UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *et al. ex rel.* ANDREW HAGERTY,	)	
Plaintiffs,	)	**Civil No. 13-10214-FDS**
v.	)	
CYBERONICS, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER ON MOTION TO DISMISS

SAYLOR, J.

This is a *qui tam* action alleging the unlawful promotion of medically unnecessary replacements of devices in epilepsy patients. Relator Andrew Hagerty has brought suit against defendant Cyberonics, Inc., a company that manufactures and sells the Vagus Nerve Stimulator Therapy ("VNS") system, a medical device used to treat refractory epilepsy and treatment-resistant depression.

On May 19, 2014, Hagerty amended the complaint. The amended complaint alleges that defendant engaged in a fraudulent scheme to promote premature, medically unnecessary VNS replacements to individuals with epilepsy who were covered by government health-care programs. It alleges violations of the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729(a) (Count 1); conspiracy to violate the FCA (Count 2); violations of various state analogues to the Federal FCA (Counts 3 through 30); retaliatory discharge of Hagerty in violation of 31 U.S.C. § 3730(h) (Count 31); breach of contract and breach of the implied covenant of good faith and fair dealing (Count 32); and wrongful termination and retaliation in violation of public policy and the

Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5J (Count 33).

Defendant has moved to dismiss the amended complaint. For the following reasons, the motion will be granted in part and denied in part.

I. Background

A. Factual Background

The facts summarized below are set forth in the amended complaint unless otherwise noted.

1. The Parties

Cyberonics, Inc., is based in Houston, Texas. (Am. Compl. ¶ 16). It is publicly traded on NASDAQ under the ticker "CYBX." (*Id.*). Cyberonics sells the VNS system in markets worldwide, including the United States. (*Id.*).

Andrew Hagerty is a resident of Massachusetts. (*Id.* ¶ 14). He was employed by Cyberonics as a sales representative from May 3, 2010, until he was terminated on January 9, 2012. (*Id.*). He has more than twelve years of experience in the medical-device industry. (*Id.*).

2. Government Health-Care Programs and the VNS

The VNS system is a medical device that is implanted into the chest and neck through surgery. (*Id.* ¶ 2). A wire runs from the device and is attached to the left vagus nerve in the neck.[1] (*Id.* ¶ 61). The system is programmed to stimulate the left vagus nerve by sending electrical signals at regular intervals. (*Id.* Exs. C, E). In 1997, the United States Food and Drug Administration approved the use of VNS to help treat certain types of epilepsy. (*Id.*).

Medicare is a health-insurance program administered by the United States Department of

[1] The vagus nerve consists of a pair of nerves, called the left and right vagus nerves, that run from the brainstem to the abdomen.

Health and Human Services. (Am. Compl. ¶ 17). Medicare provides for payment of, among other things, medical services and equipment to persons over 65 years of age and individuals who are 18 years of age or older and are eligible for disability benefits. (*Id.* ¶ 18). According to the complaint, it is a recommended practice for parents or guardians of individuals with refractory epilepsy to apply for disability benefits to qualify for Medicare and help cover living expenses. (*Id.*). Medicare reimburses qualified individuals for the purchase of the VNS system and the surgical procedures necessary to implant, remove, or replace the device. (*Id.*).

Medicaid is a health-insurance program administered by HHS jointly with agencies in each state. (*Id.* ¶ 20). It is designed to assist states in providing medical services, medical equipment, and prescription drugs for low-income persons who qualify for the program. (*Id.* ¶ 21). Like Medicare, Medicaid reimburses qualified individuals for the purchase of the VNS system and the surgical procedures necessary to implant, remove, or replace the device. (*Id.* ¶ 20). Families with children who have refractory epilepsy may qualify for Medicaid. (*Id.* ¶ 21). For example, a family below the poverty line can use Medicaid as its primary insurer. (*Id.*). A family who is not below the poverty line but has a child with refractory epilepsy may be able to obtain Medicaid as a secondary insurer. (*Id.*).

The Civilian Health and Medical Program of the United States, now known as TRICARE, provides benefits for health-care services furnished to members of the U.S. military and their family members. (*Id.* ¶ 22). TRICARE pays for medical devices and surgeries for its beneficiaries, including the VNS system. (*See id.*). According to the complaint, substantial numbers of war veterans have developed post-traumatic epilepsy resulting from traumatic brain injury. (*Id.*).

The Federal Employee Health Benefits Program ("FEHB") provides health-care benefits for qualified federal employees and their dependents. (*Id.* ¶ 23). It pays for medical devices and surgeries for its beneficiaries, including the VNS system. (*See id.*). Under the FEHB, federal employees are covered by a private health insurance policy that is subsidized in part by the federal government. (*Id.*).

The federal government also provides medical devices and surgeries directly to patients treated at government-operated hospitals. (*Id.* ¶ 24). According to the complaint, because members of the military with traumatic brain injuries frequently suffer from epilepsy, the government has established fifteen Epilepsy Centers of Excellence across the country. (*Id.*).

3. Focus on Replacement Devices by Cyberonics

In 2004, Cyberonics began focusing on marketing the VNS system to treat patients with treatment-resistant depression. (*Id.* ¶ 24). Treatment-resistant depression is defined as chronic or recurring depression for patients 18 years of age or older who are experiencing a major depressive episode and have not seen improvement with four or more antidepressant treatments. (*Id.*). In July 2005, the FDA approved the VNS system for use in treating individuals with treatment-resistant depression. (*Id.*). Within a month, Cyberonics hired a 300-person sales force to market the VNS system. (*Id.* ¶ 48).

By 2006, Cyberonics was seeking to have the Centers for Medicare and Medicaid Services ("CMS") approve Medicare reimbursement for use of the VNS system to treat depression. (*Id.* ¶ 49). According to the complaint, Medicare coverage was critical to Cyberonics because Medicare is a large payor and because other health insurance providers often follow Medicare's lead in determining what products to cover. (*Id.*). In July 2006, Cyberonics

submitted its formal request to CMS for Medicare coverage of the use of the VNS system to treat depression. (*Id.*).

In February 2007, CMS issued a proposed decision refusing Medicare reimbursement for the use of the VNS system to treat depression. (*Id.* ¶ 50). On May 4, 2007, CMS issued a final decision confirming its proposed decision. (*Id.*). At the time, according to the complaint, Cyberonics was approximately $132.5 million in debt. (*Id.* ¶ 51).

The complaint alleges that because CMS decided not to cover the use of the VNS system to treat depression, Cyberonics determined that it needed a new short-term revenue source to meet its expected revenue targets. (*Id.*). However, Cyberonics had already treated most of the willing epilepsy patients in the market. (*Id.* ¶ 53). Device sales to new epilepsy patients would not deliver enough revenue to keep the company solvent. (*Id.*). The company therefore allegedly focused on replacements of the VNS system in epilepsy patients as the key revenue generator. (*Id.* ¶ 54).

4. Pressure to Meet New Sales Quotas

On May 1, 2007, Daniel Moore became the new CEO of Cyberonics. (*Id.* ¶ 54). According to the complaint, he implemented a new incentive structure for the sales force that emphasized sales of replacement VNS devices. (*Id.* ¶ 55). Under the previous incentive structure, sales representatives only received commissions on sales of new devices, not replacement devices. (*Id.*). Under the new structure, the company began paying commissions to its sales representatives for sales of replacement devices. (*Id.*). No commissions were paid for sales of VNS devices to treat depression, although a salesperson could receive $500 for attending a VNS implant for depression at a hospital. (*Id.* ¶ 56). Sales quotas also allegedly reflected the

emphasis on replacement devices. (*Id.* ¶ 57). For example, the quota for the Boston South Region in the first quarter of 2011 was a minimum of four new devices and ten replacement devices. (*Id.* ¶ 60).

According to the complaint, almost one-third of the sales representatives earned more than $360,000 per year, with more than 66 percent of that amount coming from commissions. (*Id.* ¶ 57). Cyberonics also created a President's Club, an annual award based on successful sales that was announced at the company's nationwide sales conference. (*Id.*). Winners received awards such as an all-expenses-paid Alaskan cruise or a trip to Hawaii, Tahiti, or the Bahamas. (*Id.*). For example, at the May 2010 national sales meeting, a senior Therapeutic Consultant ("TC") received an award of $75,000. (*Id.* ¶ 58). At the May 2011 meeting, TC Travis Comstock was allegedly commended by management for replacing more than 60 devices in a single quarter. (*Id.*).

The complaint further alleges that Cyberonics ignored fraudulent and improper conduct by its sales representatives. (*Id.* ¶ 63). For example, in 2012, sales representative Berrishea Carter was allegedly caught backdating when devices had been implanted into new patients to meet her sales quota for an earlier quota. (*Id.*). She was initially fired but complained to senior management that backdating was widespread and she was being unfairly singled out. (*Id.*). Her supervisor rehired her. (*Id.*).

Another sales representative, Emily Gertch, received the President's Club award for the 2013 fiscal year. (*Id.* ¶ 64). Cyberonics later allegedly learned that she had created her own marketing materials that were not approved by the company or the FDA. (*Id.*). Cyberonics disciplined her by not offering her the standard trip awarded to other President's Club awardees.

(*Id.*).

In contrast, according to the complaint, Cyberonics did not tolerate the failure to meet sales quotas. (*Id.* ¶ 59). Sales representatives who did not meet at least 75 percent of their revenue goals in a single quarter were automatically put on a performance improvement plan ("PIP"). (*Id.*). If they did not fully satisfy the quota in the quarter after being placed on a PIP, they were terminated. (*Id.*).

According to the complaint, the sales strategy was very successful. (*Id.* ¶ 112). By 2010, the company had erased its $130 million of debt. (*Id.* ¶ 113).

5. Allegedly Fraudulent Promotion of VNS System Replacements

The complaint alleges that sales representatives across the country resorted to promoting device replacements through fraud to meet their sales goals. They were able to do so because only Cyberonics had the information concerning the remaining battery life of a VNS device. (*Id.* ¶¶ 67-69).

a. Allegedly Fraudulent Battery-Life Estimates

According to the complaint, the vast majority of epilepsy patients using the VNS device were implanted with Models 101, 102, or 102R. (*Id.* ¶ 67). The device would automatically alert the user if it fell below a certain pre-programmed threshold of battery life (usually indicating the device had approximately six months of battery life remaining). (*Id.*). However, the only way to obtain an actual estimate of the device's battery life was to obtain a battery-life calculation from a Cyberonics technician. (*Id.* ¶ 68). Individualized calculation was necessary for each device because the model of the device, the device's power source, the frequency and intensity of pulses administered by the device, the type of connectors used, and several other

factors specific to each patient affected the battery-life calculation. (*Id.*). Submissions made by Cyberonics to the FDA indicate that every model of the VNS devices had an expected battery life of at least 8.4 years. (*Id.* ¶ 79).

When a physician wanted to obtain a battery-life estimate for a specific device, he or she would relay certain information to a Cyberonics sales representative. (*Id.* ¶ 68). The representative would relay that information to a technical support employee, the technician would perform the battery-life estimate, and the estimate would be relayed back to the physician through the sales representative. (*Id.*). As a result, physicians normally relied on Cyberonics sales representatives when determining when a VNS device should be replaced. (*Id.* ¶ 69).

The complaint alleges that the management at Cyberonics encouraged promotion of early device replacements that were not medically justified. (*Id.* ¶ 70). For example, in early 2011, the company sent a list of patients for sales representatives to target for VNS device replacements. (*Id.* ¶¶ 71, 82). Those patients had been using a VNS device for five to seven years. (*Id.* ¶ 82). In April 2011, target lists were sent out of patients who had been using a device for four to seven years. (*Id.*). In November 2011, the list included patients who had been using a device for three to seven years. (*Id.* ¶¶ 71, 82). Sales representatives were encouraged to use those lists to promote replacement devices. (*Id.*).

In addition, although Cyberonics policy was that physicians with questions about battery life should request a calculation from the company through a sales representative, the complaint alleges that only two technicians were employed to do those calculations. (*Id.* ¶ 72). The costs of those calculations were charged to the budget for the sales region. (*Id.*). The regional managers who made their representatives routinely obtain battery-life calculations were

allegedly demoted or fired when their region failed to make sales quotas. (*Id.* ¶ 85).

The complaint further alleges that because of this pressure, Cyberonics sales representatives aggressively promoted early device replacements that were not justified by any battery-life calculation or other medical basis. (*Id.* ¶ 73). According to the complaint, many sales representatives falsely told physicians that all devices should be automatically replaced within a set time period due to declining battery life. (*Id.* ¶ 74). Those periods were allegedly fabricated, and varied from representative to representative. (*Id.*). The sales representatives did not request battery-life calculations that would help inform physicians whether early device replacement was necessary. (*Id.* ¶ 73). For example, Gary Muenzen, a sales representative for the Northeast region, allegedly told physicians that all VNS devices needed to be replaced five years after implantation. (*Id.* ¶ 75). Dr. James Thompson, a neurologist in Norwalk, Connecticut, consistently followed Muenzen's advice without requesting any battery-life calculations. (*Id.*). Other sales representatives allegedly made similar representations to physicians. (*Id.* ¶¶ 77-79).

b. Allegedly Misleading Use of Scientific Research

The complaint alleges that Cyberonics instructed its sales representatives to inform doctors of an article published by Joseph Lee in the October 2009 edition of *Epilepsia* entitled, "Vagus Nerve Stimulator Battery Replacement: When Is the Right Time?" (*Id.* ¶¶ 86-87). The article was a study of a sample of 48 patients whose VNS devices had been replaced. (*Id.* ¶ 87). The article did not recommend automatic replacement after a set time, but noted that some physicians had chosen to replace devices early because their patients' seizures had worsened. (*Id.*).

Sales representatives were allegedly instructed to give physicians an oral summary of the highlights of the article. (*Id.* ¶ 88). Specifically, they were told to say that physicians in some cases had elected to replace devices early to improve seizure control. (*Id.*). The complaint alleges this was misleading because, among other things, the article did not specifically recommend a set replacement time, and that the physicians who chose early replacement did so because of specific issues related to the particular patient and not because of the device's battery life. (*Id.* ¶ 89).

c. Alleged Fraud or Falsification

Finally, the complaint alleges that a number of sales representatives used fraud to sell replacement VNS devices. (*Id.* ¶ 91). For example, Gary Muenzen allegedly falsified the results of device tests so that it appeared as though the devices had run out of battery. (*Id.*). Physicians would then prescribe an unnecessary battery replacement based on those tests. (*Id.*). In addition, a TC named Janet Holland, when under pressure to meet her sales quota, allegedly gave a fabricated battery life estimate to a physician's staff for one device. (*Id.* ¶ 92). As a result, the physician prescribed a replacement of the device. (*Id.*).

The TC for the territory covering Missouri and Kansas, Michelle Bunton, allegedly told physicians that replacing the device also required replacement of the leads connecting the device to the vagus nerve. (*Id.* ¶ 94). That representation was false, as old leads were compatible with newer devices. (*Id.*). As a result, physicians prescribed unnecessary lead replacements. (*Id.*). "By doing so, she not only logged revenue (toward her total revenue quota) for the generator but also an additional $5,000 for each replaced lead." (*Id.* ¶ 96). The complaint alleges that her misrepresentations were reported to the human resources department of Cyberonics, but she was

not disciplined and was later promoted to regional manager. (*Id.* ¶ 95).

6. Hagerty's Discovery of the Allegedly Fraudulent Scheme

In 2008, Hagerty's family used the VNS system to treat his son's refractory epilepsy. (*Id.* ¶ 39). The device was surgically implanted into his chest and neck. (*Id.*). Hagerty's family enrolled in MassHealth, the Massachusetts version of Medicaid, as a secondary payor to their private primary health-care insurance to help cover the costs of the VNS. (*Id.*). The VNS system helped reduce the epilepsy-induced seizures. (*Id.*).

In 2010, Hagerty applied for and obtained employment at Cyberonics as a sales associate in the Boston area. (*Id.* ¶ 40). According to the complaint, during the course of his employment, he learned the inner workings of Cyberonics, its business model, its sales-compensation structure, and reimbursement rates for the VNS system from government health-care programs. (*Id.* ¶ 41). As a sales associate, Hagerty was assigned to work under Janet Holland, who was his mentor in how to sell the VNS system. (*Id.*). TCs acted as the lead salespersons of particular geographic territories.

On May 4, 2011, Hagerty was promoted to TC of the newly created Boston South territory, encompassing Rhode Island, Vermont, Connecticut, and a portion of Massachusetts. (*Id.* ¶ 42). As a TC, Hagerty was required to meet the new sales quotas established for his territory, a minimum of four new devices and ten replacement devices. (*Id.* ¶¶ 43, 60).

According to the complaint, to meet the sales goals of Cyberonics's new incentive plan, he investigated patient records, sales records, and physician records, and spoke with physicians and nurses in his territory. (*Id.* ¶ 43). The complaint alleges that Hagerty's investigation revealed the widespread fraudulent practices by Cyberonics described above. (*Id.*). Many of

Cyberonics's patients in Hagerty's territory were insured by government health-care programs and allegedly had devices replaced far earlier than required. (*Id.* ¶ 110).

Hagerty also allegedly found that large numbers of mentally ill and vulnerable patients had their devices replaced at around the same time. (*Id.* ¶ 114). For example, patients at the Southbury Training School in Southbury, Connecticut, had their devices implanted at different times between 2002 and 2004. (*Id.*). They all received replacements in March, April, or May 2010, based on the advice of a Cyberonics employee. (*Id.*). At least one patient was eligible for Medicare, based on his age, when his device was replaced on May 12, 2010. (*Id.*). In addition, a physician in Connecticut had three of his patients whose devices were replaced in a six-week period from September 30 to November 18, 2010. (*Id.* ¶ 115). The patients had all received implants at different times, and one was on his second replacement. (*Id.*).

The complaint alleges that Hagerty became concerned that he would not be able to meet his sales quotas without resorting to fraudulent practices. (*Id.* ¶ 44). He raised his concerns and the fraudulent practices of other Cyberonics employees with his regional manager, Craig Yannuzzi. (*Id.*). Yannuzzi allegedly disregarded Hagerty's concerns and refused to investigate them. (*Id.*). On one occasion, Yannuzzi allegedly directed Hagerty to tell physicians that VNS devices typically lasted four to five years, and to recommend early replacements. (*Id.* ¶¶ 101, 106). When Hagerty asked Yannuzzi, "So, in order for me to hit these numbers I need to recommend prophylactic replacements like Gary [Muenzen]?" Yannuzzi replied that he did. (*Id.* ¶ 106). Yannuzzi also allegedly became upset with Hagerty for requesting battery-life calculations. (*Id.*).

The complaint alleges that Hagerty met his quotas in his first quarter as a TC, missed

them in the second quarter, and was fired on January 9, 2012, before his third quarter as a TC had ended. (*Id.* ¶¶ 44, 105-06). He had met 90 percent of his quotas for the third quarter before he was fired. (*Id.* ¶ 106).

7. Alleged Harm to the Federal Government

The complaint alleges that the fraudulent practices of Cyberonics caused the submission of false claims for reimbursement to government health-care programs. (*Id.* ¶¶ 5, 111, 122). It alleges that a majority of epilepsy patients using the VNS device were covered by government health-care programs, and that Cyberonics received 20 to 25 percent of its revenues from Medicare, 25 percent from Medicaid, and additional revenues from other government health-care programs. (*Id.* ¶¶ 5, 120, 122). The company created and distributed marketing materials with CPT (current procedural terminology) codes for VNS-related surgeries, and employed reimbursement specialists who assisted health-care providers with reimbursement from various government health-care programs. (*Id.* ¶¶ 116-17). Cyberonics also allegedly targeted patients who had disabling mental conditions because that would typically qualify them for Medicare coverage. (*Id.* ¶ 118).

The complaint alleges that Cyberonics "necessarily caused the submission of numerous false statements and false and/or fraudulent claims to [g]overnment [h]ealth [p]rograms." (*Id.* ¶ 122). It further alleges that because each claimant must certify that the services and materials used were reasonable and medically necessary, any early replacement of a VNS device that was reimbursed through a government health-care program was a fraud on the requisite state or federal government. (*Id.*).

The complaint alleges that Hagerty estimates that there have been more than 10,000 medically unnecessary VNS device replacements since 2007. (*Id.* ¶ 123). According to the

complaint, assuming 50 to 60 percent of those replacements were covered by a government health-care program, those programs have suffered damages of at least $100 million. (*Id.*).

B. Procedural Background

On August 8, 2012, Hagerty filed a complaint against Cyberonics, alleging wrongful termination ("*Hagerty I*"). Complaint, *Hagerty v. Cyberonics, Inc.*, No. 1:12-cv-11465 (D. Mass. Aug. 8, 2012). The complaint made no reference to government health-care programs or the FCA, but contained allegations of fraud by Cyberonics against various physicians and patients. *Id.* It alleged one claim for breach of contract. *Id.*

On January 23, 2013, a report written by the research collective Infitialis, entitled "Blowing the Whistle on Cyberonics," was published on *The Street Sweeper*'s website, www.thestreetsweeper.org. (Madden Dec. Ex. 3). The article included, among other things, a section discussing the allegations in the complaint in *Hagerty I*. (*Id.*). Specifically, the article stated, "The claims in Andrew Hagerty's lawsuits could prove terminal to [Cyberonics] because they allege that over the last five years a large portion of battery replacements were done prematurely in order to increase the velocity of sales at Cyberonics." (*Id.* at 18). The article also mentions the possibility that "patients could organize in a class and sue Cyberonics." (*Id.*).[2]

On February 2, 2013, Hagerty voluntarily dismissed *Hagerty I*. On February 4, 2013, he filed the complaint in this case under seal. The complaint alleged, among other things, violations of the False Claims Act. The FCA claims were pursued by Hagerty on behalf of the United States as a *qui tam* action.

[2] Defendant has submitted two other articles that it alleges are prior disclosures. The first, a *Wall Street Journal* article, only vaguely describes the allegations in Hagerty's first lawsuit, stating that it alleged that Cyberonics "pressured its sales staff to have surgeons prematurely schedule battery replacements for the devices, which required surgery." (*See* Madden Decl., Ex. 4). The second is a duplicate of the Infitialis report published on a different website. (*See id.*, Ex. 5).

On October 29, 2013, the government filed a notice declining to intervene in this case. (Docket No. 12). On December 5, 2013, the case was unsealed.

On May 19, 2014, Hagerty filed an amended complaint. It was not filed under seal, and alleges violations of the False Claims Act, 31 U.S.C. § 3729(a) (Count 1); conspiracy to violate the FCA (Count 2); violations of various state analogues to the FCA (Counts 3 through 30); retaliatory discharge in violation of 31 U.S.C. § 3730(h) (Count 31); breach of contract and breach of the implied covenant of good faith and fair dealing (Count 32); and wrongful termination and retaliation in violation of public policy and the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5J (Count 33).

Cyberonics has filed a motion to dismiss for failure to state a claim upon which relief can be granted.

II. FCA Claims

Counts 1 and 2 of the amended complaint allege violations of the False Claims Act. The FCA, in relevant part, prohibits a person or entity from knowingly causing the submission of false or fraudulent claims to the United States. 31 U.S.C. § 3729(a)(1)(A). Private persons, known as relators, can file civil *qui tam* actions on behalf of the United States against persons or entities who violate the act. *Id.* § 3730(b). The government can intervene in a *qui tam* action and assume primary responsibility over it. *Id.* § 3730(b)(2), (b)(4), (c)(1). The relator is eligible to collect a portion of any damages awarded in a *qui tam* action, regardless of whether or not the government intervenes. *Id.* § 3730(d).

A. Public-Disclosure Bar

Defendant first contends that the FCA claims in the amended complaint are barred by the "public-disclosure bar" of the statute, 31 U.S.C. § 3730(e)(4)(A).

1. Relevant Law

The *qui tam* provisions of the FCA permits relators, in some instances, to reap huge financial windfalls. "Although this financial incentive encourages would-be relators to expose fraud, it also attracts 'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover." *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 719 F.3d 31, 33 (1st Cir. 2013) ("*Duxbury II*") (internal quotation marks and citations omitted).

To strike a balance between encouraging whistle-blowing and discouraging opportunistic behavior, the FCA contains a "public-disclosure bar." *Id.* The public-disclosure bar seeks to "prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of public fraud." *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 26 (1st Cir. 2009) ("*Duxbury I*") (internal quotation marks omitted) (quoting *United States ex rel. McKenzie v. Bellsouth Telecommunications, Inc.*, 123 F.3d 935, 943 (6th Cir. 1997)). The public-disclosure bar provides as follows:

> 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.

31 U.S.C. § 3730(e)(4)(A).

The statute defines "original source" as an individual who "[1] prior to a public disclosure . . . , has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions . . . ." *Id.* § 3730(e)(4)(B).

2. Standard

Defendant first contends that dismissals under the public-disclosure bar should be evaluated under Fed. R. Civ. P. 12(b)(1) because the statute defines the jurisdiction of the courts to hear an FCA claim.

Before 2010, the public-disclosure bar of the FCA was clearly jurisdictional in nature. *See* 31 U.S.C. § 3730(e)(4)(A) (2006) ("No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing . . . ."). In 2010, the public-disclosure bar was amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119 (Mar. 23, 2010) (the "PPACA"). *See United States ex rel. Estate of Cunningham v. Millennium Labs. of Cal., Inc.*, 713 F.3d 662, 669 n.5 (1st Cir. 2013). The jurisdictional language was eliminated by that amendment. 31 U.S.C. § 3730(e)(4)(A) (2010); *see also United States ex rel., Lockey v. City of Dallas*, 576 Fed. Appx. 431, 435 n.1 (5th Cir. 2014) ("In 2010, as part of the Patient Protection and Affordable Care Act, the public disclosure bar was amended such that the jurisdictional language was eliminated and other language was modified."). The parties agree that the 2010 amendments apply to the FCA claims in this case.

At least two federal courts of appeals have considered whether the PPACA amendments

changed the jurisdictional character of the FCA's public-disclosure bar.[3] In *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908 (4th Cir. 2013), the Fourth Circuit held that the PPACA amendments "make it clear that the public-disclosure bar is no longer a jurisdiction-removing provision" because Congress "deleted the unambiguous jurisdiction-removing language previously contained in § 3730(e)(4) and replaced it with a generic, not-obviously-jurisdictional phrase ('shall dismiss'), while at the same time retaining jurisdiction-removing language in" other sections of the statute. 737 F.3d at 916. In *United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805 (11th Cir. 2015), the Eleventh Circuit held "that the amended § 3730(e)(4) creates grounds for dismissal for failure to state a claim rather than for lack of jurisdiction" because "Congress removed the prior language that rendered the public disclosure bar jurisdictional in nature" without removing similar jurisdictional language from other sections of the statute, and "[t]he amended section also provides that the government can oppose dismissal, allowing the case to proceed even if the public disclosure provision would otherwise apply." 776 F.3d at 810-11.

The views of the Fourth and Eleventh Circuits are supported by two branches of Supreme Court precedent. First, to determine "whether to classify a statutory limitation as jurisdictional . . . [courts] inquire whether Congress has clearly stated that the rule is jurisdictional; absent such a clear statement, . . . courts should treat the restriction as nonjurisdictional in character." *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 824 (2013) (internal quotation marks omitted). In amending the FCA, Congress removed the clear statement

[3] The First Circuit in *Cunningham*, in a footnote, referred to the post-PPACA public-disclosure provision as a "jurisdictional bar." *See* 713 F.3d at 669 n.5. That characterization was not part of the holding in the case, and indeed was made in a footnote where the court did not otherwise interpret, apply, or discuss that provision. The Court accordingly will not treat that reference as binding authority in this proceeding.

that the public-disclosure bar is jurisdictional. Second, under the amended version of the FCA, claims are dismissed under a valid assertion of the public-disclosure bar "unless opposed by the Government." 31 U.S.C. § 3730(e)(4)(A). However, "[s]ubject-matter jurisdiction can never be waived or forfeited." *Gonzalez v. Thaler*, 132 S. Ct. 641, 648 (2012); *see also Trenkler v. United States*, 536 F.3d 85, 96 (1st Cir. 2008) ("[P]arties cannot confer subject-matter jurisdiction on a district court by sloth or acquiescence."). The new public-disclosure bar appears to be non-jurisdictional because it confers on the government the power to prevent the dismissal of an FCA claim that would otherwise fall within the public-disclosure bar.

Accordingly, the Court will evaluate the public-disclosure bar under the standard of a motion to dismiss under Fed. R. Civ. P. 12(b)(6). Under that standard, the Court "must assume the truth of all well-plead[ed] facts and give . . . plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the well-pleaded facts do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (internal quotation marks and alterations omitted).

Relator contends that the motion to dismiss under the public-disclosure bar should be

denied because it relies entirely on materials outside the pleadings that cannot be considered on a motion to dismiss. *See Trans-Spec Truck Serv., Inc. v. Caterpillar Inc.*, 524 F.3d 315, 321 (1st Cir. 2008). In this circuit, however, courts can also consider "(a) implications from documents attached to or fairly incorporated into the complaint, (b) facts susceptible to judicial notice, and (c) concessions in plaintiffs' response to the motion to dismiss." *Newman v. Krintzman*, 723 F.3d 308, 309 (1st Cir. 2013) (internal quotation marks and alterations omitted). Defendant relies on news articles that can properly be considered when evaluating the FCA's public-disclosure bar because they are (at least in this context) susceptible to judicial notice. *See, e.g.*, *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 294 (S.D.N.Y. 2013) (dismissing FCA claims based on "documents that may be considered on a motion to this dismiss, in this case, judicially-noticeable public disclosures," citing *Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) (taking judicial notice of "the *fact* that press coverage . . . contained certain information, without regard to the truth of their contents") (emphasis in original)).[4]

3. <u>Prior Public Disclosure</u>

As noted above, a court is required to dismiss an FCA claim if the allegations supporting the claim were publicly disclosed within the meaning of the statute. *See* 31 U.S.C. § 3730(e)(4)(A). The public-disclosure bar applies when "(1) a public disclosure of the allegations or transactions in a relator's complaint must have occurred; (2) said disclosure must have occurred in the manner which is specified in the FCA; and (3) the relator's suit must be 'based

[4] Even if the motion were converted to one for summary judgment under Rule 56(d), relator has not contended that discovery would allow him to produce facts sufficient to create a material dispute as to the public-disclosure bar.

upon' those publicly disclosed allegations or transactions." *Cunningham*, 713 F.3d at 669-70.[5]

Defendant contends that relator's previous lawsuit and the media coverage surrounding that case publicly disclosed the same allegations as the amended complaint in this case.[6] Relator contends that those allegations are not based upon the publicly disclosed allegations in the media report.[7] He contends that the news reports focus mainly on alleged fraud on patients, not third-party medical providers or the federal government.

"In assessing whether a given later-filed suit is 'based upon' publicly disclosed allegations, [courts] look to whether those allegations are 'substantially similar' to said allegations." *Cunningham*, 713 F.3d at 670. "A prior, public disclosure of fraud occurs 'when

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[5] The relevant statutory language previously required that an action be "based upon" the prior public disclosure. 31 U.S.C. § 3730(e)(4)(A)(2006). The 2010 PPACA amendment changed the "based upon" language to require that an action disclose "substantially the same allegations or transactions" as alleged in a prior public disclosure. Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119 (Mar. 23, 2010). "A majority of circuit courts . . . adopted the view that 'based upon' meant that a relator's allegations would be barred if they were 'substantially similar to' pre-complaint public disclosures." *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 297 n.11 (S.D.N.Y. 2013). The First Circuit was among those circuits that had previously adopted the "substantially similar" interpretation of the "based upon" language. *See Cunningham*, 713 F.3d at 670. "Pre-PPACA cases therefore remain instructive as to whether the [c]omplaint's allegations and the disclosed material are substantially the same." *Ping Chen*, 966 F. Supp. 2d at 297 n.11 (citing *Leveski v. ITT Educ. Servs., Inc.*, 719 F.3d 818, 829 n.1 (7th Cir. 2013)); *see also U.S. ex rel. Beauchamp v. Academi Training Center, Inc.*, 933 F. Supp. 2d 825, 841 (E.D. Va. 2013).

[6] Because the government was not a party to relator's first lawsuit, the complaint from that case does not count as a public disclosure under the current version of the FCA. *See* 31 U.S.C. § 3730(e)(4)(A)(i).

[7] Relator also contends that the Infitialis report does not count as a "news media" report because it was posted on-line instead of through a more traditional news medium and because it did not reflect original investigative work. First, while the term "news media" is not defined in the statute, "courts that have considered the issue have construed the term to include readily accessible websites." *United States ex rel.Green v. Service Contract Educ. & Training Trust Fund*, 843 F. Supp. 2d 20, 32 (D.D.C. 2012) (collecting cases); *see also United States ex rel. Kraxberger v. Kansas City Power & Light Co.*, 2014 WL 2898465, at *2 (8th Cir. Jun. 27, 2014) (hearing testimony qualified as a disclosure through the news media because it was publicly available on a public website). Second, the plain text of the FCA contains no "original investigative work" requirement for public disclosure from the news media, and no court has imputed such a requirement. *See, e.g., United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 110 (1st Cir. 2010) (articles published in the *New York Times* that discuss allegations in a complaint qualify as public disclosures); *United States ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 933 F. Supp. 2d 825, 844-45 (E.D. Va. 2013) (coverage of lawsuit on *Wired.com* is a public disclosure). Because the public-disclosure bar does not apply even assuming that the Infitialis report is a prior public disclosure from the news media, the Court does not need to reach the issue.

the essential elements exposing the particular transaction as fraudulent find their way into the public domain.'" *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 110 (1st Cir. 2010) (quoting *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009)). To determine whether a later-filed suit is "based upon" publicly disclosed allegations, a court "must compare the substance of the prior disclosures with the substance of the relator's complaint." *Poteet*, 619 F.3d at 114. Here, relator contends that the allegations in the amended complaint are not "substantially similar" to those in the Infitialis report because the report did not allege an "essential element" of a claim under the FCA—that is, fraud on the government.

Courts considering whether a prior public disclosure of fraud is "substantially" similar to a specific FCA claim look to whether the disclosure could give rise to an inference of a false or fraudulent claim on the government. For example, the defendants in *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186 (8th Cir. 2010), were alleged to have fraudulently obtained Medicaid funds. 613 F.3d at 1188. Under federal law, the defendants were required to pursue medical costs from tortfeasors and deduct their Medicare reimbursements by that amount. *Id.* The defendants contended that disclosures in state administrative documents barred any FCA claim because those documents showed that they had not pursued any tortfeasors for reimbursement. *Id.* The Eighth Circuit rejected that contention, finding that the documents did not bar the FCA claim because they did not "show that the defendants participated in claiming federal funds without deducting the money that they should have obtained from the tortfeasors." *Id.* The court concluded that "[b]ecause the administrative documents that the defendants relied on did not disclose this essential element—the false claim itself—we cannot say that their claims were 'based upon . . . public disclosure of allegations or transactions' under the FCA." *Id.* (alteration in original) (citing 31 U.S.C. § 3730(e)(4)(A)); *see also United States ex rel. Colquitt*

v. Abbott Labs., 864 F. Supp. 2d 499, 519 (N.D. Tex. 2012) ("[P]ublic disclosure of a predicate allegation of fraud—one that does not by itself lead to an inference of a false or fraudulent claim on the government—does not disclose 'allegations or transactions' for purposes of the FCA."); *U.S. ex rel. Smart v. Christus Health*, 626 F. Supp. 2d 647, 653-55 (S.D. Tex. 2009) (holding that public disclosure of "*predicate* violation on which Relator's False Claims Act violation is premised" that does not "address fraud *on the government*" does not provide basis for Relator's suit).[8]

In contrast, if the prior public disclosure states facts sufficient to give rise to an inference of fraud on the government, courts have found that those disclosures bar related FCA claims. For example, in *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568 (10th Cir. 1995), a relator brought an FCA claim alleging that the defendant defrauded the government by improperly assessing a 2.5 percent "tax" against nuclear waste funds in violation of the Nuclear Waste Policy Act, 42 U.S.C. §§ 10101 *et seq.* 70 F.3d at 569-70. A report from the United States Government Accountability Office published prior to the lawsuit described two such instances of "taxing" that violated appropriations restrictions. *Id.* at 569. The Tenth Circuit found that the allegations in the FCA claim were substantially similar to the allegations in the GAO report. *Id.* at 572. The court found that the GAO report had disclosed "the material elements of the fraudulent transaction" even though it did not specifically allege violations on the FCA. *Id.* It concluded that so long as there was "the public disclosure of 'allegations or transactions' upon which the *qui tam* action is based," the failure to mention the FCA does not open the door to otherwise parasitic *qui tam* actions. *Id.*; *see also A-1 Ambulance Serv., Inc. v.*

[8] Exemplary analysis from the Southern District of Texas in a case involving a relator's qui tam action alleging Medicare fraud by a hospital.

California, 202 F.3d 1238, 1245 (9th Cir. 2000) ("If a relator merely uses his or her unique experience or training to conclude that the material elements already in the public domain constitute a false claim, then a *qui tam* action cannot proceed." (quoting *United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997)).

The cases defendant cites, *United States ex rel Casady v. American Int'l Grp., Inc.*, 2014 WL 1286552 (S.D. Cal. Mar. 29, 2014), and *United States ex rel. Oliver v. Philip Morris USA, Inc.*, 949 F. Supp. 2d 238, 248 (D.D.C. 2013), are consistent with that legal framework. In *Casady*, the public disclosures stated that the defendant fraudulently lowered its underwriting standards and obtained three loans from the federal government. 2014 WL 1286552, at *5-6. In *Oliver*, the public disclosure included complaints from two military organizations involving the price of cigarettes. 949 F. Supp. 2d at 248-49. In both cases, the defendant's dealings with the federal government were publicly disclosed.

In this case, the complaint alleges that defendant violated the FCA by causing the submission of fraudulent and false claims to government health-care programs. Thus, the causing of the submission of those claims is an essential element of the FCA violations. In contrast, there are no allegations of fraud on the government in the Infitialis report (or in the complaint in relator's first lawsuit). All facts and allegations in relator's first lawsuit focus on defendant's alleged scheme to cause early replacement of VNS devices. The Infitialis report and the relator's first lawsuit therefore focus exclusively on the alleged fraud on patients and doctors. While it may be possible that the replacement of a battery for a VNS device is covered by one or more government health-care programs and that such programs were billed for those surgeries, such allegations were not made until the original complaint in this case and facts supporting those allegations were not disclosed prior to the amended complaint. Therefore, although there

was a prior, public disclosure of fraud, the essential element of fraud on the government was missing.[9]

The FCA allegations in the amended complaint are therefore not "substantially similar" to the allegations in the report. Accordingly, the public-disclosure bar does not preclude the FCA claims in this case.

4. Original Source

Even if relator's suit alleges "substantially the same allegations or transaction as alleged" in the publicly disclosed allegations in the Infitialis report (or in the complaint in relator's first lawsuit), the public-disclosure bar would not preclude the FCA claims in this case because relator is an original source.

Before 2010, the statute defined an "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B) (2006). The 2010 PPACA amendment to the public-disclosure bar made two notable changes to the definition of "original source." *See* Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119 (Mar. 23, 2010). First, it added a second definition for "original source." *Id.* Now, a relator may also qualify as an "original source" if "prior to a public disclosure under subsection (e)(4)(a), [he] voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based." *Id.* Second, the requirement for "direct" knowledge was replaced with the requirement that a

[9] Defendant contends that the report necessarily implies fraud on the government because it uses the term "whistleblower" to describe relator. However, the term "whistleblower" does not necessarily describe fraud against the government, and the report does not include any other mention of such fraud. *See Whistleblower*, BLACK'S LAW DICTIONARY 1734 (9th ed. 2009) (defining whistleblower as "[a]n employee who reports employer wrongdoing to a governmental or law-enforcement agency").

relator's knowledge must "materially add[] to the publicly disclosed allegations or transactions." *Id.* Thus, the statute now defines "original source" as an individual who

> [1] prior to a public disclosure . . . , has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and *materially adds* to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government before filing an action under this section.

31 U.S.C. § 3730(e)(4)(B).

Relator does not allege that he voluntarily provided information to the government prior to the Infitialis report. Therefore, he is an "original source" only if (1) he voluntarily provided the information to the government prior to filing this action, and (2) his knowledge is "independent" of and "materially adds" to the prior, publicly disclosed allegations. Relator alleges that he "voluntarily provided his information, based on his personal knowledge, to both the federal and [s]tate [p]laintiffs as required by the FCA and [s]tate analogues, prior to filing this lawsuit." (Am. Compl. ¶ 10). The issue is whether his knowledge is "independent" of and "materially adds" to the prior, publicly disclosed allegations.

"Knowledge is 'independent' if it did not depend on the public disclosure . . . ." *Cunningham*, 713 F.3d at 673. Put differently, "a relator who would not have learned of the information absent public disclosure [does] not have 'independent' [knowledge] within the statutory definition of 'original source.'" *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991). Here, relator's knowledge clearly did not depend on the prior public disclosure because he filed the wrongful termination complaint against defendant on which the Infitialis report is based. In addition, he was employed by defendant, and had access to the information on which his allegations in this case are based. Defendant contends that relator's knowledge is not "independent" because his

knowledge of "the alleged fraud is in large part based on information he obtained from third parties . . . ." (Def.'s Mem. Supp. Mot. Dismiss 13). However, this is not what the original source "independent" knowledge prong requires. As relator contends, "[r]elator gathered his information *through his own investigation*, unprompted by any public disclosure, news outlet, or third party." (Pl.'s Opp. 15 (citing *Duxbury I*, 579 F.3d at 27)). Therefore, relator's knowledge is "independent" of the alleged prior, public disclosure.

A relator "materially adds" to the prior public disclosure if he "materially contributes anything of import to the public knowledge about the alleged fraud." *U.S. ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 694 (8th Cir. 2014). Defendant contends that the relator here does not materially add to the prior public disclosure because "[r]elator's [f]irst [a]mended [c]omplaint contains information that is substantially similar to that which was publicly disclosed *before* this FCA lawsuit was filed." (Def.'s Mem. 13 (emphasis in original)). However, "substantial similarity" is the test used to determine whether relator's suit is "based upon" the publicly disclosed allegations. *See Cunningham*, 713 F.3d at 670. Whether a relator is an "original source" is relevant only when it is determined that relator's suit is "based upon" a prior disclosure. Relator suggests that "if the original source exception is to have any force, it must be that there are some FCA complaints that are 'substantially the same' as a public disclosure under § 3730(e)(4)(A) but still 'materially add[]' to the disclosure under § 3730(e)(4)(B)." (Pl.'s Opp. 17). That point is illustrated in the case *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34 (D. Mass. 2014). In *Booker*, prior complaints revealed defendant's off-label promotion of a pharmaceutical drug in the years prior to 2008. *Id.* at 44. In contrast, relators' allegations centered on defendant's continued off-label promotion even after a settlement in the case that was the source of the prior disclosure. *Id.* The district court

concluded that although "the difference in time frame does not necessarily change the fact that the [prior] complaints disclosed 'substantially the same allegations,'" information of fraud in "an entirely different time frame . . . reflect[s] knowledge of the Relators that is 'independent of and materially adds' to the prior public disclosures of off-label . . . promotions." *Id.* Therefore, relator may "materially add" to the prior disclosure even if the allegations in this case are "substantially the same."

Defendant further contends that "[a]lthough [r]elator provides some further details of the alleged fraud, they do not 'materially add to' the fraudulent scheme that was publicly disclosed in [r]elator's earlier wrongful-termination lawsuit." Defendant cites to three cases to support its contention. *See U.S. ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 933 F. Supp. 2d 825, 843 (E.D. Va. 2013); *U.S. ex rel. Osheroff v. Healthspring, Inc.*, 938 F. Supp. 2d 724, 735 (M.D. Tenn. 2013); *U.S. ex rel. Lockey v. City of Dallas*, 2013 WL 268371, *16 (N.D. Tex. Jan. 23, 2013). In *Beauchamp*, the Eastern District of Virginia found that a relator's knowledge did not materially add to a prior disclosure where "all essential elements" of the fraudulent scheme had previously been disclosed, and the relator's knowledge did nothing more than provide "illustrative examples of the specific behavior" in the prior disclosure. 933 F. Supp. 2d at 843. In *Osheroff* , the Middle District of Tennessee determined that additional details of a fraudulent scheme did not materially add to "widely known" information, where the additional details were a "matter of degree." 938 F. Supp. 2d at 735. In *Lockey*, the Northern District of Texas concluded that where a prior disclosure could lead to "an inference of a false or fraudulent claim on the government," an allegation that recognizes this inference does not constitute a material addition. 2013 WL 268371, at *16.

The three cases defendant cites are readily distinguishable. Here, essential elements of

the fraudulent scheme were missing from the prior disclosure. The focus of the Infitialis report (and relator's prior lawsuit) was on the fraud committed on patients and doctors. Here, relator alleges that "[d]efendant engaged in a nationwide scheme to defraud [g]overnment [h]ealth [c]are [p]rograms by aggressively promoting premature device replacement by deceiving physicians. . . ." The critical component of this allegation is the alleged fraud on the government. The additional information does not provide "illustrative examples," or contribute details that are merely a "matter of degree," or recognize an inference that could be drawn from the prior disclosure. Without relator's new information, there is no basis for an FCA claim. Therefore, even if relator's suit is "substantially similar" to the prior disclosure, relator's knowledge still "materially adds" to that disclosure because it provides information on the alleged fraud on the government for the first time.

Accordingly, relator qualifies as an original source, and the public-disclosure bar does not preclude the FCA claims in this case.

B. Mandatory Pre-Suit Requirements

Under the FCA, a *qui tam* relator must comply with the following pre-suit requirements:

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government . . . . The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

31 U.S.C. § 3730(b)(2).

Those notification requirements were enacted "to allow the Government an adequate opportunity to fully evaluate the private enforcement suit and determine both if that suit involves matters the Government is already investigating and whether it is in the Government's interest to

intervene and take over the civil action." *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 998-99 (2d Cir. 1995) (quoting S. Rep. No. 345, 99th Cong., 2d Sess. 23-24, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5289). "A secondary objective was to prevent defendants from having to answer complaints without knowing whether the government or relators would pursue the litigation." *Id.* at 999. Accordingly, "[f]ailure to comply with these mandatory threshold requirements warrants dismissal of the *qui tam* complaint with prejudice." *United States ex rel. Stevens v. Vermont Agency of Natural Res.*, 162 F.3d 195, 200 (2d Cir. 1998).

If the government declines to intervene and the *qui tam* case is unsealed, further proceedings are governed by 31 U.S.C. § 3730(c)(3). That statute provides:

> If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

31 U.S.C. § 3730(c)(3).

Courts have recognized, however, that the policy behind the sealing requirement—allowing the government to investigate the claims and decide whether to intervene—is implicated when a relator amends a complaint to add completely new FCA claims. *See East Bay Mun. Util. Dist. v. Balfour Beatty Infrastructure, Inc.*, 2014 WL 2611312, at *2 (N.D. Cal. June 11, 2014). Courts have therefore required relators to abide by those requirements when filing an amended complaint that is not "substantially similar" to the original complaint. *Id.* at *3 (collecting cases). For example, in *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111 (1st Cir. 2014), the First Circuit affirmed the denial of a motion to amend the complaint a third time. 750 F.3d at 120. The proposed amendments in that case were

completely new allegations from a new *qui tam* plaintiff. *United States ex rel. Wilson v. Bristol Myers Squibb, Inc.*, 2011 WL 2462469, at *6-7 (D. Mass. Jun. 16, 2011). The district court had found that the relators had violated the FCA's sealing requirements because the new allegations were not substantially similar to those in the complaint on file and the proposed complaint was not filed under seal. *Id.* In affirming that decision, the First Circuit stated "that the new paragraphs in the [p]roposed [complaint] were attributable to the new relator and . . . they [therefore] violated the FCA's filing and service requirements." *Wilson*, 750 F.3d at 120.

The original complaint in this case makes substantially similar allegations as the amended complaint. Both complaints allege that defendant created a scheme to induce its salespersons to fraudulently recommend early battery replacements for VNS devices. Both also allege that at least some of those replacements were billed to government health-care organizations. The amended complaint includes much more detail than the original complaint concerning the alleged fraud on the government, but the substance of the allegations is the same. The government had a full opportunity to investigate those allegations and decide whether it should intervene.

Accordingly, the amended complaint did not have to be filed under seal, and relator sufficiently complied with the pre-suit requirements of the FCA.[10]

[10] Defendant also contends that relator's first lawsuit did not comply with the sealing requirements of the FCA. However, because the complaint in that lawsuit did not allege fraud on the government or any claims under the FCA, it did not have to be filed under seal.

Defendant further contends that if the amended complaint is substantially similar to the original complaint, it must also be substantially similar to the complaint in relator's first lawsuit and therefore must be barred by the public-disclosure bar. However, the original complaint is not substantially similar to the complaint in the first lawsuit for the same reasons the amended complaint is not—there are allegations of fraud on the government in the original complaint but no such allegations in relator's first lawsuit.

C. Rule 9(b)

Defendant further contends that the FCA claims should be dismissed because the complaint does not satisfy the pleading requirements of Fed. R. Civ. P. 9(b). That rule requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Those heightened pleading requirements apply to claims brought under the FCA. *United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 123-24 (1st Cir. 2013). Thus, "[r]elators are required to set forth with particularity the 'who, what, when, where, and how' of the alleged fraud." *Id.* at 123 (quoting *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000)).

As the First Circuit explained in *Ge*:

> A relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, 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 the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegations included in a complaint. However, we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. (internal quotation marks and alterations omitted) (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-33 (1st Cir. 2004)).

"Because FCA liability attaches only to false *claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough. Rather, a complaint based on § 3729(a)(1)(A) must 'sufficiently establish that false claims were submitted for government payment' as a result of the defendant's alleged misconduct." *Id.* at 124 (emphasis in original) (citations omitted) (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). However,

"[i]n a qui tam action in which the defendant is alleged to have induced third parties to file false claims with the government, a relator can satisfy this requirement by 'providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.'" *Id.* at 123-24 (quoting *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009) ("*Duxbury I*")).

If the rule were otherwise, virtually any claim of misconduct involving the sale of medical devices, pharmaceuticals, or other medical products could be brought as a *qui tam* action. Government health-care programs such as Medicare and Medicaid represent a huge portion of health-care expenditures in the United States. As a matter of logic, any scheme that causes unreasonable or unnecessary purchases of a product or service will almost certainly result in the submission of some false claim, by someone, somewhere, to the federal government. Rule 9(b), however, requires something more than conclusory allegations that false claims must have resulted from the misconduct. *See Ge*, 737 F.3d at 124 (stating that the court "reject[s] [the] approach" sought by the relator, which was"a per se rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed").

Here, the allegations concerning the scheme itself are unquestionably adequate to survive a motion to dismiss. The complaint provides detailed allegations of a company-wide scheme to promote replacements for batteries or devices that were not medically justified, and that subjected patients to unnecessary surgeries. Among other things, the complaint alleges that physicians had to rely on the superior knowledge of the Cyberonics sales personnel as to battery life, which effectively permitted the sales people to decide when the replacement procedures were necessary.

As noted, allegations of fraudulent practices are not enough; the complaint must also allege a scheme to cause the submission of false claims to the government. The complaint here does not allege the submission of any specific false claims, and accordingly relator must establish the necessary degree of particularity through allegations of "factual or statistical evidence that strengthen[] the inference of fraud on the government beyond a mere possibility." *Duxbury I*, 579 F.3d at 29. Two recent First Circuit cases, *Ge* and *Duxbury I*, offer some guidance on when such allegations are sufficient to satisfy the requirements of Rule 9(b).

In *Ge*, the relator's complaint alleged that the defendant pharmaceutical company had failed to file accurate and timely adverse event reports with the FDA, and that if it had done so, numerous claims for those pharmaceuticals would not have been submitted to the federal government. 737 F.3d at 119-21. The FCA claim was dismissed because she "made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of [defendant's] alleged misconduct." *Id.* at 124 (emphasis in original). "What is missing are any supporting allegations upon which her conclusion rests and any particulars." *Id.*

In contrast, the court in *Duxbury I* found that the complaint sufficiently alleged factual evidence to sustain an inference of fraud. 579 F.3d at 30. The relator alleged that kickbacks provided by the defendant resulted in the submission of false claims by eight named health-care providers in the state of Washington. *Id.* As to those eight providers, the complaint provided allegations of dollar amounts and (in at least one instance) the number of claims. *Id.* The court found that those eight specific sets of allegations were sufficient factual support to satisfy the requirements of Rule 9(b): "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." *Id.* It described the question, however, as "a close call." *Id.*; *see Ge*, 737 F.3d at 124 (referring to allegations in *Duxbury I* as "barely adequate").

Here, the complaint does not identify a single specific false claim made to the government. It does not allege that any specific medical procedure, or any specific purchase of a battery or medical device, was actually unnecessary. It does not allege specific dates of claims or specific dollar amounts.

Only one patient is named in the complaint: "F.P.," who (according to the complaint) was 66 years old when his device was replaced, and was thus "Medicare *eligible* based on age alone." (Am. Compl. ¶ 114) (emphasis added). The complaint does not allege, however, that F.P. was an actual Medicare recipient. And there is no allegation that any false claim was submitted on his behalf, or even that his procedure was unnecessary.[11]

Only one physician who may have been victimized is named: Dr. James Thompson, of Norwalk, Connecticut (*Id.* ¶¶ 75, 100).[12] Dr. Thompson allegedly told the relator that the predecessor sales representative, Gary Muenzen, had told him that all device batteries must be replaced within five years, and that Dr. Thompson consistently followed that practice. (*Id.* ¶ 75). There are no allegations, however, concerning any specific patients of Dr. Thompson's, or any specific claims for reimbursement. Nor is there any allegation that any of his patients in

[11] The complaint also alleges that a salesperson for the Boston territory provided a physician with a fabricated technical estimate in order to meet a sales quota, which led the physician to prescribe a replacement for a particular patient. (Am. Compl. ¶ 92). There is no information as to the name of the physician, the patient, the date, the location, or whether the patient in question was covered by a government health-care program.

[12] The complaint also identifies another physician, Dr. Ahmed Khan of New Britain, Connecticut. (*Id.* ¶ 102). Dr. Khan, however, apparently found Muenzen to be unprofessional and unethical, and had declined to accept his advice. (*Id.* ¶ 102)

question were covered by a government health-care program.[13]

The complaint also alleges that "Cyberonics sales representatives focused their sales efforts on long term care residential facilities and group homes for the mentally disabled, whose residents were *predominantly covered* by Medicare." (Am. Compl. ¶ 118) (emphasis added). It identifies four such facilities: Wrentham Development Center, Monson Development Center, Southbury Training School, and Eleanor Slater Hospital. (*Id.* ¶ 119). The only additional details provided concern Southbury, where all of the patients' devices or batteries were allegedly changed in a three-month period in March-May 2010.[14] The apparent implication is that *some* of those procedures must have been medically unnecessary, and that *some* of the patients must have been Medicare recipients.[15] However, there is no allegation that any specific sale of any device or battery at any of those facilities was unnecessary.[16]

Thus, the complaint only identifies a single patient, a single physician, and a small handful of facilities where fraudulent activity may have occurred, and which therefore may have led to the filing of false claims. That paucity of detail is not, however, necessarily fatal to the complaint. As noted, under *Duxbury I*, where a defendant has induced third parties to file false

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[13] The complaint also alleges that a TC for the Missouri and Kansas territory falsely advised physicians that certain leads needed to be replaced, which led to unnecessary sales and surgical installations of leads when devices were replaced. (Am. Complt. ¶ 94). There is no information as to the names of the physicians, the patients, the dates, the locations, or whether the patients in question was covered by a government health-care program.

[14] The one identified patient, F.P., was apparently a resident at Southbury.

[15] The complaint also alleges that "Rhode Island Hospital had at least four VNS patients, two of whom were on their *fourth* device as of June 2010 (a surprising number of replacements given that VNS was not even introduced until 1997)." (*Id.* ¶ 119) (emphasis in original).

[16] It is by no means obvious which device or battery replacements were actually unnecessary. The complaint acknowledges that battery life "is not uniform and depends on the circumstances of each patient." (*Id.* ¶ 81). It also acknowledges that physicians sometimes elected early replacement of a device because their patient's seizures had worsened. (*Id.* ¶¶ 87-88).

claims, rather than filing them itself, a relator can satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility," without "necessarily providing details as to each false claim." *Duxbury*, 579 F.3d at 29; *see Rost*, 507 F.3d at 753. In an effort to satisfy that requirement, the complaint includes a number of additional factual assertions.

First, it alleges that Cyberonics's sales force "specifically targeted patients with disabling mental conditions that would *typically qualify* them for Medicare coverage." (Am. Compl. ¶ 118) (emphasis added).[17] It appears that the import of that statement is that defendant targeted a subset of refractory epilepsy patients who suffered from other mental and developmental disabilities. (*See id.* ¶¶ 3, 18, 118).

Second, and as noted, the complaint alleges that "Cyberonics sales representatives focused their sales efforts on long term care residential facilities and group homes for the mentally disabled, whose residents were *predominantly covered* by Medicare." (Am. Compl. ¶ 118) (emphasis added).

Third, the complaint alleges that the company changed its commission structure only for epilepsy patients (who were Medicare-eligible), but not for those with treatment-resistant depression (who were not). (Am. Compl. ¶¶ 4, 55-56). However, the complaint acknowledges that there were "hardly any" implants for patients with depression—because CMS and Medicare had not approved the product for that use—and presumably few, if any, could possibly qualify for battery replacements.

[17] The complaint also alleges that Cyberonics distributed marketing materials that included CPT (current procedural terminology codes) and employed "reimbursement specialists" to assist health-care providers. (Am. Compl. ¶¶ 116-17). Those services, however, would not be uniquely necessary for government health-care programs.

The complaint also contains a number of broad statistical allegations. It alleges that Medicare, Medicaid, and other government health-care programs cover a majority of patients with epilepsy. (Am. Compl. ¶ 5). It alleges that Cyberonics derived 20-25% of its revenues from Medicare, another 25% from Medicaid, plus additional revenues from other government health-care programs. (*Id.* ¶ 20). It alleges that "in Relator's experience, both with Cyberonics and with his own personal situation, a majority of the patients receiving replacement devices are covered by Government Health Programs." (*Id.* ¶ 120).[18] It alleges that (in the estimation of the relator) since 2007, "there have been over 10,000 medically unnecessary and unreasonable VNS device replacements," with average reimbursements of $20,000. (*Id.* ¶ 123). Finally, it alleges that patients covered by government health-care programs "account for at least 50-60% of these unnecessary replacements, resulting in damages of at least $100 million" to government health-care programs since 2007. (*Id.*).

Those statistical allegations are not particularly focused or precise. It is likely true that government health-care programs cover a majority of patients with epilepsy. But that is surely true of virtually all patients, with all conditions. It is also likely true that Cyberonics derives about half of its revenues from government health-care programs. But again, surely all suppliers of medical devices (and indeed all other health-care products that cannot be purchased off the shelf) derive a large portion of their revenue from government programs. Furthermore, the

[18] The complaint also alleges that the company provided relator with a list of approximately 170 patients who had been identified as possible candidates for "early device replacement." (Am. Compl. ¶ 120). It goes on to allege that "[w]hile 'Primary Payor' information was blank for many patients, there are many others for whom the report lists Medicare or Medicaid . . . . Many other patient and EOS lists circulated to Relator similarly indicated that significant numbers of patients were covered by Medicare and Medicaid." (*Id.*). It does not indicate how many of the patients on those lists were covered by government health-care programs, other than the phrase "significant numbers." Furthermore, no evidence is provided for how many of the patients on those lists actually had unnecessary VNS device replacements, or how many of those procedures led to false claims.

specific basis for relator's estimate of 10,000 unnecessary procedures is not set forth anywhere in the complaint.

The complaint is thus considerably more detailed than the complaint in *Ge*, which was found inadequate under Rule 9(b). But it also contains fewer specifics as to actual false claims than the complaint in *Duxbury I*, which the First Circuit said was a "barely adequate" and where dismissal was considered a "close call." *Duxbury I*, 579 F.3d at 30; *Ge*, 737 F.3d at 124.

The allegations in this case are in some ways similar to those in *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34 (D. Mass. 2014). In *Booker*, the defendant was alleged to have illegally promoted two drugs, Geodon and Pristiq, for various off-label uses, Geodon was allegedly promoted for, among other things, the off-label uses of treating bipolar disorder and enhancing cognition. 9 F. Supp. 3d at 55-57. Geodon's efficacy in treating bipolar disorder was promoted to doctors "who had patient populations that were 50% children and as much as 80% covered by Medicare/Medicaid," a child psychiatrist "with substantial Medicare/Medicaid practice who was known to prescribe [the drug] as a large part of her practice," and "other child psychiatrists in Missouri . . . with large Medicaid patient populations." *Id.* (internal quotation marks omitted). In contrast, the drug's efficacy in enhancing cognition was promoted to doctors whose Medicare or Medicaid patients constituted a "large" number of their patients, quantified in some instances as 25 to 40 percent. *Id.* The court reasoned that the allegations of off-label promotion of the drug for treating bipolar disorder were sufficient to satisfy the requirements of Rule 9(b), but the allegations of off-label promotion of the drug for enhancing cognition were not. *Id.* at 57-58. It also concluded that the allegations as to Pristiq could not survive scrutiny under Rule 9(b). *Id.*

Here, defendant is alleged to have received approximately 50 percent of its revenues

from government health-care programs. However, no allegations in the complaint link those revenues with any specificity to the unnecessary replacement of devices or batteries. Defendant is also alleged to have targeted certain patients who *qualified* or were *eligible* for Medicare or Medicaid. However, there is no allegation that those patients were actually *covered* by Medicare or Medicaid, much less any allegation that they used Medicare or Medicaid to pay for unnecessary devices. In contrast, the court in *Booker* found that targeting patients, 80 percent of whom were *covered* by Medicare or Medicaid, provided enough statistical evidence to raise the inference of fraud beyond possibility. *Id.* at 55-58.

Under the circumstances, the Court is forced to conclude that the complaint is not adequate to satisfy the standards of Rule 9(b). If the *Duxbury I* allegations—which identified specific medical providers, specific illegal kickbacks, "rough" time periods and locations, and actual filings of false claims—were "barely adequate," it is difficult to see how the allegations of the complaint in this action can pass muster. *See Duxbury I*, 579 F.3d at 30 (describing eight specific allegations of false claims submitted to government healthcare programs); *Ge*, 737 F.3d at 124.[19]

The conclusion that the complaint is insufficient under Rule 9(b) gives the Court some pause. It is certainly true that the complaint alleges a widespread scheme that, among other things, subjected vulnerable patients to unnecessary surgical operations. And it certainly seems likely—as a matter of logic—that if the scheme was as widespread as relator alleges, some false claims must have been submitted somewhere, by someone, to the federal government. The

[19] Defendant also contends that in the medical device context, particular allegations that the use of a medical device was medically unnecessary must be made to satisfy the requirements of Rule 9(b). *See United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 317, 354 (D. Mass. 2011). Because the Court finds that the statistical evidence is not sufficient, the Court does not need to decide whether Rule 9(b) requires allegations beyond statistical evidence of specific facts showing the unnecessary replacement of medical devices.

question, however, is not whether the scheme should be redressed; indeed, the government had an opportunity to intervene if it chose, and presumably has other weapons in its arsenal for dealing with the issue. Instead, it is whether the complaint here meets the relatively exacting standard for FCA claims required by *Ge* and *Duxbury I*.

In summary, the amended complaint fails to state allegations of fraud under the FCA with the particularity required by Rule 9(b). Accordingly, the motion to dismiss the FCA claims will be granted.

D. Conspiracy Claim

Because the complaint does not state allegations of fraud under the FCA with the particularity required by Rule 9(b), the conspiracy claim under the FCA must fall as well. In any event, there is an independent reason why the conspiracy claim should be dismissed.

Defendant contends that the conspiracy claim should be dismissed because a corporation cannot conspire with its officers and employees to violate the FCA. Pursuant to 31 U.S.C. § 3729, "any person who—(A) knowingly presents, or causes to be presented, a 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; [or] (C) conspires to commit a violation of subparagraph (A) [or] (B) . . . is liable" for a violation of the FCA. Count 1 alleges that defendant has violated the FCA by causing false claims to be submitted. Count 2 alleges a violation of the FCA based on a conspiracy between defendant and its employees to defraud government health care programs.

Of course, a corporation can only violate the FCA through the actions of its agents and employees. If defendant is violating the FCA, there is no meaningful distinction between relator's claims in Count 1 for "false or fraudulent claims, statements, and records" and Count 2

for "conspiracy to defraud the government health care programs."

It therefore does not make sense to permit a conspiracy claim under the FCA to proceed on the theory that defendant has conspired with its officers and employees. This concept has been endorsed by the Supreme Court in antitrust law. *See Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 769 (1984) (explaining that "officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them . . . do not provide the plurality of actors imperative for a" conspiracy under section 1 of the Sherman Act). Multiple federal judges have found that companies cannot conspire with their employees or agents in the FCA context. *See, e.g., U.S. ex rel. Ruhe v. Masimo Corp.*, 929 F. Supp. 2d 1033, 1037-38 (C.D. Cal. 2012) (holding that conspiracy claim failed to state a claim because a corporation cannot conspire with its own employees or agents); *U.S. ex rel. Head v. Kane & Co.*, 798 F. Supp. 2d 186, 201 (D.D.C. 2011) (finding that a company could not have conspired with its employees to violate the FCA); *U.S. ex rel. Loughren v. Unumprovident Corp.*, 2008 WL 4280133, *3 (D. Mass. Sept. 15, 2008) (dismissing FCA conspiracy claims during periods when defendants were corporate affiliates because parent and subsidiary corporation cannot conspire as a matter of law); *U.S. ex rel. Brooks v. Lockheed Martin Corp.*, 423 F. Supp. 2d 522, 528 (D. Md. 2006) (finding that parent company and its two wholly owned subsidiaries could not conspire among themselves to violate the FCA); *U.S. ex rel. Reagan v. East Texas Medical Center Regional Healthcare System*, 274 F. Supp. 2d 824, 856 (S.D. Tex. 2003) (finding that a parent corporation cannot conspire with various components and subsidiaries to commit a

conspiracy in violation of the FCA).[20]

In short, although corporate employees could conspire with outside individuals, such as physicians, the conspiracy cannot be between the corporation and its officers and employees. Accordingly, defendant's motion to dismiss the conspiracy claim will be granted.

III. State FCA Claims

Counts 3 through 30 of the amended complaint allege violations of various state analogues to the federal FCA.[21] Defendant contends that those claims should be dismissed for the same reasons the federal FCA claims should be dismissed. "Given the substantive similarity of the state FCAs . . . and the federal FCA with respect to the provisions at issue in this litigation, the state statutes may be construed consistently with the federal act." *New York v. Amgen Inc.*, 652 F.3d 103, 109 (1st Cir. 2011).

Out of the 28 state-law false-claims counts, 25 do not even come close to satisfying the pleading requirements of Rules 9(b) and 12(b)(6). Those counts contain nearly identical language that incorporate "by reference the allegations of the foregoing paragraphs" and allege violations of the state analogues to the federal FCA for false claims submitted to state Medicaid programs "that otherwise would not have been allowed." For 18 of the 25 state law claims, there

[20] For more examples of federal courts finding that a corporation cannot conspire with its employees or wholly owned subsidiaries to commit a conspiracy in violation of the FCA, *see United States ex rel. McCarthy v. Marathon Techs., Inc.*, 2014 WL 4924445, *3 (N.D. Ill. Sept. 30, 2014) (explaining that a corporation cannot conspire with its wholly-owned subsidiaries or employees to commit a conspiracy in violation of the FCA); *United States ex rel. Chilcot v. KBR, Inc.*, 2013 WL 5781660, *11-12 (C.D. Ill. Oct. 25, 2013) (holding that FCA conspiracy claims are barred where all the alleged conspirators were either employees or wholly-owned subsidiaries of the same corporation); *U.S. ex rel. Peretz v. Humana, Inc.*, 2011 WL 11053884, *10-11 (D. Ariz. Apr. 8, 2011) (dismissing FCA conspiracy claims because "it is a legal impossibility" for a parent corporation to conspire with its wholly owned subsidiary); *U.S. ex rel. Lacy v. New Horizons, Inc.*, 2008 WL 4415648, *6 (W.D. Okla. Sept. 25, 2008) ("FCA conspiracy claims based upon the actions of a corporation and its agents are barred by the intracorporate conspiracy doctrine.").

[21] For these purposes, the District of Columbia will be considered a "state."

are no allegations in the complaint of fraudulent conduct or false claims beyond the conclusory allegations found in the specific counts and paragraph 36 of the complaint.[22] And there is barely any mention of fraudulent activity for the other seven states.[13]

For example, there are allegations in the complaint concerning Sean O'Hara, a TC in California and Nevada, who allegedly was pressured by his Regional Manager to promote early replacements. (Am. Compl. ¶ 84). However, "O'Hara was not willing to promote early replacements to make his sales quota, and ultimately resigned." (*Id.*).

The only substantive mentions of activity in New York and New Jersey outside of paragraph 36 are in paragraphs 42 and 76, where the complaint alleges that Gary Muenzen was a TC in a territory that included those two states. (*Id.* ¶ 76). Although the complaint includes allegations that Muenzen engaged in fraudulent activity in other territories, there is no mention of any fraudulent activity relating to those two states, other than conclusory allegations.

The complaint alleges that Stephen Carroll, a TC for Oklahoma, "told doctors that a device needed to be replaced when its 'ON life' exceeded 8 to 10 thousand hours although he had no scientific or medical basis to do so." (*Id.* ¶ 78). It otherwise makes only conclusory allegations as to activities in Oklahoma.

The complaint also alleges that Lindsay Clark, a TC for the Washington, D.C. territory and the Carolina region, would contact physicians to promote device replacements for patients that had devices implanted for four or more years. (*Id.* ¶ 83). The allegations concerning the

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[22] The states are Colorado (Count 4), Delaware (Count 6), Florida (Count 7), Georgia (Count 8), Hawaii (Count 9), Illinois (Count 10), Indiana (Count 11), Iowa (Count 12), Louisiana (Count 13), Michigan (Count 15), Minnesota (Count 16), Montana (Count 17), New Mexico (Count 20), Tennessee (Count 25), Texas (Count 26), Virginia (Count 27), Washington (Count 28), and Wisconsin (Count 29).

[13] The states are California (Count 3), Nevada (Count 18), New Jersey (Count 19), New York (Count 21), North Carolina (Count 22), and Oklahoma (Count 23), and the District of Columbia. (Count 30).

District of Columbia and North Carolina barely identify anything arising to the level of fraud (and definitely do not do so with particularity).

Certainly nothing in the complaint connects these allegations to medically unnecessary device replacements or Medicaid claims arising in those states. Although not required to identify specific false claims, relator must at the very least provide (1) the particular details of a scheme to cause the submission of false claims to the government and (2) factual or statistical evidence that strengthens the inference of fraud on the government beyond a mere possibility. *Duxbury I*, 579 F.3d at 29. For the foregoing states, the complaint is obviously insufficient.

The remaining three state law claims are for Connecticut (Count 5), Massachusetts (Count 14), and Rhode Island (Count 24). Although not suffering from the obvious deficiencies to the same degree as the other state-law claims, in light of the failure of the federal FCA claims to meet the Rule 9(b) particularity requirement, these claims must also fail. *See New York*, 652 F.3d at 109 (1st Cir. 2011).

Accordingly, the motion to dismiss will be granted as to the state FCA claims for failure to comply with the requirements of Rule 9(b).[14]

IV. Relator's Individual Claims

Finally, defendant contends that the individual claims in the amended complaint should be dismissed for failure to state a claim under Rule 12(b)(6). As noted, a complaint must state a claim that is plausible on its face to survive a motion to dismiss. *Twombly*, 550 U.S. at 570. The amended complaint alleges retaliation against relator in violation of the FCA (Count 31); breach of contract and breach of the implied covenant of good faith and fair dealing (Count 32); and

[14] The Court does not decide whether the public-disclosure bar would preclude relator's state FCA claims.

wrongful termination in violation of the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5J, and public policy (Count 33).

A. Claim for Retaliation under the RCA

To prevent employers from discouraging relators from coming forward with claims under the FCA, the statute includes an anti-retaliation provision. *Harrington v. Aggregate Indus. Ne. Region, Inc.*, 668 F.3d 25, 30 (1st Cir. 2012). That provision states as follows:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1). To state a claim for retaliation under the FCA, plaintiff must allege that "he engaged in conduct protected under the FCA; the employer knew that he was engaged in such conduct; and the employer discharged or discriminated against him because of his protected conduct." *Maturi v. McLaughlin Research Corp.*, 413 F.3d 166, 172 (1st Cir. 2005) (footnote omitted).[15] Only "acts done . . . in furtherance of" an FCA action are protected. 31 U.S.C. § 3730(h)(1); *see also Maturi*, 413 F.3d at 172.

1. Conduct in Furtherance of an FCA Action

Defendant first contends that the complaint does not allege that relator engaged in conduct in furtherance of an FCA action. Conduct in furtherance of an action under the FCA is defined as "conduct that reasonably could lead to a viable FCA action." *Karvelas*, 360 F.3d at 236. However, FCA-protected conduct "is limited to activities that 'reasonably could lead' to an

[15] The requirements of Rule 9(b) do not apply to FCA retaliation claims. *Karvelas*, 360 F.3d at 238 n.23.

FCA action; in other words, investigations, inquiries, testimonies or other activities that concern the employer's knowing submission of false or fraudulent claims for payment to the government." *Id.* at 237.

Relator contends that his investigation into the fraudulent sales practices of Muenzen reasonably could have led to an FCA action. (Am. Compl. ¶¶ 7, 43, 100). He points out that a relator "need not have *known* that his actions could lead to a qui tam suit under the FCA, or even that a False Claims Act existed, in order to demonstrate that he engaged in protected conduct." *Karvelas*, 360 F.3d at 237 (emphasis in original).

It is true that there are no allegations in the amended complaint that relator specifically investigated false or fraudulent claims for payment to the government. However, the amended complaint does not allege that defendant itself submitted such claims. Instead, it alleges that defendant caused the submission of false or fraudulent claims to the government. Thus, any investigations, inquiries or other activities concerning defendant's role in causing false or fraudulent claims to be submitted to the government are also protected by the FCA. *See Booker*, 2014 WL 1271766, at *20 (finding relator engaged in protected conduct when investigating fraudulent conduct directed at physicians to encourage off-label use of a drug).

The amended complaint alleges that relator investigated fraudulent practices by several of defendant's employees directed at physicians to encourage medically unnecessary device-replacement surgeries. It also alleges that many of the patients who underwent such surgeries were covered by a government health-care program. Thus, relator's investigations into those practices "reasonably could lead" to an FCA action. *See id.*

2. Employer's Knowledge

Next, defendant contends that the complaint does not allege that defendant knew that

relator was engaged in conduct in furtherance of an FCA action. It admits that relator spoke to Yannuzzi about Muenzen's fraudulent practices, but contends that relator did not directly discuss fraud on the government with Yannuzzi.

"To meet the knowledge element of an FCA retaliation claim . . . the employer must be on notice that the employee is engaged in conduct that reasonably could lead to a False Claims Act case." *Karvelas*, 360 F.3d at 238 (internal quotation marks omitted). "[J]ust as the plaintiff is not required to know that his investigation reasonably could lead specifically to a False Claims Act action, the employer need not know that the employee has filed or plans to file a qui tam action, nor even necessarily be aware of the existence of the FCA." *Id.* Instead, "the kind of knowledge the defendant must have mirrors the kind of activity in which the plaintiff must be engaged." *Id.* (internal quotation marks omitted).

The amended complaint alleges that relator spoke with Yannuzzi about his investigation into and concerns regarding Muenzen's fraudulent practices. His investigation was conduct protected by the FCA. Defendant therefore, through Yannuzzi, had knowledge of relator's protected conduct. *See id.* at 238-39 (finding that relator provided notice of protected conduct under the FCA by notifying his employers of his investigation).

3. <u>Discharge Because of Protected Conduct</u>

Finally, defendant contends that the complaint does not allege that relator was discharged because he engaged in conduct protected by the FCA. It contends that relator admits that he was terminated for failing to reach his sales goals. (*See* Am. Compl. ¶ 107).

While the amended complaint does state that defendant said it fired relator because he failed to reach his sales goals, the reason an employer proffers for an employee's discharge is not controlling in retaliation cases, especially at the motion to dismiss stage. *See Booker*, 2014 WL

1271766, at *21 (explaining that proximity between protected activity and termination supports a plausible claim for retaliation). Relator alleges that he spoke to Yannuzzi about his investigation on November 2, 2011; on December 1, he was put on a performance improvement plan; and on January 9, 2012, his employment was terminated. He further alleges that he had met 90 percent of his quota before he was fired. The "proximity between his protected activity and abrupt termination . . . are sufficient at this stage to allege that he was discharged because of his protected conduct." *Id.* at *21.

Accordingly, the motion to dismiss will be denied as to the FCA retaliation claim.

B. Claims Based on Contract

Relator acknowledges that he cannot bring a breach-of-contract claim against defendant because he was an at-will employee of the company. *See Cochran v. Quest Software, Inc.*, 328 F.3d 1, 7 (1st Cir. 2003) (under Massachusetts law, employer has "an unfettered right to discharge" an at-will employee).

In Massachusetts, an employer can violate the implied covenant of good faith and fair dealing by terminating an at-will employee if the termination "deprived [the employee] of compensation clearly connected to work already performed (and thus, unjustly enriched the employer)." *Id.* at 8 (citing *Harrison v. NetCentric Corp.*, 433 Mass. 465, 473 (2001)). The covenant can also be violated if the at-will employee's termination was contrary to a well-defined public policy. *Woodward v. Emulex Corp.*, 854 F. Supp. 2d 149, 161 (D. Mass. 2012) (citing *Wright v. Shriners Hosp. for Crippled Children*, 412 Mass. 469, 472 (1992)).

Relator concedes that the first exception does not apply. He also admits that the second exception does not apply if his conduct was protected by the FCA's anti-retaliation provision. Accordingly, the motion to dismiss will be granted as to the claim for breach of contract and

breach of the implied covenant of good faith and fair dealing.

C. Claim for Retaliation under the Massachusetts False Claims Act

The Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 §§ 5A-5O, contains an anti-retaliation provision that is almost identical to the federal FCA. Because state acts such as the MFCA are construed consistently with the federal FCA, the motion to dismiss will be denied as to the MFCA claim. *See Amgen Inc.*, 652 F.3d at 109.

V. Conclusion

For the foregoing reasons, defendant's motion to dismiss is GRANTED as to the federal FCA claims (Counts 1 and 2), the state FCA claims (Counts 3 through 30), and the claim for breach of contract and breach of the implied covenant of good faith and fair dealing (Count 32), and DENIED in all other respects.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
Dated: March 31, 2015 United States District Judge