UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, STATE OF ILLINOIS ex rel. MICHAEL THORNTON Plaintiff, v. PFIZER INC and HOSPIRA, INC., Defendants.	Case No. 16-cv-7142 Judge John Robert Blakey

MEMORANDUM OPINION AND ORDER

Relator and Plaintiff Michael Thornton (Relator) has brought a *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, (Count I) and its Illinois counterpart, the Illinois False Claims Act (ICFA), 740 Ill. Comp. Stat. 175/1 *et seq.*, (Count II) on behalf of the United States and the State of Illinois. Relator sues Defendants Pfizer, Inc., and Hospira, Inc., alleging that Defendants knowingly mischarged Medicare and/or Medicaid for defective medical devices. [35] ¶ 1. Relator also brings an FCA retaliation claim, 31 U.S.C. § 3730(h), alleging that Defendants retaliated against him after he attempted to prevent FCA violations (Count III). *Id.* ¶ 2. Relator brings an Illinois Whistleblower Act claim, 740 Ill. Comp. Stat. 174/1 *et seq.*, under this same theory (Count IV). *Id.*

Relator filed his Amended Complaint (AC) [35] on May 24, 2018. Defendants have moved to dismiss all claims under Federal Rules of Civil Procedure 12(b)(6) and

9(b). [41]. For the reasons explained below, this Court grants Defendants' motion.

I. Background

A. The Parties

The federal government and state of Illinois jointly fund and administer the Medicare and Medicaid programs in Illinois. [35] ¶ 9. Pfizer is one of the world's leading designers, manufacturers, and distributors of health care products. *Id.* ¶ 10. It sells its products to both public and private hospitals, pharmacies, home healthcare providers, other medical organizations, and private citizens enrolled in Medicare and/or Medicaid, and therefore requests payment and receives funds (either directly or through healthcare providers) from the U.S. and/or Illinois. *Id.*

Pfizer is the parent company of Hospira, which is one of the world's leading providers of infusion pumps and other medical technologies. *Id.* ¶¶ 10, 12. Hospira also sells its products to public and private hospitals, pharmacies, home healthcare providers, other medical organizations, and private citizens enrolled in Medicare and/or Medicaid, and thus similarly requests payment and receives funds (either directly or through healthcare providers) from the U.S. and/or Illinois. *Id.* ¶ 12. Both Pfizer and Hospira are considered importers and/or manufacturers, as well as distributors, for purposes of U.S. Food and Drug Administration (FDA) regulations. 21 C.F.R. §§ 803.3, 806.2; 21 C.F.R. Part 7, 21.

Hospira employed Relator in a quality assurance role from June 2013 until February 2017, when Defendants sold its infusion systems business to ICU Medical Inc. [35] ¶ 7.

B. Hospira's Relationship with Q Core

Throughout Relator's employment with Hospira, the company maintained an international distribution agreement and business relationship with Q Core Medical Ltd (Q Core). *Id.* ¶ 16; [35-1] at 2–4. Q Core is an Israeli company focused on developing, manufacturing, and marketing infusion pumps. [35] ¶ 17. One of its products is the Sapphire Multi-Therapy Volumetric Infusion Pump (Sapphire pump); a "technologically advanced compact and lightweight infusion system." [35-1] at 2.

According to Relator, the impetus behind Hospira's relationship with Q Core began in August 2012, when the FDA issued a warning letter to Hospira about quality problems at Hospira's Costa Rica manufacturing plant. [35] ¶ 18. Hospira made most of its infusion pumps at its Costa Rica plant. *Id.* In November 2012, the FDA followed-up with an import ban, which prevented Hospira from importing and selling infusion pumps manufactured at the Costa Rica facility. *Id.* ¶ 19.

In January of 2013, while the FDA's import ban remained in place, Hospira entered an international distribution agreement with Q Core for its "Sapphire platform," which included Sapphire pumps and their accompanying microbore set. *Id.* ¶ 21; [35-1] at 2–4. Following regulatory clearance by the FDA, Hospira introduced the Sapphire pumps and microbore sets (collectively Sapphire sets) to the U.S. Market in October 2013. [35] ¶ 20; [35-1] at 2–4.[1]

According to Relator, by "designating Hospira as a distributor and Q Core as

[1] A Sapphire pump cost approximately $3,500 in 2015, and a microbore set currently ranges between $5 and $25 per unit; sets are typically purchased in high volume orders, as industry standard recommends sets be replaced every 96 hours. [35] ¶¶ 29–30.

the device manufacturer, Hospira was able to avoid the FDA import ban and compete in the U.S. marketplace for infusion pumps." [35] ¶ 21. He alleges that Hospira and Q Core operated as partners and co-manufacturers of the Sapphire pumps, sharing project managers, design and software engineers, regulatory personnel, commercial, and marketing executives at the manufacturing level. *Id.* ¶¶ 22–24.

C. Relator's Product Allegations

Relator first learned about the Sapphire sets in December 2014, when Hospira promoted him to "Senior Manager Sapphire Quality Systems," a new position intended to "provide quality assurance assistance and oversight with respect to Hospira's relationship with Q Core, and its marketing and distribution of Q Core's Sapphire products." *Id.* ¶ 31. Beginning in February 2015, Relator alleges he discovered several quality assurance issues related to Q Core and its Sapphire products after reviewing customer complaints.[2] *Id.* ¶ 33. Specifically, Relator alleges that Defendants:

- **Engaged in a Silent Recall of Defective Power Cords.** *See id.* ¶¶ 35–49; [35-1] at 5–7. Relator claims that Hospira, in an effort to avoid further FDA scrutiny, failed to notify the public and FDA about: (1) defective power cords that sparked and fell apart as customers used them and would not properly charge; and (2) Q Core and Hospira's decision to replace the original power cords with new cords. Relator claims that Hospira's failure to inform the public and FDA about the defective power cords, and its subsequent decision to

[2] Hospira kept customer complaints related to Sapphire pumps in a database, from which it ran monthly reports, which it shared with various employees, including Relator. [35] ¶ 34.

characterize the new power cords as an enhancement rather than a replacement, constituted a silent recall in violation of FDA regulations, 21 C.F.R. §§ 7.40, 7.46, 7.49, 803.1, 803.10, 803.20, 803.40, 803.50, 803.53, 806.10. Relator also claims that the new power cords failed to correct the problems associated with the original cords.

- **Engaged in a Silent Recall through Repeated Software Revisions.** *See* [35] ¶¶ 50–65. Relator claims that Hospira, in an effort to avoid further FDA scrutiny, failed to notify the public and FDA about: (1) Sapphire pumps disabling themselves due to faulty air-in-line and cassette misplaced alarms; (2) Sapphire pumps not properly resetting after these false alarms, which resulted in patients not receiving their medication in proper dosage or in a timely fashion; (3) Sapphire pumps over-and under-delivering proper dosages of medication; and (4) Q Core's and Hospira's decision to correct these issues with 55 software revisions to the Sapphire pumps over the course of four years. Relator claims Hospira's failure to inform the public and FDA about the false alarm and dosage problems, and its subsequent decision to characterize the software revisions as enhancements rather than corrections, constituted a silent recall in violation of FDA regulations, 21 C.F.R. §§ 7.40, 7.46, 7.49, 803.1, 803.10, 803.20, 803.40, 803.50, 803.53, 806.10. Relator also claims that the software revisions failed to correct these performance issues.
- **Engaged in a Silent Recall by Acquiescing to Q Core's Request to Return and/or Destroy Microbore Sets.** *See* [35] ¶¶ 66–76. Relator claims

that in late 2014, Q Core instructed Hospira to place 57 batches of microbore sets "on hold" because it discovered the batches were prone to leaking medication. Because Hospira had already sold and distributed significant quantities of those 57 batches to customers, Relator claims that he and other Hospira employees repeatedly informed Q Core that a hold would constitute an expansion of an existing Field Safety Notice (FSN)/Recall. Nevertheless, Hospira's Corporate Vice President of Quality for the Device Organization, Chris Ganser, signed off on documentation allowing those microbore sets to be either returned to Q Core or destroyed. Hospira never issued an FSN or otherwise informed the public or FDA about the microbore sets, and thus Relator alleges it engaged in a silent recall in violation of FDA regulations, 21 C.F.R. §§ 7.40, 7.46, 7.49, 803.1, 803.10, 803.20, 803.40, 803.50, 803.53, 806.10.

In addition to these product quality issues, Relator also alleges that Hospira created marketing materials that included false information to: (1) help sell the Sapphire pumps; and (2) offer "alternate messaging" around the defects. [35] ¶¶ 25–26.

D. Relator's Retaliation Allegations

Beginning in February or March 2015, Relator brought his concerns regarding the power cords, software, and microbore sets to Hospira's Senior Management team, including Ganser. *Id.* ¶ 77. In April 2015, Relator completed a site visit of Q Core's facility in Tel Aviv, Israel; he alleges that during the visit, Q Core's President, Tally Eitan, told him that, "we know the quality of our product is bad, but we are not doing

a Field Action." *Id.* ¶ 78. Upon his return, Relator provided a report of his findings on Q Core's lack of quality assurance procedures to Mr. Ganser, and over the following months raised his concerns with: Hospira's Vice President of Medical Devices, David Endicott; Hospira's Vice President of Medical, Dr. Roee Lazebnik; Hospira's Vice President of Alliance Management and Franchise, Chad Jansen; Hospira's Vice President of Quality Assurance, Joe Sener; and Hospira's Vice President of Regulatory Affairs, Amy Giertych. *Id.* ¶¶ 80–85. None of these individuals addressed Relator's concerns. *See, e.g.*, *id.*

With respect to the microbore set problem, beginning in May 2015, Jansen repeatedly requested that Relator "confirm the data used to inform Q Core about the steps that were needed to resolve the . . . issue." *Id.* ¶¶ 86–87. When Relator confirmed the data's accuracy, he claims Jansen ignored it and misled others to believe "Relator was incorrect." *Id.* ¶ 87. On June 5, 2015, Relator and Jansen spoke again about the microbore sets over the phone. *Id.* ¶ 88. At this time, Relator informed Jansen of the applicable FDA regulations and asked whether he should bring his concerns to Endicott or Michael Ball, Hospira's Chief Executive Officer. *Id.*

Shortly after this call, Ganser called Relator to reprimand him for suggesting he would contact Endicott and Ball. *Id.* ¶ 89. Less than two weeks later, on June 18, 2015, Hospira reassigned Relator from his position as Senior Manager of Sapphire Quality Systems. *Id.* ¶ 90. At the time of his reassignment, Ganser asked Relator, "What would you do [about the Q Core problems] if you were in my position?" *Id.* ¶ 91. Relator answered, "We are the ones selling the pumps. I would do the right thing.

I would inform the FDA and public." *Id*. Ganser responded by telling Relator he now "no longer had to lose sleep over Q Core." *Id*.

When Hospira reassigned Relator, it told him he would fill the "Director Lake Forest Quality" position. *Id*. ¶ 92. But, it instead gave Relator the lesser title of "Senior Manager Lake Forest Quality." *Id*. Relator claims that his reassignment constituted a demotion, as his new job duties "are significantly less than those he performed as Senior Manager [of] Sapphire Quality Systems." *Id*. ¶ 93.

E. The Present Litigation

Pfizer acquired Hospira on September 3, 2015. *Id*. ¶ 96. On September 14, 2015, Relator filed complaints with Pfizer's Compliance Department, raising his quality assurance and public safety concerns related to Q Core and the Sapphire products, as well as retaliation. *Id*. ¶ 97. In June 2016, Pfizer informed Relator that it found no evidence to substantiate his retaliation claim; it did not address his quality assurance and public safety concerns. *Id*. ¶¶ 99–100.

Relator originally filed suit in this Court under seal in July 2016. [1]. The United States and the State of Illinois declined to intervene on January 10, 2018. [15]. Relator served Defendants with his original complaint on February 21, 2018, [19] [20], and Defendants moved to dismiss in response on April 23, 2018 [32]. Relator elected to amend, and this Court thus denied the motion without prejudice and without reaching the merits. [34]. Relator filed his AC [35] on May 24, 2018, in response to which Defendants filed the motion to dismiss [41] now at issue.

II. Legal Standard

A. Motion to Dismiss Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint must provide a "short and plain statement of the claim" showing that the pleader merits relief, Fed. R. Civ. P. 8(a)(2), so Defendants have "fair notice" of the claim "and the grounds upon which it rests," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). A complaint must also contain "sufficient factual matter" to state a facially plausible claim to relief—one that "allows the court to draw the reasonable inference" that the defendant committed the alleged misconduct. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). This plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013). Thus, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Limestone Dev. Corp. v. Vill. of Lemont*, 520 F.3d 797, 803 (7th Cir. 2008).

In evaluating a complaint, this Court accepts all well-pleaded allegations as true and draws all reasonable inferences in Plaintiff's favor. *Iqbal*, 556 U.S. at 678. This Court does not, however, accept legal conclusions as true. *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009). On a motion to dismiss, this Court may consider the complaint itself, documents attached to the complaint, documents central to the complaint and to which the complaint refers, and information properly subject to judicial notice. *Williamson*, 714 F.3d at 436.

B. Rule 9(b) Standard

Additionally, the FCA "is an anti-fraud statute and claims under it are subject to the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure." *United States ex rel. Gross. v. AIDS Research All.-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005). Rule 9(b) requires that in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated "with particularity." In adding "flesh to the bones of the word particularity," the Seventh Circuit has "often incanted that a plaintiff ordinarily must describe the who, what, when, where, and how of the fraud—the first paragraph of any newspaper story." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 441–42 (7th Cir. 2011) (internal quotations omitted). Ultimately, a plaintiff must inject "precision and some measure of substantiation" into fraud allegations. *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 776 (7th Cir. 2016) (internal quotations omitted).

Rule 9(b)'s heightened pleading requirements serve three main purposes: (1) protecting a defendant's reputation from harm; (2) minimizing "strike suits" and "fishing expeditions"; and (3) providing notice of the claim to the adverse party. *Id.* Fair notice requires a plaintiff who pleads fraud to "'reasonably notify the defendants of their purported role in the scheme.'" *Id.* at 778 (quoting *Midwest Grinding Co. v. Spitz*, 976 F.2d 1016, 1020 (7th Cir. 1992)); *see also Guar. Co. of N. Am. v. Moecherville Water Dist., N.F.P.*, No. 06-cv-6040, 2007 WL 2225834, at *2 (N.D. Ill. July 26, 2007) ("The purpose of the more restrictive pleading standard is to ensure

that the accused party is given adequate notice of the specific activity that the plaintiff claims constituted the fraud, so that the accused party may file an effective responsive pleading.").

III. Analysis

Relator attempts to prove his AC allegations under several FCA theories. Specifically, he argues that: (1) Defendants' fraudulent conduct satisfies an implied false certification theory, [48] at 7–8; (2) Defendants' fraudulent conduct satisfies an express false certification theory, *id.* at 7; and (3) Defendants fraudulently induced third parties to submit false claims, *id.* at 5–7.[3]

A. FCA & IFCA Standard

To state a claim under the FCA, relators must show that Defendants "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval, 31 U.S.C. § 3729(a)(1)(A), or "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B). A "claim" under the statute "includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1996 (*Escobar II*) (citing 21 U.S.C.

[3] Relator's AC also appears to allege a "worthless services" theory. *See* [35] ¶¶ 37, 107, 115. Defendants address this theory in their motion to dismiss, arguing that Relator's allegations of "diminished quality" are insufficient to invoke the "worthless services" theory. [42] at 9–10. Relator fails to respond to this argument and does not address his "worthless services" theory in his opposition memorandum. *See generally* [48]. Thus, he concedes this argument, and this Court grants that portion of Defendants' motion to dismiss as unopposed. *See Mitsui Sumitomo Ins. Co., Ltd. v. Moore Transp., Inc.*, 500 F. Supp. 2d 942, 950–51 (N.D. Ill. 2007) ("The law of the Seventh Circuit is clear: 'Perfunctory or undeveloped arguments are waived.'" (internal citation omitted) (collecting cases)).

§ 3729(b)(2)(a)). Here, two theories of falsity under the FCA remain relevant: false certification and implied false certification—"in essence, falsity resulting from express misrepresentations or from misrepresentation by omission." *United States ex rel. Lisitza v. Par Pharm. Cos.*, 276 F. Supp. 3d 779, 789 (N.D. Ill. 2017).

The FCA's scienter and materiality requirements are "rigorous." *Id.* at 2002. "Knowingly" means "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); *see also United States ex rel. Sheet Metal Workers Int'l Ass'n v. Horning Invs., LLC*, 828 F.3d 587, 593 (7th Cir. 2016). The knowledge requirement does not, however, require "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). The term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). Moreover, a "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 1996.

Courts evaluate IFCA claims under the same standards as those applicable to FCA claims. *United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1109 (7th Cir. 2014); *Cunliffe v. Wright*, 51 F. Supp. 3d 721, 740 (N.D. Ill. 2014). Thus, this Court will apply its FCA analysis to both Counts I and II.

B. Relator's Implied Certification Theory

This Court turns first to Relator's implied certification theory.

Under the implied certification theory, when "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Escobar II*, 136 S. Ct. at 1999. In other words, the implied certification theory "treats a bill submitted to the government as an implicit assurance that the bill is a lawful claim for payment," an assurance that becomes false "if the firm submitting the bill knows" that it is not "entitled to payment." *Grenadyor*, 772 F.3d at 1106.

There are two conditions to this theory: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *United States ex rel. Nelson v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (*Sanford-Brown II*) (citing *Escobar II*, 136 S. Ct. at 2001). In the absence of any specific misrepresentation on a claim's face, relators may identify omitted information that renders the description of a good or product misleading. *Lisitza*, 276 F. Supp. 3d at 798; *Midwest Commerce Banking Co. v. Elkhart City Ctr.*, 4 F.3d 521, 524 (7th Cir. 1993) ("Omissions are actionable as implied representations when the circumstances are such that a failure to

communicate a fact induces a belief in its opposite."). The Supreme Court has cautioned that the implied certification theory still imposes the FCA's "rigorous" scienter and materiality requirements. *Escobar II*, 136 S. Ct. at 2002.

Here, Plaintiff alleges that Defendants violated FDA regulations that govern reporting recalls, removals, corrections, and other adverse events, which in turn caused the Government to make "payments for claims that otherwise would not have been allowed." [35] ¶ 106. Defendants respond that: (1) Relator has not identified any specific reimbursement claim, much less identified a false statement or other fraudulent misrepresentation that Defendants made to the Government; and (2) regardless, the alleged regulatory violations are not material to any Government payment decision. [42] at 6, 7.

1. Relator Fails to Plead Falsity with Particularity

Relator's implied certification theory fails at the outset; Relator cannot establish the "specific representation" condition, because he fails to allege false claims with sufficient particularity under Rule 9(b). In fact, Relator fails to allege a *single* claim submitted to the Government, let alone that any claim made a specific representation—whether an affirmative false statement or omission—about the Sapphire sets. *See generally* [35]. Instead, he alleges that Defendants sell their products to hospitals, pharmacies, private citizens, and other medical organizations, "and therefore request[] payment and receive[] funds . . . from the U.S. and/or Illinois." [35] ¶¶ 10, 12. But, even if Defendants submitted claims for the Sapphire sets—a fact that Relator does not expressly allege—it is well-settled in the Seventh

Circuit that "a simple demand for payment does not constitute a specific representation about the goods and services provided." *Lisitza*, 276 F. Supp. 3d at 796, 798–99 (internal quotations omitted) (finding that there is "little basis to infer that a pharmacy's Medicaid reimbursement claim constitutes a representation that the drug for which reimbursement is sought was the drug originally prescribed for the patient" given the "plethora of state laws and regulations that govern the dispensing of prescription medications"); *see also Sanford Brown II* 840 F.3d at 447 (summary judgment finding that although relator alleged that defendant submitted claims certifying compliance with all applicable laws, when in fact it had violated provisions of Title IV of the Higher Education Act, there was no proof that defendant made any representations in connection with the claims for payment; instead, the defendants simply requested a disbursement).

Relator responds to this fatal shortcoming with several arguments. First, he argues that he has sufficiently alleged that Defendants violated various FDA regulations, and thus that they made "omissions of relevant consequence" for purposes of implied false certification. [48] at 8. But, the Seventh Circuit has made clear that even under an implied certification theory, "it is not enough to allege, or even prove, that [Defendants] engaged in a practice that violated a federal regulation. Violating a regulation is not synonymous with filing a false claim." *Grenadyor*, 772 F.3d at 1107 (explaining that to comply with 9(b), relator alleging a kickback scheme under the FCA "would have had to allege either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a specific patient who had received a kickback,

or at least name a Medicare patient who had received a kickback."). Absent an allegation of a single claim, this Court cannot begin to determine whether Defendants' alleged regulatory violations misrepresented or omitted information about the Sapphire sets under the FCA.

Relator also argues that he does not need to have actually witnessed or had direct access to Defendants' specific request for payment and fraudulent paperwork to satisfy particularity. *See* [48] at 4 (citing *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 705 (N.D. Ill. 2012)). But, a relator must still "show, in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy." *Id*. (citing *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854–55 (7th Cir. 2009)). Relator's AC thus fails under Rule 9(b) not because he failed to witness or have direct access to a false claim, but because he does not *allege* the submission of *any* claim relating to the Sapphire sets, therefore offering this Court and Defendants no explanation as to the "nature of the charge." *Id*.

For example, in *Geschrey*, the court reasoned that "the fact that most of [defendant's] patients were receiving government benefits and [defendant] billed Medicare and Medicaid at a *per diem* rate for each covered patient create[d] a strong inference that bills for the care of patients as to whom fraud ha[d] been alleged were submitted to the government." *Id*.; *see also Lusby*, 570 F.3d at 854 (finding the fact that defendant's contracts with the Government required it to submit, with each request for payment, a specific form with specific representations about the relevant

goods' quality established falsity at the motion to dismiss stage). In contrast, Relator gives this Court no information from which to draw such an inference, such as whether and how Defendants ever submitted claims to the Government for the Sapphire sets. Again, without even a basic idea of what information a relevant claim might contain, this Court cannot determine whether any specific representation or omission rendered the Sapphire sets' description misleading. *See Grenadyor*, 772 F.3d at 1106–07.

2. Relator Fails to Establish Materiality

Even if Relator had pled falsity with sufficient particularity, Relator's AC fails to establish that the alleged omissions—Defendants' regulatory violations—were material to the Government's decision to pay.[4] *Sanford-Brown II*, 840 F.3d at 447 (citing *Escobar II*, 136 S. Ct. at 2001).

Under the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property" and is not "too fact intensive" to decide at the motion to dismiss stage. 31 U.S.C. § 3729(b)(4); *Escobar II*, 136 S. Ct. at 2004, 2006 n.6. In implied certification cases, "materiality looks to the effect on the likely or actual behavior of the recipient of the

[4] Relator's opposition also cites the "fraudulent conduct initiated by Hospira in mischaracterizing its role as the co-developer, manufacturer and marketer of the Sapphire pumps" in support of all three of its FCA theories. [48] at 6, 7, 8. Relator makes no attempt to explain how this allegation would render any claim description of the Sapphire sets misleading, or why it would generally be relevant or material to reimbursement. *See generally* [35], [48]. Nor does Relator allege that Defendants, as opposed to Q Core, played any role in Q Core's application for approval of the Sapphire pump, or that Defendants made any affirmative representations or certifications as to their manufacturing role to the Government. [35] ¶¶ 14–27. Therefore, this Court does not consider Hospira's alleged role mischaracterization with respect to Relator's implied certification, express false certification, or fraudulent inducement theories.

alleged misrepresentation," therefore requiring specific facts showing that the Government's payment decision would likely or actually have been different if the Government knew about the alleged regulatory violations. *Escobar II*, 136 S. Ct. at 2002; *Sanford-Brown II*, 840 F.3d at 447. Notably, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* at 2003; *Sanford-Brown II*, 840 F.3d at 447 (finding lack of materiality because "federal agencies in this case have already examined [defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted.").

Here, Relator fails to allege that the Government's decision to pay would have been different had it known of the alleged regulatory violations. Instead, his materiality argument rests solely upon the allegation that the Government "made payments for claims that otherwise would not have been allowed" because of the Sapphire sets' "defective and dangerous nature." [35] ¶¶ 106, 108. But this explanation cannot satisfy materiality under Rule 9(b). *See United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 825 (8th Cir. 2009) (finding that "the conclusory allegation that unidentified government agents would not have reimbursed through Medicare individuals submitting claims [for the product] if they had known of the defects and failure to comply with the rules and regulations of the FDA does not comply with Rule 9(b)" and thus fails to establish materiality) (internal citation omitted).

Further, Relator does not allege that the Government's *actual* decision to pay was different; specifically, he fails to allege any change to Government reimbursement for Sapphire devices, or any regulatory action taken by the FDA, in response to his suit. *Escobar II*. 136 S. Ct. at 2003; *see also City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (holding that a requirement was not material where the Government *itself* filed the FCA action but continued to pay claims) (emphasis added). Moreover, Relator does not allege that compliance with the applicable reporting and safety regulations is expressly or implicitly a condition of payment, nor has he alleged that "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance" with the relevant regulations—both of which are factors the Supreme Court identified as relevant to materiality. *Escobar II*, 136 S. Ct. at 2003; *see also United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014), *cert. denied*, 135 S. Ct. 85 (2014) ("[T]he Medicare and Medicaid statutes . . . do not require compliance with . . . FDA safety regulations as a precondition to reimbursement."). Because Relator does not explain why Defendants' purported regulatory violations are material to any Government payment decision, this Court finds that Relator's conclusory allegations fail to satisfy *Escobar II's* "demanding" materiality standard. 136 S. Ct. at 2003.

Because Relator has not pled falsity or materiality with the requisite particularity under Rule 9(b), this Court rejects Relator's implied false certification theory.

C. Relator's Express False Certification & Fraudulent Inducement Theories

Relator's express false certification and fraudulent inducement theories fail for the same reason as his implied false certification claim: he fails to plead falsity and materiality with any particularity.

Under an express false certification theory, a relator must allege that defendants *affirmatively* certified they had "complied with particular statutes or regulations that were conditions of, or prerequisites to, government payment." *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.,* 764 F.3d 699, 710–711 (7th Cir. 2014) (citing *United States ex rel. Gross v. AIDS Research Alliance-Chi.*, 415 F.3d 601, 604 (7th Cir. 2005)); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 (4th Cir. 1999) (citing *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997)). And the fraudulent inducement theory similarly requires a relator to show that defendants made a "material" and "false" record or statement, as well as a "claim for the government to pay money or forfeit money due." *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500 (8th Cir. 2016) (citing *In re Baycol Prods. Litig.*, 732 F.3d 869, 875–76 (8th Cir. 2013)).

As discussed above, Relator fails to identify a single material record, statement, claim, or certification to the Government, much less a false representation, with particularity. Thus, this Court must also reject Relator's express false certification and fraudulent inducement theories. Absent any viable theory of FCA liability, and thus IFCA liability, this Court dismisses Counts I and II

of Relator's AC [35].

D. Relator's Retaliation Claims

1. Relator's FCA Retaliation Claim

In Count III, Relator alleges that Defendants retaliated against him after he attempted to prevent Defendants' alleged FCA violations, thus violating the FCA's anti-retaliation provision, 31 U.S.C. § 3730(h). *Id.* ¶ 2. Specifically, Relator alleges that he "repeatedly complained to Hospira's senior management between February and June 2015 about how its actions with respect to the [Sapphire sets] were a silent recall in violation of FDA regulations." *Id.* ¶ 119. Two weeks after Relator made these complaints, Relator alleges that Hospira reassigned him from Senior Manager of Sapphire Quality Systems to Senior Manager of Lake Forest Quality, which had "fewer job duties" and therefore constituted a demotion. *Id.* ¶¶ 120–122.

The False Claims Act provides a cause of action to any employee who is "discharged, demoted, suspended, threatened harassed, or [otherwise] discriminated against . . . because of lawful acts" undertaken "in furtherance of" a *qui tam* action. 31 U.S.C. § 3730(h)(1). To prevail on a retaliation claim, relators must show that "(a) the plaintiff's actions were taken in furtherance of a False Claims Act enforcement action and were therefore protected by the statute; (b) his employer had knowledge that he was engaged in this protected conduct; and (c) his discharge was motivated, at least in part, by the protected conduct." *United States ex rel. Ziebell v. Fox Valley Workforce Dev. Bd. Inc.*, 806 F.3d 946, 953 (7th Cir. 2015) (citing *Fanslow v. Chi. Mfg. Ctr., Inc.*, 384 F.3d 469, 479 (7th Cir. 2004)).

As the Seventh Circuit explained in *Fanslow*, "there is an objective component to the test for a [retaliation] claim under § 3730(h)(1), as well as a subjective one." 384 F.3d at 479–80. Thus, "it's not enough for [a relator] to *think* she's enforcing the False Claims Act; a reasonable employee in the same position must be able to think the same thing." *Ziebell*, 806 F.3d at 953. To make this determination, the Seventh Circuit has held that the relevant protected activity inquiry is whether: "(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government." *Fanslow*, 384 F.3d at 480 (quoting *Moore v. Cal. Inst. Of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002)).

Relator's AC does not satisfy this inquiry. To be sure, the AC is filled with allegations of Sapphire set quality control issues, as well as allegations that Relator consistently reported such issues in keeping with his quality assurance role. *See, e.g.*, [35] ¶¶ 83–87. But, as discussed above, Relator does not allege any fraudulent *claims* activity. Complaints about regulatory violations do not, by themselves, constitute FCA protected activity. *Ziebell*, 806 F.3d at 953 (finding, on summary judgment, that a retaliation claim was "woefully lacking in factual support" because "the record [did not] show any fraudulent-claims activity; at most it show[ed] regulatory noncompliance.") A reasonable employee in the same or similar circumstances as Relator might very well believe that the Sapphire sets had significant quality control problems, and that Defendants violated FDA regulations by attempting to cover them up. But, even accepting all of Relator's allegations as true, this Court cannot find

that a reasonable employee might believe quality control problems or silent recalls constitute *fraudulent claim* activity—particularly when Relator fails to allege he made any complaints relating to government claims or payment. *See Fanslow*, 384 F.3d at 483 (finding that the protected conduct element of an employee's FCA retaliation claim needed further development because the district court should have considered "which of [defendant's] *claims* for federal funds Fanslow thought were fraudulent or false") (emphasis added).

Because Relator has not established that he engaged in protected activity under the FCA, this Court dismisses Count II of Relator's AC. [35].

2. Relator's Illinois Whistleblower Act Claim

Based upon a theory similar to the FCA retaliation claim above, Relator alleges that Defendants retaliated against Relator in violation of the IWA. Specifically, Relator argues that he refused to: (1) prepare documentation that allowed defective microbore sets to be returned to Q Core or destroyed; and (2) sign forms documenting the release of "ship hold" products that he reasonably believed to be an "illegal silent recall." *Id.* ¶¶ 126–27.

To state a claim under the IWA, Relator must establish that he refused to participate in an activity that would result in a violation of a state or federal law, rule, or regulation, and that his employer retaliated against him because of that refusal. 740 Ill. Comp. Stat. 174/20; *Corah v. Bruss Company*, 77 N.E.3d 1038, 1043 (Ill. App. Ct. 2017). Illinois courts have held that "the language of section 20 is unambiguous and that a 'plaintiff must actually refuse to participate' in an activity

that would violate a law or regulation." *Id.* (quoting *Lucas v. Cty. of Cook*, 987 N.E.2d 56, 65 (Ill. App. Ct. 2013)).

Relator has not alleged that he refused to participate in such an activity. As Relator asserts, FDA regulations do require companies to promptly *inform* the public of any recalls of defective medical devices, as well as *report* to the FDA any decision to recall their products for safety reasons, or instances in which defective medical devices have caused or contributed to death or serious injury. [35] ¶ 41. But, Relator's IWA claim does not rely upon Defendants' decision to refrain from informing the public or reporting their recall to the FDA; in fact, he does not allege that he played, or even had the authority to play, any role in Defendants' FDA reporting decisions. *See, e.g.*, *id.* ¶¶ 66–76. Instead, his claim rests upon his alleged refusal to prepare documentation to allow microbore sets to be returned or destroyed in the first place, as well as his alleged refusal to sign forms documenting the release of "ship hold" products. [35] ¶¶ 71, 126–27. In short, Relator does not point to anything unlawful about the paperwork he refused to prepare or sign, as opposed to Defendants' subsequent decision not to report the products' return and/or release. *Id.* ¶ 74.

Relator relies upon *Young v. Alden Gardens of Waterford, LLC*, 30 N.E.3d 631 (Ill. App. Ct. 2015), citing it for the principle that plaintiffs can establish an IWA claim by pleading that they: (1) refused to falsify records; and (2) were retaliated against for doing so. [48] at 15–16. But in *Young*, the plaintiff nurse filed a whistleblower claim against the defendant employer, a long-term care facility,

alleging that it terminated her employment after she refused to falsify residents' medication administration records at her superior's request. 30 N.E.3d at 637. The *Young* court held that these allegations sufficiently stated the plaintiff engaged in protected activity. *Id*. at 644–45. Here, in contrast, Relator does not allege that any supervisor asked him to falsify any record or form. Absent an allegation that Relator was responsible for publicly reporting or otherwise preparing documents to announce a public recall, that Defendants unlawfully told him not to do so, and Relator refused, this Court cannot find that he refused to engage in unlawful activity for purposes of his IWA claim. *See Corah*, 77 N.E.3d at 1043 ("[P]laintiff must actually refuse to participate in an activity that would violate a law or regulation") (internal quotations omitted). Thus, this Court dismisses Count IV of Relator's AC. [35].

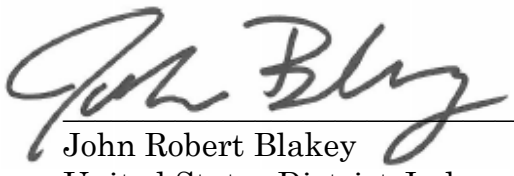
IV. Conclusion

For the reasons explained above, this Court grants Defendants' motion to dismiss [41] and dismisses Relator's AC [35]. At the July 17, 2018 hearing, Relator declined an offer under this Court's standing orders to file a second amended complaint addressing the issues raised in the motion to dismiss [41]. This Court also denied Defendants' request to stay discovery generally, and instead only deferred the taking of formal depositions pending resolution of the motion to dismiss. [47]. While this motion remained under advisement, Relator did not request leave to amend his complaint, seek to compel written discovery from Defendants, or otherwise request the ability to take any depositions. Accordingly, if Relator intends to file any further amendments to his complaint, consistent with this order and Relator's Rule 11

obligations, then he must do so within 14 days of this order. In light of the prior opportunities to amend and/or conduct discovery, and Relator's good-faith obligation to conduct a pre-filing investigation of this matter, any failure to replead within 14 days of this order will result in conversion of the dismissal of Relator's Amended Complaint to a dismissal with prejudice.

Dated: March 14, 2019

Entered:



John Robert Blakey
United States District Judge