

DEPRESSING DIAGNOSIS: STRINGENT PARTICULARITY REQUIREMENT OF THE RULE 9(B) PLEADING STANDARD AS A CRITICAL BAR TO OFF-LABEL PROMOTION FRAUD WHISTLEBLOWERS

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INTRODUCTION

The False Claims Act¹ (FCA) is the federal government's primary tool for combating fraud against the government, and it has proven invaluable as a recovery mechanism since its enactment during the Civil War.² In fact, between 2000 and 2013, the United States recovered over \$8.8 billion dollars from pharmaceutical companies alone in civil settlement agreements arising from off-label promotion cases brought under the FCA.³ In light of recent Supreme Court decisions,⁴ off-label

¹ 31 U.S.C. §§ 3729–3733 (2012).

² See discussion *infra* Part I.A.

³ Brian C. Elmer, *False Claims Act Settlements 2000–2014*, CROWELL & MORING LLP (July 25, 2014), <http://www.crowell.com/files/false-claims-act-fca-settlements-crowell-moring.pdf>. Indeed, federal recoveries from the combined civil and criminal settlements amounted to over \$15.5 billion dollars within the same period. See *id.*; Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES, May 10, 2007, http://www.nytimes.com/2007/05/10/business/11drug-web.html?pagewanted=all&_r=0; Press Release, Dep't of Justice, Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-Label Promotion of Depakote (May 7, 2012); Press Release, Dep't of Justice, Allergan Agrees to Plead Guilty & Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox® (Sept. 1, 2010); Press Release, Dep't of Justice, Amgen Inc. Pleads Guilty to Fed. Charge in Brooklyn, NY; Pays \$762 Million to Resolve Criminal Liab. & False Claims Act Allegations (Dec. 19, 2012); Press Release, Dep't of Justice, Biopharm. Co., Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Mktg. (Sept. 29, 2008); Press Release, Dep't of Justice, Biopharm. Firm Intermune to Pay U.S. Over \$36 Million for Illegal Promotion & Mktg. of Drug Actimmune (Oct. 26, 2006); Press Release, Dep't of Justice, Boehringer Ingelheim to Pay \$95 Million to Resolve False Claims Act Allegations (Oct. 25, 2012); Press Release, Dep't of Justice, Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Mktg. & Pricing (Sept. 28, 2007); Press Release, Dep't of Justice, Danish Pharm. Novo Nordisk to Pay \$25 Million to Resolve Allegations of Off-Label Promotion of Novoseven (June 10, 2011); Press Release, Dep't of Justice, Drug Maker Forest Pleads Guilty; To Pay More Than \$313 Million to Resolve Criminal Charges & False Claims Act Allegations (Sept. 15, 2010); Press Release, Dep't of Justice, Eli Lilly & Co. Agrees to Pay \$1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa (Jan. 15, 2009); Press Release, Dep't of Justice, GlaxoSmithKline to Plead Guilty & Pay \$3 Billion to Resolve Fraud Allegations & Failure to Report Safety Data (July 2, 2012); Press Release, Dep't of Justice, ISTA Pharm. Inc. Pleads Guilty to Fed. Felony Charges; Will Pay \$33.5 Million to Resolve Criminal Liab. & False Claims Act Allegations (May 24, 2013); Press Release, Dep't of Justice, Johnson & Johnson Subsidiary Scios Pleads Guilty to Misbranding Heart Failure Drug Natrecor (Oct. 5, 2011); Press Release, Dep't of Justice, Justice Dep't Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009); Press Release, Dep't of Justice, Kos Pharm. to Pay More Than \$41 Million to Resolve Kickback & Off-Label Promotion Allegations (Dec. 7, 2010); Press Release, Dep't of Justice, Medicis Pharm. to Pay U.S. \$9.8 Million to Resolve False Claims Allegations (May 8, 2007); Press Release, Dep't of Justice, Novartis Pharm. Corp. to Pay More Than \$420 Million to Resolve Off-Label Promotion and Kickback Allegations (Sept. 30, 2010); Press Release, Dep't of Justice, Novartis Vaccines & Diagnostics to Pay More Than \$72 Million to Resolve False Claims Act Allegations Concerning TOBI (May 4, 2010); Press Release, Dep't of Justice, Otsuka to Pay More Than \$4 Million to Resolve Off-Label Mktg. Allegations Involving Abilify (Mar. 27, 2008); Press Release, Dep't of Justice, Par Pharm. Pleads Guilty & Agrees to Pay \$45 Million to Resolve Civil & Criminal Allegations Related to Off-Label Mktg. (Mar. 5, 2013); Press Release, Dep't of Justice, Pfizer Agrees to Pay \$55 Million for Illegally Promoting Protonix for Off-Label Use (Dec. 12, 2012); Press Release, Dep't of Justice, Pharm. Cos. to Pay \$214.5 Million to Resolve Allegations of Off-Label Promotion of Zonegran (Dec. 15, 2010); Press Release, Dep't of Justice, Pharm. Giant AstraZeneca to Pay \$520 Million for Off-Label Drug Mktg. (Apr.

promotion cases are more important than ever in ensuring that pharmaceutical companies, particularly generic manufacturers, abide by the FDA's requisite safety and effectiveness standards⁵ and that plaintiffs are protected against generic pharmaceuticals where their recourse is greatly limited.⁶

The Supreme Court's denial of certiorari in FCA⁷ cases concerning Rule 9(b) of the Federal Rules of Civil Procedure⁸ has effectively left the circuits split over the specificity with which a private party alleging off-

27, 2010); Press Release, Dep't of Justice, Pharm. Giant, Serono, Agrees to Pay \$44.3 Million to Settle False Claims Act Case (May 4, 2011); Press Release, Dep't of Justice, Schering to Pay \$435 Million for the Improper Mktg. of Drugs & Medicaid Fraud (Aug. 29, 2006); Press Release, Dep't of Justice, Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-Label Promotion of Topamax (Apr. 29, 2010); Press Release, Dep't of Justice, U.S. Pharm. Co. Merck Sharp & Dohme to Pay Nearly One Billion Dollars Over Promotion of Vioxx® (Nov. 22, 2011); Press Release, Dep't of Justice, U.S. Subsidiary of Belgian Pharm. Mfr. Pleads Guilty to Off-Label Promotion; Co. to Pay More Than \$34 Million (June 9, 2011); Press Release, Dep't of Justice, Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liab. Relating to Off-Label Promotion (May 13, 2004); Press Release, Dep't of Justice, Wyeth Pharm. Agrees to Pay \$490.9 Million for Mktg. the Prescription Drug Rapamune for Unapproved Uses (July 30, 2013). The Department of Justice (DOJ) may prosecute criminal false claims lawsuits against individuals or entities that defraud the government under 18 U.S.C. § 287, which provides that:

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.

18 U.S.C. § 287 (2012). For the purposes of this Note, however, references to the FCA strictly encompass the civil provisions, as set forth in 31 U.S.C. §§ 3729–3733, and not the criminal provisions set forth in 18 U.S.C. § 287.

⁴ See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (holding that failure-to-warn state law claims against generic pharmaceutical manufacturers are impliedly preempted by federal law because generic manufacturers are prohibited from unilaterally changing or strengthening product labeling without prior FDA approval); see also *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (holding that generic pharmaceutical manufacturers cannot be held liable under state law for failure to adequately label a drug because such design-defect claims are preempted by federal law under *PLIVA*); *Merck KGaA v. Integra Lifescis. I, Ltd.*, 545 U.S. 193 (2005) (finding that the generic pharmaceutical manufacturer's use of patented compounds in preclinical studies was protected by the narrow experimental use exception because there was a reasonable basis for believing that the experiments would produce types of information relevant to drug applications submitted to the FDA, and that the favorable result for the generic manufacturer would encourage public policies that expedite generic pharmaceutical FDA approval processes).

⁵ See discussion *infra* Part II.B–C.

⁶ See *Bartlett*, 133 S. Ct. at 2485 (Sotomayor, J., dissenting) (“While the Court has not always been consistent on this issue, it has repeatedly cautioned against reading federal statutes to ‘remove all means of judicial recourse for those injured’ when Congress did not provide a federal remedy.” (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984))).

⁷ 31 U.S.C. §§ 3729–3733 (2012).

⁸ FED. 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.”).

label pharmaceutical promotion fraud—a *qui tam* relator⁹ or “whistleblower”¹⁰—must plead in order to satisfy the requisite particularity standard.¹¹ A number of courts have endorsed a broader construction of the particularity requirement that does not mandate identifying the specific false claims, whereas other courts have adopted a rigorous specificity analysis to meet the heightened pleading standard.¹²

⁹ See 31 U.S.C. § 3730(b) (“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.”). “*Qui tam*” is derived from the Latin phrase “*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,” which means “who as well for the king as for himself sues in this matter.” BLACK’S LAW DICTIONARY 1368 (9th ed. 2009); see also *Vartelas v. Holder*, 132 S. Ct. 1479, 1490 n.8 (2012) (noting that private individuals who bring *qui tam* actions may also be called “relator[s]”).

¹⁰ See, e.g., Robert Salcido, *The Government’s Increasing Use of the False Claims Act Against the Health Care Industry*, 24 J. LEGAL MED. 457 (2003).

¹¹ See *infra* Part II.D–F.

¹² Compare *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 32 (1st Cir. 2009) (holding that relator satisfied the particularity requirement by providing sufficient information regarding false Medicare claims filed), *cert. denied*, 561 U.S. 1005 (2010), and *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir. 2010) (“We join the Fifth Circuit in concluding, in accord with general pleading requirements under Rule 9(b), that it is sufficient to allege ‘particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.’” (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009))), and *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) (“We [do not] think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit.”), and *Grubbs*, 565 F.3d at 195 (holding that even though complaint failed to state exact billing numbers or amounts for false Medicare and Medicaid claims, complaint was still plead with sufficient particularity because it described, in substantial detail, actions of defendants in relating scheme to whistleblower), *with Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009) (holding that relators’ complaint was properly dismissed because it failed to “allege the existence of a single actual false claim”), *cert. denied*, 561 U.S. 1006 (2010), and *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013) (adopting the Eleventh Circuit standard that requires a relator to provide “some indicia of reliability” in a complaint to support the allegation that an actual false claim was presented to the government), *cert. denied*, 134 S. Ct. 1759 (2014), and *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009) (holding that to satisfy pleading requirements under Rule 9(b), a relator “must identify who, what, where, and how” (citation omitted)), and *Sanderson v. HCA-Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006) (affirming dismissal of relator’s complaint because he failed to sufficiently allege the “time, place, and content of the alleged misrepresentations on which he . . . relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud” (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161–62 (6th Cir. 1993))). Although the Second and Third Circuits have not yet weighed in on the Rule 9(b) pleading requirements under the FCA, district courts within the circuits have tended to adopt standards similar to those of the Eleventh and First Circuits, respectively. Within the Second Circuit, district courts have rejected whistleblowers’ claims that have failed to meet the more stringent pleading standard. See, e.g., *United States ex rel. Moore v. GlaxoSmithKline LLC*, No. 06 Civ. 6047(BMC), 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) (“Although it appears that plaintiff has alleged adequately the details of the purported fraudulent scheme, there is nothing in the complaint alleging with particularity that a claim was submitted to the Government for reimbursement. While there is no mandatory checklist, ‘details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are

Notably, the First Circuit held that the relator in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*¹³ satisfied the Rule 9(b) requirement by providing the dates and amounts of the false claims filed by eight healthcare providers, all of whom were prompted by the defendant pharmaceutical company's kickback scheme to file for reimbursement of off-label prescriptions.¹⁴ The relator was not required to provide details as to each false claim because he provided sufficient factual evidence—the “who, what, where, when, and how”¹⁵ explanations—to establish the inference of fraud beyond a mere possibility.¹⁶ Thus, the First Circuit's flexible particularity standard does not necessitate proof of the government's payment of specific false

the types of information that may help a relator to state his or her claims with particularity.’ . . . Here, plaintiff has failed to allege details of either a specific claim for payment that was submitted to the Government by either a medical provider or a pharmacist, or the specific details of an actual Medicaid/Medicare provider certification form signed by a particular physician.” (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004), *abrogated on other grounds* by *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)); *United States ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806(FB)(VVP), 2013 WL 1346022, at *7 (E.D.N.Y. Apr. 3, 2013) (“The Second Circuit has recognized that Rule 9(b)'s heightened pleading requirement is intended to provide notice to defendants, to prevent reputational harm due to baseless charges, and to discourage fishing expeditions.”). By comparison, district courts within the Third Circuit have permitted whistleblowers' claims to survive under a lower pleading standard. *See, e.g., United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895(JLL), 2013 WL 4710587, at *13 (D.N.J. Aug. 30, 2013) (“[T]he Third Circuit has yet to weigh in on whether a plaintiff must identify representative samples at the pleading stage in order to properly plead an FCA claim with the specificity required by Rule 9(b). . . . In light of the trend among courts of appeals and district courts in this Circuit, the Court declines to hold that a plaintiff must identify particular false claims at the pleading stage in every FCA case.”); *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. 06-3213, 2013 WL 2649704, at *5 (E.D. Pa. June 13, 2013) (“While the purpose of Rule 9(b) is to provide notice of the precise misconduct alleged, courts should apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants.” (citation and internal quotation marks omitted)); *United States ex rel. Budike v. Peco Energy*, 897 F. Supp. 2d 300, 319 (E.D. Pa. 2012) (declining to adopt heightened pleading standard that would require relator to plead at least one specific instance of fraud).

¹³ 579 F.3d 13 (1st Cir. 2009).

¹⁴ *Id.* at 29–30; *see infra* Part I.C–D.

¹⁵ *Duxbury*, 579 F.3d at 30 (reasoning that while relator did “not identify specific claims, he . . . alleged the submission of false claims across a large cross-section of providers that allege[d] . . . the who, what, where, and when of the allegedly false or fraudulent representation”) (citations and internal quotation marks omitted); *see, e.g., Rodi v. S. New England Sch. of Law*, 389 F.3d 5, 15 (1st Cir. 2004) (recognizing that the heightened Rule 9(b) pleading requirement that “fraud be alleged with particularity . . . is satisfied by an averment ‘of the who, what, where, and when of the allegedly false or fraudulent representation’” (citing *Alt. Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004))); *see also Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (dismissing whistleblower's claims for failure to provide “the who, what, where, when, and how” of defendant medical device companies' false claims (internal quotation marks omitted)).

¹⁶ *Duxbury*, 579 F.3d at 29. Moreover, the relator alleged facts that supported his claim that the pharmaceutical company intended to cause the third-party healthcare providers to submit false claims, which obviated the need to establish that the company itself submitted false claims for payments. *Id.* at 30.

claims where a relator has sufficiently plead facts that adequately establish that the false claims were filed.¹⁷

Later that same year, however, the Eleventh Circuit affirmed the district court's dismissal of the relators' claims in *Hopper v. Solvay Pharmaceuticals, Inc.*,¹⁸ concluding that the allegations that the pharmaceutical company engaged in an off-label marketing campaign to increase the sales of one of its drugs failed to meet the particularity requirement in the absence of evidence showing that the federal government did, in fact, pay a false claim.¹⁹ The Eleventh Circuit held that while a defendant was neither required to present its false statements to the government nor personally submit a false claim to violate the FCA, relators carried the burden of proof regarding the federal government's payment of the defendant's false claims.²⁰ Under this reasoning, a relator must allege with particularity facts that prove that the government paid a defendant's false claim in order to establish liability under the FCA.²¹

Due to the Supreme Court's refusal thus far to reconcile these divergent decisions, courts and commentators have continued to contribute to the fragmented Rule 9(b) jurisprudence in healthcare fraud *qui tam* litigation. Courts have recognized a number of factors that a whistleblower's allegations must meet in order to satisfy the particularity requirement, including, but not limited to: the substantive content of the alleged misrepresentation;²² the "who, what, where, when, and how" of the alleged fraud;²³ and a description of the advantage gained by the defendant in making the fraudulent representation.²⁴

¹⁷ *Id.*

¹⁸ 588 F.3d 1318 (11th Cir. 2009), *cert. denied*, 561 U.S. 1006 (2010).

¹⁹ *Id.* at 1328.

²⁰ *Id.* ("A defendant's false statements themselves need not be presented to the government, and the defendant need not personally submit a false claim. Nevertheless, because the [FCA] protects the government from loss due to fraud, and it is not 'an all-purpose antifraud statute,' the relators must show that the government paid a false claim to prove a violation of [the FCA]." (citation omitted)); *see Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671 (2008) (clarifying that in order to prove an FCA violation, a relator need not prove "that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting 'a false or fraudulent claim paid or approved by the Government'" (citing 31 U.S.C. § 3729(a)(1))).

²¹ *Hopper*, 588 F.3d at 1329 (holding that "a plaintiff must prove that the government in fact paid a false claim," and that the relator's allegation that "state health programs present[ing] false claims of uncertain amounts on uncertain dates to the government . . . resulted in a marked increase in Medicaid payments" failed to meet this requisite particularity requirement).

²² *See infra* Part II.A.

²³ *See infra* Part II.A.

²⁴ *See generally* *United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 34 (1st Cir. 2013) ("[T]he complaint must specify the time, place, and content of an alleged false representation." (citation and internal quotation marks omitted)); *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012) ("To satisfy this [particularity] requirement the plaintiff must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify

Nevertheless, no single multifactor analysis has been consistently applied throughout the courts.²⁵

Given the rapid expansion of the pharmaceutical market, this disparity in pleading standards under the FCA requires immediate redress. Without a uniform approach to the Rule 9(b) particularity requirement, a pharmaceutical company may be able to limit—or avoid altogether—liability under the FCA by restricting its business to jurisdictions that require a whistleblower’s allegations to meet stringent particularity standards.²⁶ Therefore, courts must apply a pleading standard that is compatible with the dual objectives of the FCA—battling fraud while also preventing “parasitic” lawsuits.²⁷

Although the Supreme Court has repeatedly declined to grant certiorari on this issue,²⁸ it acknowledged the importance of the circuit split in 2013, when it invited the Solicitor General to file a brief stating the views of the federal government on the Rule 9(b) pleading standard in FCA cases.²⁹ In 2010, when the Supreme Court invited the government to express its views on the Rule 9(b) pleading standard in *Duxbury*, the Solicitor General had recommended that the petition for a writ of certiorari should be denied.³⁰ The Solicitor General, however, did

the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” (citation and internal quotation marks omitted)).

²⁵ See *infra* Part II.

²⁶ See *infra* Part III.A.

²⁷ See *infra* Part I.A.

²⁸ See *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009), *cert. denied*, 561 U.S. 1005 (2010); *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318 (11th Cir. 2009), *cert. denied*, 561 U.S. 1006 (2010).

²⁹ See Order Inviting the Solicitor General to File Brief Expressing Views of the United States, *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 134 S. Ct. 374 (2013) (No. 12-1349); see also *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1759 (2014). In *Takeda*, the Fourth Circuit held that the relator, a sales manager for defendant pharmaceutical company, failed to allege that specific claims were actually presented to the government for payment. *Takeda*, 707 F.3d at 458–61. The court rejected the argument that the Rule 9(b) particularity requirement was satisfied by allegations of the existence of a fraudulent scheme, holding that a relator was required to “plead facts plausibly alleging that particular, identifiable false claims actually were presented to the government for payment.” *Id.* at 456. Where a defendant’s alleged actions “could have led, but need not necessarily have led, to the submission of false claims, a relator must allege with particularity that the specific false claims had actually were presented to the government for payment.” *Id.* at 457. Because the relator failed to allege that the doctors to whom defendant promoted off-label uses had, in fact, written off-label prescriptions, the complaint failed to meet the Rule 9(b) pleading standard and was properly dismissed. *Id.* at 458, 461. At the present, it is unclear as to whether the Solicitor General will advocate for the heightened or lowered pleading standard. Jaime Jones & Nirav Shah, *Supreme Court Invites Solicitor General to Weigh in on the Pleading Requirements for FCA Cases*, ORIGINAL SOURCE—THE SIDLEY AUSTIN FALSE CLAIMS ACT BLOG (Oct. 27, 2013, 10:17 PM), <http://fcablog.sidley.com/blog.aspx?entry=294&fromSearch=true>.

³⁰ Brief for United States as Amicus Curiae at 1, *Duxbury*, 579 F.3d 13 (No. 09-654), 2010 WL 2007742, at *1.

not advocate for a specific position,³¹ and the Supreme Court denied certiorari.

This Note argues that a stringent particularity pleading requirement presents a prohibitively high bar for healthcare fraud whistleblowers and that a flexible standard that is consistent with both the First Circuit's reasoning and the Food, Drug, and Cosmetic Act's (FDCA)³² off-label use provision is appropriate. Part I explores the background of the FCA, the FDCA, and off-label promotion fraud jurisprudence. Part II examines how courts—specifically, the First and Eleventh Circuit Courts of Appeal—and commentators have addressed the heightened Rule 9(b) pleading standard in pharmaceutical whistleblowing suits. Part III proposes a pleading standard that applies the First Circuit's lowered particularity requirement, where the relator has no burden to prove that specific false claims were submitted to the federal government for payment, but, unlike the First Circuit, requires the relator to prove all essential elements of FCA liability by clear and convincing evidence and not by the lower “preponderance of the evidence” standard. The goal of this approach is to strike a necessary balance between barring frivolous whistleblower claims and encouraging government efficiency through reports of fraud and abuse.

I. BACKGROUND

A. *False Claims Act*

The False Claims Act³³—the federal government's “primary litigation tool”³⁴ in combating fraud—imposes civil liability on any person or entity who defrauds the United States government by

³¹ Instead, the government merely noted that the First Circuit's decision to apply the lowered Rule 9(b) pleading standard “deepens an existing circuit conflict, and [the Supreme] Court's review likely would be warranted in an appropriate case.” Brief for the United States as Amicus Curiae, *supra* note 30, at *9. That “appropriate case” was *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318 (11th Cir. 2009), whose petition for a writ of certiorari was pending before the Supreme Court at the time that the federal government filed its amicus brief in *Duxbury*. Because the Supreme Court subsequently denied certiorari in both *Duxbury* and *Hopper*, the pleading issue has remained unresolved and the Supreme Court has not again expressed interest in the issue until now.

³² 21 U.S.C. §§ 301–397 (2012).

³³ 31 U.S.C. §§ 3729–3733 (2012).

³⁴ See S. REP. NO. 99-345, at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5266; see also *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010); *United States ex rel. Marcy v. Rowan Cos., Inc.*, 520 F.3d 384, 388 (5th Cir. 2008); *Avco Corp. v. U.S. Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989).

submitting false or fraudulent claims for payment.³⁵ Under the FCA's *qui tam* provisions, a private individual may file and prosecute a lawsuit on behalf of the United States to recover civil penalties and treble damages.³⁶ The complaint must be filed *in camera*, remain under seal for at least sixty days, and not be served on the defendant until the court orders as such.³⁷ The relator then must serve the complaint on the government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure, and the government may elect to intervene and prosecute the suit itself within sixty days of service of the complaint and all material evidence.³⁸ To establish liability, the relator or the government must prove all essential elements by a preponderance of the evidence.³⁹ Such *qui tam* provisions serve to strike a balance between preventing "parasitic"⁴⁰ or "copycat" lawsuits⁴¹ and encouraging private citizens to expose fraud committed against the United States Treasury.⁴²

³⁵ 31 U.S.C. §§ 3729–3733. The FCA also imposes liability upon any person who:

- (A) knowingly presents, or causes to be presented, false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
- (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
- (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
- (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]

Id. § 3729(a)(1)(A)–(G) (internal footnote omitted).

³⁶ *Id.* § 3729(a)(1)(G) (“[A defendant] is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000[] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.”).

³⁷ *Id.* § 3730(b)(2).

³⁸ *Id.*

³⁹ *Id.* § 3731(d).

⁴⁰ United States *ex rel.* Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1154 (3d Cir. 1991) (citing *False Claims Act Implementation: Hearing Before the Subcomm. on Admin. Law & Gov. Relations of the House Comm. on the Judiciary*, 101st Cong. 3 (1990) (statement of Sen. Grassley) (barring *qui tam* lawsuits based on public disclosures “sought to resolve the tension between . . . encouraging people to come forward with information and . . . preventing parasitic lawsuits”)).

Congress originally enacted the FCA⁴³ in response to President Abraham Lincoln's efforts to curb rampant private contractor fraud.⁴⁴ During the Civil War, private contractors raked in exorbitant war profits due to the radically increased government military spending.⁴⁵ However, private contractors took advantage of the Union Army's dire need for military resources and misappropriated the monies received from the federal government.⁴⁶ After lengthy hearings, Congress added *qui tam* provisions to the FCA so that private individuals would be able to prosecute defense contractors on behalf of the United States, where the offending contractor would have to pay double damages and a \$2000 civil penalty for each false claim.⁴⁷ On March 2, 1863, Congress passed the FCA and President Lincoln signed it into law.⁴⁸

The FCA remained unchanged until 1943, when Congress amended its provisions in an effort to curtail "parasitic lawsuits."⁴⁹

⁴¹ See *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004) ("[F]iling copycat suits . . . do no more than assert the same material elements of fraud, regardless of whether those later complaints are able to marshal additional factual support for the claim.").

⁴² *Id.*

⁴³ Act of Mar. 2, 1863, ch.67, § 4, 12 Stat. 696, 698 (1863) (current version codified at 31 U.S.C. § 3730(d) (1994)).

⁴⁴ See 78 AM. JUR. 3D 357 *Proof of Facts* § 3 (2004) [hereinafter *POF-FCA*]. See generally 132 CONG. REC. 22,339–40 (1986) (remarks of Rep. Berman and Rep. Bedell); David L. Haron, Mercedes Varasteh Dordeski, & Larry D. Lahman, *Bad Mules: A Primer on the Federal and Michigan False Claims Acts*, 88 MICH. B.J. 22, 22 (2009) (describing the actions of "unscrupulous defense contractors" that caused President Lincoln to urge Congress to pass the FCA).

⁴⁵ See *POF-FCA*, *supra* note 44, § 3 (citing United States *ex rel.* Newsham v. Lockheed Missiles & Space Co., 722 F. Supp. 607, 609 (N.D. Cal. 1989)).

⁴⁶ See James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1264–65 (2013). The Union Army's dearth of military resources resulted from repeated defeats at the hands of the Confederate troops. *Id.* Such fraud took the form of providing the Union Army with defective weapons, substandard clothing, and rancid rations. See, e.g., 132 CONG. REC. H6482 (daily ed. Sept. 9, 1986) (statement of Rep. Berman) (reporting that defense contractors sold the same mules "over and over again" to Army quartermasters); CONG. GLOBE, 37th Cong., 3d Sess. 955 (1863) (statement of Sen. Howard) (noting that contractors supplied infantry boots made out of cardboard and gunpowder barrels containing no gunpowder, only sawdust); WAYNE ANDREWS, *THE VANDERBILT LEGEND* 77–84 (1941) (describing how rotted ship hulls were freshly painted and then sold as new vessels to the Navy); Haron et al., *supra* note 44, at 22; Helmer, *supra*, at 1264–65; Patricia Meador & Elizabeth S. Warren, *The FCA: A Civil War Relic Evolves into a Modern Weapon*, 65 TENN. L. REV. 455, 458 n.29 (1998) ("In one instance, a contractor sold mules, blind and unfit for service, to the United States military for \$119 each.").

⁴⁷ See Act of Mar. 2, 1863, ch. 67, § 4, 12 Stat. 696, 698 (1863) (current version codified at 31 U.S.C. § 3730(d) (1994)). A whistleblower would receive 50% of the double damages, with the federal government receiving the remaining 50%—this scheme ensured that the United States was made whole even after the 50% award had been paid to the whistleblower. Helmer, *supra* note 46, at 1266.

⁴⁸ Helmer, *supra* note 46, at 1266.

⁴⁹ See Act of Dec. 23, 1943, ch. 377, 57 Stat. 608 (1943) (codified as amended at 31 U.S.C. § 3730(b) (1994)). Specifically, the term "parasitic lawsuits" evolved from the World War II era, during which a new class of war profiteers emerged. See Helmer, *supra* note 46, at 1267. The federal government, through the DOJ and the Federal Bureau of Investigation (FBI), pursued criminal prosecutions against such war profiteers, but largely ignored the civil FCA. *Id.* As such,

During World War II, a new class of war-profiteering defense contractors had emerged, and the federal government pursued criminal prosecutions against such contractors through the Department of Justice.⁵⁰ Attorney General Francis Biddle, however, largely neglected the civil FCA and failed to file companion civil FCA lawsuits simultaneously with the return of criminal indictments.⁵¹ Private citizens thus seized upon this opportunity to capitalize on the Attorney General's oversight, waiting in federal courthouses and filing civil FCA claims as soon as criminal indictments were brought against defense contractors.⁵² Accordingly, a relator did not need to introduce new information to the government to prevail in a civil FCA action.⁵³

Moreover, the Supreme Court upheld such parasitic lawsuits with its ruling in *United States ex rel. Marcus v. Hess*.⁵⁴ There, the Supreme Court held that the whistleblower was a proper *qui tam* relator, notwithstanding the fact that the federal government had already investigated the fraud claimed in the relator's civil FCA action and that the relator's suit essentially re-alleged the facts contained in the government's criminal indictment.⁵⁵ The Supreme Court's *Hess* decision and the subsequent proliferation of such "parasitic lawsuits" compelled Congress to amend the provisions of the FCA to restrict the filing of these actions.⁵⁶

Under the 1943 amendments, the Attorney General was authorized to take over *qui tam* lawsuits initiated by whistleblowers.⁵⁷ More

private citizens would immediately file civil FCA actions—the so-called "parasitic lawsuits"—against defense contractors upon knowledge that the federal government had brought criminal indictments. *Id.* ("A few enterprising citizens with knowledge of the False Claims Act would lurk in federal courthouses for criminal indictments to be brought against defense contractors then immediately file a civil False Claims Act case based on the indictment against the same contractor. Such actions, known as 'parasitic lawsuits,' infuriated the [then] Attorney General Francis Biddle."); see also Gregory G. Brooker, *The False Claims Act: Congress Giveth and the Courts Taketh Away*, 25 *HAMLIN L. REV.* 373, 378 (2002).

⁵⁰ Helmer, *supra* note 46, at 1267.

⁵¹ See 89 *CONG. REC.* 10,697 (1943) (noting that Attorney General Biddle did not bring a single civil FCA action between 1863 and 1942); see also Helmer, *supra* note 46, at 1267.

⁵² Helmer, *supra* note 46, at 1267.

⁵³ 317 U.S. 537, 541–46 (1943).

⁵⁴ 317 U.S. 537 (1943), *superseded by statute*, 31 U.S.C. § 233(c) (later codified at 31 U.S.C. § 3730(c) (1994)), *as recognized in* *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010). In *Hess*, the federal government indicted electrical contractors for collusive bidding on a government project. *Id.* The contractors did not contest the allegations and paid the \$54,000 fine. *Id.*; Helmer, *supra* note 46, at 1268. In the *qui tam* suit arising from the same collusive conduct, the relator obtained a jury verdict for \$315,000. *Hess*, 317 U.S. at 540.

⁵⁵ *Id.* at 545 (upholding relator's recovery even though it was a quintessential parasitic lawsuit because "[e]ven if, as the government suggests, the [relator] has contributed nothing to the discovery of this crime, he has contributed much to accomplishing one of the purposes for which the [False Claims] Act was passed").

⁵⁶ Brooker, *supra* note 49, at 377–78; Helmer, *supra* note 46, at 1267–71.

⁵⁷ 31 U.S.C. § 233(c) (later codified at 31 U.S.C. § 3730(c) (1994)). The 1943 amendments gave the DOJ and the Attorney General the option of intervening in a *qui tam* lawsuit. See *id.* If

importantly, whistleblowers were barred from bringing claims that alleged information already within the government's possession at the time of the filing of the action.⁵⁸ Whistleblower rewards were also significantly reduced from the 50 percent of the amount ultimately recovered by the federal government afforded to them under the FCA promulgated in 1863, to a maximum of 10 to 25 percent.⁵⁹ As a result of such restrictions, few whistleblower suits were commenced in the wake of the 1943 amendments, and fraud against the government increased once more.⁶⁰

Congress did not revisit the provisions of the FCA until 1986, as the Reagan administration's enormous national defense expenditures offered various opportunities for defense contractors to misappropriate Department of Defense funds.⁶¹ The well-publicized *United States ex rel.*

the Attorney General so chose, he had to do so within sixty days. *Id.* § 232(c). Intervention would render the relator a mere observer of the government's case. See Helmer, *supra* note 46, at 1271. DOJ intervention generally predicts the ultimate success of the case, with approximately ninety-five percent of all intervened cases resulting in government recovery. PETER B. HUTT ET AL., U.S. CHAMBER INST. FOR LEGAL REFORM, FIXING THE FALSE CLAIMS ACT: THE CASE FOR COMPLIANCE-FOCUSED REFORMS 7 (2013), available at http://instituteforlegalreform.com/uploads/sites/1/Fixing_The_FCA_Pages_Web.pdf. If the government elected not to proceed, then the whistleblower was permitted to do so at his own expense. 31 U.S.C. § 232(E)(1). However, only six percent of non-intervened cases result in success. HUTT ET AL., *supra*, at 7.

⁵⁸ 31 U.S.C. § 233(c). This bar to whistleblower recovery came to be known as the "any prior government knowledge" defense. Helmer, *supra* note 46, at 1271; see also *POF-FCA*, *supra* note 44, § 3 ("As a result of Congress' 1943 Amendments, whistleblowers could no longer bring claims that were based on evidence or information that was known to the government at the time the action was brought. This restriction was not contingent upon whether the government had any *intention* of bringing a claim and even if the whistleblower was the original source of the evidence or information.") (emphasis added)).

⁵⁹ 31 U.S.C. § 3491(E)(1)-(2). See generally *POF-FCA*, *supra* note 44, § 3 ("[T]he whistleblower's share in the proceeds of a successful action was reduced from 50 percent to a maximum of 25 percent if the government did not help with the litigation and 10 percent if the government helped with the litigation."); Brooker, *supra* note 49, at 378.

⁶⁰ See 89 CONG. REC. 10,848 (1943) (Congressman Miller warned that the 1943 amendments were an "infamous conspiracy, . . . [a] subtle scheme to set aside the only guaranty that has lasted for 80 years against unmitigated frauds perpetrated upon the government and to substitute in its stead a feeble statute that does nothing but paralyze the efforts of an honest informer"); Brooker, *supra* note 49, at 379 ("[B]y 1986, forty years of restrictive judicial interpretation of the Act had taken its toll on the [FCA]."); Evan Caminker, *The Constitutionality of Qui Tam Actions*, 99 YALE L.J. 341, 343 (1989) (noting that *qui tam* litigation fell into a "period of desuetude" between 1943 and 1986); Helmer, *supra* note 46, at 1271 (observing that the 1943 amendments "stood the False Claims Act on its head" and authorized the federal government to assume complete control over the lawsuit, which caused *qui tam* litigation to "virtually disappear[] from the legal landscape"); Ara Lovitt, *Fight for Your Right to Litigate: Qui Tam, Article II, and the President*, 49 STAN. L. REV. 853, 857 (1997) (noting decline in *qui tam* cases after 1943).

⁶¹ S. REP. NO. 99-345, at 2 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5267 (concluding that "[e]vidence of fraud in Government programs and procurement [was] on a steady rise" after reviewing reports of a thirty percent increase in Department of Defense fraud investigations from 1982-1984 and taking into advisement the fact that almost fifty percent of the one hundred largest defense contractors were under investigation for multiple fraud offenses in 1985). The defense contractor fraud during this period concerned fraud, waste, and abuse in the form of

*Wisconsin (Department of Health and Social Services) v. Dean*⁶² case, in addition to the torrent of newspaper accounts concerning defense contractor fraud,⁶³ pressured Congress to amend the FCA to “encourage more private enforcement suits.”⁶⁴ Significant amendments included increasing the relator’s reward from the ignoble percentages set forth by the 1943 provisions to a maximum recovery of 15 to 30 percent;⁶⁵ providing for treble, rather than double, damages;⁶⁶ raising the defendant’s penalties per false claim to a sum between \$5000 and \$10,000;⁶⁷ permitting the successful relator to recover attorneys’ fees and expenses from the defendant;⁶⁸ and protecting relators with protection from employment retaliation.⁶⁹

Most notably, however, Congress amended the FCA by eliminating the “any prior government knowledge” defense,⁷⁰ which had precluded whistleblowers from bringing *qui tam* suits if a government official had some knowledge of the alleged fraud.⁷¹ Instead, Congress added a “public disclosure” exception that was designed to prevent parasitic

“profit gouging.” See Helmer, *supra* note 46, at 1271 (describing alarming reports of \$400 hammers, \$7000 coffee pots, and \$640 aircraft toilet seats). See also 131 CONG. REC. 17,818 (1985).

⁶² 729 F.2d 1100 (7th Cir. 1984) (holding that Wisconsin was barred from filing a *qui tam* action where the government already had “essential information” concerning Wisconsin allegations that defendant psychiatrist had submitted 912 fraudulent Medicaid claims, notwithstanding the fact that the government had first received such information from Wisconsin).

⁶³ See Nancy G. Berner, *The Uninjured Plaintiff: Constitutional Standing of Qui Tam Plaintiffs After Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 35 U.S.F. L. REV. 783, 785 (2001) (“These amendments were made largely in response to scandals at the Department of Defense, notably the infamous \$640 toilet seat cover.” (citing James Gerstenzang, *Admiral Removed over High-Priced Ashtrays*, L.A. TIMES, May 31, 1985, § 1, at 4)); Christopher C. Frieden, *Protecting the Government’s Interests: Qui Tam Actions Under the False Claims Act and the Government’s Right to Veto Settlements of Those Actions*, 47 EMORY L.J. 1041, 1042 (1998) (“During the 1980s the government was again faced with the problem of widespread fraud in the defense industry. As President Reagan increased the national defense budget, overbilling and false claims became an increasingly serious problem.”).

⁶⁴ S. REP. NO. 99345, at 23–24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5288–89; see False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153. See generally Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 133 (2001) (“The 1986 Amendments were designed to recast the Civil War-era statute as an effective weapon against modern forms of government fraud, particularly in defense procurement and the federal health care programs.”).

⁶⁵ 31 U.S.C. § 3730(d)(1)–(2) (2012). Although the relator’s recovery was not reinstated to the 50 percent set forth in the 1863 Act, a relator was entitled to 15 to 25 percent of the recovery if the federal government—through the DOJ—chose to prosecute the case, and 25 to 30 percent if the relator litigated the case without government intervention. Helmer, *supra* note 46. For exceptions to these percentages, see James B. Helmer, Jr., *How Great Is Thy Bounty: Relator’s Share Calculations Pursuant to the False Claims Act*, 68 U. CIN. L. REV. 737, 750, 755 (2000).

⁶⁶ 31 U.S.C. § 3729(a).

⁶⁷ *Id.*

⁶⁸ *Id.* § 3730(d)(1)–(2) (1986).

⁶⁹ *Id.* § 3730(h).

⁷⁰ POF-FCA, *supra* note 44, § 3.

⁷¹ See *supra* text accompanying note 58.

lawsuits while encouraging whistleblowers.⁷² This provision barred *qui tam* actions where the allegations had already been publicly disclosed either by the media or a court hearing unless the relator was an “original source” with direct and independent knowledge of the fraudulent activity.⁷³ To date, the 1986 amendments to the FCA have spurred the filing of nearly 8000 *qui tam* lawsuits and the recovery of over \$55 billion dollars for the government.⁷⁴ Therefore, the public disclosure exception, together with the other 1986 amendments, has effectively protected whistleblowers’ financial stake in *qui tam* litigation.⁷⁵

Following several judicial decisions that significantly narrowed the applicability of the FCA to certain false claims with the imposition of an intent requirement,⁷⁶ Congress enacted various legislation directed at setting aside the restrictive rulings.⁷⁷ In the Fraud Enforcement and Recovery Act of 2009 (FERA),⁷⁸ Congress expressly struck the Supreme Court’s read-in intent requirement and amended the definition of “claim” to mean any type of demand for money or property that will be spent on behalf of the federal government or used to advance governmental programs of interest.⁷⁹ More importantly, in the Patient

⁷² 31 U.S.C. § 3730(e)(4); see Helmer, *supra* note 46, at 1274.

⁷³ 31 U.S.C. § 3730(e)(1), (4).

⁷⁴ See Helmer, *supra* note 46, at 1275 (citing DEP’T OF JUSTICE, FRAUD STATISTICS—OVERVIEW 1–2 (2010), available at <http://www.taf.org/FCA-stats-2010.pdf>); *Featured Frauds*, TAF EDUC. FUND, <http://www.taf.org/fraud-cases#case406> (last visited Aug. 29, 2014) (“Since 1987, False Claims Act lawsuits have returned over \$55 billion to federal and state Governments. Of this sum, over \$39 billion has been recovered to the federal government as a consequence of civil settlements and judgments.”). Taxpayers Against Fraud (TAF) maintains better records of FCA recovery statistics than the DOJ because when the latter announces recoveries at the end of each year, it excludes both the criminal settlement amounts and state recoveries. See *DOJ Hides its Light Under a Barrel*, TAF EDUC. FUND (Dec. 4, 2012), <http://www.taf.org/blog/doj-hides-its-light-under-barrel>. Accordingly, this Note relies more heavily upon statistics from TAF than those from the DOJ.

⁷⁵ S. REP. NO. 99-345, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5291 (noting that the public disclosure exception ensured that “the Government [did] not neglect evidence, cause undu[e] delay, or drop the false claims case without legitimate reason”).

⁷⁶ See, e.g., *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) (holding that FCA required a subcontractor to have *intended* by its conduct to obtain federal funds), *superseded by statute as stated in* *United States ex rel. Wall v. Circle C Constr., L.L.C.*, 697 F.3d 345 (6th Cir. 2012). The *Allison Engine* court further read an intent requirement into §§ 3729(a)(2) and (a)(3) that severely limited the scope and applicability of the FCA to certain false claims. *Allison Engine*, 553 U.S. at 668–73. While a whistleblower did not have to prove that the defendant *caused* a false record or statement to be presented or submitted to the government, he had to prove “that the defendant made a false record or statement *for the purpose* of getting ‘a false or fraudulent claim paid or approved by the Government.’” *Id.* at 671 (emphasis added) (citation omitted).

⁷⁷ See *infra* text accompanying notes 78–80.

⁷⁸ Pub. L. No. 111-21 § 4, 123 Stat. 1617, 1621–25 (2009).

⁷⁹ 31 U.S.C. § 3729(b)(2) (2009) (“[T]he term ‘claim’ means 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 . . . [however, the term ‘claim’] does not include requests or demands for money or property that the Government has paid to an individual as compensation

Protection and Affordable Care Act of 2010 (PPACA),⁸⁰ Congress rewrote the increasingly litigated public disclosure and original source provisions⁸¹ to clarify that *only* public disclosure by a federal report or the news media would deprive a court of subject matter jurisdiction of a *qui tam* suit.⁸²

Currently, a significant portion of FCA suits involves allegations of Medicaid fraud.⁸³ In fact, as of 2008, approximately \$8 billion—or forty percent—of the government’s recoveries under the FCA since 1986 was attributed to hospital and pharmaceutical manufacturer litigation.⁸⁴ These FCA suits cover a wide breadth of healthcare providers, including doctors, hospitals, and pharmaceutical companies, among others.⁸⁵ *Qui tam* relators have played important roles in exposing these fraudulent

for Federal employment or as an income subsidy with no restrictions on that individual’s use of the money or property.”).

⁸⁰ Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901–02 (2010).

⁸¹ These provisions, as provided for in the 1986 amendments, have resulted in a four-way split among the circuit courts. See Helmer, *supra* note 46, at 1279. See generally 31 U.S.C. § 3730(e)(4) (1986).

⁸² See 31 U.S.C. § 3730(e)(4)(A)(i)–(iii) (2012). The statute, in relevant part, provides that:

The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—

- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
- (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
- (iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Id. (footnote omitted). The PPACA effectively overrode the Supreme Court’s decision in *Graham Co. Soil & Water Conservation District v. United States ex rel. Wilson*, in which the Court restricted the scope of cases falling within the public disclosure exception by determining that public disclosures in non-federal matters could also serve as a basis to revoke jurisdiction in *qui tam* litigation. *Graham Co. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 301 (2010). Finally, Congress enacted the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank), which clarified that the appropriate statute of limitations for whistleblower retaliation cases was three years after the date of retaliation. See Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, § 1079A(c), 31 U.S.C. § 3730(h) (2010).

⁸³ See discussion *infra* Part II.A.

⁸⁴ S. REP. NO. 110-507, at 7 (2008) (“[I]t is important to note that some areas of fraud are more pervasive than others and none more so than healthcare benefits paid by the Government under the Medicare and Medicaid programs. FCA cases have touched virtually every area of the healthcare community, including hospitals, doctors, pharmaceutical companies, nursing homes, durable medical equipment retailers and manufacturers, and renal care facilities, among others. Healthcare cases have constituted a significant portion of FCA recoveries, with hospital cases recovering over \$3.4 billion and pharmaceutical manufacturer cases recovering over \$4.6 billion. That is about 40 percent of \$20 billion that the Government has recovered using the FCA over the past 20 years.”).

⁸⁵ *Id.*

practices, particularly with regard to complex Medicare billing frauds that involve off-label marketing by pharmaceutical companies.⁸⁶ The substantial healthcare recoveries have far-reaching implications for both the federal government and the taxpayers themselves, as fraud erodes public confidence in the government's ability to efficaciously manage its programs.⁸⁷ Moreover, potential FCA offenders are deterred from engaging in fraudulent actions because of the undeniable "watchdog" effect of the *qui tam* provision.⁸⁸ Because successful *qui tam* suits have resulted in this strong deterrent effect, courts should exercise caution in imposing overly restrictive constructions on what, specifically, satisfies the particularity requirement of Rule 9(b).

B. Federal Food, Drug, and Cosmetic Act and Off-Label Promotion

The FDCA⁸⁹ is the principal federal law regulating drug manufacturers and the marketing of their products.⁹⁰ Under the FDCA, the Food and Drug Administration (FDA) must approve all new prescription drugs as safe and effective before a manufacturer is permitted to market them.⁹¹ To obtain approval, a manufacturer must provide the FDA with substantial information concerning the drug, including comprehensive reports of investigations into its safety and efficacy, its proposed labeling, a full statement of its composition, and a complete description of the methods used in its manufacture, processing, and packing.⁹² The drug's labeling must have at least one

⁸⁶ *Id.* at 8. See *infra* Part I.C for an in-depth discussion of off-label promotion and marketing.

⁸⁷ S. REP. NO. 110-507, at 7. However, it is important to note that the tremendous *qui tam* recoveries under the FCA only represent *one* measure of fraud against the government. See *id.*

⁸⁸ *Id.* at 8 ("In the wake of well-publicized recoveries attributable to the *qui tam* cases, those who might otherwise submit false claims to the Federal Government are more aware than ever of the 'watchdog' effect of the *qui tam* statute. We have no doubt that the Act has had the salutary effect of deterring fraudulent conduct." (citing *The False Claims Act Correction Act (S. 2041): Strengthening the Gov't's Most Effective Tool Against Fraud for the 21st Century: Hearing Before Comm. on the Judiciary*, 110th Cong. 192 (2008)).

⁸⁹ 21 U.S.C. §§ 301-397 (2012).

⁹⁰ *Id.* §§ 331(d), 355(a), (d); see also 100 AM. JUR. 3D 1 *Proof of Facts* §§ 1-2 (2008) [hereinafter *POF-Pharmaceuticals*].

⁹¹ 21 U.S.C. §§ 331(d), 355(a), (d). 21 U.S.C. § 355(a) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."

⁹² *Id.* § 355(b)(1). The statute, in relevant part, identifies application materials to be submitted to the FDA:

Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full

approved and intended use.⁹³ The FDA, however, does not require the manufacturer to submit data concerning *every* possible use for which physicians may prescribe the proposed drug.⁹⁴ Once the FDA receives a manufacturer's application materials, the Center for Drug Evaluation and Research (CDER) evaluates the new drug by reviewing the manufacturer's data and proposed labeling.⁹⁵ If CDER determines that the drug's health benefits outweigh its known risks, then it will approve the drug for sale.⁹⁶ Therefore, the use of an approved drug for any purposes other than those provided for in the labeling submitted to the FDA—including indications, dosage, dosage administration, or age groups—constitutes off-label use.⁹⁷

While doctors are permitted to prescribe drugs for off-label uses under the FDCA,⁹⁸ manufacturers cannot promote or market drugs for such off-label uses because the FDCA prohibits false or misleading statements on drug labels.⁹⁹ Since a misleading statement about an off-label use would render the drug misbranded and thereby illegalize its distribution,¹⁰⁰ a manufacturer's off-label promotion could thus subject it to civil and criminal liability under the FCA¹⁰¹ even if the information is accurate and the drug's benefits outweigh its risks.¹⁰²

However, a manufacturer would not be held liable under the FCA if it makes a bona fide effort to disseminate evidence of dangerous uses of the drug after the FDA has already approved its initial labeling.¹⁰³ First, the manufacturer must update the drug labeling when it becomes

statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title.

Id.

⁹³ *POF-Pharmaceuticals*, *supra* note 90, § 1.

⁹⁴ *Id.*

⁹⁵ *Development & Approval Process (Drugs)*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm> (last visited Oct. 14, 2013).

⁹⁶ *Id.* The details of a manufacturer's drug-testing procedures are not relevant to this Note. Nevertheless, it must be noted that CDER does not test the drugs itself, although it may conduct limited research concerning drug quality, efficacy, and safety. *Id.* For additional information about clinical trials, see *Conducting Clinical Trials*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ConductingClinicalTrials/default.htm> (last visited Oct. 14, 2013).

⁹⁷ See *Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 182 (E.D. Pa. 2007) (noting that prescription of Paxil for children was off-label use, since children constituted an "unapproved" population); *POF-Pharmaceuticals*, *supra* note 90, § 1.

⁹⁸ *POF-Pharmaceuticals*, *supra* note 90, § 1; David S. Stone, *Off-Label Marketing as a Predicate for False Claims Act Liability*, 51 FALSE CLAIMS ACT & QUI TAM Q. REV. 9 (2009).

⁹⁹ 21 U.S.C. § 352(a) (2012).

¹⁰⁰ *Id.*; *POF-Pharmaceuticals*, *supra* note 90, § 2.

¹⁰¹ Stone, *supra* note 98, at 9.

¹⁰² 21 U.S.C. §§ 331(d), 355(a), (d).

¹⁰³ *POF-Pharmaceuticals*, *supra* note 90, § 2.

aware of new information concerning potential or established dangers of the drug.¹⁰⁴ For such label revisions, the manufacturer is required to notify the FDA with a supplemental submission detailing the changes in the labeling at least thirty days prior to the distribution of the drug with the updated labeling.¹⁰⁵ Second, the manufacturer may disseminate information regarding off-label uses apart from the revised labeling, such as advertisements, published articles, and “Dear Doctor” letters.¹⁰⁶ All pertinent information must be distributed through independent sources,¹⁰⁷ and the manufacturer must both disclose its interest in the drug and the lack of FDA approval for the off-label use.¹⁰⁸ Indeed, the FDA has promulgated regulations governing the dissemination of information to health professionals,¹⁰⁹ evincing its intent to encourage the communications.¹¹⁰

¹⁰⁴ *Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 681–82 (E.D. Pa. 2006); 21 C.F.R. § 201.57(e) (2003) (revised 2006) (“The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.”).

¹⁰⁵ 21 C.F.R. § 314.70(c)(6)(iii) (2014). Changes in the labels may accomplish the following:

- (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;
- (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;
- (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
- (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or
- (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

Id. § 314.70(c)(6)(iii)(A)–(E).

¹⁰⁶ *Perry*, 456 F. Supp. 2d at 682. Further, the Federal Register stated that:

[T]hese labeling regulations do not prohibit a manufacturer, packer, relabeler, or distributor from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered. The addition to labeling and advertising of additional warnings, as well as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters directed to health care professionals (e.g., “Dear Doctor” letters containing such information) is not prohibited by these regulations.

Labeling and Prescription Drug Advertising: Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979) (codified at 21 C.F.R. pts. 201–202)

¹⁰⁷ *POF-Pharmaceuticals*, *supra* note 90, § 3.

¹⁰⁸ *Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 182 (E.D. Pa. 2007).

¹⁰⁹ 21 C.F.R. § 200.5 (setting forth that mailings “should be distinctive in appearance so that [they] will be promptly recognized and read”).

¹¹⁰ *Perry*, 456 F. Supp. 2d at 682; *POF-Pharmaceuticals*, *supra* note 90, § 2.

For various reasons, rather than applying for FDA approval, a manufacturer may promote a drug for off-label use by sharing information with the medical community.¹¹¹ Because certain governmental entities, such as Medicaid,¹¹² do not normally reimburse for off-label prescriptions, a drug manufacturer may not want to restrict the use of its drug to only FDA-approved uses and thereby fail to maximize its profits.¹¹³ Moreover, in line with the profit maximization rationale, a drug manufacturer may want to avoid the costly clinical trials required for FDA approval and instead opt for the substantially less costly FDA-compliant off-label promotion.¹¹⁴ Lastly, insufficient or unavailable scientific evidence as to a drug's efficacy—required to obtain FDA approval—may also compel a drug manufacturer to engage in off-label promotion.¹¹⁵

C. *Off-Label Promotion Liability and Medicaid Fraud Under the False Claims Act*

A drug manufacturer's off-label promotion gives rise to a private right of action under the FCA when the manufacturer knowingly markets its drugs to medical providers for off-label uses and the prescriptions generate reimbursement claims that are submitted to a federal governmental entity,¹¹⁶ such as Medicare¹¹⁷ or Medicaid.¹¹⁸ The

¹¹¹ *POF-Pharmaceuticals*, *supra* note 90, § 3.

¹¹² Stone, *supra* note 98, at 9. For an in-depth discussion of off-label promotion and Medicare fraud under the FCA, see *infra* Part II.A.

¹¹³ *POF-Pharmaceuticals*, *supra* note 90, § 3; Stone, *supra* note 98, at 9.

¹¹⁴ *POF-Pharmaceuticals*, *supra* note 90, § 3; see *supra* text accompanying notes 105–16.

¹¹⁵ *POF-Pharmaceuticals*, *supra* note 90, § 3.

¹¹⁶ Stone, *supra* note 98, at 9. Each year, the United States spends \$2.8 trillion on health care, which encompasses the Medicare and Medicaid programs. JACK A. MEYER, TAXPAYERS AGAINST FRAUD EDUC. FUND, FIGHTING MEDICARE & MEDICAID FRAUD: THE RETURN ON INVESTMENT FROM FALSE CLAIMS ACT PARTNERSHIPS 2 (2013), available at <http://www.taf.org/TAF-ROI-report-October-2013.pdf>. Approximately fifty million Americans are enrolled in Medicare, and in any given month, sixty-two million Americans are enrolled in Medicaid. *Id.* In 2012, Medicare spent \$555 billion, and Medicaid spent \$459 billion. See *Medicare*, CONG. BUDGET OFF., <http://www.cbo.gov/topics/health-care/medicare> (last visited Aug. 29, 2014); see also Vernon K. Smith, Kathleen D. Gifford & Jack Meyer, “The Economics of Medicaid Expansion: A Look at the Direct and Indirect Fiscal Considerations for States, Stakeholders, and Policy Makers.” *Health Management Associates*, November 30, 2012. As a result, the combined spending of approximately \$1.014 trillion between Medicare and Medicaid presents a “tempting target for fraud.” MEYER, *supra*, at 2.

¹¹⁷ *Fischer v. United States*, 529 U.S. 667, 671–72 (2000) (“Medicare is a federally funded medical insurance program for the elderly and disabled. . . . [where] the Federal Government is the single largest source of funds for participating hospitals.”); see also MEDICARE, <http://www.medicare.gov> (last visited Oct. 17, 2013).

¹¹⁸ See *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650 (2003) (“[Medicaid] authorizes federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons.”).

Medicaid program provides medical assistance to low-income individuals and families who are unable to pay for the costs of necessary medical services.¹¹⁹ In order for a drug to qualify for reimbursement through Medicaid, the drug manufacturer must negotiate a rebate agreement that ensures that Medicaid pays a competitive price for the drug.¹²⁰ Medicaid providers—including pharmacies—pay the drug manufacturers for the prescription drugs and then submit claims to state Medicaid agencies for reimbursement.¹²¹ Because the federal government reimburses state Medicaid agencies,¹²² claims submitted to the latter are considered to be claims submitted to the federal government and may therefore give rise to liability under the FCA.¹²³

Medicaid, however, does not generally reimburse for off-label prescriptions.¹²⁴ Rather, it only reimburses providers for “covered outpatient drugs,”¹²⁵ which excludes medication that has been prescribed for off-label uses.¹²⁶ Reimbursement claims for off-label uses

¹¹⁹ 42 U.S.C. § 1396 (2012); *see also* MEDICAID, <http://www.medicaid.gov> (last visited Oct. 17, 2013); MEDICARE, <http://www.medicare.gov> (last visited Oct. 17, 2013).

¹²⁰ 42 U.S.C. § 1396r-8(a)(1).

¹²¹ *Id.* §§ 1396a(a)(23), (32).

¹²² *Id.* § 1396.

¹²³ *POF-Pharmaceuticals*, *supra* note 90, § 4. To boost the efficacy of the 1986 amendments to the FCA, Congress passed the Health Insurance Portability and Accountability Act (HIPAA) in 1996, which established the Health Care Fraud and Abuse Control (HCFAC) program. MEYER, *supra* note 116, at 3. HCFAC received \$294.8 million in mandatory funding in 2012, and Congress appropriated \$309.7 million in discretionary funding. *Id.* Of the total funding, \$513.7 million was provided to the Department of Human & Health Services (HHS) and \$90.9 million to the DOJ, \$35.5 million of which was directed to the U.S. attorneys. *Id.* at 3–4. HHS and DOJ partnered together and initiated the Health Care Fraud Prevention & Enforcement Action Team (HEAT) in May 2009, which coordinated collaborative action between the two departments to prevent and prosecute health care fraud. *Id.* at 5. “Strike Force” teams use advanced data analysis techniques to identify “identify high-billing levels in health care fraud hot spots, to target emerging or migrating schemes, and identify chronic fraud by criminals masquerading as health care providers or suppliers.” *Id.* The federal government’s efforts in investigating and prosecuting health care fraud caused approximately \$4.2 billion to either be deposited with the United States Department of the Treasury and the Centers for Medicare & Medicaid Services (CMS), transferred to other federal agencies administering health care programs, or paid to private individuals during the 2012 fiscal year. *Id.* at 2. That same year, whistleblowers recovered \$284.3 million out of the total \$2.5 billion in health care *qui tam* settlements and judgments. *Id.* at 3. Although whistleblower recovery amounted to less than six percent of the total federal recovery, the combination of whistleblower health care fraud actions and government assistance forms “a very powerful tool” for returning money to the Treasury. *Id.*

¹²⁴ 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3).

¹²⁵ *Id.*

¹²⁶ *Id.* § 1396r-8(k)(3)(H) (“The term ‘covered outpatient drug’ does not include . . . a drug or biological used for a medical indication which is not a medically accepted indication.”). Within the meaning of the statute, a “medically accepted indication” is one that has been approved under the FDCA or one that has been included in specified drug compendia. *Id.* § 1396r-8(k)(6). Private health insurers may thus set their own standards in determining whether or not to reimburse for off-label prescription claims. *See, e.g.,* Brannan v. Nw. Permanente, P.C., No. C05-5157(FDB), 2006 WL 2794871 (W.D. Wash. Sept. 27, 2006) (health insurance carrier’s consideration of off-label use of Adderall); State *ex rel.* Bax Global, Inc. v. Indus. Comm., 2007-Ohio-695U (workers’

that are submitted to Medicaid subsequently constitute fraudulent claims under the FCA.¹²⁷ Therefore, a typical off-label promotion claim under the FCA alleges that, but for the drug manufacturer's off-label promotion in contravention of the FDA regulations, physicians would not have otherwise prescribed the drug for off-label uses and patients would not have submitted claims to Medicaid for reimbursement.¹²⁸

II. ANALYSIS

A. Rule 9(b) and the Particularity Requirement

Federal Rule of Civil Procedure 9(b) requires that, “[i]n 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.”¹²⁹ Because fraud claims raise a substantial risk of abusive litigation, the particularity requirement is critical.¹³⁰ The heightened pleading requirement is designed to protect defendants from sweeping fishing expeditions under the pretext of a lawsuit, as well as specious allegations.¹³¹

Accordingly, broad and conclusory allegations of fraud are insufficient to meet the particularity requirement of Rule 9(b).¹³²

compensation carrier was ordered to pay for off-label use of artificial disc for spinal surgery; use of disc in off-label manner was neither “experimental” nor “investigational,” but rather, was a matter of medical judgment).

¹²⁷ See *supra* notes 116, 118, 120–23 and accompanying text. Within the context of off-label promotion FCA claims, the whistleblowers in the *qui tam* lawsuits are generally former or current employees of a drug manufacturer. See, e.g., *United States v. Ortho-McNeil Pharm., Inc.*, No. 03 C 8239, 2007 WL 2091185, at *1 (N.D. Ill. July 20, 2007) (stating that relator was a former sales representative for defendant drug manufacturer).

¹²⁸ See, e.g., *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318 (11th Cir. 2009), *cert. denied*, 561 U.S. 1006 (2010).

¹²⁹ FED. R. CIV. P. 9(b) (emphasis added).

¹³⁰ See *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 569 n.14 (2007) (“On certain subjects understood to raise a high risk of abusive litigation, a plaintiff must state factual allegations with greater particularity than Rule 8 requires.” (citing FED. R. CIV. P. 9(b)–(c))).

¹³¹ See *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007) (“Defendants would not have notice of the specific conduct with which they were charged, they would be exposed to fishing expeditions and strike suits, and they would not be protected from ‘spurious charges of immoral and fraudulent behavior.’” (quoting *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006))); *Sanderson*, 447 F.3d at 877 (holding that relator failed to plead with sufficient particularity that would “alert the defendants ‘to the precise misconduct with which they are charged and [to] protect[] defendants against spurious charges of immoral and fraudulent behavior’” (quoting *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1310 (2002))).

¹³² *Gandhi v. Sitara Capital Mgmt., LLC*, 721 F.3d 865 (7th Cir. 2013); *Radmore v. Aegis Commc’n Grp., Inc.*, 346 F. App’x 835 (3d Cir. 2009); *Universal Commc’n Sys., Inc. v. Lycos, Inc.*, 478 F.3d 413 (1st Cir. 2007); *ATSI Commc’n, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87 (2d Cir. 2007). Even though a complaint need not include “detailed factual allegations,” *Twombly*, 550 U.S. at

Instead, a pleading must contain sufficient factual allegations that would warrant a strong inference that fraudulent misconduct occurred.¹³³ A presentment clause in the FCA imposes liability upon a person who knowingly presents, or causes to be presented, a false claim to an officer or employee of the federal government.¹³⁴ The controversy surrounding the requisite degree of particularity with which allegations must be plead to satisfy the presentment factor is the source of the current circuit split.¹³⁵

A number of courts have held that where a complaint specifies the time, place, and content of an alleged false representation, the particularity requirement is met.¹³⁶ These are commonly known as the “who, what, where, when, and how” requirements.¹³⁷ Most importantly, these courts have permitted *qui tam* claims to survive without alleging with particularity that specific false claims were indeed presented to the government for payment.¹³⁸

Meanwhile, other courts have applied a more stringent analysis where, in addition to meeting the “who, what, where, when, and how” requirements, the whistleblower must also identify the actual false

545, Rule 8(a)(2) of the Federal Rules of Civil Procedure requires that the complaint “contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation and internal quotation marks omitted). Indeed, a claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*

¹³³ *United States ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (stating that pleading must state sufficient facts to “raise a reasonable expectation that discovery will reveal evidence of [the misconduct alleged]” (quoting *Twombly*, 550 U.S. at 556)).

¹³⁴ Under 31 U.S.C. § 3729(a)(1)(A) of the FCA—the presentment clause—liability is imposed where a person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A) (2012).

¹³⁵ *Cf. Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318 (11th Cir. 2009), *cert. denied*, 561 U.S. 1006 (2010) (clarifying that presentment clause requires that a relator plead specific false claims that were presented to government for payment because “[w]ithout the *presentment* of such a claim, while the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required under the False Claims Act” (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002))).

¹³⁶ *See, e.g., United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28 (1st Cir. 2013); *Lundy v. Catholic Health Sys. of Long Island Inc.*, 711 F.3d 106 (2d Cir. 2013); *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98 (2d Cir. 2012); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009), *cert. denied*, 561 U.S. 1005 (2010); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009); *Schaller Tel. Co. v. Golden Sky Sys., Inc.*, 298 F.3d 736 (8th Cir. 2002).

¹³⁷ *See supra* notes 15, 136 and accompanying text.

¹³⁸ *See, e.g., Grubbs*, 565 F.3d at 189–90 (“Fraudulent presentment requires proof only of the claim’s falsity, not of its exact contents. If at trial a *qui tam* plaintiff proves the existence of a billing scheme and offers particular and reliable indicia that false bills were actually submitted as a result of the scheme—such as dates that services were fraudulently provided or recorded, by whom, and evidence of the department’s standard billing procedure—a reasonable jury could infer that more likely than not the defendant presented a false bill to the government, this despite no evidence of the particular contents of the misrepresentation.”); *see also infra* Part II.C.

claims that were presented for payment.¹³⁹ This additional burden requires the whistleblower to present specific evidence regarding the federal government's payment of the defendant's false claims, such as details that identify *particular* false claims.¹⁴⁰ Despite the requirement that the alleged fraud be stated with particularity, however, the requisite *intent* of the defendant need not be alleged with similar specificity.¹⁴¹

B. *The Allison Engine Standard and Congressional Response*

The Supreme Court clarified the FCA's intent requirement in *Allison Engine Co. v. United States ex rel. Sanders*.¹⁴² In *Allison Engine*, the United States Navy contracted with two shipbuilders to build a new fleet of missile destroyers.¹⁴³ The shipyards hired subcontractor Allison Engine Company, Inc., who then subcontracted with General Tool Company (GTC) to assemble three-generator sets (Gen-Sets).¹⁴⁴ In turn, GTC subcontracted with Southern Ohio Fabricators, Inc. (SOFCO) to manufacture various parts of the generators.¹⁴⁵ The Navy's contract with the shipyards required that each destroyer be built according to the Navy's specifications and that the delivery of each Gen-Set was to be accompanied with certification that the unit had been manufactured according to Navy requirements.¹⁴⁶ These requirements were similarly incorporated into each subcontract.¹⁴⁷ Upon delivery of the completed destroyers, the Navy paid the shipyards approximately \$1 billion of federal government funds for each new destroyer, with Allison Engine receiving approximately \$3 million per Gen-Set, GTC receiving approximately \$800,000 per Gen-Set, and SOFCO receiving over \$100,000 per Gen-Set.¹⁴⁸

¹³⁹ See, e.g., *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724 (4th Cir. 2010); *Hopper*, 588 F.3d at 1328; *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 875 (6th Cir. 2006); *Roberts v. Francis*, 128 F.3d 647 (8th Cir. 1997).

¹⁴⁰ See *Sanderson*, 447 F.3d at 877. Courts have also required that whistleblowers provide information concerning the dates and content of the submitted claims, identification numbers, the specific amounts of money charged to the government, the particular goods or services for which the government was charged, and the length of time between the alleged fraudulent practices and the submission of claims predicated upon those practices. See, e.g., *United States ex rel. McDermott v. Genentech, Inc.*, No. 05-147-P-C, 2006 WL 3741920, at *11 (D. Me. 2006), *report and recommendation adopted*, 2007 WL 2128410 (D. Me. 2007).

¹⁴¹ See, e.g., *Wight v. BankAmerica Corp.*, 219 F.3d 79 (2d Cir. 2000). See generally FED. R. CIV. P. 9(b).

¹⁴² 553 U.S. 662, 671 (2008), *superseded by* Fraud Enforcement and Recovery Act, Pub. L. 111-21, § 4, 123 Stat. 1617 (2009) [hereinafter FERA].

¹⁴³ *Id.* at 665.

¹⁴⁴ *Id.* at 666.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

In 1995, two former employees of GTC filed suit as *qui tam* relators, alleging that Allison Engine, GTC, and SOFCO made false claims to the federal government under § 3729(a)(2),¹⁴⁹ because they had sought payment for work that was not performed in accordance with the Navy's contract specifications.¹⁵⁰ Specifically, the relators claimed that Allison Engine installed defective gearboxes in the Gen-Sets, that GTC failed to conduct the required final quality inspection for approximately half of the first sixty-seven Gen-Sets, and that SOFCO welders failed to meet military standards for those same sixty-seven Gen-Sets.¹⁵¹ The relators also alleged that Allison Engine, GTC, and SOFCO issued certificates falsely stating that the Gen-Sets had been constructed according to the Navy's requirements even though they knew that the specifications had not been met.¹⁵²

At trial, the relators provided evidence that the defendants had issued false certifications and that they had presented invoices for payment to the shipyards.¹⁵³ The relators did not, however, adduce the actual invoices that were submitted to the Navy.¹⁵⁴ Allison Engine, GTC, and SOFCO moved for judgment as a matter of law, asserting that no reasonable jury could find a § 3729 violation because the relators failed to establish that a false claim had ever been presented to the Navy.¹⁵⁵ The district court granted the defendants' motion, concluding that the absence of proof that false claims were presented to the government failed to meet the requirements of the presentment clause.¹⁵⁶

The Sixth Circuit reversed the district court's dismissal of the relators' claims on appeal.¹⁵⁷ The court held that the district court improperly granted defendants' motion for judgment as a matter of law because false claims brought under § 3279(a)(2) did not require proof of specific intent to cause a false claim to be paid by the government.¹⁵⁸ Instead, proof of intent to cause a private entity to receive government funds was sufficient for the purposes of § 3729(a)(2).¹⁵⁹

¹⁴⁹ Section 3729(a)(2) imposed civil liability upon any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2) (2008). Congress later amended this portion of the FCA by enacting FERA to legislatively overrule the holding in *Allison Engine*, so this provision is no longer in effect. See *supra* notes 78–79 and accompanying text.

¹⁵⁰ *Allison Engine*, 553 U.S. at 666.

¹⁵¹ *Id.* at 667.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 667–68.

¹⁵⁸ *Id.* at 668.

¹⁵⁹ *Id.*

The Supreme Court granted certiorari and vacated the Sixth Circuit's decision, holding that a relator bore the burden of proving that the defendant *intended* that the false statement be material to the government's decision to pay or approve a false claim.¹⁶⁰ Under this reasoning, it was insufficient merely to show that a false statement *resulted* in the payment of government funds.¹⁶¹ Nevertheless, a relator did not have to provide proof that a defendant's false statements were submitted to the government.¹⁶² The Court thus concluded that the Sixth Circuit had erred in its interpretation of the statute and accordingly remanded to the district court.¹⁶³

Congress amended § 3729(a)(2) with the enactment of FERA in 2009, thereby legislatively overruling the Supreme Court's decision in *Allison Engine*,¹⁶⁴ which had required that a relator sustain the heavy burden of proving that the defendant made a false record or statement to the government for the purpose of receiving payment or approval of a false claim.¹⁶⁵ FERA removed the old § 3729(a)(2) and created § 3729(a)(1)(B),¹⁶⁶ which effectively removed the intent requirement

¹⁶⁰ *Id.* at 668–73.

¹⁶¹ *Id.* at 671–72 (Under § 3729(a)(2), “[i]f a . . . defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim ‘by the Government.’ In such a situation, the direct link between the false statement and the Government’s decision to pay or approve a false claim is too attenuated to establish liability.” (internal quotation marks omitted)). The Court reasoned that its interpretation of § 3729(a)(2) would give “effect to Congress’ efforts to protect the Government from loss due to fraud but also ensures that ‘a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct.’” *Id.* at 672 (quoting *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 470 (2006)).

¹⁶² *Id.* at 671.

¹⁶³ *Id.* at 669 (“Under § 3729(a)(2), a defendant must intend that the Government itself pay the claim. Eliminating this element of intent, as the Court of Appeals did, would expand the FCA well beyond its intended role of combating ‘fraud against the Government.’” (quoting *Rainwater v. United States*, 356 U.S. 590, 592 (1958))); *see also id.* at 673 (“Because the decision of the Court of Appeals was based on an incorrect interpretation of [§ 3729(a)(2) . . .], we vacate its judgment and remand the case for further proceedings consistent with this opinion.”).

¹⁶⁴ *See* FERA, Pub. L. No. 111-21 § 4, 123 Stat. 1617 (2009); *see also* *United States ex rel. Wall v. Circle C. Constr., L.L.C.*, 697 F.3d 345, 356 n.3 (6th Cir. 2012).

¹⁶⁵ *See Allison Engine*, 553 U.S. at 671.

¹⁶⁶ Subsection § 3729(a)(1)(B) imposes liability upon any person who “knowingly makes, uses, or causes to be made or used, a false record or statement *material to* a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(B) (2012) (emphasis added). Subsection 3729(b)(1) defines “knowing” and “knowingly”:

- (A) mean that a person, with respect to information—
 - (i) has actual knowledge of the information;
 - (ii) acts in deliberate ignorance of the truth or falsity of the information; or
 - (iii) acts in reckless disregard of the truth or falsity of the information; and
- (B) require no proof of specific intent to defraud.

and lowered the pleading standard for relators.¹⁶⁷

C. *The First Circuit's Approach*

The First Circuit addressed the requisite particularity requirement that would satisfy the Federal Rule of Civil Procedure 9(b) pleading standard in *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*¹⁶⁸ In *Duxbury*, the relators were former sales representatives for defendant Ortho Biotech Products (OBP).¹⁶⁹ As sales representatives, the relators had promoted and sold ProCrit—an FDA-approved drug used to treat anemia caused by chemotherapy, HIV infection, and blood loss from certain types of surgeries¹⁷⁰—in the Western United States.¹⁷¹ The original complaint alleged that OBP fraudulently inflated ProCrit's Average Wholesale Price (AWP) in reports,¹⁷² which resulted in the filing of false reimbursement claims with Medicare.¹⁷³ Further, the original complaint alleged that OBP marketed the “spread”—the difference between the fraudulently-reported AWP and the lower, actual cost of ProCrit—to induce medical providers to purchase ProCrit,¹⁷⁴ which constituted illegal kickbacks under the FCA.¹⁷⁵

As a result of the dismissal and subsequent unsealing of a related *qui tam* complaint,¹⁷⁶ which was brought by another former OBP

¹⁶⁷ *Wall*, 697 F.3d at 355 n.3 (“Congress replaced the words ‘to get’ in the former version with ‘material to,’ thereby eliminating [*Allison Engine*’s] intent requirement.” (citations and internal quotation marks omitted)).

¹⁶⁸ 579 F.3d 13 (1st Cir. 2009), *cert. denied*, 561 U.S. 1005 (2010).

¹⁶⁹ *Id.* at 16.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.* at 17.

¹⁷³ *Id.* Relators filed the original complaint after a master consolidated complaint (MCC) was filed in a multi-district litigation concerning defendant OBP's fraudulent reporting of ProCrit's AWP. *See generally In re Pharm. Indus. Average Wholesale Price 7 Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61 (D. Mass. 2005).

¹⁷⁴ *Duxbury*, 579 F.3d at 17 (“The [o]riginal [c]omplaint also alleged that OBP provided free samples of ProCrit as well as non-public financial inducements, such as rebates, discounts, unrestricted education grants, and phony drug studies . . . [which it] allegedly used . . . to lower the providers' net cost of purchasing ProCrit[] and further inflate[] the AWP” (last alteration in original) (internal quotation marks omitted)).

¹⁷⁵ *Id.* *See generally* 42 U.S.C. § 1320a-7b (2012).

¹⁷⁶ *Duxbury*, 579 F.3d at 18. Kurt Blair, another former OBP sales representative, had filed a complaint pursuant to the FCA against OBP in the District Court for the District of Colorado. *Id.* (citing Blair Complaint). The complaint alleged that OBP promoted the unapproved, off-label dosage for ProCrit by marketing such off-label use to medical professionals, influencing the results of facially independent clinical studies, and offering rebate programs to increase prescriptions of ProCrit. *Id.* (citing Blair Complaint ¶¶ 22–79). Moreover, the complaint alleged that OBP's promotion of the off-label use resulted in the filing of false claims for “nonreimbursable” uses with Medicare and Medicaid. *Id.* (citing Blair Complaint ¶¶ 88–91). When the DOJ declined to intervene in the Blair *qui tam* lawsuit, it was voluntarily dismissed and unsealed in full. *Id.* at 19.

employee, the *Duxbury* relators amended the original complaint.¹⁷⁷ The amended complaint alleged that OBP engaged in an illegal kickback scheme to induce healthcare providers to prescribe ProCrit,¹⁷⁸ and that the kickbacks caused providers to submit false reimbursement claims to Medicare.¹⁷⁹ Further, the amended complaint alleged that OBP unlawfully promoted an unapproved, off-label dosage of ProCrit to oncology patients,¹⁸⁰ which contributed to the submission of false Medicare reimbursement claims.¹⁸¹

OBP moved to dismiss the amended complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1)¹⁸² and, in the alternative, for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b).¹⁸³ The district court granted OBP's motion to dismiss and entered judgment in its favor,¹⁸⁴ holding that the amended complaint failed to plead the kickback scheme and off-label promotion claims with sufficient particularity.¹⁸⁵ Specifically, the district court found that the relators failed to allege essential factors concerning the widespread scheme to promote off-label uses of ProCrit.¹⁸⁶

On appeal, the relators argued that the district court erred in dismissing their claims—that OBP engaged in an illegal kickback scheme to promote ProCrit's off-label uses—because they satisfied the requisite Rule 9(b) particularity requirement.¹⁸⁷ The First Circuit

¹⁷⁷ *Id.* at 19.

¹⁷⁸ *Id.* The amended complaint described the alleged kickbacks in full. *Id.* (“The kickbacks allegedly included free ProCrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria.” (internal quotation marks omitted)).

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.* For the purposes of this Note, the lack of subject matter jurisdiction issue under Rule 12(b)(1) is irrelevant. Though this Note will not address those arguments, they were material issues on appeal.

¹⁸³ *Id.*

¹⁸⁴ *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 116 (D. Mass. 2008), *aff'd in part, rev'd in part*, 579 F.3d 13 (1st Cir. 2009), *cert. denied*, 561 U.S. 1005 (2010).

¹⁸⁵ *Id.* The district court established its subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), but nevertheless dismissed the claims concerning the kickback scheme and off-label promotion.

¹⁸⁶ *Id.* at 113–14 (“Although the . . . [c]omplaint alleged that OBP paid physicians to participate in clinical trials and used Phase IV trials to provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods, [the] allegation does not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit. To the contrary, the complaint alleges that one trial in 1997, and not any other OBP activities or initiatives, led physicians to switch to the higher dosage of Procrit. This bare bones allegation cannot act as a placeholder for the widespread off-label marketing scheme that Relators now wish to allege.” (citations and internal quotation marks omitted)).

¹⁸⁷ *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29–32 (1st Cir. 2009), *cert. denied*, 561 U.S. 1005 (2010).

reversed the dismissal of relators' claims concerning OBP's illegal kickback scheme on the grounds that their allegations satisfied the heightened pleading standard by providing factual evidence that strengthened the inference of fraud beyond a mere possibility.¹⁸⁸ Providing specific details as to *each* false claim was not required to meet the requisite particularity of Rule 9(b).¹⁸⁹ Rather, the court held that it was sufficient that the relators surpassed the "possibility of fraud" threshold.¹⁹⁰

In support of their allegations that OBP engaged in kickbacks that caused eight healthcare providers to submit false Medicare claims, the relators not only provided the names of the eight healthcare providers but also provided the dates and amounts of the filed false claims.¹⁹¹ As such, even though the relators did not identify the *specific* false claims, they sufficiently alleged the "who, what, where, and when" of OBP's fraudulent conduct.¹⁹² Therefore, the relators satisfied the requisite Rule 9(b) particularity requirement under the First Circuit's flexible pleading standard.¹⁹³

¹⁸⁸ *Id.* at 29.

¹⁸⁹ *Id.* (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)).

¹⁹⁰ *Id.*

¹⁹¹ *Id.* The court then reproduced one of the relators' allegations, which sufficiently established that one of the defendant health care providers had filed false claims with Medicare:

In 1997–98 Western Washington Treatment Center in Olympia, Washington received more than \$5,000 of free commercially packaged ProCrit from [OBP] under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. [OBP] intended the free commercially packaged ProCrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase ProCrit and to administer ProCrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit. As a result, [OBP] *knowingly caused* the presentation by Western Washington of these false claims to the United States Government.

Id. at 30 (emphasis added). Likewise, the relators satisfied the Rule 9(b) particularity requirement with respect to another defendant health care provider by alleging that the hospital "submitted approximately 4,800 claims a month for Medicare reimbursement based upon OBP's unlawful kickbacks." *Id.* (citation and internal quotation marks omitted).

¹⁹² *Id.* ("In particular, Duxbury has identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves.").

¹⁹³ Like the First Circuit, the Fifth, Seventh, and Ninth Circuits apply a lowered pleading standard where the relator does not bear the burden of proving that specific false claims were submitted to the government for payment where the relator's allegations reasonably imply submission. See *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993 (9th Cir. 2010); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009); *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601 (7th Cir. 2005). Thus, for the purposes of this Note, the aforementioned Circuits' Rule 9(b) pleading approaches are collectively termed "the First Circuit's approach."

D. *The Eleventh Circuit's Approach*

In *Hopper v. Solvay Pharmaceuticals, Inc.*,¹⁹⁴ the Eleventh Circuit set forth the requisite particularity with which a relator would need to plead in order to sufficiently meet the heightened Rule 9(b) pleading standard. The relators, who were former sales representatives in the Mental Health Division for defendant Solvay Pharmaceuticals, Inc. (Solvay),¹⁹⁵ alleged that Solvay engaged in an off-label marketing campaign for Marinol¹⁹⁶—a drug approved by the FDA for on-label use as an appetite stimulant for AIDS patients and for the treatment of side effects associated with cancer chemotherapy, such as nausea and vomiting¹⁹⁷—because sales of the drug for on-label uses failed to generate substantial profits.¹⁹⁸ Since manufacturers are not permitted to promote or market drugs for off-label uses under the FDCA¹⁹⁹—thereby rendering third-party requests for payment from the government through programs such as Medicaid as a result of such promotion “false claims”²⁰⁰—and Solvay’s marketing scheme caused the government to pay false claims through government programs that provided prescription drug benefits, the relators asserted that Solvay should be liable under § 3729.²⁰¹ The relators’ complaint did not, however, identify any specific false claims that were presented to any government healthcare program, nor did it identify any person or entity that submitted such a false claim.²⁰² Moreover, the complaint failed to allege that Solvay intended that the federal government rely on such false statements or records in deciding whether to pay the claims.²⁰³ Rather, the complaint alleged that Solvay’s off-label marketing campaign caused

¹⁹⁴ 588 F.3d 1318 (11th Cir. 2009), *cert. denied*, 561 U.S. 1006 (2010).

¹⁹⁵ *Id.* at 1322.

¹⁹⁶ *Id.* Solvay marketed Marinol for off-label uses including the stimulation of cancer patients’ appetites and the treatment of nausea in HIV patients. *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ 21 U.S.C. § 352(a) (2012).

²⁰⁰ *Hopper*, 588 F.3d at 1322.

²⁰¹ *Id.* Specifically, the relators alleged that the marketing campaign convinced doctors to prescribe Marinol for off-label uses, and that third parties—i.e., patients—consequently submitted false claims to federal and state health programs to pay for the Marinol prescriptions. *Id.* The relators, then, did not claim that Solvay itself submitted the false claims; instead, they claimed that “every time federal funds were used to pay for an off-label prescription, the third party who requested payment from the government made a false claim.” *Id.* Because those false claims were attributable to Solvay as a result of its off-label marketing campaign and Solvay intended that its campaign cause the filing of false claims, the relators argued, Solvay should be liable under § 3729. *Id.* In support of their allegations, the relators provided evidence showing a market increase in both the prescriptions for Marinol and the Medicaid payments for Marinol between 2001 and 2005, the years during which Solvay allegedly engaged in its active off-label promotion campaign. *Id.*

²⁰² *Id.* at 1323.

²⁰³ *Id.*

healthcare providers to submit claims to state healthcare programs, which subsequently submitted false claims to the federal government.²⁰⁴

Solvay moved to dismiss the relators' complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6),²⁰⁵ and on the grounds that the relators failed to plead their allegations of fraud with particularity under the heightened Rule 9(b) standard.²⁰⁶ The district court referred the matter to a magistrate judge who recommended that the federal claims be dismissed for the relators' failure to plead with particularity their allegations concerning Solvay's marketing scheme as the cause for third-party submissions of false claims to the federal government.²⁰⁷ Despite the relators' objections to the magistrate judge's recommendations, the district court adopted it in full and dismissed the relators' federal claims with prejudice.²⁰⁸

On appeal, the Eleventh Circuit, unlike the First Circuit, held that the district court properly granted the defendant's motion to dismiss because the complaint failed to include allegations of specific false claims and failed to allege that Solvay intended for its off-label marketing campaign to influence the government's decisions to pay the claims.²⁰⁹ Thus, in order to meet the requisite Rule 9(b) pleading standard, a plaintiff must allege with particularity that the government paid the false claims and that the defendant intended that the false statement be material to the government's decision to pay or approve the false claim.²¹⁰

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 1329. (“[T]he relators’ Complaint must allege with particularity, pursuant to Rule 9(b), that Solvay’s false statements *ultimately led the government to pay amounts it did not owe.*” (emphasis added)).

²¹⁰ *Id.* at 1330. Similar to the Eleventh Circuit, the Fourth, Sixth, and Eighth Circuits apply a heightened pleading standard where the relator is required to allege specific false claims and adduce evidence showing that such claims were presented to the federal government for payment. See *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1759 (2014); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818 (8th Cir. 2009); *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873 (6th Cir. 2006). Therefore, for the purposes of this Note, the aforementioned Circuits’ Rule 9(b) pleading approaches are collectively termed “the Eleventh Circuit’s approach.” It is worth noting, however, that although the Eighth Circuit has adopted a heightened pleading standard, it recently allowed a *qui tam* suit to proceed on the grounds of “fraudulent-in-the-inducement” theory for FCA liability, which is not applicable in all FCA cases. See *United States ex rel. Simpson v. Bayer Healthcare*, 732 F.3d 869 (8th Cir. 2013); see also D. Grayson Yeargin, Emily Crandall Harlan & Hannah R. Bornstein, *Expansive False Claims Act Theories Gain Traction in Eighth Circuit Ruling*, NOW + NEXT (Nixon Peabody LLP), Oct. 22, 2013, at 2, available at http://www.nixonpeabody.com/files/164832_GIWC_Alert_10_21_2013.pdf (“The fact that [the relator] had not identified any specific false claims for payment was not fatal to her case.”); Stuart M. Gershon, Natasha F. Thoren & Benjamin M. Zegarelli, *Eight Circuit Adopts Novel False Claims Act Fraud-in-the-Inducement Theory Long Espoused by Government*, EPSTEIN BECKER GREEN CLIENT ALERTS (Jan. 5, 2014, 7:03

III. PROPOSAL

In order to resolve the circuit split over the appropriate Rule 9(b) pleading standard, courts should apply a lowered particularity requirement in off-label promotion fraud cases brought under the FCA. The First Circuit's lowered pleading standard—requiring no proof that specific false claims were, in fact, submitted to the federal government so long as a relator sufficiently alleges the “who, what, where, and when” of a defendant's fraudulent conduct—should be accepted, whereas the Eleventh Circuit's heightened pleading standard—requiring proof that the specific false claims were submitted to the federal government even if the relator offers specific and reliable indicia of claim submission—should be set aside.

However, rather than requiring proof by a preponderance of the evidence—as currently practiced by courts in accordance with the FCA²¹¹—whistleblowers should show all essential elements of liability under the higher standard of clear and convincing evidence.²¹² Accordingly, a party should be liable under the FCA only if the whistleblower proves by clear and convincing evidence that the party knowingly submitted a false claim to the federal government, even if there was no intent to defraud the government.²¹³ The lowered pleading standard, in conjunction with the heightened requirement of proof by clear and convincing evidence, best satisfies the FCA's objective of decreasing fraud and abuse committed against the federal government while barring frivolous whistleblower suits.

A. *Congressional Intent and Public Policy Favor the Application of a Lowered Rule 9(b) Pleading Standard to Off-Label Promotion Cases*

Rule 9(b) clearly requires the relator to state the fraud with particularity. There is no mention, however, of a heightened pleading standard beyond that which is set forth in Rule 8(a).²¹⁴ Nor has

PM), <http://www.ebglaw.com/showclientalert.aspx?Show=17985>; Marina Hoppas, *Eighth Circuit Addresses Scope of False Claims Act Liability*, SEDGWICK LAW PUBLICATIONS (Jan. 5, 2014, 7:37 PM), <http://www.sedgwicklaw.com/eighth-circuit-addresses-scope-of-false-claims-act-liability-11-21-2013>.

²¹¹ 31 U.S.C. § 3731(d) (2012).

²¹² This Note does not, however, argue that the standard of proof for *damages* should be similarly changed from a preponderance of the evidence, as set forth in 31 U.S.C. § 3731(d), to clear and convincing evidence.

²¹³ Under 31 U.S.C. § 3729(b)(1)(A), the term “knowingly” encompasses actual knowledge of the false information, “deliberate ignorance” as to whether the claim is true or false and “reckless disregard of the truth or falsity of the information.” Further, no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B) (2012).

²¹⁴ See notes 132, 134–35 and accompanying text.

Congress ever revealed its intent for relators to allege, at the pleading stage, that specific false claims had been presented to the federal government for payment, notwithstanding the introduction of the Fairness in Health Care Claims, Guidance, and Investigations Act (FHCCGIA) in the House on August 1, 2013.²¹⁵ The FHCCGIA proposes amendments to the FCA that would limit the scope of whistleblower suits to nonfrivolous claims²¹⁶ and raise the standard of proof to clear and convincing evidence.²¹⁷ Despite these restrictive amendments, however, Congress has not explicitly raised the pleading requirements for relators.²¹⁸ Moreover, the DOJ's statistics concerning its recoveries under the FCA unambiguously indicate that the FCA is the most important tool for American taxpayers in the recovery of

²¹⁵ Fairness in Health Care Claims, Guidance, and Investigations Act, H.R. 2931, 113th Cong. § 3734 (2013). The FHCCGIA was referred to the House Judiciary Committee, where, as of the present moment, no action has been taken.

²¹⁶ *Id.*; see also WILMERHALE, FALSE CLAIMS ACT: 2013 YEAR-IN-REVIEW 3 (2014), available at http://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/Files/PDFs/FCA%20YIR%20Final.pdf (the FHCCGIA would prohibit a relator from initiating an FCA action against a health care provider or supplier “(1) unless the amount of damages alleged to have been sustained by the government is a material amount; (2) if a claim is submitted in good faith reliance on erroneous information or written statements of federal policy provided by a federal agency or in good faith reliance on an audit or review by an agency of the entity submitting the claim or retaining an overpayment; or (3) if a claim is submitted in substantial compliance with a model compliance plan issued by the Secretary of Health and Human Services (HHS).”).

²¹⁷ H.R. 2913 § 3734(f) (“In any action brought under section 3730 with respect to a claim submitted, or an overpayment retained, with respect to a Federal health care program, section 3731(c) shall be applied by substituting ‘clear and convincing evidence’ for ‘a preponderance of the evidence.’”).

²¹⁸ In fact, Congress has appeared to strengthen the statutory protections for whistleblowers, which evinces its intent to incentivize nonfrivolous whistleblower suits. See discussion *supra* Part I.A. Congress enacted the PPACA in 2010 to resolve the ambiguity of the public disclosure and original source provisions and override the Supreme Court's decision in *Graham Co.* It rewrote the public disclosure provision to clarify that only public disclosure by a federal report or the news media would bar a relator from bringing a *qui tam* suit. That same year, Congress enacted Dodd-Frank to clarify the appropriate statute of limitations for whistleblower retaliation cases. In doing so, Congress strengthened the statutory protections for whistleblowers. Even further, following the PPACA's enactment, the federal government has intensified its efforts in the war against healthcare fraud to achieve the necessary cost savings to effectuate widespread healthcare access and insurance coverage. In 2010, Congress amended the Deficit Reduction Act of 2005 (DRA), which incentivized states to combat Medicaid fraud by allowing a state to retain ten percent of what would otherwise be the federal share of recovered Medicaid funds if the state enacted a false claims statute that was at least as effective as the federal FCA. See 42 U.S.C. § 1396h (decreasing the federal share of Medicaid fraud recoveries by ten percent if state false claims acts satisfied certain requirements). During 2013, many states successfully amended their false claims statutes in accordance with the DRA and, as a result, were able to retain ten percent of the federal Medicaid recovery. WILMERHALE, *supra* note 216, at 33 (“Following amendments in 2009 and 2010 that strengthened the federal FCA, many states were given until March or August of 2013 to update their false claims laws and bring them back into alignment with the federal statute. Accordingly, a number of states amended their false claims statutes this year, and many states have had their FCAs certified as satisfying the DRA.”). If Congress did not intend to encourage *qui tam* lawsuits, then it would not have enacted the DRA or its subsequent amendments.

funds.²¹⁹ In fact, benefit-to-cost ratio of FCA law enforcement is more than twenty-to-one,²²⁰ meaning that the federal government has earned back twenty dollars on each dollar invested in FCA-compliance programs.

A heightened pleading standard, as proposed by the Eleventh Circuit, would prevent putative relators from successfully alleging liability under the FCA and would therefore frustrate congressional intent. Within the context of off-label promotion, it is not the defendant pharmaceutical company that submits false claims; instead, patients themselves submit false claims for reimbursement after their doctors write off-label prescriptions on account of the pharmaceutical company's off-label marketing inducements.²²¹ As a result, the typical relator, who is likely a former employee of the defendant pharmaceutical company, will not be privy to doctor-patient interactions. Privacy laws, then, would pose a barrier to recover in off-label cases under the heightened pleading standard because even a relator with the most intimate knowledge of the fraudulent scheme would unlikely have access to the details of the false claims, which would consist of prescriptions written by thousands of physicians and filled by even more patients at myriad pharmacies.²²² The heightened pleading standard, then, would bar many nonfrivolous *qui tam* lawsuits at the very start and would thus undermine congressional intent encouraging private citizens to police fraud against the federal government.

B. *Rationale Supporting the Heightened Burden of Proof Under the Clear and Convincing Standard*

The heightened burden of proof requiring a relator to establish all essential elements of FCA liability by clear and convincing evidence effectively addresses judicial consternation concerning the First Circuit's lowered pleading standard. A preponderance of the evidence merely requires that evidence show that an allegation is more likely than not to be true.²²³ Under current this standard,²²⁴ a relator sufficiently

²¹⁹ Petition for Writ of Certiorari, United States *ex rel.* Nathan v. Takeda Pharm. N. Am., Inc., 134 S. Ct. 374 (2013) (No. 12-349), 2013 WL 1945156 at *21-22; *see also* Press Release, Dep't of Justice, Justice Department Recovers Nearly \$5 Billion in False Claims Act Cases in Fiscal Year 2012 (Dec. 4, 2012).

²²⁰ MEYER, *supra* note 116, at 1.

²²¹ *See, e.g.*, Brief for United States as Amicus Curiae Supporting Respondents, Ortho Biotech Prods., L.P. v. United States *ex rel.* Duxbury, 561 U.S. 1005 (2010) (No. 09-654), 2010 WL 2007742, at *16-17.

²²² Petition for Writ of Certiorari, *supra* note 219, at *23-24.

²²³ *See* BLACK'S LAW DICTIONARY 1177 (6th ed. 1990) ("As standard of proof in civil cases, is evidence which is of greater weight or more convincing than the evidence which is offered in

establishes FCA liability where there is a fifty-one percent likelihood of culpability. In conjunction with the other plaintiff-friendly elements of the FCA,²²⁵ the significant potential error rate of forty-nine percent is unfair to FCA defendants, who face both treble damages and civil penalties.²²⁶

Various anti-fraud laws in the United States require the party alleging fraud to prove the elements of his claim by clear and convincing evidence.²²⁷ The rationale for this heightened burden of proof is grounded within the stigma associated with an allegation of fraud.²²⁸ Given the broad expanse of potential FCA liability and the far-reaching effects of allegations of fraud, which may cause irreparable harm to both the reputation and goodwill of a defendant, a relator's claims should be subject to the heightened standard of clear and convincing evidence.

Further, even more damaging to an FCA defendant is the prospect of heightened monetary sanctions, should the relator sufficiently prove liability. While Congress has made patently clear its intentions to encourage *qui tam* lawsuits,²²⁹ it has also repeatedly amended the FCA to ensure that whistleblowers allege claims based on new information in order to prevent parasitic or frivolous lawsuits.²³⁰ Because DOJ-intervened lawsuits have a ninety-five percent chance of success,²³¹ it is

opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not.”)

²²⁴ 31 U.S.C. § 3731(d) (2012).

²²⁵ HUTT ET AL., *supra* note 57, at 34 (“[A] plaintiff in an FCA suit need not show an actual false representation; an ‘implied’ falsehood will suffice. Those implied falsehoods can[—]in some circuits[—]be implied certifications of compliance with regulations or contract provisions, even when those regulations or provisions have not been identified by the government as conditions of payment. And the plaintiff need not prove intent to deceive or knowing falsehood; mere reckless disregard of a claim’s falsity is enough.”); *see also* discussion *supra* Part I.A.

²²⁶ 31 U.S.C. § 3729(a).

²²⁷ *See, e.g.*, UNITED STATES TAX COURT RULES OF PRACTICE & PROCEDURE R. 142(b); *In re Bose Corp.*, 580 F.3d 1240, 1243 (Fed. Cir. 2009) (“A party seeking cancellation of a trademark registration for fraudulent procurement bears a heavy burden of proof. Indeed, ‘the very nature of the charge of fraud requires that it be proven ‘to the hilt’ with clear and convincing evidence. There is no room for speculation, inference or surmise and, obviously, any doubt must be resolved against the charging party.” (quoting *Smith Int’l, Inc. v. Olin Corp.*, 209 U.S.P.Q. 1033, 1044 (T.T.A.B.1981))); *Smith v. Comm’r of Internal Revenue*, 926 F.2d 1470, 1475 (6th Cir. 1991) (“[T]he burden of proof as to the fraud penalty is on the Commissioner, who must prove the fraud by ‘clear and convincing’ evidence.” (citations omitted)); *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204 (7th Cir. 1970) (“A finding that a patent was procured by fraud . . . must be based on clear, unequivocal and convincing evidence.” (citation and internal quotation marks omitted)).

²²⁸ *See Addington v. Texas*, 441 U.S. 418, 424 (1979) (noting that because the interests at stake in fraud cases are “deemed to be more substantial than mere loss of money,” some jurisdictions choose to “reduce the risk to the defendant of having his reputation tarnished erroneously by increasing the plaintiff’s burden of proof”); *Ross v. A.H. Robins Co.*, 607 F.2d 545, 557 (2d Cir. 1979).

²²⁹ *See* discussion *supra* Part I.A.

²³⁰ *See* discussion *supra* Part I.A.

²³¹ *See supra* note 57 and accompanying text.

necessary to protect innocent defendants against the overly punitive effects of treble monetary damages. The application of the “preponderance of the evidence” standard of proof generally causes defendants to settle FCA claims upon government intervention so as to protect the defendant from devastating liability in the event of unsuccessful litigation.²³² These so-called “blackmail settlements” are analogous to those prevalent in class action lawsuits under Rule 23(b) of the Federal Rules of Civil Procedure, where the grant of class certification signified impending settlement because defendants were pressured into settlement by the prospect of overwhelming liability and bankruptcy.²³³ Courts’ biggest concern with blackmail settlements in class action lawsuits is the fact that while a significant portion of cases may not be meritorious, defendants would nonetheless be faced with no choice but to settle.²³⁴ That same concern applies in FCA cases. However, implementing a “clear and convincing evidence” standard of proof would allay innocent defendants’ fears by reducing the risk of erroneous—and thereby financially crippling—liability and decreasing the prevalence of blackmail settlements. Such a heightened burden of proof would also encourage more innocent companies to litigate FCA claims, which would subsequently improve the FCA system by preventing abuses against the government, promoting fairer and more just resolutions of false claims disputes, and encourage the development of less ambiguous legal rules under the FCA. Therefore, the heightened “clear and convincing evidence” standard of proof would adequately provide recourse for the federal government—via the relators—while preventing the undue penalization of innocent defendants.

CONCLUSION

The current circuit split on the question of the appropriate Rule 9(b) pleading standard in off-label promotion *qui tam* cases has left courts across the nation in a quandary. This issue is aggravated by the fact that the Supreme Court has yet to address this issue and provide a satisfactory solution. A robust resolution, however, would adequately balance the need to incentivize public reporting of fraud and abuse

²³² HUTT ET AL., *supra* note 57, at 34–35.

²³³ See *Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1298 (7th Cir. 1995), where Judge Posner stated that “Judge Friendly, who was not given to hyperbole, called settlements induced by a small probability of an immense judgment in a class action ‘blackmail settlements.’” In *Rhone-Poulenc*, hemophiliacs sought class certification in an action against the manufacturers of antihemophilic factor concentrate that had become infected with Human Immunodeficiency Virus (HIV). Posner overturned the district court’s grant of class certification, citing his concern with blackmail settlements.

²³⁴ *See id.*

against the federal government against the need to bar frivolous whistleblower lawsuits. Most importantly, within the healthcare context, an effective solution would improve the integrity of federal healthcare programs while substantially contributing to their solvency.

An approach where courts apply the First Circuit's lowered pleading standard but require the relator to plead all elements of FCA liability to the satisfaction of a clear and convincing standard would sufficiently align with congressional intent. Given the enactment of the PPACA and an increasingly constrained government budget, this proposed approach would greatly restrict the incidents of fraud and abuse committed against the federal government. Although the strongest argument against the implementation of the lowered pleading standard is the fact that a number of the largest FCA recoveries in the history of the United States have been related to off-label promotion fraud, this argument holds far less water in the wake of the Supreme Court's *Bartlett* opinion. Generic pharmaceutical companies now have greater leeway in entering their drugs into the market post-FDA approval, whereas plaintiffs—consumers of the generic pharmaceuticals—have less recourse than ever. By implementing a lowered Rule 9(b) pleading standard that encourages whistleblowers to report pharmaceutical fraud and abuse, pharmaceutical companies will be encouraged to comply with regulatory requirements so as to lessen the filing of future *qui tam* suits.