

Reprinted from Health Law Handbook, 2026 Edition, with permission from Thomson Reuters. Copyright © 2026. Further use without permission of Thomson Reuters is prohibited. For further information about this publication, please visit <https://legal.thomsonreuters.com/en/products/law-books>, or call 800.328.9352.

A False Claims Act Timeline: From Investigation Through Resolution

Brandon C. Helms and Liza P. Sawyer

INTRODUCTION

1.0 BASIC FEATURES OF THE FCA

1.1 The Elements of an FCA Claim

1.2 The Potential Damages

1.3 Overview of FCA Investigations

2.0 LIFECYCLE OF A GOVERNMENT-INITIATED FCA INVESTIGATION

2.1 The Investigative Team

2.2 Initiating an FCA Investigation

2.3 Settlement Discussions or Other Next Steps

3.0 LIFECYCLE OF RELATOR-INITIATED FCA INVESTIGATIONS

3.1 The Qui Tam Complaint and Written Disclosure

3.2 The Seal Period

3.3 Seal Extensions and Good Cause

3.4 FCA Investigation Time Estimate

4.0 BREAKDOWN OF A GOVERNMENT INVESTIGATION

4.1 Review of Legal and Regulatory Framework

4.2 Damages Assessment: Data Analysis and Statistical Sampling

4.3 Interviews with Relators and Witnesses

4.4 Expert Opinions

4.5 Civil Investigative Demands to Defendants and Third Parties

4.6 Defending a CID

4.7 Review, Negotiations, and Possible Settlement

4.8 Government Decision-Intervention, Declination, or Dismissal

5.0 LITIGATION AFTER INTERVENTION OR DECLINATION

5.1 Motion Practice and Discovery

5.2 Trial

5.3 Case Example After Lengthy Seal Period

CONCLUSION

INTRODUCTION

Congress enacted the modern False Claims Act (FCA)¹ to spur the Executive Branch to more aggressively combat fraud committed by government contractors.² It has since evolved into the most powerful civil enforcement mechanism available to federal enforcement agencies.³ The statute serves two principal functions: (1) deter fraudulent acts against the government and (2) recoup funds when fraud does occur.⁴ To achieve those goals, as the U.S. Supreme Court has observed, the FCA imposes “significant penalties on those who defraud the Government” such that they are “essentially punitive in nature.”⁵ Because almost every health care provider receives federal funds from government payers like Medicare and Medicaid or through research grants, such as National Institutes of Health (NIH) grants,

¹31 U.S.C. §§ 3729–3733.

²131 CONG. REC. 22,322 (1985) (Senator Grassley, the original sponsor in the Senate, stating the statute was necessary because “the Government bureaucracy [was] ... unwilling to guard against or aggressively punish fraud”); 132 CONG. REC. 22,340 (1986) (Representative Bedell arguing the FCA was necessary because “in many cases, the authorities will not prosecute for political reasons”).

³*What Is the False Claims Act?*, NATIONAL WHISTLEBLOWER CTR. (last visited Jan. 16, 2026), <https://www.whistleblowers.org/protect-the-false-claims-act/> (“Since the False Claims Act was signed into law, it has become the most successful anti-fraud act in the United States.”).

⁴See 5B FED. PROC., L. ED. § 10:49 (Dec. 2025) (“The chief purpose of the penalty provided by the False Claims Act is to secure restitution for the government of money taken from it by fraud”).

⁵*Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 180, 182 (2016).

the health care industry has become the primary target of FCA actions.⁶

Although “Congress wrote [the FCA] expansively ... ‘to reach all types of fraud, without qualification, that might result in financial loss to the Government,’ ”⁷ the Supreme Court has recently cautioned that the FCA should not be an “all-purpose antifraud statute” nor a “vehicle for punishing garden-variety ... regulatory violations.”⁸ Nonetheless, largely due to the incentives for whistleblowing, that is the trend seen in the courts. The present enforcement environment—marked by an ever-increasing volume of qui tam actions,⁹ heightened federal oversight, sophisticated data analytics, increased cooperation between federal agencies,¹⁰ and partnerships with state authorities—has raised the stakes for health care providers, government contractors, and any entity participating in federal programs. Indeed, for companies in the health care industry, having to grapple with potential FCA violations—either through a self-disclosure process or in defense of a government investigation—is more a question of “when” than “if.” Yet, despite significant changes in investigatory focus and techniques, and with the caveat that no two FCA investigations are exactly

⁶Of the more than \$6.8 billion in False Claims Act settlements and judgments reported by the Department of Justice in FY 2025, over \$5.7 billion related to matters involving the health care industry. Press Release, *False Claims Act Settlements and Judgments Exceed \$6.8B in Fiscal Year 2025*, U.S. DEP’T OF JUSTICE, OFFICE OF PUB. AFFAIRS (Jan. 16, 2026), <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025>.

⁷*Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003).

⁸*Escobar*, 579 U.S. at 194.

⁹“Qui tam” actions, commonly known as “whistleblower” actions, allow private individuals to bring suit on behalf of the government against violators of purported fraud. See 31 U.S.C. § 3730(b), (c). The 1,297 qui tam suits filed in FY 2025 broke the prior record set in 2024 of 980 such cases. Press Release, *False Claims Act Settlements and Judgments Exceed \$6.8B in Fiscal Year 2025*, U.S. DEP’T OF JUSTICE, OFFICE OF PUB. AFFAIRS (Jan. 16, 2026), <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025>.

¹⁰See, e.g., Press Release, *DOJ-HHS False Claims Act Working Group*, U.S. DEPT. HEALTH & HUM. SERVS. (July 2, 2025), <https://www.hhs.gov/press-room/hhs-doj-false-claims-act-working-group.html>.

alike, FCA enforcement has developed into a somewhat predictable process and timeline of events.

This article provides a comprehensive review of the lifecycle of an FCA investigation and will concurrently offer strategies for defending each stage, with an aim towards narrowing and terminating the investigation as quickly and painlessly as possible. From the filing of a qui tam complaint by a relator¹¹ or the initiation of a government-led inquiry, all the way through to settlement, declination by the government, or litigation with the government or a relator—with stops in between to discuss various procedural steps—this article breaks down what to expect and how to navigate each twist and turn.

1.0. BASIC FEATURES OF THE FCA

1.1. The Elements of an FCA Claim

The FCA establishes liability for any person or entity who knowingly defrauds the United States, causes another to submit fraudulent claims, conspires to commit fraud, or knowingly retains an overpayment from the federal government.¹² Knowingly means actual knowledge, acting in deliberate ignorance of the truth, or acting in reckless disregard of the truth.¹³ In addition, to violate the FCA, the falsity of the claim must be material to the government's decision to pay.¹⁴ Hence, to violate the FCA, there must be (1) a false statement or scheme; (2) made with the requisite scienter

¹¹The citizens who bring actions on behalf of the government under 31 U.S.C. § 3730(b) are known as “relators.”

¹²§ 3729(a).

¹³§ 3729(b)(1). The Supreme Court recently clarified that this scienter prong hinges on the defendant's subjective belief rather than what an objectively reasonable person would have thought. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023).

¹⁴§ 3729(a) & (b)(4); see also *Escobar*, 579 U.S. at 181 (“a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act”).

(knowledge); (3) that was material; and (4) that caused the government to pay money or forfeit money it was owed.¹⁵

1.2. The Potential Damages

Damages for FCA violations can be catastrophic. The government is entitled to three times the amount of damages it sustains, plus a per-claim penalty that ranges from \$14,308 to \$28,619.¹⁶ Due to their severity, the Supreme Court has called FCA damages “essentially punitive in nature.”¹⁷ In fact, because FCA penalties can skyrocket, particularly in the health care context where each fee-for-service bill to Medicare or another government payer creates a new per-claim penalty, multiple courts have ruled that FCA damages could be constrained by the Eight Amendment’s prohibition against excessive fines.¹⁸

1.3. Overview of FCA Investigations

The Department of Justice (DOJ) has authority to investigate potential violations of the FCA.¹⁹ This is true whether DOJ opens its own investigation or is alerted to examine potential violations by a whistleblower. The whistleblower-initiated investigations are known as “qui tam” actions.²⁰ The citizens who file them are known as “relators.” DOJ has

¹⁵United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694, 700 (4th Cir. 2014).

¹⁶The per-claim penalty is adjusted each year for inflation. 31 U.S.C. § 3729(a); see also 28 C.F.R. § 85.5.

¹⁷Vermont Agency Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765, 784–85 (2000).

¹⁸See, e.g., Yates v. Pinellas Hematology & Oncology, P.A., 21 F.4th 1288, 1308 (11th Cir. 2021); United States v. Mackby, 261 F.3d 821, 830–31 (9th Cir. 2001); United States v. Aleff, 772 F.3d 508, 512 (8th Cir. 2014); United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 387–89 (4th Cir. 2015).

¹⁹31 U.S.C. § 3730(a).

²⁰§ 3730(c). The constitutionality of the FCA’s qui tam provisions is currently being litigated in multiple courts, and the Supreme Court will likely decide their fate in the near future. See United States ex rel. Polansky v. Exec. Health Res., 599 U.S. 419, 442 (2023) (Kavanaugh, J. & Barrett, J., concurring); *id.* at 449 (Thomas, J., dissenting); United States ex rel. Zafirov v. Fla. Med. Assocs., LLC, Nos. 24-13581, 24-13583 (11th Cir. 2025).

priority in deciding whether and how it wants to investigate a relator's claims, but if the government declines to intervene, the relator can proceed to litigate his or her case with minimal oversight by the government.²¹ At the conclusion of an FCA case, the FCA guarantees the relator at least 15% of any recovery when the government intervenes and at least 25% when the government does not; DOJ, however, retains authority to decide the terms of any settlement and has discretion to award the relator more than the minimum percentage required.²²

2.0. LIFECYCLE OF A GOVERNMENT-INITIATED FCA INVESTIGATION

2.1. The Investigative Team

For health care fraud matters, DOJ Trial Attorneys or Assistant United States Attorneys (AUSAs) work with agents from the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) to investigate potential FCA violations. Less frequently, usually when there is a parallel criminal investigation, DOJ attorneys may also work with FBI agents or DEA agents. In addition, depending on the size of the U.S. Attorney's Office, AUSAs may have assistance from in-office investigators and auditors.

2.2. Initiating an FCA Investigation

There are many ways the government identifies potential targets for investigation. One method is through data analysis. For example, if a physician is an extreme outlier in terms of performing certain procedures and is receiving millions of dollars a year from the government for those procedures, DOJ may investigate why the physician is such an outlier to determine if fraud is occurring. A second way

²¹§ 3730(c)(3).

²²§ 3730(c)(2)(B) & (d). While the FCA states that the percentage "depend[s] upon the extent to which the person substantially contributed to the prosecution of the action," it does not elaborate or provide examples. Likewise, the Justice Manual sets forth factors relevant to determining whether to dismiss a relator's action (§ 4-4.111) and how much credit to give a defendant when settling an FCA action (§ 4.112), but there are no explicit factors to consider for determining a relator's share.

entities become targets of FCA investigations is through tips by commercial insurance companies. Commercial insurance companies employ investigators, and if they determine a provider is committing fraud against the insurance company, it is likely the provider is doing the same to government payers. A third method involves criminal investigations. DOJ may decide for various reasons that a criminal investigation should not proceed to indictment but that a civil FCA claim is still worth pursuing. A fourth source involves past or pending investigations. For instance, if a home health care company is believed to be providing kickbacks to physicians in return for patient referrals, DOJ may investigate any provider that refers patients to the home health care company, and it may investigate other health care companies that receive referrals from the same providers.

Government-initiated investigations inherently begin covertly because the government has control of the investigation from the start and can choose what investigatory techniques to use to remain clandestine as long as possible. When there is no qui tam action, the government is not constrained by an initial 60-day seal period or the need to obtain court orders to maintain secrecy over its investigation.²³ At their desired pace, investigators can analyze Medicare, Medicaid, or other government payer claims data; subpoena third parties for records; and interview former employees and other witnesses.²⁴ This allows investigators to conduct these activities before pursuing methods that are likely to alert a person or company to the existence of an investigation, such as issuing a Civil Investigative Demand (CID) to the target to obtain documents, interrogatory answers, or sworn testimony.²⁵ The timeline surrounding the issuance of a CID to a target of an investigation is discussed later in this article.

²³31 U.S.C. § 3730(b)(2) & (3).

²⁴Some circumstances may compel the government to move with more haste than preferred. For example, cases involving significant patient harm (e.g., lack of medical necessity for surgical procedures) will oblige DOJ investigators to act rapidly to shut down the bad actor. Likewise, fraud schemes on a massive scale demand swift responses.

²⁵§ 3733.

2.3. Settlement Discussions or Other Next Steps

In rare circumstances, settlement negotiations may begin before the issuance of a CID, but usually the parties will not attempt to reach a resolution until the government is satisfied that all relevant documents have been produced, all interrogatories have been answered, and all necessary witnesses have been interviewed—assuming the government believes a violation of the FCA has occurred. The minutiae of those discussions will be addressed in section 4.7.

If negotiations do not result in a settlement and the government still believes an FCA violation has occurred, it must decide whether to file a civil action against the target²⁶ or terminate the investigation. This process will be discussed in more detail in section 4.9. Should the government decide to see the matter through, it will file a complaint in federal district court alleging violations of the FCA and any other causes of action the government believes it can prove. The proceedings in an FCA district court litigation will likewise be discussed later in section 5.0.

3.0. LIFECYCLE OF RELATOR-INITIATED FCA INVESTIGATIONS

3.1. The Qui Tam Complaint and Written Disclosure

While there are some commonalities, the pace and progression of a qui tam investigation differs from a government-initiated investigation. A relator-initiated investigation begins when he or she files a sealed qui tam complaint and provides to the government a “written disclosure of substantially all material evidence and information” the relator possesses.²⁷ The majority of the time, relators are current or former employees of the defendant who have inside access to documents showing the purported fraud.²⁸ Some relators, however, are data miners looking for anomalies or extreme

²⁶ § 3730(a).

²⁷ § 3730(b)(2).

²⁸ When relators are former employees, their complaints often include retaliation allegations under § 3730(h). That section of the FCA allows

outliers, and with the advent of artificial intelligence, the percentage of relators with no ties to the target is likely to increase.

The quality of a relator's complaint can have a significant impact on the course of the government's investigation. Depending on their background and time with DOJ, AUSAs and DOJ Trial Attorneys may not be knowledgeable about health care matters when assigned to an FCA investigation.²⁹ The ideal *qui tam* complaint correctly and thoroughly articulates the relevant statutory and regulatory framework underlying the allegations of fraud, and it lays out in granular detail how a claim to the government was false, who at the defendant entity knew it was false, and why the falsity was material to the government's decision to pay.³⁰ A well-pled complaint cuts down on the time the government has to spend researching relevant laws and regulations, and it allows DOJ to assess whether certain allegations fail as a matter of law before time is spent investigating the underlying facts.

On the flipside, an incomplete, poorly researched, or unclear complaint can complicate the government's job. DOJ does not want to overlook potential fraud merely because a relator makes a feeble attempt to disclose it, but when a prosecutor is responsible for numerous other cases and investigations, a badly written complaint may get less attention. Similarly, if a complaint alleges a multitude of fraudulent schemes, no matter how well-pled they are, out of necessity DOJ may choose to focus on only a few schemes.

Likewise, the level of detail in the written disclosure can

relators to seek relief when they suffer adverse employment actions because of their whistleblowing, including reinstatement, two times the amount of back pay, interest on the back pay, and special damages, including attorneys' fees. *Id.* at (h)(2).

²⁹Even when a prosecutor does have experience with health care matters, it is impossible to know every regulation and the sub-regulatory guidance associated with all possible health care law issues. A well-pled complaint can save a prosecutor hours of research.

³⁰Some jurisdictions, like the Sixth Circuit, also require a relator to identify specific claims that were paid by the government because of the alleged fraudulent scheme. See, e.g., *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 915–16 (6th Cir. 2017). In those jurisdictions, a relator's failure to identify specific claims may impact the government's decision on whether to intervene.

impact the government's investigation and its decision on whether to intervene in the lawsuit. Copies of emails, invoices, or medical records aid the government in deciding how to investigate and whether to expend resources on a particular allegation. Knowing who to interview, what bank records to obtain, what procedures to explore, and what documents to seek from a target can streamline an investigation. A scant disclosure, however, means the government has to start from scratch, which can significantly increase the duration and difficulty of an investigation.

3.2. The Seal Period

Once the government has received the complaint and the written disclosure, the statutory 60-day seal period is triggered for the government to investigate the relator's claims and determine whether it wants to pursue the investigation and potentially intervene in the lawsuit.³¹ DOJ uses the initial 60-day window to make critical early assessments, including: evaluating the legal sufficiency of the relator's complaint, reviewing the relator's evidence, and checking to see if there are any related investigations already pending (criminal investigations, investigations by other districts or components of DOJ, or administrative investigations).

In assessing the complaint, DOJ considers whether the relator's complaint satisfies federal pleading requirements and, specifically, whether the relator pled his or her claims with particularity.³² DOJ further considers whether any jurisdictional bars apply, such as the statute of limitations.³³ DOJ's initial assessment also includes whether the relator's allegations plausibly state an FCA violation.

With respect to the written disclosure, among other things, DOJ investigators review the relator's documentation, assess the relator's credibility, identify missing information and potential avenues of investigation, and compare allegations against known agency guidance. This can include

³¹§ 3730(b).

³²Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.").

³³31 U.S.C. § 3731(b).

reviewing manuals issued by the Centers for Medicare and Medicaid Services (CMS), advisory opinions, HHS-OIG resources, or speaking with representatives from Medicare Administrative Contractors (MACs). Part of this initial review helps DOJ appraise how many subpoenas or CIDs it will have to issue.

3.3. Seal Extensions and Good Cause

The seal period allows the government time to investigate and make its initial assessment of the relator's complaint and disclosure without defendants being tipped off that they are under investigation. This allows the government to consider current or ongoing concerns while the defendant continues to operate as usual—rather than having an unscrupulous defendant delete or alter records or harass or intimidate witnesses. The seal period also protects any criminal investigations that DOJ may start or already have progressing.

Because 60 days is not much time to thoroughly evaluate a relator's allegations to determine whether a violation of the FCA has occurred, the FCA permits the government to seek extensions of the seal period to allow the government to continue investigating without alerting the defendant to the existence of the investigation,³⁴ and courts have expounded on the purposes for the seal.³⁵ At any given time DOJ investigators may be undertaking numerous investigations, so having a mechanism available to extend the opportunity to investigate a relator's claim helps ensure each potential FCA violation receives adequate consideration. The government typically seeks three- or six-month extensions of the seal period, but DOJ's extension practice can vary depending on the jurisdiction and the assigned judge.

To obtain an extension of the seal period, the government must show "good cause."³⁶ Courts broadly interpret good

³⁴§ 3730(b)(3).

³⁵See, e.g., *Polansky*, 17 F.4th at 387, *aff'd* 599 U.S. 419, 439 (2023); *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 26, 35 (2016); *United States ex rel. Grupp v. DHL Express (USA), Inc.*, 742 F.3d 51, 54 (2d Cir. 2014).

³⁶§ 3730(b)(3).

cause, noting that it is flexible and nonburdensome.³⁷ Because of the amorphousness of good cause, judges vary widely on what details DOJ must disclose to justify extending seal periods. Some courts grant extensions based on boilerplate recitations that the government is still investigating and needs more time. Other courts require specific details about what the government did during the most recent seal period and what it plans to do should the requested extension be granted. It is difficult to assess whether courts in general are becoming more or less demanding when it comes to good cause, because DOJ's motions for extensions of the seal typically remain sealed even after *qui tam* complaints are unsealed.

Nonetheless, judicial patience is not limitless. By way of example, a district court in the Eastern District of Louisiana, having previously warned the government that its fourth extension in roughly eighteen months would be its last, denied a fifth motion to extend: “[t]he court has already been more than generous to the government in allowing extensions, and the government has had ample time to consider whether it will intervene in the case.”³⁸ Similarly, after three extensions spanning eighteen months, a Northern District of California court declined a fourth extension: “[d]efendants have a legitimate interest in building their defense while the evidence is still fresh. The public has a right to monitor the activities of government agencies and the courts.”³⁹ Thus, while most courts authorize several extensions without much explanation by the government—implicitly or explicitly recognizing the complexity of health care fraud investigations that often involve voluminous electronic records, complex regulatory considerations, and expert analyses—DOJ attorneys should be aware that FCA investigations cannot drag on forever.

³⁷ 31 U.S.C. § 3730(b)(2)-(4)

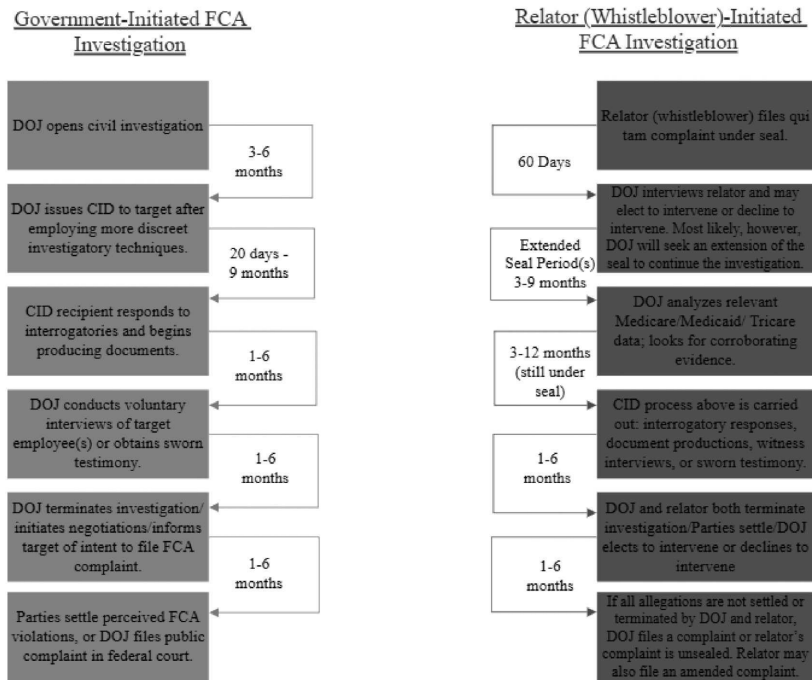
³⁸ *United States ex rel. LaCorte v. Smithkline Beecham Clinical Labs., Inc.*, No. 97-0942, 1998 WL 840012, at *2 (E.D. La. 1998).

³⁹ *United States ex rel. Costa v. Baker & Taylor, Inc.*, 955 F. Supp. 1188, 1189-90 (N.D. Cal. 1997); see also *United States ex rel. Brasher v. Pentec Health, Inc.*, 338 F. Supp. 3d 396, 401 (E.D. Pa. 2018); *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 912 F. Supp. 2d 618, 623 (E.D. Tenn. 2012); *United States ex rel. Smith v. Serenity Hospice Care, LLC*, No. CV 313-001, 2014 WL 4269063 (S.D. Ga. Aug. 28, 2014).

3.4. FCA Investigation Time Estimate

No two investigations are exactly alike, but there are common timeframes associated with each stage of an investigation. Here is a general timeline for FCA investigations without any unexpected delays:

A Sample False Claims Act Timeline



While the government endeavors to advance investigations with diligence, many factors influence how quickly an investigation can proceed. Examples abound of FCA investigations remaining under seal for years before the government intervenes or a defendant settles. And once the government does intervene, the court and the defendant have considerable influence over how speedily an FCA case moves toward resolution. As those who have litigated in federal court know, lawsuits rarely move as quickly as the parties would like.

4.0. BREAKDOWN OF A GOVERNMENT INVESTIGATION

As noted above, an FCA investigation typically includes several interconnected components, including legal analysis, review of documentary evidence, interviews with relevant parties, and issuance of CIDs. These steps are all necessary before DOJ can decide whether to bring a civil action under

31 U.S.C. § 3730(a) or intervene in a qui tam action under § 3730(b)(4).

4.1. Review of Legal and Regulatory Framework

DOJ investigators review statutes, regulations, CMS guidance, HHS-OIG advisory opinions, applicable case law, and other legal authorities against the relator's complaint to understand whether the issues presented hold legal merit. DOJ may also consult Medicare billing manuals or other specialized guidance specific to the allegations at issue.

DOJ will likely give more weight to an alleged violation of a statute, regulation, or National Coverage Determination (NCD) as compared to a violation of sub-regulatory guidance like a Local Coverage Determination (LCD). This is because under Supreme Court precedent, interpretive rules that do not originate from notice and comment periods “do not have the force of law.”⁴⁰ For this reason, DOJ's Justice Manual reiterates that guidance documents do not bind the public or have the force and effect of law.⁴¹

Should a defendant find themselves facing an investigation premised on a violation of an LCD⁴² or other sub-regulatory guidance document, they should reference the above cases and DOJ guidance documents in correspondence to federal prosecutors. DOJ attorneys may be persuaded to end their investigations.

⁴⁰*Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995); *Azar v. Allina Health Servs.*, 587 U.S. 566, 568, 583–84 (2019).

⁴¹U.S. JUSTICE DEPT., JUSTICE MANUAL, 1-19.000 (Apr. 2022). The Attorney General recently emphasized this position in a memo dated February 5, 2025. Memorandum, Office of the Attorney General, General Policy Regarding Charging, Plea Negotiations, and Sentencing, n.1 (Feb. 5, 2025), <https://www.justice.gov/ag/media/1388541/dl>; see also Memorandum, Office of the Attorney General, Issuance and Use of Guidance Documents By the Dept. of Justice (July 1, 2021) <https://www.justice.gov/d9/2022-12/attorney-general-memorandum-issuance-and-use-of-guidance-documents-by-the-doj712021.pdf>.

⁴²See 42 C.F.R. § 405.1062 (stating ALJs are “not bound” by LCDs but will “give substantial deference to these policies”).

4.2. Damages Assessment: Data Analysis and Statistical Sampling

Health care fraud cases often involve payer data from Medicare, Medicaid, the U.S. Department of Veterans Affairs (VA), and other federal payors. When tens of thousands or hundreds of thousands of claims may be at issue, DOJ investigators do not have the time or resources to review each and every single claim to determine whether they are tainted by the alleged fraudulent scheme. Therefore, as a proxy, DOJ reviews a representative sample of claims, usually 100 or more, and then uses statistics to extrapolate damages across large datasets.⁴³ To make sure samples are statistically valid to stand up in court, DOJ utilizes the services of in-house or external statisticians.

If litigation ensues, defendants often use *Daubert* motions to attack the methodology and findings of DOJ's statisticians.⁴⁴ Moreover, defendants use their own experts to conduct sample analyses and extrapolate against the larger dataset. Since the burden of proof is on the government, the defendant benefits from any ambiguity or sources of contention that it can introduce into the investigation or later trial.

4.3. Interviews with Relators and Witnesses

Almost always, the first interview the government conducts is with the relator. Interviewing the relator is essential for exploring what witnesses may be helpful to the government's investigation, what documents may exist to help prove the alleged fraud, and what arguments the defendant may have in response to relator's allegations.

Interviewing the relator also helps the government assess the relator's credibility, but contrary to popular belief among defendants, the relator's penchant for truthfulness has little impact on the investigation. Even the most trustworthy relator makes for a poor witness at trial because they have a

⁴³See *United States v. Hodge*, 933 F.3d 468, 475 (5th Cir. 2019) (permitting the use of statistical sampling); *United States ex rel. Calderon v. Carrington Mortgage Servs., LLC*, 70 F.4th 968, 980 (7th Cir. 2023) (applying the analysis of *Hodge* and statistical sampling to its controversy).

⁴⁴See *Hodge*, 933 F.3d at 477 (stating the defendants filed a *Daubert* motion to challenge statistical sampling).

financial interest in the outcome of the case⁴⁵ and thus an easily exploited bias on cross-examination. As a result, most federal prosecutors build their FCA cases with the expectation that the relator will not be a witness at trial, let alone a star witness.

After interviewing the relator, DOJ will interview other witnesses—both before and after issuing a CID. Usually before serving a CID, DOJ will interview former employees of the defendant whom the relator believes will be helpful to the government and will not alert the defendant to the existence of an FCA investigation. DOJ may also interview, or serve subpoenas or CIDs on, non-target medical providers. Depending on the type of allegations involved, DOJ may also interview Medicare and Medicaid beneficiaries, especially if the allegations involve questions of medical necessity or questions regarding whether services that were billed were actually provided. Once a CID has been served and the defendant is aware of the investigation, DOJ will be willing to conduct more overt actions, such as interviewing current employees.⁴⁶

4.4. Expert Opinions

Some FCA investigations do not require expert assistance. For example, FCA cases involving violations of the Anti-Kickback Statute (AKS)⁴⁷ require obtaining evidence that a medical provider was induced by remuneration to perform a service or refer a patient for a service, and that a claim was submitted to the government as a result of the inducement. Usually, AKS investigations do not necessitate assistance from a medical expert.

In contrast, FCA cases alleging a lack of medical necessity for a certain procedure or service, or allegations that procedures were performed so poorly that they were worthless and thus lacked medical necessity, almost always require a medical expert to review medical charts. In the same man-

⁴⁵Depending on whether the government intervenes, a relator is entitled to between 15% and 30% of any recovery. 31 U.S.C. § 3730(d)(1) & (2).

⁴⁶DOJ may also seek sworn deposition, similar to a deposition, under § 3733(a)(1)(C), (a)(2)(D) & (h).

⁴⁷42 U.S.C. § 1320a-7b(b).

ner, FCA cases based on a violation of a National Coverage Determination (NCD) likely require expert testimony to demonstrate how the defendant failed to meet the requirements of the NCD. As noted above, these cases may also require a statistician to perform a statical analysis to extrapolate across a larger dataset.

DOJ does have some in-house resources like nurses or MAC employees available to conduct coding reviews, and statisticians, available to perform statistical analyses. For medical necessity or quality of care reviews, DOJ usually retains an outside expert, and hiring the right person with the right experience can take time.

A company defending an investigation involving experts should look for ways to poke holes in the analysis performed by the government's expert. Sometimes this can be done without the defendant engaging its own expert, but a defendant's pushback can be more persuasive to DOJ or a court when buttressed by the defendant's own expert. Moreover, a defendant can better identify potential opportunities to undermine a government expert by retaining its own expert.

4.5. Civil Investigative Demands to Defendants and Third Parties

A CID, which is similar to a subpoena, allows DOJ to compel the production of documents, written responses, and oral testimony from individuals or entities.⁴⁸ To issue a CID, DOJ need only have reason to believe that the defendant or a third party has evidence material to a potential violation of the FCA.⁴⁹ The authority to issue a CID, vested in the Attorney General, has been delegated to the Assistant Attorney General for the Civil Division and further extended to U.S. Attorneys in monitored and delegated cases.⁵⁰

The issuance of a CID follows a formal approval process within DOJ to ensure compliance with statutory and regulatory requirements. Generally, to obtain approval from supervisors to issue a CID, an AUSA or DOJ Trial Attorney

⁴⁸ § 3733(a)(1)(A)–(C).

⁴⁹ § 3733(a)(1).

⁵⁰ 28 C.F.R. Ch. 1, Pt. 0, App. Subpt. Y, § 5.

must write a memo explaining the investigation, the need for the CID, and efforts made to narrowly tailor the scope of the CID. Unlike discovery requests in a litigation, the government can only issue CIDs before it commences a civil lawsuit or intervenes in a qui tam action.⁵¹ In practice, this means the government must obtain the bulk of the evidence it needs to prove its case before it files suit.

Once served, CID recipients have 20 days to respond.⁵² If a recipient fails to respond, or inadequately responds, DOJ may petition a federal district court to enforce the CID (i.e., move to compel).⁵³ In the same vein, a recipient may move to modify or quash the CID.⁵⁴

4.6. Defending a CID

Responding to a CID, particularly if it is clear that the recipient is the target of DOJ's investigation, can be perilous for the recipient. After all, the government is asking a person or company to produce documents that may shine a spotlight on fraudulent activity, rendering them liable for treble damages and per-claim penalties.⁵⁵ For many of the same reasons that companies retain outside counsel to handle litigation, the authors recommend that companies engage outside counsel to assist with responding to CIDs. Among other benefits, outside counsel can act as an intermediary between DOJ and the CID recipient and help the CID recipient avoid being put on the spot to answer difficult questions.

Because the 20-day statutory deadline provides scant time for a CID recipient to collect and review documents, answer interrogatories, or prepare a witness for a deposition, one of the first things a CID recipient or its outside counsel should do is seek an extension from DOJ to respond to the CID. In almost all instances, DOJ will be willing to grant some amount of extra time to comply. Among other factors, the scope of the CID, the urgency of DOJ's need for the informa-

⁵¹ 31 U.S.C. § 3733(a)(1).

⁵² § 3733(a)(2)(E).

⁵³ § 3733(j)(1).

⁵⁴ § 3733(j)(2) & (3). Because the "reason to believe" threshold is such a low bar to meet, motions to quash CIDs in their entirety are generally unsuccessful.

⁵⁵ § 3729(a)(1).

tion, and the sophistication of the CID recipient will affect how much of an extension DOJ is willing to give.

In addition to seeking an extension, a CID recipient should issue a legal hold to preserve all potentially relevant documents and electronically stored information (ESI). Failure to do so can result in spoliation claims and increased exposure for the CID recipient, and it can hinder the recipient's ability to defend itself should it have to litigate.

Next, recipients should attempt to negotiate with DOJ to narrow the scope of the CID and to try to reduce the burden of compliance. For example, CIDs note a relevant timeframe for the documents or information being sought (or should if they do not). If that timeframe spans many years, DOJ may be willing, at least on an initial basis, to limit the response to a shorter timeframe. As another example, if a CID requires the search and collection of ESI, which many do, the recipient should attempt to negotiate with DOJ limits on custodians and search terms.⁵⁶

Likewise, a CID recipient could persuade DOJ to agree to a rolling production that permits the recipient to produce documents on an ongoing basis, usually on an agreed-upon timeline. Whatever arrangement is negotiated, it is critical that the recipient follows through on the commitments it makes during negotiations. Failure to meet deadlines or negotiated terms can damage credibility, escalate enforcement risks, and eliminate the possibility of getting future extensions or concessions from DOJ. Moreover, maintaining open communication with DOJ attorneys fosters transparency and may lead to more favorable outcomes.

Before any documents are produced, a CID recipient or its outside counsel should review potentially responsive documents to make sure they are relevant and not privileged. Ideally, all documents marked for production should also be reviewed for potential problems so any ambiguous documents can be explained, and to make sure the CID recipient is prepared to address any questions from DOJ.

⁵⁶Some CID recipients unilaterally decide to search only certain custodians' documents or unilaterally develop their own search terms. While this approach has its benefits, including likely streamlining the response and reducing costs, it could complicate matters and lead to more costs on the back end should DOJ question whether the recipient has been reasonably diligent in responding to the CID.

Similarly, conducting an internal investigation in parallel to the government's investigation is essential. First, it helps to understand the facts and craft a coherent narrative that rebuts the government's theories and presumptions. This narrative can guide communications with DOJ and inform strategic decisions about whether to initiate or engage in settlement discussions.

Second, an internal investigation will reveal whether any compliance issues do exist and, to the extent they do, will help the company establish a corrective action plan to terminate the non-compliant practice and prevent it from happening again in the future. The benefits of corrective action are many, including cutting off FCA liability for any violations, demonstrating that the defendant is serious about compliance obligations, and potentially gaining lenience from DOJ when negotiating a settlement, as discussed later.

Third, even if an internal investigation fortuitously reveals that the focus of the government's investigation is not, in actuality, a compliance problem, the investigation may make the CID recipient aware of peripheral issues that would be problematic if disclosed to DOJ. In that situation, the recipient could fix any issues, reimburse any overpayments, or disclose to OIG or CMS any concerns before DOJ expands its investigation to include the tangential issues.

At this point, many readers are likely thinking that this all sounds great hypothetically, but the costs must be astronomical, not only in terms of legal fees but also in terms of employee work hours. There is no sugarcoating it: the cost of defending an FCA investigation, even before any settlement is negotiated or any cause of action is litigated, can be crushing. For this reason, many FCA defendants settle just to end the investigation.⁵⁷ But for those who cannot or do not want to settle, they have to prepare themselves for an expensive and grueling marathon. Ultimately, defending a CID requires balancing cooperation with protecting legal rights. A proactive approach—combining negotiation, internal review, strategic communication, and cost savings

⁵⁷See, e.g., Benjamin J. McMichael, et al., *A Constitutional False Claims Act*, 102 WASH. U. L. REV. 677, 680 (2025) (“With individual FCA cases sometimes involving thousands, or tens of thousands, of individual claims, the treble damages and penalties add up quickly, providing obvious incentives for defendants to settle for the damages claims.”).

where possible—can significantly mitigate the burden and potential liability associated with these investigative demands.

4.7. Review, Negotiations, and Possible Settlement

Once DOJ receives documents, depending on the volume, it will likely take months for the investigators to review the information. While they review, DOJ investigators will question whether they have everything they need, whether the documents support an FCA violation, and what other types of evidence they may need, including obtaining sworn testimony. If an expert is used, like in a medical necessity case, the review period will likely last longer.

Discussions between the government and the recipient, whether through counsel or not, may occur during this period. It is more likely, however, for the defendant to produce documents to DOJ and hear nothing in response. Similarly, if defense counsel poses questions to DOJ about the nature of the investigation or the government's timetable, DOJ is likely to provide nothing of substance. This waiting game can wear on defendants.

At some point, DOJ will decide it has received enough information to determine whether an FCA violation occurred. If the answer is yes, DOJ will inform the defendant what it believes single damages are—in a health care fraud case, typically the amount that Medicare, Medicaid, and other government payers paid the defendant for services tainted by fraud—and what multiplier DOJ believes should be applied to the single damages to settle FCA liability (up to three times under the FCA, but DOJ usually settles somewhere around two times the single damages amount).⁵⁸ The more money involved, the more people at DOJ who need to approve the demand before it is made; in some instances, an investigation previously handled solely by a U.S. Attorney's Office may now require oversight and approval from the chain of command in the Attorney General's Office.⁵⁹ Follow-

⁵⁸31 U.S.C. § 3729(a)(1).

⁵⁹U.S. JUSTICE DEPT., JUSTICE MANUAL, 4-3.100.

ing department guidance to hold individuals accountable,⁶⁰ DOJ may also specify that certain bad actors within the defendant's employ need to be held personally responsible for a portion of the settlement.

Before presenting their demand, DOJ attorneys must consider a variety of factors. One is the degree of cooperation by the defendant beyond just simply responding to the CID; maximum credit requires being proactive in voluntarily disclosing wrongdoing and identifying responsible individuals.⁶¹ Other factors include how hard the case will be to prove at trial, how much it will cost to collect on a claim in comparison to the expected recovery, and the need to compromise to prevent injustice.⁶² DOJ must also consider the nature and seriousness of the FCA violation, the harm or risk of harm from the violation, the scope of the violation, and the ability for a wrongdoer to satisfy an eventual judgment.⁶³

Defendants may not yet believe they need to settle when DOJ makes a demand. If that is the case, federal prosecutors may be willing to conduct a reverse proffer to highlight for the defendant some of the evidence that the government believes supports an FCA violation. Assuming the defendant is ready to engage in settlement discussions, negotiating with the government is not like negotiating with a private party that has its own legal costs to worry about. There is no nuisance value from the government's perspective, and because federal prosecutors are expected to consider a number of elements in the Justice Manual before making a demand, there may be little room for negotiation. But that is not always the case, and defendants should do everything they can to (1) undermine the government's single damages calculation and (2) persuade DOJ that the relevant factors warrant a smaller multiplier than DOJ proposed. Throughout the CID process, as discussed above, the defendant should have been working on a rebuttal narrative and conveying it to the government at all opportunities. If that has not happened, or if the defendant has not fully presented

⁶⁰*Id.* at 4-3.100.

⁶¹*Id.* at 4-3.100(3).

⁶²*Id.* at 4-3.200.

⁶³*Id.* at 4-4.112.

its story, now is the time to point out the flaws in the government's case and paint the defendant in the best possible light.

Occasionally, a defendant may want to settle but cannot afford to pay what it agrees is the single damages amount plus a multiplier. In that situation, a defendant may opt to explore an ability-to-pay analysis.⁶⁴ A defendant seeking such consideration must submit a detailed financial disclosure, which includes audited statements and cash flow projections. If DOJ determines that the entity cannot pay the full amount without risking insolvency, it may agree to a reduced settlement or structured payment plan. This process is rigorous and requires the utmost transparency from the defendant because government auditors will scrutinize all financial representations.

If the parties agree on a single damages amount and a multiplier, DOJ uses a standard settlement agreement that does not vary much from case to case. In addition, health care defendants will likely have to negotiate with OIG over the terms of a corporate integrity agreement (CIA).⁶⁵ A CIA is an agreement between the defendant and HHS-OIG that outlines the defendant's obligations to improve compliance and prevent further instances of fraud. They typically impose compliance obligations for five years, including independent monitoring, reporting requirements, and enhanced internal controls.

Finally, the government is prohibited from making settlements confidential, so defendants cannot hope to hide the fact that they settled FCA allegations.⁶⁶ In fact, it is almost certain that DOJ and OIG will issue press releases to announce the FCA settlement.

4.8. Government Decision—Intervention, Declination, or Dismissal

Once the government has completed its investigation, if DOJ has not reached a settlement with the defendant, DOJ

⁶⁴U.S. JUSTICE DEPT., JUSTICE MANUAL, 4-3.110 & 4-3.200.

⁶⁵U.S. Dept. of Health & Hum. Servs., Office of Inspector General, *Corporate Integrity Agreements* (last visited Jan. 20, 2026), <https://oig.hhs.gov/compliance/corporate-integrity-agreements/>.

⁶⁶U.S. JUSTICE DEPT., JUSTICE MANUAL, 4-3.410.

must decide whether to initiate an FCA action⁶⁷ or intervene in a qui tam lawsuit.⁶⁸ Obviously, this decision is pivotal. In government-initiated investigations, no lawsuit means no liability for the defendant. In relator-initiated lawsuits, whether the government intervenes has a dramatic effect on the trajectory of the case.

The Justice Manual states that “[c]ivil remedies against fraud should be vigorously enforced ... to make the government whole, if possible, and to provide a strong deterrent”⁶⁹ To guide DOJ’s decision making, some of the factors federal prosecutors consider are the merits of the case, the existence of earlier government investigations into the same conduct, potential interference with agency policies, the preservation of litigation resources, the amount of damages at stake, and the ability to recover from the defendant. If DOJ elects to intervene, it typically files its own complaint in intervention, which may not include all of the relator’s allegations, particularly if the relator alleged retaliation under § 3730(h).

On the flip side, DOJ may decline to intervene where there is insufficient evidence, minimal damages relative to litigation costs, or the potential to create bad precedent. DOJ may also decline to intervene when parallel criminal investigations take priority or a case duplicates prior claims without adding substantive value.⁷⁰

Beyond just declining to intervene, DOJ may affirmatively move to dismiss a qui tam complaint under 31 U.S.C. § 3730(c)(2)(A) to curb meritless cases that involve defective legal theories or frivolous factual allegations.⁷¹ DOJ may also decide to move to dismiss when the factors supporting declination are particularly strong. These considerations serve an important function in preserving government resources, ensuring that enforcement efforts remain focused on cases that meaningfully advance the FCA’s goals of protecting federal funds and deterring fraud.

⁶⁷31 U.S.C. § 3730(a).

⁶⁸§ 3730(b)(4).

⁶⁹DEPT. OF JUSTICE, JUSTICE MANUAL, 4-4.110.

⁷⁰*Id.* at 4-4.111.

⁷¹*Id.* at 4-4.111.

The FCA gives DOJ the ability to dismiss even over a relator's objection, so long as the relator receives notice and an opportunity for a hearing.⁷² The Supreme Court recently reaffirmed this authority in *United States ex rel. Polansky v. Executive Health Resources, Inc.*⁷³ In *Polansky*, the Court confirmed that DOJ may seek dismissal at any stage of the litigation, regardless of whether the government previously declined to intervene in the action.⁷⁴ This is because the government remains the real party in interest at all times.⁷⁵ Accordingly, the government's views on the litigation are "entitled to substantial deference: [i]f the Government offers a reasonable argument for why the burdens of continued litigation outweigh its benefits, the court should grant the motion ... even if the relator presents a credible assessment to the contrary."⁷⁶

5.0. LITIGATION AFTER INTERVENTION OR DECLINATION

Under the FCA, either the government or the relator can decide to litigate if the parties are not able to resolve all alleged violations through settlement. In general, defendants would much rather litigate against relators, who likely have considerably less resources than DOJ, including no easy access to claims data.⁷⁷ However, the stages of litigation and

⁷²§ 3730(c)(2)(A).

⁷³*United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419, 439 (2023).

⁷⁴*Id.* at 438.

⁷⁵*Id.* at 435, 437.

⁷⁶*Id.* at 437–38.

⁷⁷A comprehensive review of litigation involving the government as compared to relators is beyond the scope of this article. However, each presents unique challenges and opportunities for defendants. For example, litigating against the government increases the chances that retaliation claims are not at issue, and it means that discovery could be condensed because the defendant has already produced documents in response to a CID. Settling with the government can be difficult, however, because if it has filed an FCA complaint or intervened in a qui tam action, the government already has a strong opinion of what single damages are and will be unlikely to budge from that threshold amount. With a relator, the parties can be more flexible in compromising on a dollar amount. But discovery

the potential strategies are largely the same regardless of who is manning the ship on the plaintiff's side.⁷⁸

5.1. Motion Practice and Discovery

Following intervention, defendants typically pursue aggressive early motion practice to narrow or dismiss claims. The most common approach is to file a Rule 12(b)(6) motion to dismiss, challenging the sufficiency of the allegations under the pleading requirements of Rule 9(b).⁷⁹ Defendants also assert the public disclosure bar under Section 3730(e)(4) by filing Rule 12(b)(1) motions to challenge jurisdiction, and more recently defendants have been filing 12(b)(1) motions to challenge the constitutionality of the FCA qui tam provisions.⁸⁰

Assuming the case survives the dismissal stage, the parties have discovery to look forward to, which is often the most resource-intensive stage of an FCA litigation—aside from trial. Because health care fraud claims involve protected health information (PHI), protective orders are a necessity. Moreover, because a plaintiff needs to prove the defendant's state of mind, the collection and review of emails, text messages, and other ESI is inevitable, and this information may be more extensive than what the defendant searched for and produced in response to a CID. The cost of ESI production can climb swiftly and often leads to disputes between the parties.

In addition to fact discovery, expert discovery plays a

may be more time consuming because the relators cannot serve CIDs, there may be other causes of action in addition to FCA claims, and courts are more likely to grant extensions to private counsel than to the government.

⁷⁸Even if the government initially declines to intervene, it may later elect to intervene in the case. *Polansky*, 599 U.S. at 432-33. DOJ can also influence the litigation through Statements of Interest. These filings allow the government to weigh in on key legal issues—such as the interpretation of materiality or the application of statutory bars—without formally joining the case. A Statement of Interest can sway a judge away from a defendant's position even when the relator does a poor job rebutting the defendant's argument.

⁷⁹Fed. R. Civ. P. 12(b)(6); Fed. R. Civ. P. 9(b).

⁸⁰See, e.g., *United States ex rel. Zafirov v. Fla. Med. Assocs. LLC*, 751 F. Supp. 3d 1293, 1321 (M.D. Fla. 2024).

central role in FCA cases. Common expert topics include coding accuracy, the medical necessity of services provided, whether the quality of care was so lacking as to render the services worthless, statistical sampling methodologies, and damages analyses. Experts often face *Daubert* challenges, where the parties contest the reliability and relevance of the experts' methodologies and conclusions.⁸¹ These disputes weigh heavily on an FCA claim, as they can significantly shape the scope of admissible evidence and provide leverage for settlement.

As a last resort before trial, defendants attempt to narrow the issues or dismiss the case entirely through a motion for summary judgment, arguing that there are no genuine disputes of material fact.⁸² Given the complexity of the issues in health care FCA matters, these motions are hard to win and require voluminous briefs supported by deposition transcript excerpts, exhibits, declarations, and oral arguments. The difficulty is only enhanced by the Supreme Court's *SuperValu* decision, which held that the scienter element of an FCA claim refers to the defendant's "knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed."⁸³ A plaintiff seeking to go to trial can usually find at least one factual dispute regarding what an FCA defendant knew or believed.

5.2. Trial

Trials are becoming exceedingly rare in American courts.⁸⁴ FCA cases are no exception. In the extraordinary event that a case proceeds to trial—after the expenditure of legal fees, costs, and other resources over the course of several years—the parties can expect a multi-week trial involving numerous fact and expert witnesses and exhibits. Both sides typically employ highly sophisticated counsel knowledgeable about health care regulations and FCA liability. The government and relators must explain intricate billing systems and

⁸¹Fed. R. Evid. 702.

⁸²Fed. R. Civ. P. 56.

⁸³United States ex rel. Schutte v. SuperValu Inc., 598 U.S. 739, 749, 757 (2023).

⁸⁴Wood R. Foster Jr., *How "Trial Lawyer" Became an Oxymoron*, 97-OCT MICH. B. J. 32, 32 (2018) ("real civil trials are disappearing").

compliance frameworks to juries, while defendants attempt to poke holes or craft alternative stories and explanations.

Government trial themes highlight the need to protect the public fisc, the obligation to hold bad actors accountable for fraud, and the pursuit of justice. In contrast, defense themes emphasize ambiguities and gray areas in regulations and agency guidance, play up good-faith efforts to comply, and stress a lack of materiality. When all else fails, defendants tirade about the threat of government overreach and painstakingly point out steps not taken during the course of the FCA investigation to show the “all powerful” government cut corners.⁸⁵ Ultimately, the jury will choose between these competing narratives to decide whether the defendant is liable for treble damages and per claim penalties.

5.3. Case Example After Lengthy Seal Period

A recent Fifth Circuit case, *United States ex rel. Aldridge v. Corporate Management, Incorporated*,⁸⁶ illustrates the risks and complexities of FCA cases. The investigation spanned more than a decade, with government intervention occurring only after eighteen seal extensions. Even though the defendants were informed of the government’s investigation in 2010, the government did not intervene until 2015, and filed a complaint in intervention several months later.

After lengthy and costly litigation over the course of years, in early 2020 the matter went to trial, lasting nine weeks. Ultimately, a jury found the defendants liable for over \$10 million dollars in fraudulent claims, which trebled to over \$30 million in damages. However, on appeal, the Fifth Circuit found that some of the allegations in the government’s complaint did not relate back to the original *qui tam*. Further, the court refused to apply the FCA’s tolling provision under 31 U.S.C. § 3731(b)(2) because the government had not acted with due diligence in its investigation. As a

⁸⁵Consider the “CSI effect,” which occurs when juries expect criminal investigation procedures to mirror those witnessed on forensic television shows. See *United States v. Dennis*, 19 F.4th 656, 671 (4th Cir. 2021) (permitting the use of a jury instruction to counteract the CSI effect by informing jurors “that the government was not obligated to use any particular investigative techniques such as fingerprints or DNA”).

⁸⁶*United States v. Corporate Management, Incorporated*, 78 F.4th 727 (5th Cir. 2023).

result, the Fifth Circuit halved the jury award due to statute of limitations issues.⁸⁷ This case underscores the potential for lengthy disputes and the unpredictability of FCA trials, as well as the importance of strategic decision-making regarding settlement versus litigation.

CONCLUSION

The False Claims Act is one of the federal government's most powerful tools to combat fraud. For a variety of reasons, FCA enforcement has hit the health care industry the hardest. Should a health care system, hospital, physician group, laboratory, or any other medical provider find themselves the target of an FCA investigation, they should know they face a long, expensive, and arduous process to clear their name or resolve any potential violations.

Understanding the timeline of an FCA investigation and having a response plan in place is essential for strategic compliance and operational readiness. Effective management requires early engagement with the government, proactive internal investigation, and sophisticated understanding of DOJ expectations.

Whistleblowers and the government will continue to prioritize curbing health care fraud. Therefore, medical providers and related companies must prepare by strengthening compliance programs, promptly addressing internal concerns, and understanding the procedural and strategic complexities of FCA matters.

⁸⁷*Id.* at 747.