

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIFTH CIRCUIT**

United States Court of Appeals  
Fifth Circuit

**FILED**

August 20, 2013

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No. 12-20314  
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Lyle W. Cayce  
Clerk

UNITED STATES OF AMERICA, ex rel., LESLIE STEURY,

Plaintiff - Appellant

v.

CARDINAL HEALTH, INCORPORATED, formerly known as  
Alaris Medical Systems, Incorporated;  
CARDINAL HEALTH 303, INCORPORATED, formerly known as  
Alaris Medical Systems, Incorporated;  
CARDINAL HEALTH SOLUTIONS, INCORPORATED,

Defendants - Appellees

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Appeal from the United States District Court  
for the Southern District of Texas  
\_\_\_\_\_

Before JONES, DENNIS, and HIGGINSON, Circuit Judges.

PER CURIAM:

Two questions are posed in this appeal. The first is whether relator Steury's third amended complaint states a claim under the False Claims Act ("FCA") based solely on an implied false certification of "merchantability" by defendants, Cardinal Health, Inc.; Cardinal Health 303, Inc.; and Cardinal Health Solutions, Inc., successors in interest to Alaris Medical Systems, Inc. (collectively, "Cardinal") to the United States Department of Veterans Affairs ("VA") in connection with the sales of Cardinal's Signature Edition Infusion

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Device (“Signature pump”). Related to this issue is the sufficiency of Steury’s pleading to allege this theory of liability. The second issue is the viability of a worthless goods claim. Because Steury’s third amended complaint still fails to plead her claims with sufficient particularity, we AFFIRM the district court.

This is the second time this matter has been before this court. *See U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262 (5th Cir. 2010) (“*Steury I*”).

### I. Background

Steury marketed Cardinal’s Signature pump to various hospitals, including VA hospitals, from 1996 until she was terminated in 2001. The Signature pump regulates the rate at which intravenous fluids flow into patients. Steury alleges that a design flaw in the Signature pumps allowed air bubbles to accumulate and be released into a patient’s intravenous line, potentially causing death on entering the patient’s bloodstream. Steury alleges that Cardinal sold Signature pumps to the VA from 1997 until it suspended production and sales for a separate problem in 2006.

Steury became aware of the defect in late 2000 and discussed it with an area manager in early 2001. In mid-2001, Cardinal suspended shipment of Signature pumps for three months while it reviewed the defect. Steury continued to market the Signature pumps during this period. Cardinal fired Steury at the end of the three-month review period. According to Steury, she was scheduled to fill a major order of Signature pumps with a VA hospital in Ohio only five days later and by that time a number of Cardinal employees were aware of the defect.

Steury sued Cardinal in 2007 for alleged violations of the FCA and several state statutes. The government declined to intervene.<sup>1</sup> Cardinal moved to dismiss after Steury filed an amended complaint. The district court adopted the

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<sup>1</sup>The government submitted a brief as *amicus curiae* and participated in oral argument on this appeal.

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magistrate judge's report and recommendation and dismissed Steury's complaint for failure to satisfy the heightened pleading standards of Rule 9(b).

We largely affirmed the district court on appeal but remanded to allow Steury an opportunity to amend her complaint. *Steury I*, 625 F.3d 262. On remand, Steury filed a second amended complaint, which the district court again dismissed. Steury filed a third amended complaint, and Cardinal moved to dismiss under Rules 12(b)(6) and 9(b) for failure to state a claim and for failure to plead a claim alleging fraud with sufficient particularity. The magistrate judge recommended dismissal, and the district court adopted that recommendation in full. Steury timely appealed.

## II. Standard of Review

“[C]laims brought under the FCA must comply with the particularity requirements of Rule 9(b)” for claims of fraud. *Steury I*, 625 F.3d at 266 (citation omitted). Rule 9(b) provides: “In alleging fraud . . . a party must state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). Thus, “Rule 9(b) requires, at a minimum, that a plaintiff set forth the who, what, when, where, and how of the alleged fraud.” *Steury I*, 625 F.3d at 266 (citations and internal quotation marks omitted). “A dismissal for failure to plead fraud with particularity under Rule 9(b) is treated as a dismissal for failure to state a claim under Rule 12(b)(6).” *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 n.8 (5th Cir. 2009) (citation and internal quotation marks omitted).

We review “de novo a district court’s ruling on a Rule 12(b)(6) motion[,] . . . interpret[ing] the complaint in the light most favorable to the plaintiff.” *Steury I*, 625 F.3d at 266 (citing *U.S. ex rel. Willard v. Humana Health Plan of Tex. Inc.*, 336 F.3d 375, 379 (5th Cir. 2003)). “The plaintiff’s factual allegations must support a claim to relief that is plausible on its face and rises above mere speculation.” *Id.* (citation omitted); accord *Ashcroft v. Iqbal*, 556 U.S. 662,

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678–79 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). We view all well pleaded facts in the light most favorable to the plaintiff. *Jebaco, Inc. v. Harrah’s Operating Co., Inc.*, 587 F.3d 314, 318 (5th Cir. 2009) (internal citations omitted).

### III. Discussion

A claim under the FCA requires presentation of a knowingly false claim to the government for payment; i.e., the requirements are a knowing conduct, falsity, and materiality. 31 U.S.C. § 3729(a)(1)(B) (2009). Again, because a claim under the FCA falls under Rule 9(b), it is necessary to plead with particularity the who, what, when, where, and how of the falsity. *Steury I*, 625 F.3d at 266 (citations omitted).<sup>2</sup>

#### A. Implied False Certification

Although the *Steury I* court expressly stated that the Fifth Circuit has not yet adopted the implied false certification theory of FCA liability, we also noted that any such claim (whether express or implied) must assert that a certification was a “prerequisite” to the payment sought:

The FCA is not a general “enforcement device” for federal statutes, regulations, and contract. *Thompson*, 125 F.3d at 902; *see*

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<sup>2</sup> Cardinal contends that Steury waived or forfeited her implied false certification claim by not objecting to the magistrate judge’s report and recommendation and waived or forfeited her worthless goods claim by abandoning it in her third amended complaint. This court has held that plain error review applies when a party did not object to a magistrate judge’s findings of fact, conclusions of law, or recommendation to the district court, so long as the party was served with notice of the consequences of failing to object. *Douglass v. United Servs. Auto. Ass’n*, 79 F.3d 1415, 1428–29 (5th Cir. 1996) (en banc). Steury, however, objected thoroughly to each of the relevant portions of the magistrate judge’s report. Nor did Steury abandon her worthless goods claim. Her third amended complaint alleges facts evidently intended to establish such a claim. 3d Am. Cmplt. ¶ 36 (“An infusion pump that kills patients when used as intended is *of no value* to the hospital that is using it. Instead, the infusion pump actually has a *negative value* because it will create tort liability for the hospital given its defective condition.”) (emphasis added).

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*also Mikes*, 274 F.3d at 699 (observing that FCA “was not designed for use as a blunt instrument to enforce compliance”). Not every breach of a federal contract is an FCA problem. We have thus repeatedly upheld the dismissal of false-certification claims (implied or express) when a contractor’s compliance with federal statutes, regulations, or contract provisions was not a “condition” or “prerequisite” for payment under a contract. *See, e.g., Marcy*, 520 F.3d at 389–90 (upholding dismissal); *Willard*, 336 F.3d at 381 (same); see also *Thompson*, 125 F.3d at 902–03 (remanding for fact determination as to whether payment was “conditioned” on certification). This prerequisite requirement seeks to maintain a “crucial distinction” between punitive FCA liability and ordinary breaches of contract. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 680 (5th Cir. 2003) (en banc) (Jones, J., specially concurring). The prerequisite requirement recognizes that unless the Government conditions payment on a certification of compliance, a contractor’s mere request for payment does not fairly imply such certification. *See Mikes*, 274 F.3d at 700 (observing that a mere claim for payment does not suggest fraud unless it can be said that the defendant submitted the claim “while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant”); *United States ex rel. Siewick v. Jamieson Sci. & Eng’g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (“Courts have been ready to infer certification from silence, but only where certification was a prerequisite to the government action sought.”).

*Steury I*, 625 F.3d at 268–69.

The gist of our holding in *Steury I* was that Cardinal “did not make an implied certification [within the warranty of merchantability] simply because the Government’s standard commercial-acquisition contract [under Federal Acquisition Regulations] includes a warranty of merchantability.” *Steury I*, 625 F.3d at 270. Instead, this court held that a “knowing delivery of defective goods” might be actionable under the FCA if, for instance, a particular government contract specifically conditioned payment on a certification of compliance with the warranty of merchantability, or by the knowing provision of “worthless goods” to the government. *Id.* We vacated the dismissal and

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authorized a remand so that Steury could attempt to comply with these requirements.

On remand, Steury changed her complaint somewhat, and she now alleges that her FCA claim is based solely on an implied false certification theory (in addition to a worthless goods theory based on the same facts). In particular, she now alleges that Cardinal “expressly warranted that the [Signature pumps] were ‘merchantable,’” that Cardinal’s “contract with the VA specifically required that the [Signature pumps] be merchantable,” that Cardinal’s “contract with the VA required it to implicitly certify that the [Signature pumps] were merchantable,” and that “[t]he requirement that the [Signature pumps] be merchantable was a material contractual requirement.” 3d Am. Compl. ¶¶ 28, 31, 41, and 42. The district court concluded that these pleadings were insufficient both because the Fifth Circuit has rejected implied false certification claims and because Steury still failed to allege that “the Government conditioned payment for the Signature pumps on a certification that the Signature pumps complied with the warranty of merchantability.” *Steury I*, 625 F.3d at 269. The district court erred in its first determination—*Steury I* did not reject the implied false certification theory of FCA liability. The sufficiency of Steury’s allegations, however, gives us pause and forms the basis for our decision.

In *Steury I* we held that “a false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.” *Steury I*, 625 F.3d at 269. In a footnote, we explained that this fact about the contract’s conditions will “depend on the specific statutes, regulations, and contracts at issue in a particular case.” *Id.* at 269 n.4 (citing *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902–03 (5th Cir. 1997)).

Steury’s new allegations that merchantability was a “standard condition,” or material condition, of Cardinal’s contracts with the VA, or that the VA would

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not have paid for the Signature pumps had it known of the defect, are deficient under Rule 9(b). These conclusory allegations do not identify the contractual provisions regarding merchantability. In this context, simply stating the conclusion will not do. As we have noted, an FCA relator must clearly state the substance of the fraud that has been committed; here, the essence of the fraudulent activity of implied false certification of compliance cannot be gauged unless Steury reveals how the Signature pumps deviated from the government's specifications. For example, in other implied false certification cases, the relator has relied on express statutes or regulations, e.g., the Medicare Act, *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001); the Clean Water Act, *U.S. ex rel. Marcy v. Rowan Cos., Inc.*, 520 F.3d 384, 390 (5th Cir. 2008); and the Medicare Anti-Kickback statute and Stark laws, *Thompson*, 125 F.3d at 901–02, when pleading that the defendant's payment request falsely and impliedly certified compliance. Indeed, *Steury I* analyzed the standard government procurement regulations (i.e., the Financial Acquisition Regulations), on which Steury relied at that time, and found them patently wanting because the government may choose to override implied merchantability provisions with express warranties. Further, *Steury I* noted, "That the government may accept (and pay) for noncompliant commercial items under the [Financial Acquisition Regulations] confirms that payment is not conditioned on compliance with the warranty of merchantability." *Steury I*, 625 F.3d at 270. At this point in the litigation, Steury had to know that merely descriptive or conclusory allegations about the Cardinal contracts were insufficient.

Steury's pleadings are ambiguous, but apparently Steury is also relying on an implied warranty of merchantability, in which case she should have articulated some court opinion or regulation that imports such warranties into the government's contracts. Again, however, an implied warranty can be overridden by express warranty terms. Her claim is no better off for relying on

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an implied rather than an express warranty. It becomes more out of kilter with existing implied false certification case law because it asks this court to reckon actionable as a knowingly false claim an implied certification of an implied contract provision.

Moreover, Steury still fails to allege, in more than an utterly conclusory manner, that the contractual merchantability provision, whether express or implied, was a condition without which the government would not have paid Cardinal. So, she alleges an implied certification of an implied contract provision that is an implied prerequisite to payment. While this court has not definitively ruled on the cognizability of implied false certification claims, *Steury I* accepted the predominant view among circuit courts<sup>3</sup> and clearly stated that certifications must be a prerequisite of payment. As *Steury I* explained, “The prerequisite requirement has to do with more than just the materiality of a false certification; it ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place.” *Steury I*, 625 F.3d at 269. Without this crucial allegation, in addition to the deficiencies in Steury’s pleading of a contract violation, Steury’s third amended complaint fails to cross the threshold of a cognizable implied false certification claim under the FCA.

### **B. Worthless Goods**

In addition to her implied false certification argument, Steury also alleges that Cardinal violated the FCA under a worthless goods theory. Specifically, Steury alleges that the Signature pumps were worthless because the expected cost due to tort liability from using the Signature pumps exceeded the expected benefit of using them. We refused to examine the viability of a worthless goods

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<sup>3</sup> John T. Boese, 1 Civil False Claims and Qui Tam Actions § 2.02(B)(3) (4th ed. 2012) (“[M]ost of the courts that have accepted the implied false certification theory have done so only where the government expressly conditioned payment on compliance with the underlying statute or regulation.”).

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theory in this circuit in *Steury I* because “Steury has so far failed to allege this type of claim with particularity.” 625 F.3d at 270. We again do not reach the issue of whether an FCA claim may be viable under a worthless goods theory in this circuit because Steury’s third amended complaint remains deficient. It fails to plead a worthless goods theory with the requisite particularity because it fails to allege that any Signature pump sold to the VA over nine years was ever found to be deficient or worthless. It fails to allege that any patient was harmed due to the use of the Signature pump at a VA hospital. It fails to allege that the VA was ever sued due to injury caused by a malfunctioning Signature pump. There is no who, what, when, where, or how on this claim to comply with Rule 9(b).

#### **IV. Conclusion**

For these reasons, the judgment of the district court is AFFIRMED.

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HIGGINSON, Circuit Judge, concurring:

Courts have struggled with delimiting liability under the False Claims Act (“FCA”). Among the issues wrestled with have been whether to distinguish “factually false” from “legally false” claims, whether to recognize “express” and “implied” certification theories of liability, and whether to limit liability under those theories to cases where the government conditions payment on a certification of compliance (the “prerequisite” requirement).

“Courts have created these categories in an effort to clarify how different behaviors can give rise to a false or fraudulent claim,” *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385 (1st Cir. 2011), and to maintain what we have deemed the “‘crucial distinction’ between punitive FCA liability and ordinary breaches of contract,” *United States ex rel. Steury v. Cardinal Health, Inc. (“Steury I”)*, 625 F.3d 262, 268 (5th Cir. 2010). “Judicially-created categories sometimes can help carry out a statute’s requirements, but they can also create artificial barriers that obscure and distort those requirements.” *Hutcheson*, 647 F.3d at 385.

The majority opinion bases its holding that Steury failed to state a claim under the FCA on its judgment that, even if this court were to adopt the implied false certification theory of FCA liability, Steury’s third amended complaint did not properly allege that “a certification was a ‘prerequisite’ to the payment sought.” But “[t]he text of the FCA does not refer . . . to ‘express certification’ or ‘implied certification.’ Indeed, it does not refer to ‘certification’ at all.” *Hutcheson*, 647 F.3d at 385. Nor does the FCA contain the term “prerequisite.” These are judicial constructs that, in my view and the view of another circuit court, “do more to obscure than clarify the issues before us.” *Id.* at 385–86.

I would redirect attention to the plain language of the statute. The FCA subjects a person to liability for “knowingly present[ing] . . . a false or fraudulent claim for payment.” 31 U.S.C. § 3729(a)(1)(A). Courts initially distinguished

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false from fraudulent claims in the civil FCA context,<sup>1</sup> but these concepts have merged over time. See Claire M. Sylvia, *THE FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT* § 4:26 (2d ed. 2013) (“Courts do not always distinguish between ‘false’ claims and ‘fraudulent’ claims, and often simply refer to ‘falsity’ or, as the statute’s title does, ‘false claims.’”).

“As a walk through Title 18 and other titles of the United States Code reveals, Congress has long honored the distinction [between falsity and fraud] in criminalizing many types of conduct.” *United States v. Kurlemann*, 708 F.3d 722, 728 (6th Cir. 2013) (interpreting 18 U.S.C. § 1014). Criminal analogues of the FCA make it a federal crime to present a claim to the government knowing it to be “false, fictitious, or fraudulent,” 18 U.S.C. § 287, and to knowingly and willfully make a “materially false, fictitious, or fraudulent statement or representation” on a matter within the jurisdiction of the United States, 18 U.S.C. § 1001(a). These statutes have proved workable without judicial embellishment by employing traditional, common-sense understandings of what it means for a statement or claim to be “false” and “fraudulent.”

The two terms are not co-extensive. *Kurlemann*, 708 F.3d at 728 (“‘False’ and ‘fraudulent’ representations do not cover the same thing.”). Falsity requires “a ‘factual assertion’ capable of confirmation or contradiction.” *Id.* (citing *Williams v. United States*, 458 U.S. 279, 284 (1982)); see also *United States v. Shah*, 44 F.3d 285, 294 n.16 (5th Cir. 1995) (“A statement is false if it was untrue when made and then known to be untrue by the person making it”).

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<sup>1</sup> *E.g.*, *United States v. TDC Mgmt. Corp.*, 24 F.3d 292, 297 (D.C. Cir. 1994) (“In 1982, Congress recodified the False Claims Act to substitute, ‘without substantive change, . . . simple language . . . for awkward and obsolete terms.’ Before this recodification, the False Claims Act forbade knowing presentation of a ‘false, fictitious, or fraudulent claim.’ In recodifying the Act, Congress eliminated the word ‘fictitious’ but retained both ‘false’ and ‘fraudulent’ as part of the statutory language. We infer from this that Congress distinguished ‘false’ from ‘fraudulent’ claims and presume the distinction to turn on whether the defendant acted with an intent to deceive.”) (citations omitted).

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Fraud has long been understood to include a broader range of deceptive conduct. “The gist of the action,” in the Supreme Court’s words, “is fraudulently producing a false impression upon the mind of the other party; and, if this result is accomplished, it is unimportant whether the means of accomplishing it are words or acts of the defendant, or his concealment or suppression of material facts not equally within the knowledge or reach of the plaintiff.” *Stewart v. Wyo. Cattle Rancho Co.*, 128 U.S. 383, 388, 9 S.Ct. 101, 32 L.Ed. 439 (1888); *see also Black’s Law Dictionary* 731 (9th ed. 2009) (defining fraud as “[a] knowing misrepresentation of the truth or concealment of a material fact to induce another to act to his or her detriment”).

*Kurlemann*, 708 F.3d at 728–29.<sup>2</sup>

I would favor restoring Congress’s statutory distinction between falsity and fraud, and using traditional, common-sense understandings of those terms to decide whether Steury and plaintiffs like her state a claim under the FCA. Steury did not specifically allege in the operative complaint that Cardinal Health knew of material product defects but, with the intent to deceive, sought to collect payment from the government nonetheless—indeed, she stated that “no specific intent to defraud the government is required” to prove a false claim. So our focus must in this case be on whether Cardinal Health’s claim for payment was a false one: whether it contained a falsifiable assertion that was untrue when made.

The Supreme Court has answered a conceptually similar question: whether the deposit of a check without sufficient funds to support it constitutes a false statement under 18 U.S.C. § 1014. *See Williams*, 458 U.S. at 284–87. The government argued that a check not supported by sufficient funds contains an implicit false statement or representation that the account contains sufficient

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<sup>2</sup> “[T]he terms ‘knowing’ and ‘knowingly,’ ” as used in the FCA, “require no proof of specific intent to defraud”; rather, they “mean that a person, with respect to information -- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)–(B).

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funds to cover it. *Id.* at 285–86. The Supreme Court granted that the government’s implied certification theory was a plausible, functional understanding of how checks work, but expressed “reluctan[ce] to base an expansive reading [of the statute] on inferences drawn from subjective and variable ‘understandings.’ ” *Id.* at 286. “[T]echnically speaking,” the Court reasoned,

a check is not a factual assertion at all, and therefore cannot be characterized as “true” or “false.” Petitioner’s bank checks served only to direct the drawee banks to pay the face amounts to the bearer, while committing petitioner to make good the obligations if the banks dishonored the drafts. Each check did not, in terms, make any representation as to the state of petitioner’s bank balance.

*Id.* at 284–85.

Just as an insufficient funds check alone makes no falsifiable assertion, neither does an unadorned invoice contain a false claim. Steury did not allege in the operative complaint that the invoice presented by Cardinal Health contained, on its face, a factual assertion capable of confirmation or contradiction that was untrue when made, so the claim is not “false” under the FCA. It may be true, as the appellant and government reason, that by presenting a claim for payment, Cardinal Health “implicitly certified” that the infusion pumps were “merchantable”; that is one plausible, functional understanding of how invoices work. Not surprisingly, the Supreme Court has cautioned that this “‘common understanding’ [is] a particularly fragile foundation” upon which to base an interpretation of a federal statute with severe penalties. *Id.* at 286 n.7.

Not only does it depart from the plain meaning of the FCA, “the implied certification theory is prone to abuse by the government and *qui tam* relators who, seeking to take advantage of the FCA’s generous remedial scheme, may attempt to turn the violation of minor contractual provisions into an FCA

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action.”<sup>3</sup> *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010). To cabin liability under the implied certification theory, many courts have limited its application to situations in which the defendant makes an implied certification of compliance with the material terms of the contract between the parties, a prior express certification, or the statutes or regulations governing the government program at issue. See Susan C. Levy, Daniel J. Winters, & John R. Richard, *The Implied Certification Theory: When Should The False Claims Act Reach Statements Never Spoken Or Communicated, But Only Implied?*, 38 PUB. CONT. L.J. 131, 131–52 (2008) (collecting cases). In so doing, however, some courts have “adopt[ed] a circumscribed view of what it means for a claim to be false or fraudulent.” *Sci. Applications Int’l Corp.*, 626 F.3d at 1270. “[T]o avoid foreclos[ing] FCA liability in situations that Congress intended to fall within the Act’s scope,” *United States ex rel. Jones v. Brigham & Women’s Hosp.*, 678 F.3d 72, 85 (1st Cir. 2012) (quoting *Hutcheson*, 647 F.3d at 387), I would favor instead restoring Congress’s statutory distinction between falsity and fraud, and using traditional, common-sense understandings of those terms, in combination with “strict enforcement of the Act’s materiality and scienter requirements,” *id.* (quoting *Sci. Applications Int’l Corp.*, 626 F.3d at 1280), to maintain the “‘crucial distinction’ between punitive FCA liability and ordinary breaches of contract,” *Steury I*, 625 F.3d at 268.

I respectfully concur.

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<sup>3</sup> In many cases, including this one, it is difficult to discern what implied certifications are even at issue. Steury alleged in her initial and amended complaints that Cardinal Health implicitly certified that its products were “safe and reliable”; she alleged in her second amended complaint that the implicit certification was that the products were “free from defects,” “fit for the purposes for which they were designed to be used,” and “fit for the particular purpose for which they were being sold”; she alleged in her third amended complaint that the implicit certification was that the products were “merchantable,” which it defined as “reasonably fit for the ordinary purposes for which such item is used,” “at least average, fair, or medium-grade quality,” and not “unreasonably dangerous.”