes several provisions designed to fight back. For example, the Act created:

- A Special Inspector General for Pandemic Recovery to oversee Treasury Department loans and investments and to track and investigate disbursements made under the Act.
- A Pandemic Response Accountability Committee composed of federal inspectors general to investigate, issue, and enforce subpoenas and to hold public hearings in connection with funds disbursed under the Act or other federal programs.
- A Congressional Oversight Commission to examine decisions made by the Treasury Department and Federal Reserve and to monitor how aid is spent.

The Act also granted the U.S. Comptroller General the authority to monitor and audit the use of the disbursed funds.

4. THE GOVERNMENT HAS BROUGHT DOZENS OF COVID-19-RELATED ENFORCEMENT ACTIONS IN RECENT MONTHS.

The new enforcement entities established by the CARES Act provide unprecedented levels of oversight of federal funds to prevent and detect fraud, waste, abuse, and mismanagement, which have already led to increased DOJ enforcement activity.

For instance, Assistant Attorney General Brian Rabbitt announced in September that DOJ's Criminal Division had charged more than 50 people attempting to collectively steal over \$175 million from the PPP and stated that he "expect[ed] to see many more PPP cases brought by the Department [of Justice] in the future."⁶

Below are some examples of other COVID-19-related government enforcement actions, drawn from press releases posted on the DOJ website⁷:

- On May 5, 2020, DOJ announced that it had charged two businessmen in Rhode Island with allegedly filing fraudulent loan applications for over \$500,000 under the PPP. The men claimed to have dozens of employees earning wages at four different business entities when, in fact, there were no employees working for any of the businesses.
- On May 15, 2020, DOJ announced that it had charged a Georgia woman with violations of the Anti-Kickback Statute and conspiracy to commit healthcare fraud by paying and receiving illegal kickbacks in exchange for COVID-19 tests.
- On June 9, 2020, DOJ announced that it had charged the president of a California-based medical technology company for his alleged participation in schemes to mislead investors, manipulate the company's stock price, and commit healthcare fraud by submitting over \$69 million in false and fraudulent claims related to an unproven COVID-19 test.
- On September 10, 2020, DOJ announced that it had charged seven individuals in South Carolina with laundering over \$750,000 of fraudulently obtained funds, including over \$390,000 obtained from a fraudulent PPP loan based on misrepresentations about a business's number of employees and payroll expenses.
- On September 29, 2020, DOJ announced that it had charged a man in North Carolina with committing wire fraud, bank fraud, and engaging in unlawful monetary transactions by submitting fraudulent PPP loan applications for more than \$6 million. The man submitted applications on behalf of entities with fake Game of Thrones-inspired names like White Walker, Khaleesi, and The Night's Watch.
- On December 18, 2020, DOJ announced that it had charged the CEO of a California-based medical device company with securities fraud for falsely telling investors the company was developing a 15-second finger prick test for COVID-19. The CEO allegedly made false statements, misappropriated company funds, and knew all along that the test was merely an idea and not a validated method of accurately detecting COVID-19, much less an actual product ready for manufacture and sale. The SEC also filed a parallel civil suit against the CEO and his company for issuing false claims in press releases and misleading investors.

5. THE NEW SOURCES OF FEDERAL FUNDING RAISE FCA COMPLIANCE CONCERNS.

As with the above allegations of fraud, the COVID-19 pandemic has also led to an increase in cases raising common FCA issues such as false or misleading statements made in connection with marketing drugs or devices, improper coding or billing for testing or treatments that were not actually provided, and billing for testing or treatments that were not medically necessary.

The "false certification" theory of FCA liability may prove to be particularly relevant to entities accepting federal funds under the CARES Act and other relief programs outlined above, as they require certifications of compliance with

various eligibility requirements. A defendant can be liable under the FCA for falsely certifying compliance with a federal statute or regulation or a prescribed contractual term.

For example, healthcare providers receiving payments from the Provider Relief Fund must sign an electronic attestation confirming receipt of funds and their agreement to certain terms and conditions. The terms and conditions, in turn, require healthcare providers to certify that they: (i) provided diagnosis, testing, or care for individuals with “actual or possible cases of COVID-19”; (ii) billed Medicare in 2019; (iii) are not currently excluded from participation in Medicare, Medicaid, and other federal healthcare programs; (iv) will only use the funds to prevent, prepare for, and respond to coronavirus and to serve as reimbursement for healthcare-related expenses or lost revenues attributable

to coronavirus; and (v) will not use the funds to reimburse expenses or losses that have been or will be reimbursed from other sources. Any false certification of these items could be grounds for an alleged violation of the FCA.

The Second Circuit confirmed in 2019 that loan applications submitted to federal reserve banks during the 2008 financial crisis constituted “claims” for FCA purposes and that false certifications in those applications could lead to FCA liability. *See United States ex rel. Kraus v. Wells Fargo & Co.*, 943 F.3d 588, 601-06 (2d Cir. 2019). False certifications in Provider Relief Fund attestations and other documents related to funding under the CARES Act could likewise lead to FCA liability.

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- ¹ Remarks available at <https://www.justice.gov/opa/speech/keynote-address-deputy-attorney-general-jeffrey-rosen-combatting-fraud-age-covid-19-bbb>.
 - ² Remarks available at <https://www.justice.gov/opa/speech/keynote-address-deputy-attorney-general-jeffrey-rosen-combatting-fraud-age-covid-19-bbb>.
 - ³ Release available at <https://www.justice.gov/opa/pr/attorney-general-william-p-barr-urges-american-public-report-covid-19-fraud>.
 - ⁴ Remarks available at <https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims>.
 - ⁵ Remarks available at <https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act>.
 - ⁶ Remarks available at <https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-rabbitt-delivers-remarks-ppp-criminal-fraud> and <https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-c-rabbitt-delivers-remarks-practicing-law>.
 - ⁷ Releases available at <https://www.justice.gov/news>.

2020: A Look Back at the Numbers and Notable Settlements

The federal government recovered more than \$2.2 billion in settlements and judgments from FCA cases during fiscal year 2020.¹ While this is nearly \$1 billion less than fiscal year 2019, this represents the twelfth year in a row that DOJ's annual recovery exceeded \$2 billion. Total recoveries since 1986, the year Congress significantly strengthened the FCA, now exceed \$64 billion.

DOJ further reported:

- Of the \$2.2 billion recovered, over \$1.8 billion came from the healthcare industry.
- Whistleblowers filed 672 new *qui tam* actions in 2020.
- Of the \$2.2 billion recovered, nearly \$1.7 billion related to cases filed by private whistleblowers, with whistleblowers receiving over \$309 million for their share of the rewards.

The cases resolved in 2020 included many notable settlements and recoveries. Two of the largest settlements involved allegations of pharmaceutical companies using charitable foundations to subsidize patients' copays for their own drugs:

- A New Jersey-based pharmaceutical company agreed to a \$642 million settlement to resolve allegations that it illegally used three charitable foundations as conduits to pay copayments of Medicare

patients taking drugs sold by the company to treat multiple sclerosis and cancer. The government described the alleged conduct as "a kickback scheme that undermined the structure of the Medicare program and illegally subsidized the high costs of [the company's] drugs at the expense of American taxpayers." The settlement also resolved allegations that the company paid kickbacks to physicians, such as fees for speaker events, to induce them to prescribe its other drugs.

- Gilead Sciences agreed to a \$97 million settlement to resolve similar allegations that it illegally used a charitable foundation as a conduit to pay copayments of Medicare patients taking a drug sold by Gilead to treat pulmonary arterial hypertension.

Several settlements involved allegations of payments to providers and other referral sources to induce referrals in violation of Anti-Kickback Statute ("AKS") or the Stark Law. For example:

- A \$72.3 million settlement with a specialty hospital and a physician group to resolve allegations of an improper relationship whereby the hospital was paying remuneration in exchange for patient referrals, in violation of the AKS and the Stark Law.
- A \$50 million settlement with Wheeling Hospital, an acute care hospital in West Virginia, to resolve allegations that it

systematically paid referring physicians above fair market value and/or based on the volume or value of referrals, in violation of the AKS and the Stark Law.

- A \$48 million settlement with a physician-owned hospital in Plano, Texas, to resolve allegations that it violated the AKS and Stark Law by requiring physician owners to maintain an unnecessarily high number of “patient contacts” at the hospital to retain their ownership interests and the lucrative returns from those interests.
- An \$11.9 million settlement with Cordant Health Solutions, a drug-testing laboratory company in Washington, to resolve allegations that it paid kickbacks to two companies, Northwest Physicians Laboratories (“NWPL”) and Genesis Marketing Group, in exchange for referrals of urine drug tests reimbursable by federal healthcare programs, in violation of the AKS.

This civil settlement was part of a larger criminal kickback case involving NWPL and three of its executives, who were previously indicted for conspiracy to pay and solicit kickbacks in their dealings with various drug-testing laboratories.

Several other settlements involved allegations of billing for medically unnecessary services, including:

- A \$117 million settlement with a hospital management company to resolve allegations that, between 2006 and 2018, its acute care inpatient psychiatric facilities admitted and failed to discharge patients who were ineligible for inpatient or residential treatment, billed for services not rendered, and billed for improper and excessive lengths of stay, among other things.

- A \$41 million settlement with Logan Laboratories, Inc., a reference lab, Tampa Pain Relief Centers, Inc., a pain clinic, and two executives to resolve allegations that they billed for medically unnecessary urine drug tests. Between 2010 and 2017, they allegedly ordered urine drug tests for all patients at every visit without physicians making an individualized determination that a test was medically necessary.

Further, DOJ continued its focus on combatting the opioid crisis with several large settlements, including:

- A \$2.8 billion settlement with opioid manufacturer Purdue Pharma LP to resolve allegations that it promoted its opioid drugs to providers over an eight-year period despite knowing the providers were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion. The settlement also resolved allegations that Purdue was paying kickbacks to providers, specialty pharmacies, and an electronic health records company to increase opioid prescriptions.²
- A \$300 million civil settlement with pharmaceutical company Indivior to resolve allegations that it promoted the use of opioid-addiction-treatment drug Suboxone that was medically unnecessary and provided misleading information about its benefits. Indivior also pleaded guilty to criminal charges related to its false statements about Suboxone and agreed to pay a criminal fine, forfeiture, and restitution totaling \$289 million.

Finally, some other significant settlements outside the healthcare industry included:

- A \$57.8 million settlement with major federal contractors Bechtel National Inc., Bechtel Corp., and AECOM Energy & Construction, Inc., and their subsidiary Waste Treatment Completion Company, LLC, to resolve allegations that they fraudulently overcharged the U.S. Department of Energy for their workers' idle time in constructing and operating a radioactive waste treatment plant in Washington.
- A \$37.8 million settlement with QuantaDyn Corporation, a Virginia-based software engineering firm specializing in developing training simulation systems for the U.S. Department of Defense. The settlement resolved allegations that QuantaDyn and its former CEO paid bribes to steer the award of government contracts for training simulators to QuantaDyn.
- A \$29 million settlement with Hybrid Tech Holdings LLC, Hybrid Technology LLC, and Ace Strength International Ltd. to resolve allegations that they colluded to rig the bidding of an auction to purchase the U.S. Department of Energy's non-performing loan to Fisker Automotive. Specifically, they allegedly put pressure on and suppressed bids by other parties during the live action and thereby deprived the Department of a fair bidding process.
- A \$22 million settlement with chemical company Linde GmbH and its U.S. subsidiary, Linde Engineering North America LLC, to resolve allegations that they made false statements to U.S. Customs and Border Protection on customs declarations to avoid paying duties on imported goods.

¹ Release available at <https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020>.

² The settlement with Purdue Pharma LP was announced in late October and, as such, counts towards fiscal year 2021.

Legislative and Policy Updates

1. 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 June 19, 2020, DOJ announced its final rule increasing the civil monetary penalty amounts that can be assessed for violations of the FCA, to a minimum of \$11,665 per false claim and a maximum of \$23,331.

2. DOJ UPDATED ITS GUIDANCE FOR EVALUATING CORPORATE COMPLIANCE PROGRAMS.

DOJ has previously assessed the existence and adequacy of a company’s compliance program when determining whether, and to what extent, charges should be brought against that company and how investigations should be resolved.

In February 2017, DOJ issued guidance to assist prosecutors in evaluating a company’s compliance program and determining appropriate forms of prosecution, penalties, and ongoing compliance obligations. The guidance was updated in April 2019 and again most recently in June 2020. While primarily intended for use in the criminal context, the same guidance be considered during a civil investigation against a company, such as in an FCA investigation.

The updated guidance explains that a prosecutor’s review and assessment of a company’s compliance program focuses on three overarching inquiries:

- Is the corporation’s compliance program well designed?
- Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
- Does the corporation’s compliance program work in practice?

In answering these questions, the guidance explains that prosecutors may evaluate a company’s performance on various topics, including but not limited to:

- Identification, assessment, and definition of risk;
- Policies and procedures that give both content and effect to ethical norms that aim to reduce risks identified by a company as part of its risk assessment process;
- Appropriately tailored training and communications;
- Existence of an efficient and trusted mechanism by which employees can anonymously or confidentially report allegations of a breach of the company’s code of conduct, company policies, or suspected or actual misconduct;

- Application of risk-based due diligence to its third-party relationships and acquisition targets;
- Creation and fostering of a culture of ethics and compliance with the law at all levels of the company;
- Sufficiency of the personnel and resources dedicated to compliance;
- Incentives for compliance and disciplinary measures for non-compliance;
- Whether and how misconduct is detected;
- Resources to investigate suspected misconduct; and
- The nature and thoroughness of a company's remedial efforts.

Importantly, the guidance notes that these questions and topics should be addressed while considering the compliance program “both at the time of the offense and at the time of the charging decision and resolution.”

But the guidance is not a checklist or a best practices guide. Instead, it is intended to facilitate the assessment of whether a compliance program being presented to prosecutors establishes four basic pillars: credibility, accountability, measurable results, and continual data-driven improvement. Companies should carefully review the updated guidance and consult with counsel to determine if review and/or revision of their compliance program is necessary.

3. DOJ FORMALIZED ITS PRACTICE OF CONSIDERING AN ENTITY'S INABILITY TO PAY WHEN ASSESSING FINES OR PENALTIES.

On September 4, 2020, Acting Assistant Attorney General Ethan Davis issued a memorandum

formalizing DOJ's practice of considering an entity's inability to pay when negotiating civil settlements and outlining a framework for evaluating a company's claim that it cannot pay a civil fine or monetary penalty.

In short, a company claiming inability to pay must complete a certified Financial Disclosure Form, and provide, as requested, tax returns, audited financial statements, and access to appropriate personnel. The company must also certify under penalty of perjury that the information it provides is complete, accurate, and current. DOJ may also consider other factors, including:

- Background on current financial condition, including projected financial earnings and expenses;
- Alternative sources of capital, including a company's ability to borrow funds (e.g., by obtaining a mortgage on real property) or to raise capital (e.g., through existing or new credit facilities or via a sale of assets or equity);
- Timing of payments;
- Tax deductibility of any monetary payments;
- Contingency arrangements;
- Collateral consequences, such as disproportionate impacts on an individual's ability to provide support to other family members or on a company's operations and obligations; and
- Third-party liability.

¹ Updated guidance available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

² Memorandum available at <https://www.justice.gov/civil/page/file/1313361/download>.

The Granston Memorandum and Government Motions to Dismiss

As discussed in previous Reviews, one of the most significant developments in the realm of FCA litigation has been DOJ's renewed emphasis on dismissing FCA suits brought by private citizens when they do not advance the government interests. Under the FCA, private citizens with knowledge of alleged fraudulent practices may file and litigate FCA cases on behalf of the government (called "*qui tam*" actions).

If such a suit is filed, the government has three options: (1) intervene in the litigation and take over the case; (2) decline intervention and allow the relator to litigate; or (3) move for dismissal over the objections of the relator. See 31 U.S.C. § 3730(b)-(c).

In the past, the government used its dismissal power sparingly. But in 2018, DOJ Civil Frauds Section Director Michael Granston issued a memorandum emphasizing the federal government's role as a "gatekeeper" of FCA *qui tam* actions to ensure only cases that advance the government's interests go forward. The memorandum, known as the Granston Memorandum, advised Assistant U.S. Attorneys to exercise "unfettered" discretion in moving to dismiss FCA suits pursuant to Section 3730(c) (2)—instead of simply declining intervention—when dismissal would advance the government's interests, preserve limited resources, and avoid adverse precedent.

The Granston Memorandum outlined seven, non-exhaustive factors for DOJ to consider in the dismissal decision:

- Curbing meritless *qui tam* actions;
- Preventing parasitic or opportunistic *qui tam* actions;
- Preventing interference with agency policies and programs;
- Controlling litigation brought on behalf of the United States;
- Safeguarding classified information and national security interests;
- Preserving government resources; and
- Addressing egregious procedural errors.

It was initially unclear whether the Granston Memorandum would lead DOJ to be more assertive in seeking dismissal of cases. In a December 19, 2019 letter to Senator Charles Grassley, DOJ explained that it had moved to dismiss 45 *qui tam* cases between January 1, 2018 and October 25, 2019—roughly four percent of the 1,170 cases filed during that time. But even that was a notable increase. There was only a single reported instance of such a motion to dismiss between 1986 to 1996. While these motions have continued to increase over the past few years, they remain the exception, not the rule. Nevertheless, some patterns have emerged—along with some open questions—in how this authority will be applied and reviewed.

1. COMMON REASONS FOR DISMISSAL

When filed, Granston motions to dismiss are almost always granted. One of the most common reasons cited to support dismissal is DOJ's costs of litigating even in a non-intervened FCA case, including the expense and time required to monitor the case (e.g., filing statements of interest and briefs), costs related to responding to discovery and preparing document production, and attorney time associated with preparing and defending depositions of government personnel.

Some dismissal rulings note the importance of DOJ conducting an adequate investigation before determining that the costs of litigation outweigh the benefits. For example, DOJ moved to dismiss a case filed in the Northern District of California only after investigating the relators' allegations for over two years, having consulted with experts from the Department of Health and Human Services' Office of Inspector General (OIG) and the Food and Drug Administration, met with the relator and defendant on multiple occasions, interviewed witnesses, reviewed over 600,000 pages of documents, and physically reviewed the manufacturing lots identified by the relator in that case as having serious problems. *United States ex rel. Campie v. Gilead Scis., Inc.*, No. 3:11-cv-00941, 2019 WL 5722618, at *5 (N.D. Cal. Nov. 5, 2019).

Similarly, motions have been granted because DOJ stated that it had doubts about the relator's likelihood of establishing FCA liability. For example, the Eastern District of Pennsylvania dismissed an FCA case where DOJ raised concerns about the relator's ability to prove his case because he did not have access to medical records to determine whether all of the claims at issue were false. *Polansky v. Executive Health Res., Inc.*, 422 F. Supp. 3d 916, 927 (E.D. Pa. 2019).

Finally, DOJ may move to dismiss a case because it threatens to interfere with another agency's

enforcement efforts. For example, a Northern District of Mississippi case involved FCA allegations premised on a hospital's violations of the Emergency Medical Treatment and Labor Act ("EMTALA"). *United States ex rel. Sibley v. Delta Reg'l Med. Ctr.*, No. 4:17-cv-00053, 2019 WL 1305069, at *8 (N.D. Miss. Mar. 21, 2019). The hospital was in the process of administratively settling penalties associated with the underlying EMTALA violations with OIG. DOJ moved to dismiss the FCA case since the hospital could not finalize settlement with OIG out of fear that such a settlement would increase its risk of liability under the relator's FCA *qui tam* action.

2. CIRCUITS ARE SPLIT ON THE STANDARD OF REVIEW FOR GRANSTON MOTIONS TO DISMISS.

Circuit courts are divided over the role of the judiciary in scrutinizing Granston motions to dismiss and the applicable standard of review, because Section 3730(c)(2) does not provide statutory grounds for granting or denying dismissal.

In *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, the Ninth Circuit endorsed 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." 151 F.3d 1139, 1145 (9th Cir. 1998). 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.*

The D.C. Circuit in 2003 rejected the Ninth Circuit's two-part "rational relation" standard, concluding that Section 3730(c)(2)(A) does not give courts oversight over the government's dismissal decision. *Swift v. United States*, 318 F.3d 250, 252-53 (D.C. Cir. 2003). Instead, the court found that the statutory language "suggests the absence of judicial constraint"

and that there is a presumption that the government's decisions not to prosecute are essentially unreviewable. *Id.* The D.C. Circuit interpreted that provision as giving the government an “unfettered right” to dismiss an action.

In 2005, the Tenth Circuit rejected the “unfettered right” standard, and instead adopted the Ninth Circuit’s two-part “rational relation” standard. *Ridenour v. Kaiser-Hill Co., L.L.C.*, 397 F.3d 925, 936 (10th Cir. 2005) (quoting *Sequoia*, 151 F.3d at 1145). The Tenth Circuit explained that the “rational relation” standard “recognizes the constitutional prerogative of the Government under the U.S. Constitution’s Take Care Clause, comports with legislative history, and protects the rights of relators to judicial review of a government motion to dismiss.” *Id.* The Tenth Circuit conceded, however, that the “rational relation” need not be a “tight fitting relationship.” *Id.* at 936–37. It is enough if there are “plausible, or arguable, reasons supporting the agency decision.” *Id.* at 937.

Generally speaking, district courts in the Third, Ninth, and Tenth Circuits have followed the “rational relation” standard. *See, e.g., United States ex rel. Campie v. Gilead Scis., Inc.*, No. 3:11-cv-00941, 2019 WL 5722618 (N.D. Cal. Nov. 5, 2019).

District courts in the Fifth, Eighth, and D.C. Circuits follow the more deferential “unfettered right” standard, with one court explaining that “[g]iving the government the unilateral power to dismiss *qui tam* actions is consistent with the notions of prosecutorial and executive discretion” provided by the FCA. *See United States ex rel. Sibley v. Delta Reg’l Med. Ctr.*, No. 4:17-cv-00053, 2019 WL 1305069, at *4 (N.D. Miss. Mar. 21, 2019); *see also United States ex rel. Davis v. Hennepin Cty.*, No. 0:18-cv-01551, 2019 WL 608848, at *6 (D. Minn. Feb. 13, 2019), *appeal dismissed*, No. 19-1530, 2019 WL 4296887 (8th Cir. May 14, 2019); *United States ex rel. Kammarayil v. Sterling Operations, Inc.*, No. 1:15-cv-01699, 2019 WL 464820, at *1 (D.D.C. Feb. 6, 2019).

3. RECENT APPELLATE DECISIONS FAIL TO ADD CLARITY TO THE DISMISSAL STANDARD.

Several cases addressed this dismissal standard in 2020 but did nothing to resolve the split. Indeed, the U.S. Supreme Court denied certiorari in a D.C. Circuit case in which the relator urged the Court to address the circuit split and adopt the stricter rational relation standard. *See United States ex rel. Schneider v. JPMorgan Chase Bank, Nat’l Ass’n*, No. 19-7025, 2019 WL 4566462, at *1 (D.C. Cir. Aug. 22, 2019) (per curiam), *cert. denied*, No. 19-678, 2020 WL 1668623 (U.S. Apr. 6, 2020).

Several other courts refused to take a clear stand in the circuit split, finding that the relators in those cases would fail under either standard. *See, e.g., United States ex rel. Borzilleri v. AbbVie, Inc.*, No. 19-2947, 2020 WL 7039048, at *2 (2d Cir. Dec. 1, 2020) (“[W]e do not decide which standard should govern, as the relator fails even the more stringent *Sequoia* standard.”).

Only two district courts have denied a Granston motion to dismiss. The appellate decisions in those two cases exacerbated the circuit split in 2020.

In *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, the district court denied DOJ’s motion to dismiss under the two-part “rational relation” standard because it concluded that DOJ did not conduct on a “minimally adequate investigation, including a meaningful cost-benefit analysis.” No. 3:17-cv-00765, 2019 WL 1598109, at *3 (S.D. Ill. Apr. 15, 2019).

On appeal, the Seventh Circuit held that neither the D.C. Circuit’s “unfettered right” standard nor the Ninth Circuit’s “rational relation” standard provided the appropriate standard of review. *United States ex rel. CIMZNHCA, LLC v. UCB, Inc.*, 970 F.3d 835, 839 (7th Cir. 2020).

Rather, the court turned to the Federal Rules of Civil Procedure. Rule 41(a)(1)(A)(i) states that “the plaintiff may 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.” FED. R. CIV. P. 41(a)(1)(A)(i). Since DOJ’s motion to dismiss was filed in the case before defendants had answered or moved for summary judgment, DOJ was within its rights to move for automatic dismissal without justification.

The Seventh Circuit disagreed with the district court’s view that DOJ must conduct a “meaningful cost-benefit analysis” before moving to dismiss, explaining that “[t]he government is not required to justify its litigation decisions in this way.” *CIMZNHCA, LLC*, 970 F.3d at 852. As a result, the Seventh Circuit conceded its approach “lies much nearer” to the extremely deferential “unfettered right” standard than the more stringent “rational relation” standard. *Id.* at 840.

An additional issue was whether the Seventh Circuit actually had jurisdiction to review a denial of a motion to dismiss pursuant to Section 3730(c)(2)(A). Under 28 U.S.C. § 1291, appellate courts have jurisdiction over “appeals from all final decisions of the district courts.” This statute is most often invoked as the basis for appellate jurisdiction over final judgments. But it also encompasses a small set of pre-final judgment orders that are “collateral to” the merits of an action and too important to be denied immediate review. This has become known as the “collateral order doctrine.”

The Seventh Circuit held it had jurisdiction because DOJ’s motion would be construed as one “both to intervene and then to dismiss,” and denials of motions to intervene have been held to be appealable collateral orders in various federal jurisdictions. *See, e.g., Edwards v. City of Houston*, 78 F.3d 983, 992 (5th Cir. 1996) (en banc) (“The denial of a motion to intervene of right is an appealable final order under 28 U.S.C. § 1291.”).

In the second case, *United States ex rel. Thrower v. Acad. Mortgage Corp.*, the district court denied DOJ’s motion, finding evidence submitted by the relator showed DOJ had performed only a limited investigation of the original complaint’s allegations and no investigation of the amended complaint. No. 3:16-cv-02120, 2018 WL 3208157, at *3 (N.D. Cal. June 29, 2018).

On appeal, the Ninth Circuit held that the order denying the DOJ’s motion to dismiss was not appealable as a collateral order. *United States ex rel. Thrower v. Acad. Mortg. Corp.*, 968 F.3d 996, 1000 (9th Cir. 2020). In other words, unlike the Seventh Circuit in *CIMZNHCA*, the Ninth Circuit did not construe a Granston motion to dismiss as also being a motion to intervene. Rather, the court justified the dismissal of the appeal by explaining that the government’s interests become “qualified” and “particularly attenuated” once it has declined intervention. *Id.* at 1008.

The Ninth Circuit also dismissed the concern that its ruling would render district courts’ denials of Granston motions to dismiss essentially unreviewable. The court deemed any likelihood of an erroneous denial “extraordinarily low” and DOJ would not be subject to significant discovery burden in a non-intervened case. *Id.* In other words, the government’s interest in “avoiding burdensome discovery expenses in a case [it] does not think will ultimately be worth the cost” was “not an interest important enough to merit expanding the narrow scope of the collateral order doctrine.” *Id.*

The Seventh and Ninth Circuits’ recent decisions do little to resolve the circuit split. Both decisions could be read to suggest that a Granston motion to dismiss must be preceded or accompanied by a motion to intervene. But the Seventh Circuit appears to endorse a new standard of review that is similar—though not identical—to the “unfettered right” standard. Conversely, the Ninth Circuit seemed less deferential to DOJ’s dismissal decision (corresponding to its “rational relation” standard), somewhat indifferent to its

concerns about costs outweighing benefits in a non-intervened FCA case, and unconcerned about denials of motions to dismiss being unreviewable on appeal.

There may be additional rulings in 2021 that address the circuit split because appeals of rulings on Granston motions to dismiss remain pending in the First and Fifth Circuits. See *United States ex rel. Health Choice All., LLC v. Eli Lilly & Co.*, No. 19-40906 (5th Cir.); *United States ex rel. Borzilleri v. Bayer Healthcare Pharm., Inc.*, No. 20-1066 (1st Cir.).

4. TAKEAWAYS

DOJ is increasingly willing to exercise its clear statutory authority to dismiss *qui tam* actions, though motions to dismiss remain rare in non-intervened cases. *Qui tam* litigants should evaluate weaknesses in the case based on the Granston Memorandum factors while the case is still under seal and being investigated. Litigants should be aware that different jurisdictions treat these factors differently, though courts are generally deferential to DOJ's dismissal decision regardless of the standard of review.

¹ Memorandum available at <https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismisal-Pursuant-to-31-U-S.pdf>.

² Letter from Stephen E. Boyd to Charles E. Grassley, Office of the Assistant Attorney General, U.S. Department of Justice (Dec. 19, 2019), <https://www.arnoldporter.com/en/-/media/files/perspectives/publications/2020/01/doj-response-to-senator-grassley.pdf>.

³ Steven L. Schooner, *False Claims Act: Greater DOJ Scrutiny of Frivolous Qui Tam Actions?*, 32 NASH & CIBINIC REP. ¶ 20 at 60 (2018), https://scholarship.law.gwu.edu/cgi/viewcontent.cgi?article=2593&context=faculty_publications.

Significant Judicial Decisions

1. STATUTE OF LIMITATIONS

There are two limitations periods applicable to FCA cases. Relators must bring their cases either (1) within six years of the alleged violation, or (2) within three years after the government has knowledge of “facts material to the right of action,” but no later than ten years after the alleged violation was committed. 31 U.S.C. § 3731(b).

In 2019, the Supreme Court resolved a circuit split regarding whether the government’s “knowledge” of an alleged FCA violation triggers the three-year limitations period in cases where the government declines to intervene. See *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507 (2019). *Cochise* confirmed that the three-year statute of limitations does indeed apply even if the government declines to intervene.

This year, a decision in the Eastern District of Texas applied *Cochise* to deny a motion to dismiss. *United States ex rel. Hernandez v. Team Fin., L.L.C.*, No. 2:16-cv-00432, 2020 WL 731446 (E.D. Tex. Feb. 13, 2020). In *Hernandez*, the defendants moved to dismiss for failure to comply with the six-year period contemplated by 31 U.S.C. § 3731(b)(1), arguing that the three-year extension provided by § 3731(b)(2) did not apply because the government declined to intervene. *Id.* at *10. But the court cited *Cochise* to deem the extended three-year statute of limitations applicable. *Id.* at *11 (“[T]he United States Supreme Court has made clear that subsection (b)(2) applies in nonintervened actions. As a result, Relators may be entitled to the FCA’s extended limitations period.”) (citations omitted) (quotations omitted).

Note, however, that the government’s knowledge does not always favor the relator. One case this year held that the three-year limitation period ran *concurrently* with the six-year period because the government learned of the alleged violation during the six-year period. See *Houpt v. Wells Fargo Bank, N.A.*, 800 F. App’x 533 (9th Cir. 2020) (mem.) (unpublished), *cert. denied*, No. 20-461, 2020 WL 7132335 (U.S. Dec. 7, 2020).

In *Houpt*, the relator brought suit in September 2017, alleging the defendant submitted false claims related to a Small Business Administration (“SBA”) loan secured by the defendant’s property. The district court granted summary judgment for the defendant based, in part, on the relator’s failure to bring the claim within the limitations period. *Id.* at *14. The violations were alleged to have occurred in April 2010, meaning that the six-year limitations period expired in September 2016. See *Houpt*, 800 F. App’x at 534.

But it was undisputed that the SBA knew or should have known of the defendant’s alleged violations by April 2014. *Id.* Thus, the three-year extension began during the six-year limitations period and would have run, at the latest, in April 2017—several months before the suit was filed. Accordingly, the Ninth Circuit affirmed the district court’s grant of summary judgment in favor of the defendant. *Id.* at 535.

2. RULE 9(B): PLEADING WITH PARTICULARITY

The submission of a fraudulent claim to the government is the *sine qua non* of an FCA violation. Because it alleges fraud, any FCA

allegation must satisfy Rule 9(b)'s heightened pleading standard. That is, a party "must state with particularity the circumstances constituting fraud" so that the opposing party has adequate notice of the claims against which it must defend. FED. R. CIV. P. 9(b). Whether the allegations are sufficient to meet this standard depends, in part, on where the claim is brought, as courts have long been divided on the kinds of allegations that are sufficient. This year was no different.

A. THE CIRCUIT SPLIT AND ALTERNATE ROUTES TO SATISFY RULE 9(B) REMAIN.

As discussed in previous Reviews, circuit courts are split over how Rule 9(b) applies to FCA claims. Some circuits, including the Fourth, Sixth, and Eleventh Circuits, favor—and in some cases *require*—detailed allegations of a specific false claim that was actually submitted to the government. Other circuits take a less stringent approach, placing more emphasis on sufficient allegations of the fraudulent scheme at issue, rather than the precise claim itself.

Split aside, the circuits generally agree that Rule 9(b) can be satisfied through one of two alternatives: (1) a representative sample of false claims that were actually submitted to the government, or (2) particular details of a scheme to submit false claims to the government *plus* indicia of reliability that false claims were actually submitted.

B. DETAILS OF SPECIFIC FALSE CLAIMS SATISFY THE PLEADING STANDARD.

Under the first alternative, a plaintiff can satisfy Rule 9(b) by offering sufficient "details of an actually submitted [false] claim." *United States ex rel. Jamison v. Career Opportunities, Inc.*, No. 3:16-cv-03248, 2020 WL 520590 (N.D. Tex. Jan. 31, 2020). *Jamison* shows how this is done in the Fifth Circuit.

There, the relator successfully pleaded "details of an actually submitted false claim" in a case arising out of the defendant's contract with the U.S. Department of Labor to operate a Job Corps center. *Id.* at *5. The court concluded that the relator satisfied Rule 9(b) by following the "who, what, when, where, how" pleading method to allege specific false claims. Indeed, the court tracked each prong, explaining how the complaint alleged that "Relator Williams (who) . . . inputted data that was false" and "was used to complete lines 28 and 38 of the Form 2110's (what)," which were submitted to the Department of Labor "every month from April 2012 through April 2014 (when) at the NTJCC in McKinney, Texas (where)." *Id.* The "false information related to . . . the number and qualifications of students to increase Defendant's base and incentive pay (how)." *Id.*

C. DETAILS OF A FRAUDULENT SCHEME BASED ON CONJECTURE ARE NOT ENOUGH.

To proceed under the second alternative, plaintiffs must plead with particularity *both* a fraudulent scheme *and* sufficient indicia that false claims were submitted to the government. Although this is an ostensibly lower standard, adequately alleging both prongs can still be a challenge for relators.

For example, in *United States ex rel. Anham Fzco v. Supreme Foodservice GmbH*, the relator attempted to show that a food supplier had submitted false claims to the Defense Logistics Agency as part of a scheme to delay a logistic-services company's work and extend its own contract in the interim. No. 1:17-cv-01290, 2020 WL 4579458, at *1-3 (E.D. Va. July 8, 2020), *appeal filed*, No. 20-1845 (4th Cir. Aug. 6, 2020). The relator tried to plead a false scheme by "relaying conversations between various defendants" and citing bid protests initiated by the food supplier as well as meetings the food supplier had with the agency. *Id.*

But the court held that these allegations were inadequate as “[n]o ‘who, what, when, where, and how’ of the fraudulent scheme itself was ever alleged. *Id.* at *16. Moreover, the details lacked any indicia of reliability as relator was not present at the meetings, and the allegations were therefore “based on conjecture,” falling “woefully short of meeting the [Rule 9(b)] standard.” *Id.*; see also *United States ex rel. Levine v. Vascular Access Ctrs. L.P.*, No. 1:12-cv-05103, 2020 WL 5534670 (S.D.N.Y. Sept. 15, 2020) (dismissing as insufficient allegations identifying a few patients and the month and year of their access procedures without identifying defendants who were involved in the alleged treatment or referral).

D. SOME COURTS REQUIRE A CONNECTION BETWEEN THE ALLEGED FRAUDULENT CONDUCT AND THE FALSE CLAIMS BEING PRESENTED.

Some courts also require that a plaintiff clearly “connect the dots” between the alleged fraudulent activity and the presentment of false claims to the government. *United States ex rel. Rauch v. Oaktree Med. Ctr., P.C.*, No. 6:15-cv-01589, 2020 WL 1065955, at *13 (D.S.C. Mar. 5, 2020).

In *Rauch*, the relator alleged that the defendant “created compensation agreements that generated money for healthcare providers, in part, as a result of gross collections for ancillary services.” *Id.* at *15. The court concluded that these “broad strokes” were insufficiently particular; but even if they were particularized, the plaintiff “fail[ed] to connect the dots between this activity and the presentment of false claims to the Government for payment.” *Id.* at *13. To put it plainly, “[m]erely alleging fraudulent conduct and an umbrella payment, without more, is insufficient particularity where the Defendant is not the party directly submitting the claims to the Government.” *Id.* at *17.

So, it is not enough for a plaintiff or relator to plead with particularity a fraudulent scheme; the plaintiff must also plead some indicia of reliability that the scheme led to false payments. This hurdle typically requires the relator to have some “basis for knowledge” that a false claim was indeed made. *United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 740 (8th Cir. 2020). That basis “may include, ‘direct, first-hand knowledge of defendants’ submission of false claims gained through his employment with the defendants.” *United States ex rel. Olhausen v. Arriva Med., LLC*, No. 1:19-cv-20190, 2020 WL 5077170, at *8 (S.D. Fla. Aug. 27, 2020).

But even high-level executives, depending on their roles, may not be able to meet this standard. For example, a Senior Vice President of Business Development and Marketing who alleged that he learned about the alleged fraudulent payments through his role did not provide the requisite “indicia of reliability” because participating in weekly meetings and receiving reports from employees merely established that he was an “insider,” but did not “meaningfully aid the Court in its search for . . . reliability.” *Id.* at *9.

E. STATISTICS CAN HELP BUT ARE NOT ENOUGH STANDING ALONE.

Statistics may be useful in establishing a fraudulent scheme with some indicia of reliability, but they are no substitute for particularized allegations. In *United States ex rel. Integra Med Analytics LLC v. Baylor Scott and White Health*, for example, the relator alleged that the defendant engaged in an upcoding scheme to increase its Medicare reimbursement, trained its employees to upcode, pressured physicians to alter their original diagnoses, and provided unnecessary treatments to submit high-value codes. 816 F. App’x 892, 895–96 (5th Cir. 2020) (per curiam) (unpublished).

To demonstrate that this fraudulent scheme occurred, the relator 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 defendant. Despite this detailed analysis, the relator failed to establish “particular details of a scheme to defraud Medicare.” *Id.* at 900. The court instructed that “[e]ven when plaintiffs in an FCA case use statistics, which can be reliable indicia of fraud, they must still plead particular details of a fraudulent scheme for each claim.” *Id.*

That was especially true because the relator’s statistics and its own complaint indicated that 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. *Id.* at 898. Specifically, CMS acknowledged that new rules regarding secondary diagnosis codes may lead to increased reimbursement, many of relator’s allegations were practices that CMS encouraged hospitals to employ after it implemented new coding rules, and other hospitals were also increasing their use of these codes each year. *Id.* at 897–98.

F. DETAILS OF A FRAUDULENT SCHEME AND INDICIA OF RELIABILITY SATISFY THE PLEADING STANDARD.

In contrast, some courts find that a relator can satisfy Rule 9(b) without specific false claims by describing “the alleged scheme in adequate detail, explaining the mechanism of the alleged fraud and the generic identities of those involved.” *Sturgeon v. PharMerica Corp.*, 438 F. Supp. 3d 246, 270 (E.D. Pa. 2020).

In *Sturgeon*, relators sued a long-term care pharmacy for allegedly submitting false claims for illegally altered prescriptions. The court held that the relators met the particularity requirement by alleging “with adequate specificity” that the defendant “altered the drug form on prescriptions for non-controlled

substances,” and “altered the dosage and quantity, which are undisputedly required elements of a valid prescription.” *Id.* In other words, “Relators describe[d] the alleged scheme in adequate detail, explaining the mechanism of the alleged fraud and the generic identities of those involved (i.e., data clerks, pharmacists, etc.)” *Id.*

The court in *Sturgeon* found sufficient indicia of reliability through the details alleged, including “the specific time frame,” “a definite number of claims allegedly submitted,” and “further specification that 143 of those claims involved prescriptions for” specific drugs. *Id.* at *274.

In another case, relators that previously worked for the defendant-company as regional sales directors adequately alleged a fraudulent scheme to pay providers through an “opinion leadership” program—involving speaker and advisor payments, travel, and other remuneration—to induce them to prescribe defendant’s drugs. See *Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 390 (E.D. Pa. Feb. 13, 2020).

Because relators pleaded “significant detail about the selection process, honorarium and other payments to participating providers,” names of “paid participants,” and allegations that “federal, state, and local governments, through their Medicaid, Medicare, TRICARE, Veteran’s Administration and other Government healthcare payors” were among “the principal purchasers of Gilead’s pharmaceuticals,” the court held that “these allegations alone offer[ed] at strong enough inference [that] participating providers wrote [specific] prescriptions leading to claims for government payor reimbursement.” *Id.*

In sum, Rule 9(b) is an exacting standard in any case, but it has particular “bite” in the FCA context. Where a plaintiff seeks to survive a motion to dismiss under this standard, a plaintiff must either provide precise details of a specific false claim or provide enough details of the

fraudulent scheme and requisite indicia of reliability. When in doubt, the colloquial “who, what, when, where, and how” test provides helpful guidance in pleading an FCA claim to satisfy Rule 9(b).

3. 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 2020.

A. THE THIRD AND NINTH CIRCUITS HELD THAT SUBJECTIVE MEDICAL JUDGMENTS MAY BE FALSE IN SOME CIRCUMSTANCES.

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 (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.

Other courts have followed *AseraCare*’s determination that an “objective falsehood” is necessary to establish FCA liability where clinical judgment is the basis for the alleged fraud. See,

e.g., United States ex rel. Holzner v. DaVita Inc., No. 8:18-cv-01250, 2020 WL 3064771, at *8 (C.D. Cal. Apr. 10, 2020) (granting defendants’ motion to dismiss and finding no falsity where relator relied on a medical study to support its allegations that patients were placed on dialysis several months before treatment was medically necessary, as there was “a significant difference of opinion as to the proper time to initiate dialysis”).

But in 2020, two appellate courts rejected that view and created a circuit split. 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. Mar. 23, 2020), *petition for cert. docketed*, No. 20-805 (U.S. Dec. 14, 2020).

The Third Circuit likewise rejected the 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. *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 95 (3d Cir. 2020), *petition for cert. docketed*, No. 20-371 (U.S. Sept. 23, 2020).

Petitions to review both the Third Circuit and Ninth Circuit decisions have been filed with the Supreme Court, and amici curiae in support of the defendants have characterized the rules established by those decisions as “potentially affect[ing] any entity, public or private, that receives federal funds in myriad contexts” by “punish[ing] routine good-faith professional and business judgments.” The Supreme Court’s ruling on this circuit split will be closely watched in 2021.

B. SUBMITTING CLAIMS WITHOUT CAREFUL REVIEW OF THE UNDERLYING FILES DOES NOT CREATE FCA LIABILITY UNLESS FALSITY IS OBVIOUS.

In *United States ex rel. Vatan v. QTC Medical Services*, the Ninth Circuit determined that generic complaints about the quality of work and an alleged deviation from the purpose of the contract, without pointing to any specific misrepresentation, do not create FCA liability. 812 F. App'x 485, 486 (9th Cir. 2020) (mem.) (unpublished).

In *Vatan*, the relator alleged that the defendant falsely certified that the “entire claims folder” was reviewed when its analysts answered “yes” to that question on a checklist that was submitted with defendant’s requests for payment. *Id.* at 486. The district court granted summary judgment for the defendant, however, holding that there was no evidence that the government expected the defendant’s analysts to review every page to truthfully answer “yes” to the checklist question. *Id.*

In contrast, in *United States v. Dynamic Visions Inc.*, the district court granted summary judgment in favor of the government because there was no genuine dispute of material fact that a valid plan of care (“POC”) did not exist for many of the defendant’s submitted claims, and because defendant “[wa]s a small operation and ‘even a cursory review’ of the files would have revealed the ‘rampant’ false claims.” 971 F.3d 330, 335 (D.C. Cir. 2020).

The D.C. Circuit affirmed “as to those claims for which the falsity stems from the absence of any POC, or from a POC with no signature from a physician, an untimely signature, or an authorization of services more confined in scope than the services for which reimbursement was sought.” *Id.* at 336. In other words, when “even the shoddiest recordkeeping would have

revealed that false submissions were being made,” the claims’ falsity was obvious and the defendant was acting in reckless disregard for their falsity. *Id.* at 337.

C. WHEN THE STATUTORY OR CONTRACTUAL REQUIREMENT UNDERLYING AN FCA CLAIM CONTAINS “IMPRECISE AND DISCRETIONARY LANGUAGE,” THERE IS ONLY A “DISPUTED LEGAL ISSUE” RATHER THAN AN OBJECTIVE STATEMENT OF FACT THAT CAN BE DEEMED “FALSE.”

A claim can be false when a person “makes specific representations about the goods or services provided” but fails “to disclose noncompliance with material statutory, regulatory, or contractual requirements.” *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

In *United States v. McKesson Corp.*, the district court held that relators failed to adequately allege that the defendant made any false statements when relators claimed that the defendant’s pharmaceutical distribution centers failed to adopt security measures to adequately prevent diversion of Schedule II opioids, as required by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (“CSA”), and then failed to disclose these CSA violations when submitting federal claims. No. 4:19-cv-02233, 2020 WL 4805034, at *5 (N.D. Cal. Aug. 18, 2020).

The court found that the CSA regulations “do not always require strict compliance” and the government has broad discretion to interpret them. *Id.* In other words, any representations that the defendant made about its compliance with the CSA’s imprecise regulations and standards could not be deemed “false” for purposes of FCA liability. *Id.*

4. SCIENTER

The FCA's scienter element requires plaintiffs to show that the defendant "knowingly" submitted a false or fraudulent claim. 31 U.S.C. § 3729(a)(1). To act "knowingly," a defendant must have acted with "actual knowledge of the information" or in "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information." 31 U.S.C. § 3729(b)(1).

While the FCA does not require plaintiffs to show a specific intent to defraud, it does require more than a showing of negligence. See *United States v. Wagoner*, No. 2:17-cv-00478, 2018 WL 4539819, at *6 (N.D. Ind. Sept. 20, 2018) (citation omitted) ("Innocent mistakes or negligence are not actionable.").

A. VAGUE AND CONCLUSORY ALLEGATIONS OF KNOWLEDGE ARE INSUFFICIENT.

Vague and conclusory allegations of knowledge are generally insufficient, and in *Adomitis ex rel. United States v. San Bernardino Mountains Community Hospital District*, the Ninth Circuit affirmed a dismissal for just that reason. 816 F. App'x 64, 66 (9th Cir. 2020) (mem.) (unpublished). There, the relator alleged that the defendant-hospital submitted claims for Medicare reimbursements at rates authorized only for critical access hospitals despite not meeting distance requirements to qualify for critical access hospital designation.

To substantiate its allegations, the relator pleaded that defendant's senior officials "must have known" about the distance requirements applicable to critical access hospital simply because they routinely drove the roads at issue. *Id.* at 67. But the district court dismissed the complaint with prejudice, and the Ninth Circuit affirmed, holding that such allegations of scienter were "too vague and conclusory." *Id.*

Similarly, in *United States ex rel. Complin v. North Carolina Baptist Hospital*, the relator alleged that the defendant-hospitals knowingly submitted fraudulent cost reports to Medicare by failing to report costs for providing care to their own employees as "related party transactions." 818 F. App'x 179, 181 (4th Cir. 2020) (per curiam) (unpublished).

The relator "asked the court to infer scienter from the alleged regulatory violation itself: Because the Hospitals were sophisticated entities presumed to know the law . . . their failure to comply with the Related-Party Rule could only have been 'knowing.'" *Id.* at 182. But the court refused to "infer scienter," and the Fourth Circuit affirmed dismissal on appeal, holding that the relator failed to "allege any facts from which one could infer knowledge of a false claim." *Id.* at 183.

B. RELIANCE ON A REASONABLE INTERPRETATION OF RELEVANT LAW MAY DISPROVE SCIENTER.

To disprove scienter, courts often allow defendants to show that they acted in reliance on a reasonable interpretation of relevant law. This defense finds its support in the non-FCA case of *Safeco Insurance Company of America v. Burr*, 551 U.S. 47 (2007), which held that a defendant who follows an objectively reasonable but erroneous interpretation of an ambiguous legal standard is not reckless as a matter of law.

Many circuits have found that the Safeco scienter standard applies to the FCA. See, e.g., *United States ex rel. Streck v. Allergan Inc.*, 746 F. App'x 101 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015). Consequently, defendants frequently cite *Safeco* when arguing lack of scienter.

In *United States ex rel. Proctor v. Safeway Inc.*, for example, the defendant cited *Safeco* to argue that it relied on a reasonable interpretation of “usual and customary pricing” when it failed to include certain discount prices provided to other customers in its pricing for government programs. 466 F. Supp. 3d 912, 931 (C.D. Ill. 2020).

In response, the relator argued that the *Safeco* standard does not apply to the FCA and that recklessness was demonstrated by evidence of defendant’s subjective understanding of the rule through internal emails, corporate policy documents, and communications from regulators. *Id.* at 932. The relator also argued that even if *Safeco* did apply in the FCA context, it only applied to the “reckless disregard” formulation of the FCA’s scienter requirement, and it did not affect the relator’s ability to demonstrate that defendant acted with actual knowledge, or at least deliberate ignorance. *Id.* at 930–31.

The court applied *Safeco* to grant summary judgment in favor of defendant, however, finding that defendant’s application of “usual and customary pricing”—though later determined to be incorrect—had been objectively reasonable at the time the claims were submitted. *Id.* at 941. The court found it determinative that “there was no authoritative guidance warning [defendant] away from its interpretation of the law.” *Id.*

In contrast, another court found defendants’ reliance on its interpretation of relevant legal guidance to be “border[ing] on the absurd,” and therefore, insufficient to defeat scienter. *United States ex rel. Drummond v. BestCare Lab. Servs., L.L.C.*, 950 F.3d 277, 282 (5th Cir. 2020). In *Drummond*, the relator alleged the defendants improperly sought Medicare reimbursement for miles purportedly driven by technicians to collect specimens from patients when in reality the samples were shipped by plane. *Id.* at 279. Defendants argued that they believed their billing practices were legal because they were based on guidance in the CMS Medicare Claims Processing Manual.

The district court granted summary judgment for the government. Defendants appealed, arguing that their reliance on the CMS Manual foreclosed the government’s ability to prove scienter at the summary judgment stage. *Id.* at 281. The Fifth Circuit rejected this argument because (1) defendants’ interpretation of the CMS Manual “border[ed] on the absurd,” since the provisions at issue applied to “technicians who’re *actually* traveling somewhere”; and (2) the CMS Manual is a “policy statement” that has “no binding legal effect,” and defendants therefore cannot assert reasonable reliance upon it in contravention of actual law. *Id.* at 281 (emphasis in original).

5. POST-ESCOBAR MATERIALITY

The Supreme Court’s 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar* has continued to receive significant attention from the lower courts. 136 S. Ct. 1989, ___ U.S. ___ (2016). By way of background, *Escobar* issued two key holdings.

First, the Court resolved a circuit split by confirming the validity of the “implied false certification theory of liability,” under which a defendant’s failure to disclose noncompliance with a statute, regulation, or contract requirement can render a claim “false or fraudulent” even if the claim does not expressly certify such compliance. *See id.* at 1995–96. The Court clarified that “not every undisclosed violation of an express condition of payment automatically triggers liability.” *Id.* Instead, the misrepresentation about compliance “must be material to the government’s payment decision.” *Id.* at 2002 (emphasis added).

Second, the Court held that determining materiality is a “rigorous” and “demanding” fact-based inquiry of whether a noncompliance has a natural tendency to influence, or be capable of influencing, the government’s payment decision. *See id.*; *see also United States ex rel. Gelman v. Donovan*, No. 1:12-cv-05142, 2017 WL 4280543, at *5 (E.D.N.Y. Sept. 25, 2017) (“[After *Escobar*,]

materiality is essentially a matter of common sense rather than technical exegesis of statutes and regulations.”).

This inquiry may be influenced by non-exclusive factors such as whether the alleged noncompliance goes to the “essence of the bargain,” whether the noncompliance 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). *Escobar*, 136 S. Ct. at 2003–04.

Since the Supreme Court issued its opinion in *Escobar*, numerous district and appellate courts have attempted to interpret what is and is not “material.” The following is a summary of some key decisions issued in 2020.

A. A FALSITY DIRECTLY IMPACTING HOW MUCH THE GOVERNMENT PAYS IS STRONG EVIDENCE OF MATERIALITY.

In *Ruckh v. Salus Rehabilitation, LLC*, the relator alleged that defendants violated the FCA by (1) upcoding to inflate the amount of therapy and nursing services that residents received; (2) impermissibly scheduling more extensive services to coincide with the assessment period that Medicare uses to set its reimbursement levels for facilities (a practice known as “ramping”); and (3) submitting claims to Medicaid for reimbursement without comprehensive care plans. 963 F.3d 1089, 1097 (11th Cir. 2020).

After trial, the jury awarded the relator over \$115 million in damages, which, with trebling and penalties, totaled \$347.9 million. *Id.* at 1098. But the district court granted the defendants’ post-trial motion for judgment as a matter of law and set aside the jury’s verdict. The court held that the relator failed to offer competent evidence

that defendants knew the government regarded the disputed practices as material under *Escobar* and would have refused to pay the claims had it known about the disputed practices. *Id.* at 1098–99. The district court also dismissed the relator’s allegations of upcoding as merely “a handful of paperwork defects.” *Id.* at 1105.

But the Eleventh Circuit reversed in part, reinstating \$85 million in damages (before trebling and penalties) for the claims related to upcoding and ramping. The Eleventh Circuit held that the issue of upcoding went to “heart of the [facilities’] ability to obtain reimbursement from Medicare.” *Id.* As such, the false representations about the level of care provided necessarily influenced the government’s payment decision and was material. Similarly, ramping fraud was also material because defendants’ inflation of the level of services they provided caused Medicare to pay more than it owed and thus directly affected the payment Medicare made. *Id.* at 1105–06.

B. THE GOVERNMENT’S ACTIONS AFTER LEARNING OF THE ALLEGED VIOLATION IS AN IMPORTANT FACTOR TO CONSIDER IN ANALYZING MATERIALITY.

Government inaction and/or continued payment of claims after learning about alleged noncompliance or violation is a factor weighing towards a finding of immateriality in many cases.

In *United States ex rel. Janssen v. Lawrence Memorial Hospital*, for example, the relator alleged that the defendant falsified patients’ arrival times to increase its Medicare reimbursement under certain pay-for-reporting and pay-for-performance programs that the government uses to study and improve hospitals’ quality of care. 949 F.3d 533, 535–38 (10th Cir. 2020), *cert. denied*, No. 20-286, 2020 WL 5883407 (U.S. Oct. 5, 2020).

The district court granted defendant's motion for summary judgment, and the Tenth Circuit affirmed, because the relator had previously reported the inaccurate quality data to a CMS fraud hotline in 2013, which triggered an investigation by a CMS contractor. *Id.* at 538. But in 2014, the contractor closed its investigation, stating that "CMS [was] aware of the quality issue." *Id.* at 539. The court noted that CMS had not taken any action against the defendant and continued to pay Medicare claims despite knowing of the alleged falsifications. The court found that CMS's "inaction in the face of detailed allegations from a former employee suggests immateriality." *Id.* at 542.

Similarly, in *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, the court found no materiality where the state took no action after the relator complained about the conduct alleged in her complaint. 810 F. App'x 237, 242 (5th Cir. 2020), *petition for cert. docketed*, No. 20-786 (U.S. Dec. 9, 2020). Instead, the state "continued payment and renewed its contract with [the defendant] several times. And even after [the relator]'s suit was unsealed, [state Medicaid] awarded [the defendant] a contract for the fourth time." *Id.*

C. THE GOVERNMENT'S PAYMENT DECISION ENCOMPASSES BOTH THE INITIAL AWARDING OF A CONTRACT AND SUBSEQUENT PAYMENTS OF CLAIMS UNDER THE CONTRACT.

Many lawsuits allege that a false statement or misrepresentation fraudulently induced the government to award a contract. Courts have held that this can lead to FCA liability, even if there are no false statements or misrepresentations in the claims submitted during the performance of the contract, because the initial fraudulent inducement "taints" every subsequent claim. Accordingly, courts have held that the government's "payment decision" under *Escobar* encompasses both its decision to award a contract and its ultimate decision to pay under that contract.

For example, in *United States v. Strock*, the government alleged that the defendant received federal funds through government contracts reserved for service-disabled veteran-owned small businesses ("SDVOSBs") when it did not actually qualify for those contracts. 982 F.3d 51, 57-58 (2d Cir. 2020). The district court dismissed the complaint because the government had not adequately pleaded that the alleged misrepresentation—that the defendant qualified as an SDVOSB—was material to the government's decision to make payments under the awarded contracts or that defendants knew of this materiality. *Id.* at 56-57.

But the Second Circuit reversed, holding that the district court applied an unduly restrictive interpretation of materiality in light of *Escobar*. The court held that several factors weighed in favor of a finding of materiality, including the government expressly designating SDVOSB compliance a condition of contract eligibility. *Id.* at 62. This rendered the defendant's misrepresentations about its status as an SDVOSB material to the government's decision to award the contracts, which was sufficient to survive a motion to dismiss.

6. 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). In order 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 (2) if it does, 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. The public disclosure bar and the original source exception were substantively amended in 2010 by the Affordable Care Act (“ACA”). Due to the lengthy nature of most FCA suits, courts have continued to grapple with cases implicating the pre-ACA version of these provisions years after the ACA was enacted.

A. WHETHER THE PUBLIC DISCLOSURE BAR IS IMPLICATED IS A FACT-SPECIFIC DETERMINATION.

The Sixth Circuit in *United States ex rel. Holloway v. Heartland Hospice, Inc.*, was the first appellate court to address whether a relator is the government’s “agent” for purposes of the public disclosure bar. 960 F.3d 836 (6th Cir. 2020).

The relator in *Holloway* argued that a prior non-intervened *qui tam* suit was not a public disclosure because a relator is not the government’s agent—meaning the case could not be “public” unless and until the government intervened. See *id.* at 845. Most district courts had already rejected that rationale, reasoning that the government is the real party in interest even in a non-intervened *qui tam* suit since it exerts control over the litigation, receives copies of all pleadings, can move to stay discovery, and has the right to approve or reject a dismissal. *Id.*

The Sixth Circuit agreed with those courts, holding that a *qui tam* relator is in all instances the government’s agent for purposes of the public disclosure bar. *Id.* at 845–46. Thus, the bar applies even where the government does not intervene.

In *United States ex rel. Shahinian v. Kimberly-Clark Corp.*, the relator challenged the district court’s dismissal based on the post-ACA public disclosure bar, arguing that his allegations were related to a new fraud and *not* “substantially the same” allegations that had already been publicly disclosed in earlier litigation. 807 F. App’x 710, 710 (9th Cir. 2020) (mem.) (unpublished).

The Ninth Circuit agreed, holding that relator’s complaint contained allegations about a new

fraud based on subsequent statements made by the defendant regarding a new and different surgical gown. *Id.* at 711. While the relator’s complaint and the publicly-disclosed claims both generally alleged that the defendant misrepresented the permeability of surgical gowns, this was *not* enough to bar the instant action because it dealt with a fraud purportedly occurring during a later time period and concerning a different product. *Id.*

B. THE ORIGINAL SOURCE EXCEPTION

As noted above, the 2010 amendments affected the original source exception. The pre-ACA public disclosure bar required that an original source have “direct and independent knowledge” of the information forming the basis of the allegations.

The post-ACA public disclosure bar, on the other hand, qualifies a relator as an “original source” if 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).

C. PRE-ACA ORIGINAL SOURCE EXCEPTION

The First Circuit applied the pre-ACA version of the original source exception in *United States ex rel. Banigan v. PharMerica, Inc.*, holding that relator was an original source. 950 F.3d 134, 146–47 (1st Cir. 2020). The case involved former employees of a drug manufacturer who alleged that the defendant participated in a scheme that rewarded it financially for incentivizing physicians to change prescriptions to defendant’s antidepressant medications. See *id.* at 138–41.

The district court dismissed the relators’ FCA claims under the public disclosure bar, holding that relators failed to qualify as “original sources” because they did not have “direct knowledge” of the information underlying their allegations. *Id.* at 142.

But the First Circuit reversed, interpreting “direct” to mean “immediate”—involving no intervening agency, instrumentality, or influence. See *id.* at 146. Because one of the relators was a corporate insider who learned of the fraudulent scheme while he was employed there, the court found that his knowledge was “direct” under the statute even though he did not actually participate in the fraud or have knowledge of the fraud as it was occurring. See *id.* The court reasoned that Congress could not have intended to reward as original sources only those who *participated* in the fraud. *Id.*

D. POST-ACA ORIGINAL SOURCE EXCEPTION

The Second Circuit interpreted the “materially adds” requirement of the post-ACA original source exception in *Vierczhalek v. MedImmune Inc.*, 803 F. App’x 522 (2d Cir. 2020) (unpublished). The Second Circuit affirmed the district court’s dismissal based on the public disclosure bar, finding that the relator was not an “original source.”

The court held that a relator could not qualify as an original source by simply “conduct[ing] some collateral research and investigations in response to public allegations, and pair[ing] the results of that research with her background information.” *Id.* at 525. And the court held that the relator did not “materially add” to the public disclosures because she “at most augmented the ‘where’ of the kickback allegations against MedImmune” and did not substantially or considerably add to the already public information. *Id.* at 526. In other words, she did not contribute to the who, what, or how of the alleged scheme. *Id.*

Similarly, in *United States ex rel. Maur v. Hage-Korban*, the Sixth Circuit held that an integrity agreement posted on a publicly accessible website constitute a publicly disclosed “federal report” that contained “substantially the same” allegations as the relator’s complaint. 981 F.3d 516, 524 (6th Cir. 2020).

The court also held that the relator was not an original source because his allegations were

“neither novel nor so removed from the ‘resolved’ conduct” to add anything “material” to the “prior problematic [procedures] already disclosed.” *Id.* at 528. 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 and wrongfully paid by Medicare. *Id.* at 526. The relator’s only contributions—the addition of certain corporate entities as additional defendants—did not materially add to the previously disclosed allegations.

7. 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 based on the same essential facts.

In 2020, the Third Circuit held that the first-to-file bar does not bar new relators from entering a *qui tam* suit by amendment, focusing on the meaning of the word “intervene.” See *In re Plavix Mktg., Sales Practices & Products Liab. Litig.* (No. 11), 974 F.3d 228, 230 (3d Cir. 2020). The court reversed dismissal of a *qui tam* suit based on the first-to-file bar, finding that the partnership which was formed with the sole purpose of filing the suit did not lose standing when it replaced one of its members. See *id.*

The court examined the ways in which nonparties with interests in traditional civil suits can become parties to a suit, which include (1) intervening in the existing suit, (2) filing their own related suit based on the same facts, or (3) being added to the existing suit by the court or the existing parties. *Id.* at 233. While the first-to-file bar precludes the first two options in FCA suits, the court held that it does *not* preclude the third. *Id.* at 233–34.

8. GOVERNMENT ACTION BAR

A third statutory bar, the government action bar, prohibits relators from bringing an FCA action “based upon allegations or transactions which are the subject of a civil suit ... in which the Government is already a party.” 31 U.S.C. § 3730(e)(3).

In 2020, the Eastern District of Pennsylvania held that the government action bar did not preclude an action because the relator’s allegations were not “based on the same underlying facts” as the government’s complaint in a prior action. *Sturgeon v. PharMerica Corp.*, 438 F. Supp. 3d 246, 268 (E.D. Pa. 2020).

The court focused on the whether there was a host/parasite relationship—that is, whether the facts in a case are similar enough to be characterized as feeding off of allegations the government has already made. *Id.* at 261. The court found that no such relationship existed, and in fact there were many differences between the alleged schemes. *See id.* at 267. For instance, the relator alleged a different and more sophisticated method of fraud—separate and apart from that which was already alleged by the government. *See id.*

9. 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).

An employee can succeed on a retaliation claim under the FCA even where the employee fails to adequately plead that the employer committed

a substantive FCA violation. *See, e.g., Nesbitt v. Candler Cty.*, 945 F.3d 1355, 1357 (11th Cir. 2020) (explaining that employee’s retaliation claim could proceed even after the employee and government voluntarily dismissed underlying claims of fraud against the defendant employer).

A. MANY COURTS EMPLOY A THREE-STEP FRAMEWORK WHEN THERE IS NO DIRECT EVIDENCE OF RETALIATION.

Circuit courts have generally held that when there is no direct evidence of retaliation, a successful FCA retaliation action involves three steps:

- (i) *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.
- (ii) *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.
- (iii) *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., Barreto v. SGT, Inc., 826 F. App’x 267, 270 (4th Cir. 2020) (adopting the burden-shifting framework of *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802–03 (1973)).

In order to qualify as “protected activity” under the first step, the employee’s conduct: (1) “must have been in furtherance of an FCA action,”

and (2) “must be aimed at matters which are calculated, or reasonably could lead, to a viable FCA action, meaning the employee in good faith believes, and . . . a reasonable employee in the same or similar circumstances might believe, that the employer is possibly committing fraud against the government.” *Sherman v. Berkadia Com. Mortg. LLC*, 956 F.3d 526, 531–32 (8th Cir. 2020).

But “protected activity” generally excludes “the scope of conduct that fall[s] within the employee’s regular duties.” *Bennett v. Abiomed, Inc.*, No. 1:13-cv-12277, 2020 WL 1429847, at *6 (D. Mass. Mar. 24, 2020) (granting summary judgment for defendant-employer where employee’s job was “to review and approve his subordinates’ expense reports and ensure that they followed [employer’s] travel and expense policies”).

In addition, the employer’s knowledge of the protected activity is presumed where the employee alleges that she “complained directly to her supervisors.” *United States v. Dental Health Programs, Inc.*, No. 3:18-cv-00463, 2020 WL 3064712, at *16 (N.D. Tex. June 8, 2020).

B. RETALIATION CLAIMS ARE NOT SUBJECT TO RULE 9(B).

Unlike underlying FCA claims—which, by definition, involve allegations of fraud and are subject to the heightened pleading standard of Rule 9(b)—the majority of federal courts hold that retaliation claims under the FCA are held to the more lenient pleading standard under Rule 8(a), requiring only “a short and plain statement of the claim showing that the pleader is entitled to relief.” *Paige v. AM Hospice, Inc.*, No. 3:19-cv-00319, 2020 WL 2543301, at *2–4 (W.D. Tex. May 15, 2020) (denying employer’s motion to dismiss retaliation claim where plaintiff alleged her internal reporting of fraudulent Medicare billing resulted in her termination 10 days later).

C. RETALIATION CLAIMS REQUIRE CONCERN FOR GOVERNMENT FRAUD AND THE EXISTENCE OF AN EMPLOYER-EMPLOYEE RELATIONSHIP.

Although the success of an employee’s retaliation claim is not necessarily dependent on the proof of the employer’s underlying violation, the employee is required “to show that her decision to report the noncompliance *itself* was motivated by a concern that the noncompliance was defrauding the government.” *Nichols v. Baylor Research Inst.*, 418 F. Supp. 3d 143, 149 (N.D. Tex. 2019) (emphasis in original) (partially dismissing employee’s claim for retaliation where employee failed to allege that her internal complaints were motivated by a concern of fraud against the government, as opposed to some other motive—noting that “simply reporting violations, without more, is not the same as attempting to expose fraud, and therefore d[oes] not constitute protected activity”); see also *United States ex rel. Benaissa v. Trinity Health*, 963 F.3d 733, 742 (8th Cir. 2020) (affirming dismissal of employee’s retaliation claim where employee’s alleged complaints of unnecessary surgeries by a coworker were motivated by concerns for the “medical propriety and ethical ramifications” of the surgeries, rather than “a concern over improper billing or the submission of false claims to the government”).

Additionally, the employee must plead the existence of an employer-employee relationship with the defendant. See *Dental Health Programs*, 2020 WL 3064712 at *16–17 (noting that “a defendant must be a party with whom the plaintiff is an employee, contractor, or agent” and concluding that, although plaintiff adequately pleaded a retaliation claim against her employer, plaintiff failed to allege an employment relationship or retaliation by additional affiliated entities); *United States ex rel. Complin v. N. Carolina Baptist Hosp.*, 818 F. App’x 179, 183–85 (4th Cir. 2020) (affirming dismissal of retaliation claim on the basis that “the FCA’s retaliation provision does not provide a remedy where, as here, the alleged retaliation is against a former rather than current employee”).

D. COURTS ARE SPLIT ON THE CAUSATION STANDARD FOR RETALIATION CLAIMS.

Courts are split as to whether an employee must prove that she would not have been terminated “but-for” engaging in protected activity, or if it is enough that she prove that her protected activity was a “motivating factor” in her subsequent termination. See *Nesbitt*, 945 F.3d at 1360 (comparing recent opinions from Third and Fifth Circuits applying a “but-for” standard with opinions from the Sixth, Seventh, and D.C. Circuits applying the more plaintiff-friendly “motivating factor” standard).

The court in *Nesbitt* ultimately adopted the “but-for” standard of causation, reasoning that the use of “because” in the FCA’s anti-retaliation provision indicated that Congress intended a “but-for” standard to apply. *Id.* (noting that the Supreme Court reached the same conclusion when construing similar causal language in Title VII and the Age Discrimination in Employment Act). The First Circuit also recently adopted the “but-for” standard of causation for a similar reason. See *Lestage v. Coloplast Corp.*, 982 F.3d 37, 46 (1st Cir. 2020).

Under either causal standard, courts require more than “implausible inferences and speculation” to support an employee’s claim that her retaliatory termination was pretextual. *Nesbitt*, 945 F.3d at 1357. Several cases in 2020 ruled in favor of defendant-employers where the plaintiff did not sufficiently establish a causal link between the protected activity and the retaliation. For example:

- *Barreto*, 826 F. App’x at 271 – affirmed summary judgment for defendant-employer where “[t]he record plainly reflects that [plaintiff] was notified that her position with [defendant] was ending before she engaged in any allegedly protected activities.”
- *Sherman*, 956 F.3d at 533 – granted summary judgment for defendant where there was no “tight causal link” showing that plaintiff’s termination was “motivated solely by” protected activity; record evidence indicating the plaintiff’s supervisors disapproved of other aspects of his job performance “would not allow a reasonable jury” to find for the plaintiff on his FCA retaliation claim.
- *Bennett*, 2020 WL 1429847, at *7-8 – granted summary judgment for employer upon finding that employer’s discovery of employee’s dishonesty during the application process in the interval between the employee’s allegedly-protected activity and the employee’s subsequent termination “undermine[s] the causal relationship based on temporal proximity”.
- *Katterheinrich v. Al-Razaq Computing Servs.*, No. 5:17-cv-01797, 2020 WL 5847648, at *6 (N.D. Ala. Oct. 1, 2020) – concluded that “a reasonable juror could not find there was a causal connection between the protected activity and the adverse employment action” where there was an intervening six-month gap.

10. ANTI-KICKBACK STATUTE

The Anti-Kickback Statute (“AKS”) prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate) to induce or reward referrals for items or services reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b). The AKS was amended in 2010 to clarify that a claim for government payment “that includes items and services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g).

A. SOME COURTS BROADLY INTERPRET THE DEFINITION OF “REFERRAL” UNDER THE ANTI-KICKBACK STATUTE.

In 2020, the Seventh Circuit reversed a district court’s order after a bench trial, which held that there was no evidence the defendants paid any remuneration with the intent to induce referrals. *Stop Illinois Health Care Fraud, LLC v. Sayeed*, 957 F.3d 743 (7th Cir. 2020). Relying on an “expansive” definition of the term “referral,” the Seventh Circuit explained that referrals “go[] beyond explicit recommendations to include more subtle arrangements. And the inquiry is a practical one that focuses on substance, not form.” *Id.* at 750.

As such, the court vacated the judgment and remanded to utilize “this inclusive understanding of a referral” in considering evidence suggesting the defendants made monthly payments to a non-profit organization in return for access to the organization’s client records, which defendants used to solicit clients. *Id.* at 750–51.

B. COURTS CONTINUE TO ANALYZE WHETHER AND HOW AKS VIOLATIONS SATISFY FCA ELEMENTS OF FALSITY AND MATERIALITY.

In an Eastern District of Pennsylvania case, the relator alleged that a program that helped doctors submit reimbursement claims for a cancer drug, handled administrative appeals when those claims were denied, and gave doctors free replacement vials of the drug when appeals were unsuccessful was a kickback scheme in violation of the AKS and the FCA. *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. 2:02-cv-02964, 2020 WL 4260797, at *3–5 (E.D. Pa. July 24, 2020).

Both sides filed motions for summary judgment. But the court denied summary judgment, finding that the parties had presented countervailing evidence on several AKS and FCA elements. For example, on the element of materiality, the

relator argued that AKS violations are per se material under the FCA and provided evidence that the government frequently initiates FCA enforcement actions to recover money paid on AKS-tainted claims. *Id.* at *13–17. Conversely, the defendant argued that the government had repeatedly declined to intervene in the case despite awareness of relator’s allegations for many years. *Id.* In short, there remained sufficient disputes of fact to preclude summary judgment in either party’s favor.

11. RELATORS’ RIGHTS

A. RELATORS CANNOT PROCEED PRO SE.

One of the most well-known aspects of the FCA is that it allows a private individual (a relator) to file a *qui tam* action on behalf of the government. The FCA “is silent as to whether a private individual can bring a *qui tam* suit *pro se*,” but the consensus among federal courts is that a relator may not do so. *Ford v. Helms Career Inst.*, 825 F. App’x 719, 721 (11th Cir. 2020).

Although a relator’s *pro se* status mandates dismissal of its claims for lack of subject-matter jurisdiction, several federal circuits hold that such dismissal is without prejudice because it is not on the merits—meaning the relator has an opportunity to find a lawyer to handle the case. *See Ajahnnon v. St. Joseph’s Univ. Med. Ctr.*, No. 20-2386, 2020 WL 7694086, at *2 (3d Cir. Dec. 28, 2020) (per curiam) (unpublished); *Taylor v. Multiplan Network*, 817 F. App’x 947 (11th Cir. 2020); *Wojcicki v. SCANA/SCE&G*, 947 F.3d 240, 242 (4th Cir. 2020).

Note, however, that courts may dismiss such claims with prejudice if they are deemed frivolous. *See Downey v. United States*, 816 F. App’x 625, 627 (3d Cir. 2020) (summarily affirming district court’s sua sponte dismissal of *pro se* litigant’s claims—including his FCA claim—as frivolous under 28 U.S.C. § 1915(e)(2)(B)(i)); *Genrette v. Bank of New York Tr. Co., N.A.*, 808 F. App’x 77, 78 (3d Cir. 2020) (same).

B. RELATORS MAY BE ENTITLED TO A SHARE OF PROCEEDS RECOVERED SEPARATELY BY GOVERNMENT AUDITS, AS AN “ALTERNATE REMEDY” UNDER 31 U.S.C. § 3730(C)(5).

One of the options available to the government in an FCA case is to pursue “any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty.” 31 U.S.C. § 3730(b)-(c).

If the government declines to intervene in the *qui tam* action and instead pursues an “alternate remedy” in another proceeding, the FCA expressly states that the relator “shall have the same rights in such proceeding as such person would have had if the action had continued under this section.” 31 U.S.C. § 3730(c)(5). 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).

The purpose of this provision is to ensure that a relator is not excluded from any recovery after assuming sole risk and responsibility of the *qui tam* action if the government elects not to intervene. See *United States ex rel. Guardiola v. Renown Health*, 442 F. Supp. 3d 1319, 1328 (D. Nev. 2020) (explaining that without this protection, “relators will be less likely to engage in costly *qui tam* suits if, after years of litigation, they find out their claims have already been recovered” through an alternate remedy), *appeal filed*, No. 20-15831 (9th Cir. May 1, 2020).

In *Guardiola*, the relator filed a *qui tam* action in 2012, alleging that the defendant submitted improper billing for government-funded health insurance. *Id.* at 1321. The government declined to intervene and the relator proceeded with the *qui tam* action individually, ultimately reaching a \$9.5 million settlement in 2016, of which the relator was awarded a share of \$1.7 million. *Id.* at 1322.

But the relator learned prior to the settlement that the government had separately recovered

\$3.5 million from the same defendant for improper billing practices after CMS conducted a series of audits, beginning in 2010 and continuing for the duration of the *qui tam* litigation. *Id.* at 1323. The relator argued that she was entitled to a portion of those proceeds, in addition to her recovery in the *qui tam* action, because the audit process constituted an “alternate remedy” under § 3730(c)(5).

In response, the government argued that its recovery from the audits was not an “alternate remedy” because: (1) the audit process commenced two years prior to the filing of the *qui tam* action and three years prior to the government’s decision not to intervene; (2) the government had no duty to prevent the CMS audit process from interfering with the *qui tam* action; and (3) the government’s recovery from the audits did not “entirely preclude [the relator] from all recovery” in the *qui tam* action. *Id.* at 1325.

The district court ruled in favor of the relator, reasoning that the audit process was an “alternate remedy” under the FCA and that the relator was entitled to a share of the audit proceeds. *Id.* The court found it significant that the CMS audit process effectively allowed the government to interfere with the relator’s *qui tam* action even after the government declined to intervene. *Id.* at 1327. Specifically, the government failed to either cease the CMS audits or issue a timely litigation hold, and the proceeds recovered by the audit could otherwise have been included in the relator’s settlement with the defendant. *Id.* at 1326. So, the court awarded the relator a 29% share of the \$3.5 million recovered through the audits. The government has appealed the decision to the Ninth Circuit.

C. THE FCA ADDRESSES FRAUD AGAINST THE GOVERNMENT, NOT BY THE GOVERNMENT

While the *pro se* status of the plaintiff in a recent opinion by the D.C. district court provided

an independent basis for dismissing the suit, the court relied on a different—and more fundamental—holding regarding the “nature of the False Claims Act[.]” *Ndoromo v. Barr*, No. 1:19-cv-03781, 2020 WL 5107546, at *6 (D.D.C. Aug. 31, 2020).

The plaintiff in *Ndoromo* alleged that the government violated the FCA by successfully pursuing civil forfeiture against him after he was convicted of healthcare fraud and money laundering. But the court dismissed the claim, noting that the FCA is “meant to ensure that funds are not falsely taken *from* the government” and therefore cannot be used to “allege that *the government has falsely taken funds*’ from the plaintiff. *Id.*

12. OTHER NOTABLE DECISIONS

A. COURTS GENERALLY LACK JURISDICTION OVER FCA APPEALS FILED BY NONPARTIES.

The Ninth Circuit held that it lacked jurisdiction over an appeal of an FCA claim filed by a nonparty. *United States ex rel. Alexander Volkhoff, LLC v. Janssen Pharmaceutica N.V.*, 945 F.3d 1237 (9th Cir. 2020). After the defendants moved to dismiss a *qui tam* complaint filed by Alexander Volkhoff, LLC, Volkhoff’s counsel filed an amended complaint that replaced Volkhoff with Jane Doe as the relator—because LLCs lack standing to assert a claim. The district court dismissed the amended complaint pursuant to the first-to-file bar. 31 U.S.C. § 3730(b)(5). It also held that Jane Doe had not demonstrated a need to proceed anonymously.

Volkhoff filed an appeal that did not mention Jane Doe, and Doe did not appeal separately. The Ninth Circuit dismissed the appeal on jurisdictional grounds. Volkhoff ceased being a party to the case when it was removed as the relator, and nonparties may only appeal a decision under “exceptional circumstances”

that did not apply. The court also rejected Volkhoff’s argument that it should infer from the Notice of Appeal that Jane Doe intended to appeal, commenting that “we do not accept the proposition that an LLC is interchangeable with a natural person.” *Id.* at 1245.

B. GOVERNMENT OFFICIALS CANNOT INVOKE QUALIFIED IMMUNITY TO SHIELD THEMSELVES FROM FCA CLAIMS.

Qualified immunity is not an available defense for government officials sued under the FCA. *United States ex rel. Citynet, LLC v. Gianato*, 962 F.3d 154 (4th Cir. 2020). After a district court deferred a ruling on whether two West Virginia officials could claim qualified immunity as a defense to a *qui tam* claim, the Fourth Circuit clarified that qualified immunity does not apply to protect government officials from claims against them for fraud under the FCA. The court observed that “the state of mind required to establish liability under the FCA is also sufficient to preclude immunity protection, and therefore immunity cannot protect a public official from a suit alleging a claim under the FCA.” *Id.* at 160.

C. FCA DAMAGES MAY—OR MAY NOT—BE CALCULATED BASED ON FULL CONTRACT VALUE.

The Ninth Circuit affirmed a district court’s calculation of damages as the entire value of the contract at issue. In *Ellis v. Zheng*, the court explained:

Because the FCA is concerned with fraud on the government, damages are determined not by how much [defendant] overcharged the [relators], but rather by how much [defendant] overcharged the government—that is, the amounts she received from the government without lawful entitlement. . . . [Defendant] would not be entitled to any funds from the

government if, as occurred here, she failed to comply with the terms of the agreement. Accordingly, the damages owed are the entire amount [defendant] received from the government.

799 F. App'x 551, 552 (9th Cir. 2020) (mem.), *cert. denied*, No. 20-210, 2020 WL 6385805 (U.S. Nov. 2, 2020). The court acknowledged that this resulted in “substantial” penalties, but explained that the “FCA deliberately prescribes harsh penalties, reflecting Congress’s judgment that committing fraud on the government is a serious offense.” *Id.*

In contrast, the First Circuit held that a relator was not entitled to recover the entire price of a contract as FCA damages where the government received some benefit from the services provided under the contract. *See United States ex rel. Concilio De Salud Integral De Loiza, Inc. v. J.C. Remodeling, Inc.*, 962 F.3d 34, 44 (1st Cir. 2020), *petition for cert. docketed*, No. 20-781 (U.S. Dec. 8, 2020).

The relator, a nonprofit providing healthcare services to the uninsured, used federal grant funds to repair its roof. The defendant was hired to complete the repair, offering a 15-year warranty on the roof. Within a year, the roof began leaking again and relator filed a *qui tam* action alleging that the defendant misrepresented its services, defrauded the relator, and illegally appropriated the full amount of federal funds. *Id.* at 37-38. After a seven-day jury trial, the defendant was found to have violated the FCA. But the court imposed only a \$5,500 civil penalty as the relator did not attempt to provide any evidence of actual damages until after discovery was complete and the pretrial report had been submitted; the relator’s attempt to amend the pretrial report was denied.

On appeal, the relator argued that it was entitled to damages equal to the full contract price. But the First Circuit disagreed, explaining that damages are instead measured by a “benefit of the bargain analysis, under which “[t]he Government’s actual damages are equal to the difference between the market value of the [goods] it received and retained and the market value that the [goods] would have had if they had been of the specified quality.” *Id.* (quoting *United States v. Bornstein*, 423 U.S. 303, 316 n.13 (1976)). The full contract price is only awarded when the government received no tangible benefit or value. *Id.* at 44. So, the First Circuit affirmed the district court’s denial of the relator’s motion to amend the pretrial report.

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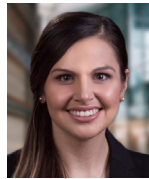
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