RECKLESS ABANDON: THE CASE FOR AN OBJECTIVE RECKLESSNESS STANDARD UNDER THE FALSE CLAIMS ACT

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INTRODUCTION

The False Claims Act (FCA)[1] is the federal government's primary statute for litigating fraud in the United States.[2] The FCA's use has evolved significantly since its inception, transforming into one of the most important tools to combat healthcare fraud and abuse.[3] Healthcare spending in the United States accounts for almost 18 percent of the country's overall gross domestic product (GDP).[4] With significant spending comes the opportunity for widespread fraud, particularly with the expansion of technology and artificial intelligence (AI). The United States General Accounting Office estimates that $100 billion is lost annually to healthcare fraud, waste, and abuse—about 10 percent of all healthcare expenditures.[5] Consequently, the federal government's efforts to combat healthcare fraud and abuse using the FCA have widespread impacts on the United States' economy.

Though aspects of the FCA's scienter, or knowledge, requirement have been defined by federal circuit courts and the Supreme Court, the recklessness standard of the FCA has gone largely undiscussed. Clarifying the definition of recklessness under an objective standard when applying the FCA would allow for greater opportunity to litigate healthcare fraud. An objective recklessness standard would ensure that healthcare entities and providers are not using technology as a shield for submitting false claims to the federal government.

Part I of this Comment discusses the background of the FCA, including its history, purpose, and the requirements for proving a cause of action under the statute. It also discusses the evolution of the FCA and two amendments that overhauled the Act in 1943 and 1986. Part II focuses on the modern use of the FCA to litigate healthcare fraud. It points to the tremendous rise in healthcare spending in the United States and the subsequent rise in healthcare fraud and

1. 31 U.S.C. §§ 3729–3733.

2. CLAIRE M. SYLVIA, THE FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT § 1.1, Westlaw (database updated July 2024).

3. *See Fraud and Abuse Laws*, HHS (2025), https://perma.cc/P343-JCVL.

4. *Historical*, CMS (Dec. 18, 2024), https://perma.cc/4KKT-69GC.

5. U.S. DEP'T OF JUST., CRIM. RES. MANUAL § 976 (2020).

litigation, outlining the four most common kinds of healthcare fraud actions under the FCA. Part III discusses the origin of the recklessness standard in the FCA and its interpretation by federal circuit courts and the Supreme Court. Part IV discusses the potential for the Supreme Court to establish an objective recklessness standard for the FCA. It concludes by highlighting the need for a more apparent recklessness standard for the FCA, given the rapid expansion of AI-powered claims processes used by major healthcare entities. This could lead to an increase in FCA suits involving recklessness.

I. BACKGROUND

Since its passage in 1863, the FCA has transformed both in structure and in use.[6] Its history and evolution over time point to Congress's desire to prioritize litigating fraud and empowering individuals to assist the government in redressing fraud.[7]

A. History and Purpose of the FCA

Popularly known as the "Informer's Act" or the "Lincoln Law,"[8] the FCA's original purpose was to combat fraud committed by military contractors.[9] Specifically, the FCA was created to combat fraud by the Union Army during the Civil War by imposing civil liability on those submitting false claims for supplies.[10] The FCA effectively "deputized" private citizens to bring suits against alleged wrongdoers for fraud that may otherwise go unnoticed.[11]

Though its original intentions were to combat military fraud, false claims actions may be filed against any person or entity submitting false claims.[12] The FCA, therefore, provides an avenue for civil liability for those that knowingly submit false claims for reimbursement to the federal government.[13] The FCA is the "primary

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6. *See* SYLVIA, *supra* note 2, § 2.1.

7. *See id.* § 1.1.

8. United States *ex rel.* Graber v. City of New York, 8 F. Supp. 2d 343, 352 (S.D.N.Y. 1998).

9. 3 JOEL M. ANDROPHY, WHITE COLLAR CRIME § 21:19, Westlaw (database updated Feb. 2023); *see also* United States v. McNinch, 356 U.S. 595, 599 (1958) ("[The FCA was enacted] following a series of sensational congressional investigations into the sale of provisions and munitions to the War Department. Testimony before the Congress painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and [was] generally robbed in purchasing the necessities of war. Congress wanted to stop this plundering of the public treasury." (citing H.R. REP. NO. 37-2, pt. 2 (1861))).

10. ANDROPHY, *supra* note 9.

11. *Id.*

12. *Id.*

13. *The False Claims Act*, DOJ (Jan. 15, 2025), https://perma.cc/355Z-3WZF ("The FCA provides that any person who knowingly submits, or causes to submit,

litigative tool for combatting fraud" by instituting significant financial implications for those who submit false claims.[14]

B. Proving a Claim Under the FCA

There are "two essential elements" of an action under the FCA: "(1) the falsity of the claim and (2) the defendant's knowledge of the claim's falsity."[15] A claim is a request to the federal government for reimbursement—whether it be through money or property.[16] Under the language of the statute, persons can be liable not only for submitting false claims, but also for making a false record pertaining to a fraudulent claim, returning only a portion of money or property loaned from the government, submitting a receipt to the government the person does not know to be true, and committing other fraudulent activities that pertain to making or concealing false claims.[17] The false claim must also be material, meaning that it "ha[s] a natural tendency to influence, or [is] capable of influencing, the payment or receipt of money or property."[18]

The FCA differs from other federal statutes because it allows private individuals, called "relators," to bring a false claims action on behalf of the government.[19] These actions, called *qui tam* suits, originated in English law.[20] After a *qui tam* suit is filed, the government may join the suit at any point during the case and take over primary responsibility upon a showing of "good cause."[21] However, the government is not required to take over the action for it to proceed.[22] If the government refuses to intervene and the relator proceeds and prevails, they are entitled to 25 to 30 percent of the proceeds.[23] The provisions detailing *qui tam* actions are also known

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false claims to the government is liable for three times the government's damages plus a penalty that is linked to inflation." (citing 31 U.S.C. § 3729(a)(1))).

14. S. REP. NO. 99-345, at 2 (1986).

15. United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1394 (2023).

16. 31 U.S.C. § 3729(b)(2)(A) (defining claim as "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property").

17. *Id.* § 3729(a)(1).

18. *Id.* § 3729(b)(4).

19. *Id.* § 3730(b)(1) ("A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government.").

20. United States *ex rel.* Stillwell v. Hughes Helicopters, Inc., 714 F. Supp. 1084, 1086 n.1 (C.D. Cal. 1989) (explaining that the phrase "*qui tam*" is derived from the Latin phrase "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*," meaning "who brings the action for the king as well as for himself" (citing 3 WILLIAM BLACKSTONE, COMMENTARIES *160)).

21. ANDROPHY, *supra* note 9, § 21.22 (citing 31 U.S.C. § 3730(c)(3)).

22. 31 U.S.C. § 3730(c)(3).

23. *Id.* § 3730(d)(2).

as "whistleblower provisions" and provide significant power to litigate fraud by incentivizing oversight by private actors on behalf of the government.[24]

C. Amendments to the FCA

1. 1943 Amendments

After the Civil War, the FCA's use dropped dramatically alongside government spending.[25] As a result, the FCA was virtually dormant for about 100 years.[26] The tide shifted upon the United States' entry into World War II, when the "government's 'economic role in national life [expanded] . . . and with it the opportunities for those receiving government funds' to violate one or more of the innumerable regulations governing entitlement to provide government benefits."[27] However, the resurgence of the FCA led to new complications with its use. Because the original FCA did not limit recovery to *qui tam* plaintiffs with firsthand knowledge of fraud, other individuals with little personal involvement initiated "parasitical" actions to gain a windfall.[28]

The Supreme Court pointed out a considerable flaw in the FCA that led to these parasitical actions in *United States ex rel. Marcus v. Hess*.[29] In *Hess*, the Court turned to the original language of the FCA, which stated that an "action may be instituted by '*any*' person on behalf of the government."[30] The Court held that though the current

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24. Marc S. Raspanti & David M. Laigaie, *Current Practice and Procedure Under the Whistleblower Provisions of the Federal False Claims Act*, 71 TEMP. L. REV. 23, 24 (1998).

25. John R. Thomas Jr. et al., *The False Claims Act Past, Present, and Future*, FED. LAW. 65, 66 (Dec. 2016), https://perma.cc/2JSJ-2LER (first citing JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 1.01[B], at 1–13 (4th ed. 2016); and then citing Francis E. Purcell Jr., *Qui Tam Suits Under the False Claim Act Amendments of 1986: The Need for Clear Legislative Expression*, 42 CATH. U. L. REV. 935 (1993)).

26. *Id.*

27. Malcolm J. Harkins, III, *The Ubiquitous False Claims Act: The Incongruous Relationship Between a Civil War Era Fraud Statute and the Modern Administrative State*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 131, 144 (2007) (quoting 1 JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS § 1.01[B], at 1–11 (3d ed. 2007)).

28. S. REP. NO. 77-1708, at 2 (1942). Then-Attorney General Francis Biddle stated that such actions were "brought only after law-enforcement offices ha[d] investigated and prosecuted persons guilty of a violation of law and solely because of the hope of a large reward." *Id.*

29. 317 U.S. 537 (1943).

30. *Id.* at 540 (emphasis added).

> The bill offers, in short, a reward to the informer who comes into court and betrays his co-conspirator, if he be such; but it is not confined to that class. Even the district attorney, who is required to be vigilant in the prosecution of such cases, may be also the informer, and entitle

construction of the FCA made it vulnerable to parasitical actions, "there are no words of exception or qualification" that prevent *any* person from bringing such an action and subsequently gaining a windfall.[31] The Court held that the government brought up policy issues that were inappropriate for judicial review.[32] In short, "[c]onditions may have changed, but the statute ha[d] not," and as such, the Court "could not, without materially detracting from its clear scope, decline to recognize the petitioner's right to sue under the Act."[33]

As a response to the Supreme Court's holding in *Hess*, Congress passed a "series of limiting amendments," such as allowing the Department of Justice to intervene and take over an FCA action and capping the relator's share to 25 percent of the recovery.[34] It also limited the relators' power by denying recovery to those who raised claims based on evidence already in possession of the government, regardless of whether the relator was the "original source" of information.[35] These alterations provided safeguards against potential abuse of the FCA and "effectively overrul[ed] *Hess*."[36]

2. 1986 Amendments

Despite Congress's intentions for sweeping change, the 1943 Amendments were relatively short-lived. More significant changes were implemented in 1986 in response to growing fraud against the federal government.[37] Indeed, it was estimated that at the time, fraud was draining anywhere between $10 billion and $100 billion of government funds per year.[38] "By 1985, four of the largest defense contractors . . . had been convicted for criminal fraud offenses."[39]

> himself to one half the forfeiture under the *qui tam* clause, and to one half of the double damages which may be recovered against the persons committing the act.

Id. at 546 (quoting CONG. GLOBE, 37th Cong., 3d Sess. 955–56 (1863)).

31. *Id.*

32. *Id.* at 547.

33. *Id.* at 547–48.

34. Raspanti & Laigaie, *supra* note 24, at 25–26.

35. *Id.* at 25.

36. Kamal Al-Salihi, *Keeping It Simple: Finding Falsity Under the False Claims Act*, 36 WHITTIER L. REV. 431, 440 (2015) (citing A.G. Harmon, *Bounty Hunters and Whistleblowers: Constitutional Concerns for False Claims After Passage of the Patient Protection and Affordable Care Act of 2010*, 2 AM. U. LAB. & EMP. L.F. 1, 8 (2011)).

37. S. REP. NO. 99-345, at 1–2 (1986).

38. *Id.* at 3 (citing *Hearings on the Subcomm. on the Dep'ts of State, Just. & Com., the Judiciary & Related Agencies of the H. Comm. on Appropriations*, 96th Cong. (1980)).

39. James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1272 (2013).

Congress intended to amend the FCA to ensure it was a powerful enough tool to combat fraud as a response.[40] Its goals for the Amendments were twofold: to "reject[] suits which the government is capable of pursuing itself, while promoting those which the government is not equipped to bring on its own."[41]

In his prepared testimony before Congress, Richard Willard, then-Assistant Attorney General for the General Civil Division of the Department of Justice, stated that the 1986 Amendments promoted the original purpose of the FCA: "to make sure that there is some duty imposed on the contractors to take steps to assure that they are not submitting false claims."[42] The 1986 Amendments increased the ability to bring an action and receive an award if successful.[43] Though the Amendments required that the relator be an "original source of information," it also allowed for "reverse false claims," which instituted penalties for entities that avoid payments to the government.[44] These changes bolstered the FCA's power by increasing incentives for potential relators and brought the FCA closer to its originally-intended purpose: to be a powerful tool against fraud.[45]

Together, the 1943 and 1986 Amendments highlight lawmakers' efforts to balance promoting incentives for relators while curbing "parasitic" litigation.[46]

II. SHIFTING TIDES: USING THE FCA TO COMBAT HEALTHCARE FRAUD

The 1986 Amendments, along with other amendments made in 2009 and 2010,[47] were transformative for expanding the use of the

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40. S. REP. NO. 99-345, at 4.

41. United States *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994).

42. *False Claims Act Amendments: Hearings Before the Subcomm. on Admin. L. & Governmental Rels. of the H. Comm. on the Judiciary*, 99th Cong. 159 (1986) [hereinafter *1986 Hearings*] (statement of Richard Willard, Assistant Att'y Gen., Civ. Div., Dep't of Just.).

43. S. REP. NO. 99-345, at 2.

44. *Id.* at 12, 18.

45. *See* James J. Belanger & Scott M. Bennett, *The Continued Expansion of the False Claims Act*, 4 J. HEALTH & LIFE SCI. L. 26, 28 (2010).

46. *See* Beverly Cohen, *Kaboom! The Explosion of Qui Tam False Claims Under the Health Reform Law*, 116 PENN ST. L. REV. 77, 78–79 (2011) (discussing the 1943 and 1986 Amendments and Congress's desire for the "golden mean" between these two opposing interests (citing United States *ex rel.* Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 649 (D.C. Cir. 1994))).

47. *See* Belanger & Bennett, *supra* note 45, at 30 ("In 2009, [the Fraud Enforcement and Recovery Act] expanded the FCA in several ways, including: making it easier for the government (or a relator) to prove a reverse false claim; adopting a low standard for materiality; and expanding the FCA to cover claims submitted to intermediaries."); *see also* Helmer, *supra* note 39, at 1279–80 (describing how the 2010 Amendment made through the Patient Protection and

FCA to encompass all fraud committed by government contractors. These various amendments transformed the use of the FCA. Between the creation of Medicare and Medicaid programs in 1965[48] and the 1986 Amendments, few FCA cases were filed pertaining to false Medicare or Medicaid claims.[49] Forty years later, it has transformed into one of the most important statutes to litigate fraud against the federal government—in particular, healthcare fraud.[50]

A. The Modern Surge of Healthcare Spending

The significant shift in the use of the FCA can be attributed to the astounding rise in healthcare spending. When Medicare and Medicaid were first created in 1965, national health expenditures in the United States comprised more than 5 percent of the United States' total GDP.[51] Since 1965, spending has increased steadily each year.[52] Current data indicates that healthcare expenditures account for nearly 18 percent of the United States' total GDP.[53] The United States has therefore experienced a "twenty-fold increase in healthcare expenditures" in less than a single lifetime.[54] This is a statistic unique to the United States; it spends more on a per capita and percentage of GDP basis on healthcare than any other nation in the world, and that is only projected to increase.[55]

B. The Rise of Healthcare Fraud Litigation

With the rise of healthcare spending and subsidy programs, the opportunity for healthcare fraud continues to balloon. The passage of the Affordable Care Act (ACA) in 2010, for example, greatly expanded

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Affordable Care Act, which changed the statute to provide that "only a public disclosure by a *federal* hearing or report or from the news media could deprive the court of jurisdiction . . . [and] overruled another Supreme Court opinion that had determined that public disclosures in non-federal matters also could serve as a basis to revoke jurisdiction in a *qui tam* case").

48. *History*, CMS (Sept. 10, 2024), https://perma.cc/TWX3-F7XN.

49. Robert Salcido, *The Government's Increasing Use of the False Claims Act Against the Health Care Industry*, 24 J. LEGAL MED. 457, 461 (2003).

50. *Fraud and Abuse Laws*, HHS (2025), https://perma.cc/87AH-H9DQ.

51. AARON C. CAITLIN & CATHY A. COWAN, HISTORY OF HEALTH SPENDING IN THE UNITED STATES, 1960-2013, at 3 (Nov. 19, 2015), https://perma.cc/U3MR-EEAK.

52. *Id.* at 3, 32 fig. 1.

53. NATIONAL HEALTH EXPENDITURES 2023 HIGHLIGHTS, CMS (2023), https://perma.cc/KQ35-EKXZ.

54. THOMAS W. MERRILL ET AL., PRESIDENT'S COUNCIL ON BIOETHICS, HEALTH AND MEDICAL CARE REFORM IN THE UNITED STATES: ETHICAL QUESTIONS AND CONCERNS (2008), https://perma.cc/65GN-2QJV.

55. *Id.*

Medicaid eligibility.[56] Medicare and Medicaid programs are administered by the Centers for Medicare & Medicaid Services (CMS).[57] To receive payment after treating a Medicare or Medicaid patient, a healthcare provider must apply for enrollment in the Medicare or Medicaid program through CMS and submit reimbursement claims for medical services and supplies.[58]

The claims systems for Medicare and Medicaid make them uniquely susceptible to fraud.[59] Healthcare fraud cases that implicate the FCA typically fall into four categories: (1) billing for unnecessary services or items, (2) billing for services or items not furnished, (3) upcoding, and (4) unbundling.[60] Though there are other common causes of healthcare fraud, such as kickbacks[61] and improper prescription of off-label drugs,[62] such actions implicate other federal statutes.

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56. Olena Mazurenko et al., *The Effects of Medicaid Expansion Under the ACA: A Systematic Review*, 37 HEALTH AFFS. 944, 944 (2018) (discussing specific Medicaid expansions resulting from the ACA).

57. *See History*, CMS (Sept. 10, 2024), https://perma.cc/GTB3-29F8.

58. CMS, ICN 906764, MEDICARE CLAIM SUBMISSION GUIDELINES 2, 9 (June 2012), https://perma.cc/Y7UK-U5MP.

59. *See* Cohen, *supra* note 46, at 89 nn.80 & 82 (first citing Parija Kavilanz, *Health Care: A 'Goldmine' for Fraudsters*, CNN MONEY (Jan. 13, 2010), https://perma.cc/4LSY-LB75; and then citing Belanger & Bennett, *supra* note 45, at 29).

60. CMS, FACT SHEET: COMMON TYPES OF HEALTH CARE FRAUD 2–3 (July 2016), https://perma.cc/M9Z8-ARF2.

61. *See* 42 U.S.C. § 1320a-7b(b); *see also* Kathryn DeMallie et al., *Health Care Fraud*, 59 AM. CRIM. L. REV. 975, 983–84 (2022) ("The Anti-Kickback Amendment to the Social Security Act . . . also known as the Anti-Kickback Statute, prohibits knowingly and willfully paying (or offering to pay) or receiving (or soliciting) any remuneration (including any kickback, bribe, or rebate)—directly or indirectly, overtly or covertly, in cash or in kind—in exchange for prescribing, purchasing, or recommending any service, treatment, or item for which payment will be made by Medicare, Medicaid, or any other federally-funded health care program." (citing 42 U.S.C. § 1320a-7b(b))).

62. *See* Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41, 43 (2005) ("An off-label use is one other than that for which the drug was FDA approved. If a company has a product that is approved by the Food and Drug Administration (FDA), it may seek off-label uses for that product in order to gain market share without the expense and time demanded by the standard FDA approval process. While doctors may legally prescribe a drug approved by the FDA for unapproved or 'off-label' uses, manufacturers are generally prohibited from promoting such 'off-label' usage." (first citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001); and then citing James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 76 (1998))).

1. Billing for Unnecessary Services or Items

CMS requires providers to meet certain requirements in order to receive compensation for services, one of which being that the services provided be medically necessary.[63] Failure to do so can trigger liability under the FCA.[64]

This was the crux of the issue in *United States ex rel. Riley v. St. Luke's Episcopal Hospital*,[65] where the defendants were sued, in part, for defrauding Medicare and billing for unnecessary services.[66] Specifically, the defendants "artificially upgraded" patients' organ transplants and admitted patients to intensive care units without medical justification.[67] The Fifth Circuit reversed the district court's decision to dismiss the government's complaint due to lack of adequate proof, holding that there was sufficient proof that the defendants defrauded the federal government by billing for unnecessary services.[68]

2. Billing for Services or Items Not Furnished

Providers billing Medicare or Medicaid for services furnished must also indicate what service they provided on a form promulgated by CMS.[69] Providers who attempt to bill Medicare or Medicaid for services that were not performed can be sued for filing a false claim.[70]

This was the case in *United States v. Speqtrum, Inc.*[71] Speqtrum, a personal care aide service provider, allegedly "defrauded Medicaid of over a million dollars" by "(i) charging the Government for services not rendered—*e.g.*, services allegedly provided to dead or hospitalized patients—and (ii) charging the Government for unauthorized services—*e.g.*, services that were rendered without an operative plan of care."[72] The government presented significant evidence of Speqtrum's wrongdoing, including evidence of "fabricated records" and billing for services rendered to patients that were never or no longer affiliated with Speqtrum.[73] The United States District Court

63. *See* CMS, *supra* note 60, at 2 ("Providers should only bill for the medically necessary or otherwise authorized services or items provided to beneficiaries, and should ensure that proper documentation is in place.").

64. *See id.*

65. 355 F.3d 370 (5th Cir. 2004).

66. *Id.* at 373.

67. *Id.* at 376–77.

68. *Id.* at 377.

69. *See* CMS, *supra* note 60, at 2.

70. *See* United States *ex rel.* Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1167 (10th Cir. 2010) ("The FCA 'covers all fraudulent attempts to cause the government to pay out sums of money.'" (quoting United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008))).

71. 47 F. Supp. 3d 81 (D.D.C. 2014).

72. *Id.* at 85.

73. *Id.* at 86.

for the District of Columbia awarded summary judgment to the government's claims of "billing for services not rendered" based on the evidence provided.[74]

3. Upcoding

A provider is upcoding if they bill for services "at a higher level of complexity than the service actually provided or documented in the file."[75] This is what occurred in *United States ex rel. Mamalakis v. Anesthetix Management LLC*,[76] where Dr. John Mamalakis, an anesthesiologist, alleged that his former employer, Anesthetix Management LLC, "fraudulently billed Medicare and Medicaid for services performed by its anesthesiologists."[77] Specifically, he alleged that the anesthesiologists with Anesthetix "regularly failed to perform preanesthetic exams and evaluations [and] did not personally prescribe anesthesia plans," but nonetheless billed the federal government at the "medical-direction rate . . . and therefore knowingly submitted false bills to the government for payment," in addition to other allegations.[78] The court held that this case was reflective of the facts in *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*,[79] where "the provider 'billed Medicaid *for a completely different treatment*' and thus made an express false statement by 'misus[ing] a billing code and falsely represent[ing] to the state and federal governments that a certain treatment was given by certain medical staff when in fact it was not.'"[80] The court reversed the district court's dismissal of the government's claims based on this evidence of upcoding.[81]

4. Unbundling

"Unbundling 'is the practice of submitting bills in a fragmented fashion in order to maximize the reimbursement for various tests or procedures that are required to be billed together at a reduced cost.'"[82] Billing for services separately "when they should have been billed together" was one of the alleged violations of the FCA in *United States ex rel. Salters v. American Family Care, Inc.*[83] In *Salters*, the relator claimed that American Family Care "knowingly submitted unbundled claims" by charging lab draw fees and injection

74. *Id.* at 95.
75. CMS, *supra* note 60, at 2.
76. 20 F.4th 295 (7th Cir. 2021).
77. *Id.* at 297.
78. *Id.* at 299.
79. 836 F.3d 770 (7th Cir. 2016).
80. *Mamalakis*, 20 F.4th at 303 (quoting *Presser*, 836 F.3d at 779).
81. *Id.*
82. CMS, *supra* note 60, at 3 (quoting FBI, FINANCIAL CRIMES REPORT TO THE PUBLIC: FISCAL YEARS 2010–2011, at 20 (2011), https://perma.cc/5S52-9NTZ).
83. 262 F. Supp. 3d 1266, 1284 (N.D. Ala. 2017).

administration separately for venipuncture services.[84] Ultimately, the court determined that the question of whether venipunctures were "'routinely bundled' claims," and requiring lab draw fees and injection administration to be billed together, should be determined by a jury.[85]

5. FCA Recoveries

These various practices used by providers to fraudulently obtain government reimbursement are widespread. Since 1986, the government has recovered over $78 billion,[86] approximately 60 percent attributed to healthcare fraud.[87] In recent years, the concentration of healthcare fraud actions initiated under the FCA has increased; between 2018 and 2022, 80 percent of the government's recovery from FCA suits were from actions involving healthcare fraud.[88]

As healthcare spending and fraud only continue to rise, the most powerful weapon in the federal government's arsenal continues to be the FCA and its *qui tam* provisions. However, recent decisions interpreting the FCA are changing the landscape for FCA litigation—notably, the decisions are attempting to interpret and apply the scienter standard in the statute.

III. THE RECKLESSNESS STANDARD IN THE FALSE CLAIMS ACT

Prior to the 1986 Amendments, the FCA laid out two categories that captured the scienter requirement: actual knowledge and deliberate ignorance.[89] The 1986 Amendments implemented a third category: reckless disregard.[90] This third standard, lawmakers indicated, was distinguishable from an accidental violation of the FCA.[91] Specifically, acting Assistant Attorney General Phillip Brady

84. *Id.*

85. *Id.* at 1285.

86. *False Claims Act Settlements and Judgments Exceed $2.9B in Fiscal Year 2024*, DOJ (Jan. 15, 2025), https://perma.cc/WA6J-YANP.

87. Belanger & Bennett, *supra* note 45, at 28 (noting that "25 [of the] highest-dollar settlements under the FCA have been healthcare related, as have more than 60 of the top 100 settlements").

88. Eli Y. Adashi & I. Glenn Cohen, *Health Care Fraud: The Leading Violation of the False Claims Act*, 135 AM. J. MED. 558, 558 (2022) (citing *Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute*, DOJ (Dec. 2, 2020), https://perma.cc/7R73-MNU6).

89. United States *ex rel.* Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1155 (11th Cir. 2017) (quoting Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1058 (11th Cir. 2015)).

90. *Id.* (quoting *Urquilla-Diaz*, 780 F.3d at 1058); *see also* 31 U.S.C. § 3729(b)(1)(iii).

91. *See 1986 Hearings*, *supra* note 42, at 153 (letter to Hon. Charles Mathias from Acting Assistant Att'y Gen. Phillip D. Brady).

affirmed that "mistake, inadvertence, or mere negligence in the submission of a false claim would not be actionable under either bill."[92] Instead, reckless disregard required that the federal government "prove something more than mere negligence but less than specific intent to defraud."[93] This scienter standard would "define[] the same standard of conduct" as gross negligence.[94] Lawmakers characterized it as "a *should-have-known* standard . . . which says that . . . you acted in reckless disregard of the truth."[95]

A. Understanding the Recklessness Standard

The scienter standard in the FCA reflects the traditional common law understanding of fraud.[96] Under common law, recklessness can be understood as "knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent."[97] The Model Penal Code (MPC) has a similar definition, stating that recklessness is a "gross deviation from the standard of conduct that a law-abiding person would observe in the actor's situation."[98] It was this traditional understanding of recklessness—referred to interchangeably as "gross negligence" in its legislative history—that lawmakers amending the FCA in 1986 had in mind.[99]

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92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.* at 271 (discussion between Mr. Dan Glickman, Chairman for the Comm. on the Judiciary, and Mr. Christopher T. Cross, President & COO of the Univ. Rsch. Corp., on behalf of the U.S. Chamber of Com.) ("Mr. Glickman: You would want a definitional standard of should have-known that would be clear enough and severe enough so that it would not lead to an unnecessarily vague interpretation that might push you down toward the negligence standard? Mr. Cross: That is correct.").

96. *See* United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1400 (2023) ("To this day, the FCA refers to 'false or *fraudulent*' claims, pointing directly to 'the common-law meaning of fraud.' . . . And here, the FCA's definition of 'knowingly' confirms that assumption by largely tracking the common-law scienter standards for fraud." (citing Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 579 U.S. 176, 181, 186–87 (2016))).

97. RESTATEMENT (SECOND) OF TORTS § 500 (AM. L. INST. 1965).

98. MODEL PENAL CODE § 2.02 (AM. L. INST., Proposed Initial Draft 1962).

99. *1986 Hearings*, *supra* note 42, at 154 (letter to Hon. Charles Mathias from Acting Assistant Att'y Gen. Phillip D. Brady) ("[R]eckless disregard often is defined as gross negligence and gross negligence frequently is said to require a reckless disregard.").

Reckless disregard, while separate from "mistake, inadvertence, or mere negligence,"[100] does not require any proof of an intentional, deliberate, or willful act.[101] Recklessness covers those "who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway."[102] The sponsors of the 1986 Amendments and the Department of Justice believed that reckless disregard would cover defendants "who insulated themselves . . . from knowledge about the truth or falsity of a claim."[103] Assistant Attorney General Willard described the standard as a "situation . . . where the responsible person was *reckless* in submitting a claim without taking the appropriate steps to determine whether or not it was false."[104]

Deliberate ignorance and recklessness are often confused in the context of the FCA, mainly because courts are largely silent regarding the difference between the two.[105] Courts will often address "both standards together" rather than distinguishing between the two.[106] However, "actual knowledge, deliberate ignorance, and reckless disregard are distinct" and "function[] as a hierarchy," with recklessness being the lowest threshold.[107] Correct application of the scienter requirement under the FCA requires an understanding of the distinction between each standard, particularly deliberate ignorance and recklessness.

Deliberate ignorance, for purposes of the FCA, is "incorporate[ed] . . . into the definition of knowingly," and is therefore a subjective standard.[108] The Supreme Court recently stated that an actor is acting in deliberate ignorance when they are "aware of a substantial risk that their statements are false, but *intentionally*

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100. *Id.* at 153.

101. *Id.*

102. *Schutte*, 143 S. Ct. at 1401 (first citing *Reckless Disregard*, BLACK'S LAW DICTIONARY (5th ed. 1974); then citing Farmer v. Brennan, 511 U.S. 825, 836 (1994); and then citing RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR ECONOMIC HARM § 10 cmt. c (AM. L. INST. 2018)).

103. *1986 Hearings*, *supra* note 42, at 153 (letter to Hon. Charles Mathias from Acting Assistant Att'y Gen. Phillip D. Brady).

104. *Id.* at 460 (statement of Karen Hastie Williams, Chairman, Legislative Liaison Comm. of the Public Contract Law Section of the American Bar Association, accompanied by Alan C. Brown, Chairman of the Section's Procurement Fraud Committee).

105. SYLVIA, *supra* note 2, § 4.59.

106. *Id.*; *see* United States *ex rel.* Gugenheim v. Meridian Senior Living, LLC, 36 F.4th 173, 179 (4th Cir. 2022) (noting that the plaintiff argues that the defendants acted with reckless disregard *or* deliberate ignorance).

107. United States *ex rel.* Sheldon v. Allergan Sales, LLC, 24 F.4th 340, 349 (4th Cir.), *vacated en banc*, 49 F.4th 873 (4th Cir. 2022), *vacated*, 143 S. Ct. 2686 (2023).

108. SYLVIA, *supra* note 2, § 4.59; *see also* United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1399, 1401 n.5 (2023).

avoid taking steps to confirm the statement's truth or falsity."[109] This standard was created to capture "the 'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted."[110]

Taking both definitions into account, the key difference between deliberate ignorance and recklessness is the *level of knowledge*. Deliberate ignorance is knowing that a claim is false but burying one's head in the sand to the truth of the matter. Recklessness, on the other hand, addresses conduct that is not deliberate, but that is grossly negligent. As such, the Supreme Court declared that deliberate ignorance, like the knowingly standard, "depends on a subjective test" in the context of the FCA.[111] The recklessness standard's interpretation and whether it is established based on a subjective or objective test have not yet been decided.

B. Circuit Court Interpretation and Application of the Recklessness Standard

Circuit courts are divided on the exact interpretation of recklessness within the FCA, with some using a "gross negligence plus" standard and others using a traditional "knew or should have known" standard.[112] Though the Supreme Court has yet to explicitly address the recklessness standard within the FCA, its interpretation of recklessness in other contexts can shed light on future decisions involving the FCA recklessness standard.

1. Gross Negligence Plus Standard

The prevailing understanding of the recklessness standard is the definition recognized in *United States v. Krizek*.[113] In *Krizek*, the federal government initiated an action against Dr. George Krizek, a psychiatrist based in the District of Columbia.[114] The government alleged that Dr. Krizek acted in recklessly by "submit[ing] 8,002 false or unlawful requests for reimbursement in an amount exceeding $245,392" for services provided for Medicare and Medicaid patients.[115] Citing legislative history behind the 1986 Amendments,

109. *Schutte*, 143 S. Ct. at 1400 (emphasis added) (first citing Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 769 (2011); then citing *Deliberate Ignorance*, BLACK'S LAW DICTIONARY (5th ed. 1974); and then citing Derry v. Peek [1889] 14 App. Cas. 337 (HL) 376 (appeal taken from Eng.)).

110. S. REP. NO. 99-345, at 21 (1986).

111. *Schutte*, 143 S. Ct. at 1401 (quoting RESTATEMENT (THIRD) OF TORTS: LIAB. FOR ECON. HARM § 10 cmt. a (AM. L. INST. 2018)).

112. *See* Richard Doan, *The False Claims Act and the Eroding Scienter in Healthcare Fraud Litigation*, 20 ANNALS HEALTH L. 49, 67 (2011).

113. 111 F.3d 934 (D.C. Cir. 1997).

114. *Id.* at 935–36.

115. *Id.* at 936.

the court defined recklessness for purposes of the FCA as a "gross negligence plus" standard.[116] Notably, the court indicated that "an FCA violation may be established *without reference to the subjective intent* of the defendant."[117] Under this definition, the D.C. Circuit upheld the trial court's determination that Krizek's system for Medicare and Medicaid payments was "seriously deficient" and he was therefore acting "with reckless disregard as to the truth or falsity of the submissions."[118]

This interpretation of recklessness was reaffirmed by the D.C. Circuit in *United States ex rel. Folliard v. Government Acquisitions, Inc.*[119] in 2014, and again in *United States ex rel. Davis v. District of Columbia*[120] in 2015. Other federal circuit courts have followed suit with the *Krizek* definition of recklessness, including the Tenth Circuit[121] as well as the Sixth Circuit.[122] While the *Krizek* decision addresses subjectivity and objectivity in determining recklessness explicitly,[123] subsequent cases using the "gross negligence plus" standard in the D.C. Circuit and elsewhere do not.[124]

2. The "Knew or Should Have Known" Standard

Other circuits have discussed how to establish recklessness more overtly, pointing to a "knew or should have known" standard.[125] Under this standard, defendants are held to an objective scienter standard for purposes of recklessness or gross negligence.[126] In other words, if the defendant knew *or should have known* that the claims they were submitting were false or they were unsure of their truthfulness, they can be liable under the FCA.

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116. *Id.* at 941–42 (citing 132 CONG. REC. 29322 (1986)).

117. *Id.* at 942 (emphasis added).

118. *Id.* at 936–37.

119. 764 F.3d 19, 29 (D.C. Cir. 2014).

120. 793 F.3d 120, 124 (D.C. Cir. 2015).

121. *See* United States *ex rel.* Aakhus v. Dyncorp, Inc., 136 F.3d 676, 682 (10th Cir. 1998) (citing *Krizek*, 111 F.3d at 941); United States *ex rel.* Burlbaw v. Orenduff, 548 F.3d 931, 945 n.12 (10th Cir. 2008) (citing *Krizek*, 111 F.3d at 941–42).

122. United States *ex rel.* Williams v. Renal Care Grp., Inc., 696 F.3d 518, 531 (6th Cir. 2012) (first citing United States *ex rel.* K & R Ltd. P'ship v. Mass. House. Fin. Agency, 530 F.3d 980, 983 (D.C. Cir. 2008); then citing *Orenduff*, 548 F.3d at 945 n.12; and then citing United States *ex rel.* Ervin & Assocs., Inc. v. Hamilton Sec. Grp., Inc., 370 F. Supp. 2d 18, 41 (D.D.C. 2005)).

123. *See Krizek*, 111 F.3d at 941–42.

124. *See* Doan, *supra* note 112, at 67–69 (citing various post-*Krizek* FCA cases applying the "gross negligence plus" standard without addressing subjectivity and objectivity).

125. *See* United States v. King-Vassel, 728 F.3d 707, 713 (7th Cir. 2013).

126. *See id.*

The Seventh Circuit made this determination in 2013 in *United States v. King-Vassel*.[127] In *King-Vassel*, a relator initiated a whistleblower action against Dr. Jennifer King-Vassel alleging that several of her "off-label prescriptions" for which she submitted Medicaid reimbursement constituted false claims.[128] In determining whether Dr. King-Vassel's conduct constituted reckless behavior, the court used the *Krizek* definition of recklessness and referenced legislative history behind the 1986 Amendments.[129] The court stated that individuals acting with reckless disregard fail to act as a reasonable and prudent person would under the circumstances.[130] However, the court also looked to the common law definition of recklessness, specifically "'when the actor knows or has reason to know of facts that would lead a reasonable person to realize' that harm is the likely result of the relevant act."[131] This interpretation of recklessness—establishing a gross negligence plus, "knew or should have known" standard—was adopted by the Eleventh Circuit in 2015[132] and the Seventh Circuit in 2016.[133]

C. The Supreme Court's Interpretation of Recklessness in Other Contexts

The Supreme Court has never directly addressed recklessness in the context of the FCA. However, in a few limited cases, it has issued guidance on interpreting and applying recklessness standards in other contexts. These holdings point to the adoption of an objective standard in the future.

The Court briefly addressed subjectivity versus objectivity for the recklessness standard in the context of the Eighth Amendment in *Farmer v. Brennan*.[134] In *Farmer*, a class of inmates sued prison officials for acting with "deliberate indifference to a substantial risk of serious harm to an inmate," rather than recklessness or gross negligence.[135] However, in determining that the officials acted in deliberate indifference of a substantial risk of harm, the Court held that recklessness is acting with "an unjustifiably high risk of harm that is *either known or so obvious that it should be known*."[136] Further,

127. 728 F.3d 707 (7th Cir. 2013).
128. *Id.* at 708–09.
129. *Id.* at 712–13.
130. *Id.* at 713 (quoting S. REP. NO. 99-345, at 20 (1986)).
131. *Id.* (quoting *Reckless Disregard*, BLACK'S LAW DICTIONARY (9th ed. 2009)).
132. *See* Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1058 (11th Cir. 2015) (quoting United States v. Krizek, 111 F.3d 934, 942 (D.C. Cir. 1997)).
133. *See* United States *ex rel.* Sheet Metal Workers Int'l Ass'n, Local Union 20 v. Horning Invs., LLC, 828 F.3d 587, 593 (7th Cir. 2016).
134. 511 U.S. 825 (1994).
135. *Id.* at 828–29.
136. *Id.* at 836 (emphasis added) (citing W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 34, at 213 (5th ed. 1984)).

it held that subjective recklessness is the appropriate test for *deliberate ignorance*, whereas recklessness, in traditional criminal law, requires an objective approach.[137]

The Supreme Court later addressed this question in a civil context in *Safeco Insurance Co. of America v. Burr*.[138] The Court, addressing an alleged reckless violation of the Fair Credit Reporting Act (FCRA),[139] held that recklessness, in the civil context, is "objectively assessed."[140] The Court characterized recklessness as "an unjustifiably high risk of harm that is either known or so obvious that it should be known."[141] Under this definition, there is a two-part analysis for liability: (1) whether the defendant's "interpretation of the relevant statute or regulation was *objectively reasonable*, even if incorrect," and (2) whether the defendant lacked "'authoritative guidance' that warned the defendant from their interpretation."[142] If one or both of these two elements are not satisfied, the defendant has acted in reckless disregard of the statute.[143]

This was the precedent that informed the Seventh Circuit in its interpretation of the FCA scienter standard.[144] Critically, however, the Seventh Circuit erred in applying the *Safeco* Court's holding to not only the recklessness standard, but also the knowingly and deliberate ignorance standards. The Seventh Circuit stated that under FCRA, "the objective scienter standard . . . preclude[s] liability under either term," meaning both "knowing" and "reckless disregard."[145] It deduced that "[t]here is no reason why the scienter standard established in *Safeco* (for violations committed knowingly or with reckless disregard) should not apply to the same common law terms used in the FCA."[146] The Supreme Court later overturned the Seventh Circuit's decision and held that the knowingly and deliberate ignorance standards should be evaluated subjectively, but

137. *Id.* at 837.

138. 551 U.S. 47 (2007).

139. *See id.*; 15 U.S.C. § 1681(m)(a).

140. *Safeco*, 551 U.S. at 69 (citing W. PAGE KEETON ET AL, PROSSER AND KEETON ON THE LAW OF TORTS § 34, at 213 (5th ed. 1984)).

141. *Id.* at 68 (quoting Farmer v. Brennan, 511 U.S. 825, 836 (1994)). The Court went on to note that "[w]e have no reason to deviate from the common law understanding in applying the statute." *Id.* at 69 (citing Beck v. Prupis, 529 U.S. 494, 500–01 (2000)).

142. John Eason, *Recent False Claims Act Developments at the Supreme Court*, 35 HEALTH L. 21, 30 (2023) (quoting *Safeco*, 551 U.S. at 70).

143. *See id.*

144. *See* United States v. SuperValu Inc., 9 F.4th 455, 464 (7th Cir. 2021), *vacated and remanded sub nom.* United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391 (2023).

145. *Id.* at 465 (citing *Safeco*, 511 U.S. at 60, 70 n.20).

146. *Id.*

deliberately avoided the question of how recklessness should be evaluated.[147]

IV. THE CASE FOR AN OBJECTIVE RECKLESSNESS STANDARD

Recent precedent declares that the "knowingly" and "deliberate ignorance" scienter standards should be judged subjectively. Though the Supreme Court has not issued explicit guidance on how to judge the recklessness standard, Court precedent suggests that it may be judged objectively. An objective recklessness standard would serve several important purposes. First, it would allow for a greater opportunity to litigate healthcare fraud by holding healthcare companies and providers responsible for making claims they *should have known* were false. Further, healthcare companies and providers are taking advantage of the modern technology boom, particularly the birth of AI, to assist in making claims to the government for Medicare and Medicaid reimbursement. However, those making false claims to the government via AI billing systems have the power to abuse them by using them as a shield against liability. An objective recklessness standard would reflect the desires of the lawmakers who amended the FCA and would ensure that healthcare entities and providers making false claims using AI-powered billing systems are still held liable.

A. The Supreme Court's Nod to an Objective Recklessness Standard

On June 1, 2023, the Supreme Court delivered its decision in *United States ex rel. Schutte v. SuperValu Inc.*,[148] a case initiated under the FCA.[149] In *Schutte,* relators brought suit against Safeway and SuperValu alleging that both companies "overcharged Medicare and Medicaid programs" by offering discounted prescription drugs to customers while filing for reimbursement at higher rates.[150] CMS requires that pharmacies and providers file claims to Medicare and Medicaid for the "usual and customary" drug prices, i.e., the price that is offered to customers.[151]

In deciding whether the defendants had violated the FCA, the Court broke its silence on scienter in the context of the FCA. In doing so, it settled a longstanding debate about its requirements: whether or not "knowingly" should be judged subjectively or objectively.[152]

147. *See infra* Section IV.A.
148. 143 S. Ct. 1391 (2023).
149. *Id.* at 1396.
150. *Id.*
151. 42 C.F.R. § 447.512(b)(2) (2025).
152. *See* 31 U.S.C. § 3729(a)(1) ("[A]ny person who—*knowingly* presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty . . . ." (emphasis added)).

Justice Thomas, writing for the majority, recognized the FCA's three categories for scienter: "actual knowledge," "deliberate ignorance of the truth or falsity of the information," and "reckless disregard of the truth or falsity of the information."[153] In the Court's decision, Justice Thomas clarified the interpretation courts should use for "knowingly," characterizing it as "respondents' knowledge and *subjective* beliefs—not . . . what an objectively reasonable person may have known or believed."[154] Though Justice Thomas announced a subjective interpretation of scienter as it pertains to actual knowledge and deliberate ignorance, he left open the scienter standard required to establish reckless behavior. He wrote:

> In some civil contexts, a defendant may be called "reckless" for acting in the face of an unjustifiably high risk of illegality that was so obvious that *it should have been known*, even if the defendant was not actually conscious of that risk. We need not consider how (or whether) that objective form of "recklessness" relates to the FCA today . . . .[155]

Justice Thomas's comment, citing the Court's interpretation of recklessness in *Farmer*,[156] leaves the door open for an exception to the subjective scienter requirement as it relates to recklessness. It also shows that the Court recognizes that there are situations in civil contexts where an objective form of recklessness may apply.

B. Arguing for the Adoption of an Objective Recklessness Standard

There are three reasons why the Supreme Court should adopt an objective recklessness standard when it addresses scienter under the FCA in the future. First, this standard reflects the common law roots and legislative history of the FCA and its amendments. Second, it would take into account the duty of care providers and healthcare companies have to the government to submit claims that are not false. Third, it would provide a clear delineation between the "deliberate ignorance" and "recklessness" standards in the FCA, which are often confused by courts.

1. An Objective Recklessness Standard Reflects the Common Law Roots and Legislative History of the FCA

The common law understanding of recklessness is objective, holding an actor to a "reasonable" standard where they are expected to know that certain conduct would be considered more severe than

153. *Schutte*, 143 S. Ct. at 1399–1400 (quoting 31 U.S.C. § 3729(b)(1)(A)(i)–(iii)).

154. *Id.* at 1399 (emphasis added).

155. *Id.* at 14001 n.5 (emphasis added) (citation omitted).

156. *See* case discussed *supra* Section III.C.

mere negligence.[157] Indeed, both civil and criminal common law point to a "knew or should have known" standard when interpreting recklessness.[158] This understanding of recklessness is clear in the legislative history of the 1986 Amendments to the FCA. Specifically, legislative history points to previous circuit court language: "gross negligence . . . is determined by an *objective standard* . . . one who should have known a fact but did not is negligent."[159]

Instituting a subjective knowledge requirement for recklessness would be counterintuitive to the purpose of this additional standard. The recklessness standard exists to encapsulate false claims made with a flagrant disregard for their falsity. A subjective recklessness standard would require defendants to have actual knowledge of the falsity of their claims, which is not required under traditional common law and MPC definitions of recklessness and would conflate "recklessness" with the "knowingly" standard.[160] An objective standard, by contrast, would reflect both the common law understanding of recklessness and the intent lawmakers had while crafting the 1986 Amendments.

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157. 3 STUART M. SPEISER ET AL., THE AMERICAN LAW OF TORTS § 10:1 (2023) (quoting RESTATEMENT (SECOND) OF TORTS § 500 (AM. L. INST. 1965)).

158. *See* RESTATEMENT (SECOND) OF TORTS § 500 (AM. L. INST. 1965) ("The actor's conduct is in reckless disregard . . . if he does an act or intentionally fails to do an act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize . . . that such risk is substantially greater than that which is necessary to make his conduct negligent."); *see also* RESTATEMENT (THIRD) OF TORTS: GENERAL PRINCIPLES § 2 cmt. c (AM. L. INST., Discussion Draft 1999) (stating that section 500's definition of recklessness "requires that the actor at least have actual knowledge of those facts that should lead the actor, as a reasonable person, to appreciate the danger" but "does not require the actor's actual knowledge").

159. *1986 Hearings*, *supra* note 42, at 460–61 (statement of Karen Hastie Williams, Chairman, Legislative Liaison Comm. of the Public Contract Law Section of the American Bar Association, accompanied by Alan C. Brown, Chairman of the Section's Procurement Fraud Committee) (emphasis added) (quoting Comput. Sys. Eng'g, Inc. v. Quantel Corp., 571 F. Supp. 1365, 1374 (1st Cir. 1984)).

160. *See* James Wiseman, *Reasonable, but Wrong: Reckless Disregard and Deliberate Ignorance in the False Claims Act After* Hixson, 117 COLUM. L. REV. 435, 450 (2017) ("[E]stablishing reckless disregard has involved an objective inquiry that may be satisfied without evidence of the defendant's state of mind." (first citing United States v. Krizek, 111 F.3d 934, 941–42 (D.C. Cir. 1997); then citing United States *ex rel.* Aakhus v. Dyncorp, Inc., 136 F.3d 676, 682 (10th Cir. 1998); and then citing Siebert v. Gene Sec. Network, Inc., 75 F. Supp. 3d 1108, 1116 (N.D. Cal. 2014))).

2. An Objective Recklessness Standard Recognizes Provider Responsibility

Just as providers and healthcare companies owe a duty of care to provide sufficient care to patients,[161] they also have a responsibility to avoid knowingly submitting false claims to the government.[162] Issuing claims to the government can be a complicated and nuanced process. However, given the millions of Americans enrolled in either Medicaid or Medicare,[163] providers and companies have and will continue to encounter a significant number of enrollees and are expected to have an understanding of the claims systems.

CMS has spearheaded initiatives in recent years to educate claimants on best practices, for example, by publishing thorough literature online for providers and companies to ensure that they maintain compliance with proper billing practices.[164] It also administers robust prior authorization and pre-claim review processes, which exist to "reduc[e] improper Medicare billing and payments."[165] Under prior authorization and pre-claim review, the provider or supplier can submit a request to the government to receive "provisional affirmation of coverage for the item or service" by their Medicare Administrator Contractor.[166]

It should be emphasized that the FCA does not cover claims made negligently or by mistake.[167] CMS guidance provided in its Medicare Program Integrity Manual recognizes that many errors made in the process of submitting claims are not made knowingly.[168] It differentiates negligence or mere mistake from behavior that is actionable under the FCA by focusing on "situations where a provider has repeatedly submitted claims in error."[169] This differentiation recognizes that human error is inevitable, but providers and

161. *See* RESTATEMENT (SECOND) OF TORTS § 324 (AM. L. INST. 1965).

162. *Your Billing Responsibilities*, CMS (Sept. 10, 2024), https://perma.cc/2TTY-7RLA ("For Medicare programs to work effectively, providers have a significant responsibility for the collection and maintenance of patient information.").

163. *Medicare-Medicaid Enrollee State Profiles*, CMS (Sept. 10, 2024), https://perma.cc/HG42-TPAD (reporting that over 12.2 million Americans are enrolled in Medicaid or Medicare).

164. CMS, MLN909160, COMPLYING WITH MEDICAL RECORD DOCUMENTATION REQUIREMENTS 3–5 (Mar. 2024), https://perma.cc/8A53-7TND (showing common medical procedures billed to Medicare or Medicaid with insufficient documentation).

165. *Prior Authorization and Pre-Claim Review Initiatives*, CMS (Jan. 17, 2025), https://perma.cc/MV35-3VTK.

166. *Id.*

167. Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1058 (11th Cir. 2015).

168. CMS, MEDICARE PROGRAM INTEGRITY MANUAL: CHAPTER 1, sec. 1.3.9 (Rev. 11032, Sept. 2021), https://perma.cc/8YE3-A9MF.

169. *Id.*

healthcare entities are still required to understand their responsibility to avoid making false claims.

An objective recklessness standard would establish a stricter baseline for providers and healthcare companies submitting claims for federal reimbursement. It would do so by instituting a "knew or should have known" standard for claimants where they would be responsible for making claims in a reasonable or prudent manner. A subjective recklessness standard, on the other hand, would create more opportunity for providers and healthcare companies to claim mere negligence or misunderstanding of government claims systems to cover up fraudulent activity. This would place relators and the federal government at a disadvantage and allow fraudulent claimants to avoid liability. Therefore, an objective standard would hold claimants accountable for understanding the legal implications of recklessly submitting potentially false claims.

3. An Objective Recklessness Standard Distinguishes Recklessness from Deliberate Ignorance

The Supreme Court briefly differentiated between the two standards in *Schutte*:

> "[D]eliberate ignorance" encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity. And . . . "[r]eckless disregard" similarly captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway.[170]

Affirming this interpretation of the FCA's scienter standard and distinguishing between deliberate ignorance and recklessness by defining them as subjective and objective, respectively, would prevent lower courts from confusing the standards. Establishing a subjective standard for recklessness would only further muddy the waters between recklessness and deliberate ignorance.

Distinguishing between the two standards allows them to remain in their original hierarchy alongside "knowingly."[171] This structure ensures that deliberate ignorance would serve as a middle ground between insufficient "objective factors . . . to find recklessness" and actual knowledge.[172]

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170. United States *ex rel.* Schutte v. SuperValu Inc., 143 S. Ct. 1391, 1400 (2023) (citations omitted).

171. *See* Wiseman, *supra* note 160, at 464, 468–70.

172. *Id.* at 468.

C. The Objective Recklessness Standard and Combatting AI-Facilitated Healthcare Fraud

Healthcare companies and individual providers are harnessing technology, particularly AI, to expand and optimize care. AI's potential to revolutionize the healthcare industry cannot be overstated. Out of the 200 top CEOs that attended the 2025 Yale CEO Summit, 48 percent anticipated that "AI is likely to make the most transformative contribution" to the healthcare industry compared to any other industry.[173] The expansion of AI in the industry, however, can serve as an example for future healthcare fraud issues, particularly in making false claims to the federal government. Justice Department officials continue to stress the government's dedication to combatting AI-facilitated healthcare fraud. Recent healthcare investigations and litigation point to AI-related healthcare disputes as an emerging issue.[174] Without an objective recklessness standard, fraudulent actors may be able to shield themselves from liability by hiding behind AI systems. This standard is needed now more than ever, with the federal government exhibiting a strong appetite for pursuing AI-related healthcare fraud.[175]

1. The Expansive Use of AI in the Healthcare Industry

AI technology harnesses large data sets to solve complex problems by making predictions and uncovering patterns.[176] These algorithms use machine learning, or deep learning, to use data sets more efficiently in order to improve performance.[177] Providers and companies alike are looking to AI to improve healthcare delivery and cut costs.[178] In an effort to reach those goals, many are looking to one of the largest pieces of the United States' healthcare expenditures:

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173. *See* Jeffrey A. Sonnenfeld & Steven Tian, *We Put Aside the Hype and Asked CEOs What They're Actually Planning for AI*, YALE INSIGHTS (June 22, 2023), https://perma.cc/9VCQ-C5HS.

174. *See* Kate Driscoll et al., *Artificial Intelligence in Healthcare: New Avenues for Liability*, MORRISON & FOERSTER LLP (Mar. 4, 2024), https://perma.cc/TGQ7-FY4Q.

175. *See* Seth A. Goldberg, *EMR Software Utilizing AI Targeted for Fraud and Abuse*, DUANE MORRIS HEALTH L. (Jan. 29, 2024), https://perma.cc/K4NN-4GMQ ("AI related healthcare fraud and abuse actions are clearly on the DOJ's radar and will likely become increasingly common.").

176. *See* Cole Stryker & Eda Kavlakoglu, *What is Artificial Intelligence (AI)?*, IBM (Aug. 9, 2024), https://perma.cc/7G3U-8XRL; Pavel Hamet & Johanne Tremblay, *Artificial Intelligence in Medicine*, METABOLISM, Apr. 2017, at S36, S36 ("Artificial Intelligence (AI) is a general term that implies the use of a computer to model intelligent behavior with minimal human intervention.").

177. *See id.* at S37.

178. Narendra N. Khanna et al., *Economics of Artificial Intelligence in Healthcare: Diagnosis vs. Treatment*, HEALTHCARE, Dec. 2022, at 1, 2.

administrative expenses.[179] Administrative costs account for about 15 to 25 percent of overall expenditures in the United States, or anywhere from "$600 billion to $1 trillion per year of the total national health expenditures."[180] Administrative work in the healthcare industry is broad, encompassing notetaking by providers to scheduling surgeries.[181] Notably, it also includes working with insurance providers and federal programs such as Medicare and Medicaid.[182]

A growing number of healthcare providers and companies are also harnessing AI to optimize the claims process, particularly for prior authorization and pre-claim review. Providers report spending upwards of thirteen hours per week on prior authorization.[183] Automating this process alone could significantly boost efficiency.

2. Recent Examples of Healthcare Fraud Using AI and Potential Issues in Establishing Recklessness

Harnessing AI in the healthcare industry may improve provider and patient experiences by increasing efficiency and accuracy. However, it also opens the door to new opportunities for fraud, waste, and abuse. Examples of companies and providers implicating the FCA by using AI during the claims process are beginning to emerge as AI becomes more accessible and effective. It is clear that the government has taken notice of these opportunities for fraud. Several pharmaceutical and digital health companies, for instance, recently reported that they have received subpoenas from the Justice Department regarding "generative technology's role in facilitating anti-kickback and false claims violations."[184] At least three major pharmaceutical companies—"GSK Plc in 2023, AstraZeneca Plc in 2020, and Merck & Co. in 2019"—received subpoenas related to their maintenance and use of electronic medical records.[185]

Some FCA cases involving the use of AI are already being litigated. In 2021, for example, the government intervened in six related suits alleging that "the Kaiser Permanente consortium

179. *See* Michael Chernew & Harrison Mintz, *Administrative Expenses in the US Health Care System: Why So High?*, 326 JAMA 1679, 1679–80 (2021).

180. *Id.* at 1679.

181. SHASHANK BHASKER ET AL., MCKINSEY & CO., TACKLING HEALTHCARE'S BIGGEST BURDENS WITH GENERATIVE AI 2 (July 2023), https://perma.cc/A9CR-3794.

182. *Id.*

183. SHAHED AL-HAQUE ET AL., MCKINSEY & CO., AI USHERS IN NEXT-GEN PRIOR AUTHORIZATION IN HEALTHCARE 5 (Apr. 2022), https://perma.cc/F93X-SGYT.

184. Ben Penn, *DOJ's Healthcare Probes of AI Tools Rooted in Purdue Pharma Case*, BLOOMBERG L. (Jan. 29, 2024), https://news.bloomberglaw.com/us-law-week/dojs-healthcare-probes-of-ai-tools-rooted-in-purdue-pharma-case.

185. *Id.*

violated the False Claims Act by submitting inaccurate diagnosis codes for its Medicare Advantage Plan enrollees in order to receive higher reimbursements."[186] These cases, consolidated under *United States ex rel. Osinek v. Permanente Medical Group*,[187] involved in part a "data-mining algorithm to identify potential cachexia diagnoses."[188] The algorithm would analyze patient data and prompt physicians to "addend their patient medical records to add cachexia diagnoses" even if there was insufficient evidence for such diagnoses.[189] The government alleged that Kaiser recklessly violated the FCA because it failed to respond to clear evidence that there was "a high error rate with respect to cachexia diagnoses made through addenda."[190] This case is ongoing.

In another case, medical device manufacturers Alere Inc. and Alere San Diego Inc. (Alere) agreed to pay $38.75 million to resolve allegations that they violated the FCA by billing Medicare for blood coagulation monitors that relied upon a defective algorithm.[191] The INRatio monitors lead to "inaccurate and unreliable results for some patients," causing "over a dozen deaths and hundreds of injuries."[192] Alere allegedly knew about such defects but nonetheless continued to bill "Medicare for the use of defective INRatio devices."[193]

These cases serve as just two examples of how the use of AI will impact the Justice Department's fight against healthcare fraud, waste, and abuse. They also point to another justification for an objective recklessness standard. Moving forward, healthcare providers and companies could conceivably use an algorithm as a scapegoat for liability, pointing to an unintended flaw in the system as the reason for a false claim. Establishing an objective recklessness standard would prevent such a defense by ensuring that merely adding a middleman—an algorithm—would not absolve the defendant of liability. Rather, defendants could still be found to be acting in reckless disregard if they knew or should have known that the claims being made by or with assistance from AI were false. In other words, the objective recklessness standard would hold claimants to an objectively reasonable standard in making claims and

186. *Government Intervenes in False Claims Act Lawsuits Against Kaiser Permanente Affiliates for Submitting Inaccurate Diagnosis Codes to the Medicare Advantage Program*, DOJ (July 30, 2021), https://perma.cc/9BPP-VGDA.

187. 640 F. Supp. 3d 885 (N.D. Cal. 2022).

188. *Id.* at 902.

189. *Id.*

190. *Id.* at 904.

191. *Medical Device Companies Alere Inc. and Alere San Diego Inc. Agree to Pay $38.75 Million to Settle False Claims Act Allegations*, DOJ (July 8, 2021), https://perma.cc/4YPF-9Z76.

192. *Id.*

193. *Id.*

would not allow claimants to excuse false claims made simply because they were made using AI.

3. The Road Toward Future Enforcement Efforts

The federal government has largely pledged to prioritize its focus on AI—to harness its benefits and to prevent its use in fraud, discrimination, and bias.[194] The Justice Department, in particular, has indicated that it plans to carry out heavy enforcement efforts against those who perpetrate fraud using AI.[195] Former Deputy Attorney General Lisa Monaco discussed the Department's aggressive approach in her keynote remarks at the American Bar Association's 39th National Institute on White Collar Crime.[196] She stated that the Justice Department is "alert to [the] risks" of AI and "will be using [their] tools in new ways to address them."[197] She warned, "[t]o be clear: Fraud using AI is still fraud."[198]

In 2024 alone, the Justice Department launched several new initiatives to carry out these promises. In April of 2024, the DOJ announced that "five new cabinet-level federal agencies"—including the Department of Health and Human Services—are joining in an effort to heighten enforcement actions for fraud using AI.[199] Just two months later, Monaco hosted the fourth convening of the "Justice AI Initiative" to discuss how the use of AI will transform healthcare fraud and how the Justice Department plans to "leverage AI to fight crime."[200] And in August, the DOJ announced its Whistleblower Awards Pilot Program, created to incentivize private actors to "uncover and prosecute corporate crime" by offering awards for, in part, information on "health care fraud schemes involving private insurance plans."[201] This program mirrors whistleblower programs in other federal agencies such as the SEC[202] and Commodity Future Trading Commission.[203]

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194. Exec. Order No. 14,110, 88 Fed. Reg. 75191 (Oct. 30, 2023).

195. *See* Goldberg, *supra* note 175.

196. *Deputy Attorney General Lisa Monaco Delivers Keynote Remarks at the American Bar Association's 39th National Institute on White Collar Crime*, DOJ (Mar. 7, 2024), https://perma.cc/DVH3-A6KB.

197. *Id.*

198. *Id.*

199. *Five New Federal Agencies Join Justice Department in Pledge to Enforce Civil Rights Laws in Artificial Intelligence*, DOJ (Apr. 4, 2024), https://perma.cc/8YZD-T3TD.

200. *Update on Deputy Attorney General Lisa Monaco's Justice AI Convenings*, DOJ (June 7, 2024), https://perma.cc/85CP-W7NV.

201. *Criminal Division Corporate Whistleblower Awards Pilot Program*, DOJ (Aug. 1, 2024), https://perma.cc/Z5LG-B5SZ.

202. *Whistleblower Program*, SEC (Nov. 21, 2024), https://perma.cc/Q54S-6G7G.

203. *Whistleblower Program Overview*, CFTC (2025), https://perma.cc/7GUR-P4XR; David Nakamura, *Targeting White-Collar Crime, Justice Dept. Seeks More*

This appetite for pursuing healthcare fraud and abuse via the FCA remains even with the new Trump Administration. Attorney General Pam Bondi indicated during her confirmation hearing that the Justice Department would continue to pursue "robust FCA enforcement."[204] The FCA, she stated, "brings [money] back" to the treasury.[205] Despite President Trump's vow to remove barriers to AI innovation in his January 23, 2025 Executive Order,[206] the Justice Department can still be expected to pursue "traditional concerns" that involve AI, such as upcoding or billing for services not provided.[207]

These efforts indicate that the federal government is aware that AI may make it more difficult to establish responsibility for fraudulent behavior, and more creative and aggressive approaches are needed to be effective.[208] They also serve as a reminder that healthcare fraud will evolve alongside technology.

CONCLUSION

As fraud in the United States continues to transform, so, too, will the FCA. Its original purpose and subsequent amendments, however, point to a goal that has persisted as other elements are restructured: to combat fraud against the United States government. This overarching goal continues to guide the federal government in its pursuit for justice, particularly fighting against the boom of healthcare fraud in recent decades. This landscape has made the FCA one of the most important tools for federal recovery.

Though the Supreme Court determined that "knowingly" and "deliberate ignorance" are measured subjectively for purposes of the FCA, federal circuit courts and the Supreme Court's rulings in other contexts suggest that an objective recklessness standard may be adopted. An objective recklessness standard would align with the statute's common law roots, legislative history, and both the civil and criminal understanding of recklessness. Such a standard would ensure accountability for providers and companies submitting false claims and would clarify the distinction between "recklessness" and "deliberate ignorance."

Looking to the future of healthcare fraud in the United States, courts are likely to encounter FCA cases involving new technology, particularly AI. In these cases, providers and companies could

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Whistleblowers, WASH. POST (July 9, 2024), https://www.washingtonpost.com/national-security/2024/07/09/justice-whistleblowers-white-collar-crimes/.

204. Jaime L.M. Jones et al., *DOJ Enforcement Outlook in Compliance for 2025*, REUTERS (Mar. 18, 2025), https://www.reuters.com/legal/legalindustry/doj-enforcement-outlook-health-care-compliance-2025-2025-03-18/.

205. *Id.*

206. Exec. Order No. 14,179, 90 Fed. Reg. 8741 (Jan. 23, 2025).

207. Jones et al., *supra* note 204.

208. Penn, *supra* note 184.

attempt to use this technology as a shield from liability. An objective recklessness standard would ensure that fraudulent actors recklessly issuing automated claims systems without verifying their accuracy are held accountable. Such guidance would ensure that the FCA remains a powerful weapon against federal fraud.

Meredith Gillespie[*]

* J.D. Candidate, 2025, Wake Forest University School of Law. Thank you to the *Wake Forest Law Review* editors and staff members for their invaluable help and insight on this article. This Comment, like my (forthcoming) law degree, is dedicated to my late father, Casey—a lifetime learner whose commitment to family and community I hope to embody. Thanks also to my mother, Nancy, and my brothers, Stephen and Colin, for their constant support and encouragement. Finally, thank you to my husband, Ben, for always believing in me.