[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

Nos. 13-10973; 13-11949

D.C. Docket No. 1:09-cv-22302-KMW

UNITED STATES OF AMERICA,
Ex rel., et al.,

Plaintiff,

MICHAEL KEELER,
Relator,

Plaintiff-Appellant,

versus

EISAI, INC.,

Defendant-Appellee,

100 TICE BLVD, et al.,

Defendants.

Appeals from the United States District Court
for the Southern District of Florida

(June 11, 2014)

Before MARTIN, FAY, and SENTELLE,[*] Circuit Judges.

PER CURIAM:

We affirm the dismissal of this case for the reasons set forth in the district court's scholarly and thorough January 31, 2013, Order and its April 1, 2013, clarification Order.

AFFIRMED.

[*]Honorable David Bryan Sentelle, United States Circuit Judge for the District of Columbia, sitting by designation.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 09-22302-CV-WILLIAMS

UNITED STATES OF AMERICA, *et al.,*
ex rel. Michael Keeler,

Plaintiffs,

vs.

EISAI, INC.,

Defendant.

ORDER

THIS MATTER is before the Court on Defendant Eisai Inc.'s ("Eisai") Motion to Dismiss (DE 95). Eisai is a Japanese manufacturer of pharmaceutical drugs. Michael Keeler ("Relator") was one of twenty-four sales representatives for Eisai's United States subsidiary, a position he held during a three-year period from sometime in 2006 through April 2009. He initiated this *qui tam* action on August 4, 2009 under the False Claims Act ("FCA"), which allows individuals to bring private actions in the name of the Government against individuals who defraud the Government. 31 U.S.C. § 3730(b).[1]

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[1] More specifically, the Act imposes liability on anyone who knowingly presents "or causes to be presented" a false claim for payment to be approved by the government. 31 U.S.C. § 3729(a)(1) (2006). It also prohibits knowingly making, using, or causing to be used "a false record or statement to get a false or fraudulent claim paid or approved by the government." *Id.* § 31 U.S.C. 3729(a)(2). The Fraud Enforcement of Recovery Act ("FERA"), Pub. L. No. 111-21, § 4, 123 Stat. 1617 renumbered portions of the FCA and revised Section (a)(2) – now Section (a)(1)(8) – so that it imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Although this case was commenced after the FERA's June 7, 2008 effective date, the false claims

After reviewing the pleadings and the parties' arguments, the Court concludes that although the Complaint – at 189 pages – recites numerous factual allegations and legal conclusions,[2] it fails to plead key elements of fraud in accordance with Federal Rule of Civil Procedure 9(b). Because Relator has had ample opportunities to correct the deficiencies, the Court will now dismiss his claims with prejudice.

I. BACKGROUND

Principally, Relator claims that Eisai promoted its drugs for non-approved uses and paid medical providers to use its drugs in non-approved ways, which he personally observed or became aware of while working at the company. According to Relator, service providers allegedly submitted claims for reimbursement through government-administered health care programs that were not reimbursable and with respect to which they falsely certified that they had not received a kickback in connection with the claim. Further, Relator contends that Eisai falsified drug payment information and submitted it to the Government, thereby failing to give the Government preferred rates as it was contractually obligated to do. The Complaint describes this conduct as beginning in 2006 and continuing to this date.

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alleged bridge that timeframe and implicate both versions of the law. *See United States ex rel. Hopper v. Solvay Pharmaceuticals, Inc.,* 588 F.3d 1318, 1327 n.3 (11th Cir. 2009). Nevertheless, the distinction between the old and new statutory language is immaterial for purposes of the motion and for ease of convenience, the Court refers to the superseded numbering. *See United States ex Rel. Nowak v. Medtronic, Inc.,* 806 F. Supp. 2d 310, 342 nn.19-20 (D. Mass. 2011).

[2] In arguing against dismissal, Relator notes "the Complaint now contains 86 more pages" than the previous complaint. As is made clear from this order, volume does not necessarily equate to specificity.

A. Off-Label Promotion

Relator contends that the Defendant marketed and promoted two cancer-treating drugs, Ontak and Dacogen, for off-label uses, i.e., uses that go beyond what has been approved after an exacting review process by the Food and Drug Administration. Ontak was approved to treat cutaneous T-Cell lymphoma "for patients whose malignant cells express the CD-25 component of the IL-2 receptor." (Compl. ¶ 92.) Despite this, Eisai allegedly promoted the drug for treatment of follicular non-Hodgkin's lymphoma, chronic lymphatic lymphoma, relapsed/refractory B-cell non-Hodgkin's lymphoma, adult T-cell leukemia lymphoma, peripheral T-cell lymphoma, graft versus host disease and melanoma. *(Id.* ¶ 83).[3] Dacogen is indicated solely for the treatment of myleodysplastic syndromes, a condition in which bone marrow does not produce enough healthy blood cells, but Eisai allegedly promoted it for treatment of acute myelogenous leukemia, which is a cancer affecting blood cells. *(Id.* ¶¶ 165-66.)

As a sales representative for Eisai, who also attended company meetings and interacted with other employees, Relator claims to have direct and personal knowledge of the message Eisai sought to communicate to physicians. (Compl. ¶ 12-14, 54.) While Eisai's official policy was that off-label studies should not be distributed during sales, he was "supplied with numerous articles of dubious scientific nature, touting various off-label uses of Ontak which were to be distributed to physicians and referred to during visits to physicians." *(Id.* ¶¶ 87, 96, 125.) Apart from educating physicians about the suitability of its drugs for other indications, Eisai "marketed the spread": that

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[3] Additionally, Relator suggests that Eisai might have promoted Ontak for cutaneous T-Cell lymphoma, a treatment outside the approved parameters. (Compl. ¶¶ 92-93.)

is, Eisai alerted certain providers of the profit to be earned based on the difference between the discounted price of Ontak they received and the reimbursements they would recoup. *(Id.* ¶ 129.) The "spread" was approximately $700 per dose administered and motivated doctors to prescribe the drug as much as possible. *(Id.* ¶ 133.)[4] He alleges that sales representatives were trained to use similar tactics to market Dacogen. *(Id.* ¶ 172.)

Eisai incentivized its representatives to act by providing "lucrative commissions to its marketing force" and counting off-label sales toward representatives' sales quotas. (Compl. ¶ 36.) The pressure was such that Relator complained to his supervisor, David Trexler, about having "to achieve the company's required sales quotas which were inflated because they included a high percentage of off-label sales." *(Id.* ¶ 109.) In October 2008, Eisai's oncology sales representatives compiled sales information showing that between 50 and 70 percent of Ontak's total sales were derived from off-label sales. *(Id.* ¶ 111.)

In the Complaint, Relator refers to just a few instances in which Eisai engaged in this promotional conduct. For example, in November 2006, Relator was a trainee in an Ontak sales class in which he received off-label studies to use in making presentations to physicians and other similar materials. (Compl. ¶¶ 81-82, 88-90.) At an unspecified time and with no details of its contents, an Eisai District Manager distributed a paper advocating off-label use of Ontak to sales representatives. *(Id.* ¶ 90.) In June 2007,

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[4] Because of this, at least one medical institution, the University of Louisville Cancer Center, was ultimately persuaded to purchase Ontak for off-label treatment. (Compl. ¶ 131 ("The University of Louisville Cancer Center was an institution persuaded to purchase Ontak for the off-label treatment of melanoma due to the "spread.'").)

Eisai's director of research wrote an e-mail to Eisai's sales managers suggesting that an unapproved off-label marketing update (which is not further described) should be shown to providers but not left with them. (*Id.* ¶ 99.)[5] At an unspecified time and without elaboration, Eisai's Vice President of Sales, Leslie Mirani, instructed unknown sales representatives to promote Dacogen for off-label use, to promote longer administration at more frequent intervals, and to use larger dosages. *(Id.* ¶ 174.) Finally, without describing who was involved, where it occurred, or when it was said, Relator claims he "was directed to tell physicians . . . that there were studies showing that CD-25 positive/negative made no difference in the treatment of patients, which was known to be untrue." *(Id.* ¶ 93.)

Beyond employing its sales force to deliver such sales messages, Relator alleges that Eisai engaged physicians to promote off-label uses. "Dr. Peter Heald was compensated by Eisai to speak and write articles on off-label uses of Ontak." (Compl. ¶¶ 90, 154.) Additionally, Lauren Pinter-Brown, M.D. was paid $20,000 as another Ontak consultant and spoke to a group of South Florida physicians in 2008 about off-label uses of Ontak and "presenting claims to Medicare and Medicaid." *(Id.* ¶¶ 154, 164, 249.) And in October 2008, Dr. Francine Foss spoke at a dinner in South Florida "on the use of Ontak for treating peripheral T cell lymphoma." *(Id.* ¶ 153.)[6]

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[5] Eisai's director of research "routinely provided Eisai sales representatives updates and information on studies, events, and use of Ontak for various off-label uses for the sales representatives to use in their marketing and promotion of Ontak." (Compl. ¶ 98.)

[6] Through "Advisory Board" meetings starting in 2008, Eisai hired doctors to speak about off-label uses for Ontak and Dacogen and hosted conferences at high-end resorts. (Compl. ¶¶ 152-54.) Attendees were "frequently paid thousands of dollars for their attendance." (Compl. ¶ 158.) Two speakers – Drs. Dang and

According to the allegations, doctors were also paid to conduct off-label studies. Relator provides a single example of this: a doctor named Nam Dang, M.D. was paid $50,000 in consulting fees, and authored "clinical studies related to the off-label use of Ontak for unapproved conditions, including B-cell lymphoma and [peripheral T-cell lymphoma]." (Compl. ¶ 248.) Dr. Dang was also identified as an Eisai contact to physicians, who were told to "call [him] directly with questions about the suitability of Ontak for off-label uses." *(Id.* ¶¶ 148, 154, 248.)[7]

Additionally, Eisai funded hospitals for their role in facilitating Eisai's promotion of off-label uses of its products to doctors. In March 2007, the University of Miami Sylvester Cancer Center was given an "educational grant" to allow a doctor to make a presentation on Ontak's approved uses, but which ultimately addressed the off-label use of Ontak. (Compl. ¶¶ 148-49.) Likewise, in July 2007, the University of Arizona and a doctor received a "preceptorship" grant, which was followed by that doctor presenting on Ontak's use for treatment of 8-cell lymphoma. *(Id.* ¶ 150.) Relator believes that similar educational grants were given to two other facilities – the Dana Farber Cancer Center and the Lurie Cancer Center at Northwestern University. *(Id.* ¶ 151.)

Finally, although it is not tied to any payment, prescription, or claim submission, Relator makes much of Eisai's Oncology Reimbursement Assistance ("OAR") Program,

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Foss – received $50,000 and $25,000, respectively, on an annual basis in speaking and consulting fees. (Compl. 164.)

[7] The complaint also briefly mentions that Dr. Foss was paid "to conduct supposed clinical trials which were not submitted to the FDA . . . primarily to encourage and reward Dr. Foss and [her institution] for prescribing Ontak off-label and making false and fraudulent claims to Medicare and Medicaid." (Compl. ¶ 256(a).) It is unclear whether the results of this study were included in marketing materials sent to physicians. (*See* Compl. ¶ 88 (referring to a "Foss paper").)

which guaranteed that prescribers would be paid at Medicare rates. As purportedly reflected in an e-mail that Relator sent to an Eisai employee in March 2007, Eisai promised to cover the price of Ontak if it was not covered in whole or in part by Medicare when a claim was submitted, regardless of whether it was ultimately approved or rejected by the Government. (Compl. ¶¶ 139, 146.)[8] Relator alleges that this practice "greatly increase[ed] the number of drug prescriptions and, indirectly, the amount of money spent by the federal government for reimbursement of prescriptions covered by the Government Health Care Programs." *(Id.* ¶¶ 139-141.) More to the point, he alleges that this practice was a recognition by Eisai that off-label uses might not be reimbursed by the government. *(Id.* ¶¶ 142-43.) Relator claims that unnamed Eisai sales representatives were trained at unspecified times to deliver messages that Relator loosely describes in his Complaint as "essentially" comprised of the following:

> Medicare could reject these claims because you're prescribing Ontak for an offlabel use. But don't worry: We'll coach you on the claims submission process to optimize reimbursement. With our tips on coding, these claims submissions will fly below the radar. Trust us. Besides, we've got your back—If Medicare or Medicaid doesn't pay you, we will ensure that you are not out of pocket!

(Id. ¶ 142.)

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[8] The e-mail states in relevant part: "FCS financial coordinator called me they are having problems getting the [Ontak] credit from the wholesaler even though we have officially taken care of everything on our end. I asked her to send me an email with what's going on with wholesaler names & emails. That's the 1st problem that occurred today." Although not entirely straightforward, Relator contends that "[t]his e-mail reflects the existence of the OAR Program, and Eisai's efforts to assure providers that they would not be out-of-pocket when a claim for reimbursement of Ontak was not approved." (Compl. ¶ 146.)

B. Kickbacks

Next, Relator alleges that Eisai engaged in a "nationwide system" of kickbacks as part of its marketing strategy. (Compl. ¶ 33.) In addition to the payments to physicians for conducting off-label studies and advocating off-label use and payments to hospitals for hosting related lectures,[9] Relator cites several other instances of what he takes to constitute illegal kickbacks: "any money, fee, commission, credit, gift, gratuity, thing of value, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor or subcontractor employee, for the purpose of improperly obtaining or rewarding favorable treatment in connection with a prime contract or in connection with a subcontract relating to a prime contract." (*Id.* ¶¶ 20-21 (quoting 41 U.S.C. §§ 52-53).)

However, there few details regarding the payments these health care providers received from Eisai. For example, Relator contends that at an unidentified Tampa resort at some point in 2007, one unnamed physician received $3,000 in accommodations relating to his attendance at a lecture "focus[ing] on Ontak's use for T-cell lymphoma and other cancers." (Compl. ¶ 157.) In July 2007, unspecified "[m]onies" were paid to a "Dr. Miller" for making a "presentation regarding use of Ontak for B cell lymphoma." (*Id.* ¶ 150.) And without elaboration, Relator claims that "[o]ther physicians promoting off-label use of Ontak who received very substantial compensation from Eisai were Dr. Nam Dang, Nevada Cancer Center, Dr. Pinter-Brown, UCLA, Dr. Timothy Kuzel with Northwestern, and Dr. Peter Heald, a

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[9] The kickback allegations overlap significantly with details of Eisai's scheme to promote off-label uses, particularly aspects that involved payments to physicians and hospitals for their assistance in promoting Eisai's drugs.

dermatology professor." (*Id.* ¶ 154.) "[S]imilar educational grants were paid in return for off-label presentation access to such well-known cancer treatment centers as: the Dana Farber Cancer Center in Boston, Lurie Cancer Center at Northwestern University in Chicago, and the M.D. Anderson Cancer Center in Houston, Texas." (*Id.* ¶ 151.)

C. Submission of False Claims for Reimbursement

Relator alleges that any claim for reimbursement resulting from Eisai's off-label promotion or payment of kickbacks is fraudulent, unreimbursable, and constitutes a "false claim" within the meaning of the FCA. (Compl. ¶¶ 135, 219, 229.) Providers can receive payment by submitting claims through three government-funded programs: Medicare, which provides health services for individuals 65 and older (Compl. ¶ 2); Medicaid, which provides health services to low-income individuals, and is paid for by states that are reimbursed to some degree by the federal government (*Id.* ¶ 3); and TRICARE, which provides health services to military personnel and their dependents. (*Id.* ¶ 4.)

With respect to kickbacks, providers seeking Medicare coverage agree that their claims are "conditioned upon the claim and the underlying transaction complying with [Medicare] laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and Stark law, and on the [provider's] compliance with all applicable conditions of participation in Medicare." (*Id.* ¶ 224.) Similar language is contained in certifications accompanying cost reports they must submit. (*Id.* ¶¶ 225-226.)[10] Individual state statutes control Medicaid reimbursements, but they generally

[10] In greater detail, the complaint alleges that:

provide that payment may be withheld for fraud or misrepresentation, concealment of a material fact, or receipt of a kickback in connection with furnishing treatment. *(Id.* ¶¶ 230-237.) According to Relator, kickbacks run afoul of the FCA because Medicare participants must certify compliance with the Anti-Kickback Act to receive payments for prescriptions given to their Medicare patients. *(Id.* ¶ 23.) Alternatively, because the Government would not have paid the claims had it known of the violation of a law, they are false under an "implied certification" theory. *(Id.* ¶ 31.)

However, there are few details to support a conclusion that any hospital or doctor that received payments from Eisai as described above – assuming they constitute

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224. In order to be eligible for Medicare reimbursement, both hospitals and doctors are required to sign a Provider Agreement which states: "I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]....I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti- kickback statute and Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

225. Hospitals, but not physicians, are also required to submit a Hospital Cost Report with their submissions of requests for claims reimbursement. It states: punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report [were] provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

226. The person signing the Hospital Cost Report must certify: "To the best of my knowledge and belief, [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

kickbacks – submitted a claim for reimbursement. As best the Court can tell, Dr. Foss, whose role is otherwise described as a speaker and director of off-label studies, "prescribe[ed] Ontak off-label and ma[de] false and fraudulent claims to Medicare and Medicaid." (Compl. ¶ 256(a).) The Dana Farber Cancer Center and the M.D. Anderson Cancer Center appear on a company report as having purchased Ontak, a purchase for which Relator believes they sought reimbursement. (*Id.* ¶ 240.) Dr. Pinter-Brown was paid for serving as a consultant; at one point in the Complaint, Relator refers to the fact that she "made off-label Ontak claims to Medicare and Medicaid." *(Id.* ¶ 249.) Finally, the Complaint suggests that the most frequent lecturers were also the top off-label prescribers. (Compl. ¶¶ 156, 163). As discussed below, without more, these conclusory allegations are insufficient to assert that claims were actually submitted to the Government for reimbursement.

Similarly, with regard to off-label promotion - assuming this activity can render a claim false – there are few allegations to support Relator's assertion that doctors who were persuaded by Eisai to prescribe medication off-label submitted claims to the Government. With respect to the three doctors who were paid for speeches regarding Ontak as described above – Drs. Heald, Pinter-Brown, and Foss – the Complaint is conspicuously silent as to whether any prescribing doctor was in attendance or whether any speaker caused any particular off-label claim to be submitted. The same is true of Dr. Dang, who was allegedly hired as Eisai's consultant and to conduct off-label studies, and the hospitals that were paid to host off-label presentations. In sum, it is unclear whether any doctor who attended any of those lectures, read any of those articles or

studies, or spoke to Eisai's consultants were persuaded to make off-label prescriptions and to seek reimbursement for them.

Nevertheless, the Complaint does provide limited discussion of submissions that resulted from Eisai other promotional activities. Over a nine month period, Eisai sales representatives made in-person sales calls to three doctors at Baptist Hospital, stating that clinical data demonstrated that Dacogen was effective for an off-label indication and leaving behind Eisai-sponsored studies and marketing materials. (Compl. ¶ 177.) According to the Complaint, Baptist Hospital then used Dacogen for non-approved uses. (*Id.* ¶ 177.) Relator alleges that Eisai "intended that [its] above-described marketing practices would result in the submission of off-label claims to Medicare and Medicaid" and that they "caused [the hospital] to submit false or fraudulent claims . . . which were approved and paid by Medicare and Medicaid respectively." (*Id.* ¶ 178.) Relator makes verbatim allegations with respect to in-person sales calls by unspecified "Eisai sales representatives" to two doctors at Memorial Regional Hospital, two doctors at Sylvester Cancer Center, and two doctors at Boca Raton Community Hospital. (*Id.* ¶¶ 179-184.) Relator asserts that the promotions and other activities resulted in false claims by roughly two dozen hospitals during the two-and-a-half year timeframe of the Complaint and Relator provides approximate dollar figures based on his estimation. (*Id.* ¶¶ 57, 59, 256.)

Relator also alleges that Eisai was directly involved in falsifying submissions. Without specifying exactly who, where, when, or what statements were made, the Complaint states that Eisai hired reimbursement specialists to coach physicians, hospitals, and other medical providers on how to present off-label Ontak claims for

reimbursement, including through telephone support. (Compl. ¶¶ 241-42.) For instance, Eisai recommended that they provide an "off-label secondary diagnosis code[]" on a Medicare claim form, such as diabetes. (*Id.* ¶¶ 241-246.)[11] Through this, Eisai intended and caused false claims for payment to be submitted to Medicare and Medicaid. (*Id.* ¶¶ 243-45.)

The most significant document Relator points to regarding false submissions is a GOERS report, which was provided to Eisai's sales representatives. This report shows the number of units of Ontak that Eisai sold to 188 named providers, and lists their addresses and reporting dates. (Compl. ¶¶ 59, 238, 240; Compl. Ex. G.) Although the report provides little more than the provider's name and the quantity of drugs each had bought by a certain date (notably, it includes no billing information, such as dollar value of the sales and how much was reimbursed by the Government}, he alleges that he "was informed by managers that the providers listed in the GOERS report routinely bill Medicare and Medicaid." (*Id.* ¶ 240.) Based on his own experience, Relator estimates that of his $5.5 million in sales of Ontak, twenty-five percent was later falsely or fraudulently submitted to Medicare for reimbursement and two percent was submitted to Medicaid. (*Id.* ¶ 255.) He further estimates that 2,000 hospitals, oncology offices,

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[11] Like other allegations, this claim fails to identify who was involved, what precisely was said at what time and in which location, or whether there were any specific instances where a prescriber followed Eisai's guidance. Moreover, the Court is unsure how the statement furthers the scheme alleged. There is no allegation that using such codes reflected false diagnoses – that is, that the patient did not suffer from diabetes- and there is no explanation of how listing them rendered the claims more likely to be reimbursed.

oncologists, and pharmacies submitted claims that involved off-label promotion or kickbacks. (*Id.* ¶ 59.)

D. Best Price Violations

While all other allegations assert that Eisai engaged in conduct that caused false claims to be filed, Relator asserts one way in which Eisai made a false claim to the Government directly – falsely reporting pricing information. Medicare and Medicaid rebate programs ensure that pharmaceutical companies offer state governments reimbursement rates for drugs that are no greater than the rate charged to other entities (i.e., manufacturers must provide the Government with the "Best Price"). (Compl. ¶¶ 187-88.) As part of the agreement to provide such rebates, manufacturers must make quarterly reports that disclose pricing information for covered drugs, including the best price offered to any purchaser. (*Id.* ¶¶ 188-89, 191.) Relator contends that Eisai falsified information about its drug pricing to the Government with respect to Ontak, Dacogen, and two other drugs: Aloxi, which is used to treat nausea caused by chemotherapy, and Fragmin, which is used to treat blood clots caused by cancer or heart conditions. (*Id.* ¶¶ 185-86.) Relator alleges that this conduct is actionable under the FCA. (Compl. ¶ 192.)

These drugs were highly profitable to Eisai, but also faced stiff competition from rival manufacturers making versions under their own name. (*Id.* ¶¶ 194-96.) Accordingly, Eisai gave prospective buyers aggressive discounts, which were approved at the sales representative and management level, but not tracked centrally by Eisai. (*Id.* ¶¶ 194, 196.) Eisai's discounts were based on volume and bundling with other drug sales. Relator was told by unnamed supervisors that Eisai's best customers were

allowed volume discounts that were not included on company price lists or information sent to the Government. (*Id.* ¶ 201.) At a conference in 2008, Relator and other sales representatives learned that Eisai planned to falsely report an increase in the cost of Aloxi – which would increase its average sales price – and obtain a higher reimbursement rate from Medicare and Medicaid. (*Id.* ¶¶ 204-05.) In reality, because of discounts offered to physicians, the sales price was decreasing. (*Id.* ¶ 205.) At a sales meeting in 2008, an Eisai sales representative named "Frank" told Relator that "[n]obody else" but Jackson Memorial Hospital in Miami, Florida was getting a low price on Fragmin. (*Id.* ¶¶ 207-08.) While he did not specify a price that Jackson paid or the price Eisai reported to the Government, he mentioned that "[w]e are almost giving it away." (*Id.* ¶ 207.) And finally, two upper level Eisai managers launched a plan to bundle Aloxi and Dacogen in order to "gain a formulary position at each institution purchasing them." (*Id.* ¶¶ 214-15.)

E. Procedural History

This case has a procedural history commensurate with the breadth and complexity of the allegations. After his initial complaint, Relator filed an amended complaint on July 8, 2010 (DE 19).[12] On February 24, 2011, the Government filed a notice declining to intervene in this action, leaving Relator to prosecute this action on its

[12] Additionally, while it does not involvethe issues currently before the Court, Keeler brought an action for retaliation under Florida's Whistleblower's Protection Act in state court sometime after filing his initial complaint under seal in this case. That action was removed to federal court and re-captioned *Keeler v. Eisai Inc.,* No. 10-cv-60959 (S.D. Fla.). Keeler and Eisai then reached a settlement of their claims that resulted in the dismissal of that action with prejudice. As part of the settlement, Keeler executed a release of claims against Eisai, but failed to disclose the existence of this *qui tam* action, which was still under seal. The Court previously ruled that Keeler's *qui tam* claims can proceed because they were already pending at the time of the release and could only be dismissed with the consent of the Court and the Attorney General. (*See* DE 61.)

behalf.[13] The Court subsequently ordered that the complaint be unsealed and served upon the Defendant (DE 25). The First Amended Complaint was dismissed by order dated June 21, 2011 (DE 61). Relator filed a Second Amended Complaint on July 1, 2011 (DE 62) and a Third Amended Complaint on July 29, 2011. The Court had warned Relator that he "will not be afforded any more opportunities to amend his complaint." (DE 85.)

Based on the allegations described above, Relator essentially brings three distinct claims. Count I alleges that Defendant's promotion of off-label uses caused doctors to prescribe drugs for off-label purposes and submit false claims for reimbursement, violating the False Claims Act. Second, in that same Count, Relator alleges that Eisai failed to provide the Government with "best prices" for Ontak, Dacogen and two other drugs, Aloxi and Fragmin. Finally, Count II alleges that Eisai paid prescribers to induce them to prescribe Eisai's drugs and to submit claims for reimbursement to Medicare and Medicaid, and also paid for physicians' speeches and for physicians to conduct off-label clinical trials. In so doing, Relator asserts that Eisai violated the Anti Kickback Act, 41 U.S.C. §§ 52 *et seq.,* and by extension, the FCA.[14]

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[13] Although the United States declined to intervene in this suit, it filed a statement of interest in connection with the instant motion. The United States takes no position on "whether the relator has adequately plead[ed] facts that would state a cognizable claim under the FCA as properly interpreted" and "whether the relator has sufficiently plead[ed] elements of falsity, causation, or materiality." (DE 110, at 2.)

[14] Counts I and II seek relief under § 3729(a)(1) and (a)(2) of the False Claims Act, as amended by FERA. Count II alleges that Eisai violated the Anti-Kickback Act, rendering false the claims of health care providers for purposes of the FCA. (Compl. ¶¶ 30.)

Because of this conduct, Relator also brings claims under various state anti-fraud statutes (Counts III-XXXII). Eisai has moved to dismiss primarily on the ground that Relator has failed to sufficiently state a claim.

II. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must plead sufficient facts to state a claim that is "plausible on its face." *Ashcroft v. Iqbal,* 556 U.S. 663, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). The Court's consideration is limited to the allegations presented. *See GSW, Inc. v. Long Cnty.,* 999 F.2d 1508, 1510 (11th Cir. 1993). All factual allegations are accepted as true and all reasonable inferences are drawn in the plaintiff's favor. *See Speaker v. U.S. Dep't of Health & Human Servs. Ctrs. for Disease Control & Prevention,* 623 F.3d 1371, 1379 (11th Cir. 2010); *see also Roberts v. Fla. Power & Light* Co., 146 F.3d 1305, 1307 (11th Cir. 1998). Nevertheless, while a plaintiff need not provide "detailed factual allegations," the allegations must consist of more than "a formulaic recitation of the elements of a cause of action." *Twombly,* 550 U.S. at 555 (internal citations and quotations omitted). Additionally, "conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Air Lines, Inc.,* 326 F.3d 1183, 1185 (11th Cir.2003). The "[f]actual allegations must be enough to raise a right of relief above the speculative level." *Watts v. Fla. Int'l Univ.,* 495 F.3d 1289 (11th Cir. 2007) (quoting *Twombly,* 550 U.S. at 545).

In addition to the requirements of *Twombly, Iqbal,* and Federal Rules of Civil Procedure 8(a) and 12(b)(6), claims asserted under the False Claims Act (as well as other fraud claims) are subject to the pleading standards of Federal Rule of Civil

Procedure 9(b). *See United States ex. rel. Clausen v. Laboratory Corp. of Am., Inc.*, 290 F.3d 1301, 1309-10 (11th Cir. 2002).[15] That rule provides that "[i]n allegations of fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake" but that "[m]alice, intent, knowledge, and other condition of mind of a person shall be averred generally." FED. R. CIV. P. 9(b). Rule 9(b) is satisfied if the plaintiff pleads "(1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud." *Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001) (quoting *Brooks v. Blue Cross & Blue Shield of Fla., Inc.,* 116 F.3d 1364, 1371 (11th Cir. 1997)).

In the context of the False Claims Act, the complaint must set forth "facts as to time, place, and substance of the defendant's alleged fraud" and "the details of the [defendant's] allegedly fraudulent acts, when they occurred, and who engaged in them." *Clausen,* 290 F.3d at 1309-10 (quotation omitted); *accord United States ex rel. Sanchez v. Lymphatx, Inc.,* 596 F.3d 1300, 1302 (11th Cir. 2010). "Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b)." *United States ex. rel. Karvelas v. Melrose-Wakefield Hosp.,* 360

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[15] Based on the Eleventh Circuit's FCA precedent, the Court rejects Relator's suggestion that because he is pursuing a false claim and not a fraudulent claim, the pleading requirements applicable to fraud claims are not controlling. (*See* Opp'n at 9.) Accordingly, Relator is incorrect that he need not provide the "who, what, where, when" of fraud under that rule. (Opp'n at 9.)

F.3d 220, 232 (1st Cir. 2004). As discussed herein, the Eleventh Circuit has recognized that while these requirements of Rule 9(b) may, in practice, make it difficult for a *qui tam* plaintiff to bring an action, they are necessary to prevent "[s]peculative suits against innocent actors for fraud" and charges of guilt by association. *Clausen,* 290 F.3d at 1308 (quoting *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.,* 19 F.3d 562, 566-67 (11th Cir. 1994) (per curiam)).

III. DISCUSSION

The Court previously found that Relator stated a claim under Rule 12(b)(6), but that his claims were not pleaded with the degree of particularity required by Rule 9(b). Significantly, Relator failed to describe specifically what Eisai did to cause false claims to be submitted, omitted critical details of claim presentation, and did not describe how the alleged kickbacks "crossed the line from legal conduct in compliance with federal statutes to illegal kickbacks." (DE 61.)[16] Now, despite having greatly expanded his pleading and having crafted additional arguments to support his FCA claims, Relator's complaint – however prolix – fails to provide the requisite particularity to survive dismissal. The Court addresses each of Relator's claims in turn.

[16] In particular, Judge Ungaro, who presided over this action until it was transferred to the undersigned on September 8, 2011 (DE 99), held that "Plaintiff fails to identify with particularity a false claim that was presented to the government as a result of Defendant's conduct. Plaintiff fails to identify who presented the claim, what it was for, when it was presented, and what specific conduct on the part of the Defendant caused the presentment of the claim." (DE 61). For purposes of this order, the Court presumes that Relator's claims are not subject to dismissal under Rule 12(b)(6).

A. Scheme to Promote Off-Label Uses

The bulk of Relator's complaint is focused on imposing liability under the FCA due to Eisai's scheme to promote off-label use of its pharmaceutical products.[17] Section (a)(1) requires that the Defendant make or cause a claim to be made; that the claim was false; that the falsity was known to the Defendant; and that payment was actually sought from the Government. Under the FCA's "cause to be submitted" language, a defendant may be liable notwithstanding the fact that it was not the submitter of a claim or that it was not in contractual privity with the government. *United States v. Tauber Extrusions, LP,* 341 F.3d 843, 835 (8th Cir. 2003) (quoting, *inter alia, United States ex rel. Marcus v. Hess,* 317 U.S. 537, 544-45 (1943)). According to the Complaint, Eisai allegedly did this in four ways: (1) Eisai trained sales representatives to promote off-label uses (providing incentives to do so), gave prescribers materials showing off-label effectiveness, and marketed the spread; (2) Eisai paid consulting doctors to promote such uses and to conduct off-label clinical studies; (3) Eisai gave medical facilities grants and other payments for supporting Eisai's promotion; and (4) Eisai ran reimbursement programs to guarantee payment for off-label prescriptions to doctors.

The Court need not delve into the myriad arguments made by the parties in their extensive briefing since there are immediately apparent defects regarding the circumstances of the fraud.[18] As to the fraud's "who" and "where," although Relator

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[17] Keeler asserts that this is a *"cause to be submitted"* case in which Eisai has *caused* providers to present claims for improper Medicare and Medicaid reimbursement, stemming from Eisai's schemes." (Opp'n at 12.)

[18] The parties' prolific briefing does not focus on the central, threshold question for the Court – whether the claims properly plead the circumstances of the fraud. Rather than addressing the actual allegations of the Complaint, Plaintiff

concentrates on the standard of review, arguing that this Court need not adhere to the Eleventh Circuit's precedent applying Federal Rule of Civil Procedure 9(b) to *qui tam* actions like this one. As noted above, the Court rejects that argument. And for the reasons explained below, the Court declines to relax the pleading requirements under the circumstances here.

For its part, Defendant seeks a ruling that no false claim is implicated as a matter of law because even if Eisai promoted its drugs for off-label uses and they were prescribed for an off-label use, the claims were still reimbursable. Cases recognize that while off-label promotion is an illegal act under federal law, a relator may not have standing to bring suit for it; a defendant is not subject to FCA liability unless it seeks government compensation (or causes someone else to seek compensation) for which it is not entitled. *See United States ex rel. Bennett v. Boston Scientific Corp.,* No. H-07-2467, 2011 WL 1231577, at *12 (S.D. Tex. Mar. 31, 2011) (collecting authority). Looking at the reimbursement requirements of the government programs at issue, Defendant asserts that off-label prescriptions are reimbursable if a physician determines that the use is medically reasonable and necessary. *See, e.g.,* 42 U.S.C. § 1395y(a)(1)(A). Because of that statutory language and because the Court is not bound to accept a plaintiffs assertions regarding legal conclusions, Defendant suggests that the Court should find that the off-label allegations could never implicate a false claim. However, other courts, including the Eleventh Circuit, have declined to address this issue where, as here, Plaintiff fails to sufficiently articulate the details of the fraud. *See Solvay,* 588 F.3d at 1326 (assuming *"arguendo* that when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription will be borne by the federal government, and when a claim is ultimately submitted to the federal government to pay for that prescription, 31 U.S.C. § 3729(a)(1) may have been violated," but dismissing the complaint for failure to link promotion to submission of false claims); *see also United States ex rel. Carpenter v. Abbott Labs., Inc.,* 723 F. Supp. 2d 395, 410 (D. Mass. 2010).

While the Court ultimately does not reach the issue of whether Defendant's theory is correct as a matter of law, it notes that it would have difficulty accepting that Relator's allegations, *as pleaded,* satisfy the FCA's falsity requirement. Relator has not developed, in pleading or in argument, how the mere act of promoting the subject drugs resulted in the submission of a claim containing a *false* representation. *See United States ex rel. Hess v. Sanofi-Synthelabo, Inc.,* No. 4:05CV570MLM, 2006 WL 1064127, at *10 (E.D. Mo. Apr. 21, 2006) (requiring a relator basing a claim on a promotion scheme to allege "conduct which was designed to present *false* information"); *see also Nowak,* 806 F. Supp. 2d at 345-46. For instance, he does not contend that a prescribing physician falsely represented that the treatment was for an indicated condition when seeking reimbursement from the Government. Similarly, he has not alleged that a claim for reimbursement is the equivalent of a representation that the requested service is covered, that submission of off-label claims runs afoul of any

specified receiving training and marketing materials advocating off-label use, he has failed to properly demonstrate Eisai's act of promotion. Relator has not alleged which individuals at Eisai instructed him (or other sales representatives) to fraudulently promote off-label uses, what those instructions were, which doctors sales representatives contacted and induced to prescribe Eisai's drugs, and what was said to them to cause them to do so. There are no allegations that Eisai's inducing statements themselves were expressly false with the exception of one conclusory allegation that he "was directed to tell physicians . . . that there were studies showing that CD-25 positive/negative made no difference in the treatment of patients, which was known to be untrue." (Compl. ¶ 93.) He has not alleged, for instance, that off-label studies Eisai provided to physicians contained false data, that its representatives gave the impression that the drugs were reimbursable when they were in fact not, or that Eisai misrepresented the indications for which the drugs were approved. See *Bennett,* 2011 WL 1231577, at *26 ("Importantly, there is no allegation that the defendants concealed or misstated the limits of the FDA's approval on the use of the FlexView system.").

That same key information is lacking with respect to the speakers and lecturers who allegedly were engaged to promote Eisai's products. Notably, the Complaint is completely silent as to the substance of their remarks and whether any plan participants

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of the certifications that prescribers make, or that the Government would not have reimbursed the claim had it known of the off-label nature of the use or the fact of the promotion. See *United States ex rel. Polansky v. Pfizer,* No. 04-cv-0704, 2009 WL 1456582, at *7-8 (E.D.N.Y. May 22, 2009) (citing authorities explaining the FDA's position and concluding that "the entities to which reimbursement claims are made could hardly be understood to have operated on the assumption that the physician writing the prescription was certifying implicitly that he was prescribing [the subject drug] in a manner consistent with the Guidelines").

were present. One example states in its entirety that "[i]n June 2007, Dr. Dang gave a presentation at the University of Miami's Sylvester Cancer Center. Dr. Dang's presentation was advertised as being on Ontak's use in treating CTCL. Instead, Dr. Dang lectured on his off-label use of Ontak." (Compl. ¶ 149.) Or, "in October, 2008, Dr. Franine Foss, a longstanding paid speaker of Eisai, spoke in south Florida at a dinner program for physicians on the use of Ontak for treating peripheral T cell lymphoma." (*Id.* ¶ 153.) The Complaint makes other passing references to unnamed physicians speaking about Eisai's products at unspecified dates and locations. These allegations fail to comply with the basic elements of pleading any fraudulent scheme. *See, e.g., Sanofi-Synthelabo, Inc.,* 2006 WL 1064127, at *7 ("Plaintiff fails to allege the who, what, when, where, and how regarding Defendant's sales representatives allegedly promoting the off-label uses of Elitek to doctors nor does he makes such allegations regarding Defendant[ ] allegedly training its sales representatives in off-label uses of Elitek." (citation omitted)); *Franklin v. Parke-Davis,* 147 F. Supp. 2d 39, 50 (D. Mass. 2001) (discussing promotion claim under Rule 9(b) where relator failed to specify who "engaged in [the scheme to cause false submissions], where such conduct took place, which [of defendant's] personnel were involved, or any specific fraudulent statements made to personnel"); *see also United States ex rel. Butler v. Magellan Health Servs, Inc.,* 74 F. Supp. 2d 1201, 1216-17 (M.D. Fla. 1999) (noting that the "complaint fails to refer to specific employees who may have been involved in submitting false claims").

Moreover, even if there were sufficient allegations of statements made by and to physicians, Relator has failed to explain how the representations resulted in prescriptions and requests for reimbursement. For instance, the Complaint does not tie

the efforts of Drs. Heald, Brown, Foss, and Dang – all of whom allegedly received payment for lecturing on off-label uses or conducting off-label studies – to any claim submitted by them or others. There is no allegation that a prescribing doctor who later sought reimbursement attended those lectures or considered the studies. At no point does Relator allege that any *particular* prescriber that is alleged to have submitted off-label claims was actually aware of any of Eisai's representations as communicated by these doctors. The same is true of the named hospitals and institutions that received money in exchange for research and lectures regarding Eisai's drugs. For instance, the University of Arizona is alleged to have received a grant in July 2007 (presumably for allowing a presentation on off-label use of Ontak) (Compl. ¶ 150), but it is not one of the institutions that is alleged to have submitted claims. Indeed, it is not mentioned again anywhere else in the Complaint.

Similarly, Relator has failed to plead with particularity that *any* claims for off-label use were in fact submitted to the Government and reimbursed as a result of the scheme, which is a requirement for an action based on off-label promotion under Section (a)(1) and which deficiency scuttled the previous iteration of his Complaint. *See Solvay,* 588 F.3d at 1325 (requiring a plaintiff to link the fraudulent scheme to the submission of false claims); *United States ex rel. Atkins v. McInteer,* 470 F.3d 1350, 1359 (11th Cir. 2006) (holding that a plaintiff must "provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes"); *Corsello v. Lincare, Inc.,* 428 F.3d 1008, 1013-14 (11th Cir. 2005) (affirming dismissal where complaint "did not allege that a specific fraudulent claim was in fact submitted to the government"); *Clausen,* 290 F.3d at 1311 (calling the

submission or presentment of a claim to the government the "*sine qua non*" of a False Claims Act violation).

Whether submission of the claim is sufficiently established is a different question than whether the scheme has been sufficiently pleaded. *See Corsello,* 428 F.3d at 1014 ("In short, Corsello provided the 'who,' 'what,' 'where,' 'when,' and 'how' of improper practices, but he failed to allege the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government."). The presentment requirement calls on relators not only to describe details about how the schemes operated (however well that might be pleaded), but to cite specific occurrences of actual *fraud. Clausen,* 290 F.3d at 1305, 1311-1312 & n.21. Thus, for at least some of the claims, a relator must provide the following: "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." *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.,* 360 F.3d 220, 232-33 (1st Cir. 2004) (quoting *Clausen,* 290 F.3d at 1312 n.21).

Illustrating this principle is the decision in *Clausen* (relied on for various points by both sides), which involved allegations that a medical testing company submitted claims for unnecessary tests to government programs, thereby violating the FCA. *Clausen,* 290 F.3d at 1303-04, 1306. Additionally, there were allegations of illegal kickback and self-referral schemes that resulted in improper billing. *Id.* at 1304. The Eleventh Circuit affirmed the district court's dismissal of the complaint because the relator provided

details about the preparatory scheme, but failed to submit any bill, claim, or payment; amounts charged by the defendant on what dates; or details of how the billing was fraudulent. *Id.* at 1306, 1311-12. It concluded that "nowhere in the blur of facts . . . can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government . . . as to the plot's execution, Clausen merely offers conclusory statements, and does not adequately allege when – or even if – the schemes were brought to fruition." *Id.* at 1312. As the Fifth Circuit noted, "[t]he *Clausen* court made plain its position that to plead a presentment claim, the minimum indicia of reliability required to satisfy the particularity standard are the specific contents of actually submitted claims, such as billing numbers, dates, and amounts." *United States ex rel. Grubbs v. Kannenganti,* 565 F.3d 180, 186, 190 & n.32 (5th Cir. 2009) (commenting that "[t]o require these details at pleading is one small step shy of requiring production of actual documentation with the complaint" (citing *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of* Am., *Inc.,* 238 F. Supp. 2d 258, 269 (D.D.C. 2002)).[19]

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[19] Although the Fifth Circuit in *Grubbs* criticized the stringent requirements of *Clausen,* subsequent cases decided by the Eleventh Circuit emphatically reaffirms the holding as binding precedent. Indeed, in *Solvay*- a promotion case – the relators were able to provide "a highly-compelling statistical analysis [that] renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of [the subject drug] resulted from [the defendant's illegal marketing] campaign." 588 F.3d at 1326. However, even that evidence was deficient in that it did "not allege the existence of a single actual false claim." *Id.* ("In fact, we are unable to discern from the complaint a specific person or entity that is alleged to have presented a claim of any kind, let alone a false or fraudulent claim."). To tie the promotion to false claims, relators must "identify specific persons or entities that participated in any step of this process" as well as "dates, times, or amounts of individual false claims." *Id.* And in *Atkins,* the relator could point to dates of services, name the patients that received the

As applied to this case, Relator broadly alleges that Eisai engaged in "endemic," "nationwide," and "systemati[c]" fraud by causing physicians and hospitals to submit false claims for reimbursement under Medicare Part D. and Medicaid. (Compl. ¶¶ 53-55, 255.) He also approximates the dollar amounts that hospitals purportedly received in false claims during a time period covering three years, without any basis for his guess or reference to any actual financial data of those hospitals. (*Id.* ¶¶ 177-84, 256). But Relator never discusses or proffers a single false claim that was made to the Government in the detail required by *Clausen,* nor has he submitted a copy of such a bill or payment. Instead, he proffers only conclusory assertions based on his own speculation that claims were submitted. For these reasons, Relator's claims based on a promotional scheme are fatally deficient.

B. Kickback Allegations

Relator's kickback allegations present an independent ground for an FCA violation, but also fail to meet the applicable heightened pleading standards. The Complaint alleges that as part of the promotion of its drugs, Eisai paid doctors to speak and write articles regarding off-label uses; paid doctors to conduct off-label studies; paid hospitals, through grants and other mechanisms, to use Eisai's drugs; and paid providers guaranteed revenue through Eisai's Oncology Reimbursement Program. Those payments, the Complaint contends, constitute illegal kickbacks. Relator's claim implicates the FCA because he asserts that physicians receiving those payments certified compliance with the anti-kickback laws on reimbursement forms. (Compl. ¶¶

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services, and identify the records that would prove his claim, but could not show that any claims were actually submitted to the Government. 470 F.3d at 1354.

224-226, 230-37.) For instance, Medicare requires providers to sign a provider agreement acknowledging that reimbursement is "conditioned upon the claim and the underlying transaction complying with [Medicare] laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and Stark law)," as well as other certifications. (*Id.* ¶¶ 224-226.) With respect to Medicaid, which is a state-run program funded by the federal government, the Complaint asserts that Eisai ultimately caused states to submit claims to the federal government for reimbursement that falsely certified that the claims were in compliance with federal law. (*Id.* ¶¶ 264.)[20]

Courts have recognized that under an express certification theory, "[f]alsely certifying compliance with the . . . Anti-Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA." *United States ex rel. Wilkins v. United Health Gp., Inc.*, 659 F.3d 295, 312 (3d Cir. 2011)

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[20] The anti-kickback regulations applicable to the Medicaid program state that:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42. U.S.C. § 1320a-7b(b)(2).

(quotation and citation omitted); *see also Parke-Davis*, 147 F. Supp. 2d at 54 (stating that "a violation of the federal antikickback provision is not a *per se* violation of the FCA" and that "[i]n order for the antikickback violation to be transformed into an actionable FCA claim, the government must have conditioned payment of a claim upon the claimant's certification of compliance with the antikickback provision" (citations omitted)).

Alternatively, an implied certification theory, which is also alleged, recognizes that the FCA is violated where compliance with a law, rule, or regulation is a prerequisite to payment but a claim is made when a participant has engaged in a knowing violation. Wilkins, 659 F.3d. at 313. So, for example, in *McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005), the Eleventh Circuit affirmed the denial of a motion to dismiss finding that allegations of kickbacks can create FCA liability where compliance with the Anti-Kickback Statute is a prerequisite for payment. *Id.* at 1259-60. In particular, the alleged kickbacks in *McNutt* – which the Government identified with "detailed facts" as well as "specific claims" that were submitted for reimbursement – disqualified the defendants' medical services from reimbursement under the Medicare program, but the defendants nevertheless submitted claims for reimbursement. *Id.* at 1257-1259. The court concluded that "[w]hen a violator of government regulations is ineligible to participate in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the [FCA], for its submission of those false claims." *Id.* at 1259.

It is important to note, however, that as with any basis for FCA liability, such claims are subject to Rule 9(b)'s pleading requirements. *Cf. Wilkins,* 659 F.3d. at 313 n.20 (finding that relator stated a claim but declining to address whether it was pleaded with particularity). Thus, the Court in *Parke-Davis* held that even if kickbacks are illegal, dismissal was proper since the relator "failed to allege that physicians either expressly certified or, through their participation in a federally funded program, impliedly certified their compliance with the federal antikickback statute as a prerequisite to participating in the federal program." 147 F. Supp. 2d at 55. In particular, the complaint did not assert that the defendant "caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute." *Id.*

Herein lies the problem with Relator's claims. Even assuming that the payments alleged constitute illegal kickbacks,[21] the allegations that participants actually received payments and falsely certified compliance - like the complaint in *Parke-Davis* and in contrast to *McNutt*- are not sufficiently pleaded. As noted above, there are scarcely any allegations that any doctor or facility that received such payments filed a claim for reimbursement - and none that are pleaded with any degree of particularity. With respect to those few who did submit claims for reimbursement, there are no submission allegations that can satisfy *Clausen*. Thus, Relator fails to connect the scheme to particular instances of fraud or misrepresentation. His allegations are insufficient to support claims under Rule 9(b).

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[21] Eisai contends that the payments at issue were not reciprocity for physicians' prescriptions of its drugs and that its rebate program falls under a statutory safe harbor exception that allows discount arrangements.

C. Best Price Violations

Finally, the Court is compelled to reach the same conclusion with respect to Relator's FCA claims based on allegations of false best price submissions. As with other claims, the linchpin of these allegations is not that Eisai violated any law requiring it to provide the Government with the best price of its drugs or provided less in program rebates than what was owed, but that it falsified information provided to the Government and profited from it (although Relator confuses the two in the Complaint and in argument). Section 3729(a)(1)(B) imposes liability on "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. Before the May 2009 amendment, the statute exposed a person to damages if he or she "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government." 31 U.S.C. § 3729(a)(2) (2006).

In this regard, the Complaint alleges that Eisai provided participants with discounts that presumably did not factor into best price reports?[22] It also alleges that Eisai affirmatively and knowingly falsified information provided to the Government by altering its reported prices. Because of this, Eisai presumably was able to charge the Government more than it otherwise would have. Again, as with Relator's other allegations, these claims are subject to Rule 9(b). *See United States ex. rel. Foster v. Bristol-Myers Squibb* Co., 587 F. Supp. 2d 805, 825 (E.D. Tex. 2008).

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[22] The Complaint also alleges that Eisai failed to instruct sales representatives that they could not provide prices to prescribers that were less than the best price offered to the Government. However, Relator does not tie this practice to a false price that was reported to the Government.

Very briefly, the Complaint fails to allege with specificity what data was submitted by Eisai to the Government that was false or fraudulent. The time periods alleged are broad and often run from when Eisai acquired the rights to produce the drugs at issue until Relator ended his employment. Nevertheless, there is not one description of a single discount that was offered to a single provider. There is no discussion of any particular pricing report and any assertions that discounts were not reported are conclusory and unsupported by specific facts. None of the allegations set forth precisely what statements were made, when such statements were made, where such statements were made, and who made them. *See Ziemba,* 256 F.3d at 1202 (citations omitted). Relator's best price violations thus fail to meet the 9(b) standard.

D. Relaxation of the 9(b) Standard

Despite the infirmities of his complaint, Relator devotes the majority of his brief to arguing against a heightened pleading standard. In particular, to the extent that his Complaint is deficient, he asks the Court to apply a relaxed standard that would allow him to proceed to discovery based upon his information and belief. He contends that as an insider, he is able to proffer sufficient indicia of reliability that can excuse a lack of particularity; that because he has alleged a far-reaching scheme, general discussions of unlawful conduct are sufficient to establish his claim; and that the information needed to properly plead his claim is exclusively in the hands of the Defendant, depriving him of the ability to plead with particularity. Nevertheless, the Court concludes that relaxation is not warranted here.

First, it is true that some courts have recognized that information based on first-hand knowledge can lend credibility to the relator's claims and propel it over pleading

hurdles. For instance, in *Hill v. Morehouse Medical Associates, Inc.,* No. 02-14429, 2003 WL 22019936 (11th Cir. Aug. 15, 2003)- a case upon which Relator heavily relies (*see* Opp'n at 10-11) – the Eleventh Circuit allowed an FCA claim against a medical services provider to proceed where the relator was a billing coder in the department where the fraud occurred and possessed first-hand knowledge of the fraudulent conduct (i.e., altering diagnosis codes to qualify for payment) based on her experience there. Among other things, she was able to name some of the participants in the scheme, describe the defendant's practices in detail, recount the frequency of submission of each type of claim, and identify the documents in the defendant's possession that would prove the fraud. *Hill,* 2003 WL 22019936, at *4-5. However, she could not recite the names of patients or the dates that the claims were submitted, at least in part because copying private records would violate laws regarding patient confidentiality. *Id.* at *2, 4-5 & n.8. The Eleventh Circuit concluded that these were appropriate circumstances in which 9(b)'s heightened pleading requirements could be relaxed. Therefore, the district court's dismissal was reversed notwithstanding the fact that Hill could not point to a specific false claim.

However, it is important to understand that the Court in *Atkins* later emphasized that *Hill* was not binding precedent and stated that *"Clausen* supercedes *Hill* to the extent that *Hill* is inconsistent with *Clausen." United States ex rel. Atkins v. McInteer,* 470 F.3d 1350, 1358 n.15 (11th Cir. 2006). Thus, while the relator in *Atkins* "cite[d] particular patients, dates and corresponding medical records for services that he contend[ed] were not eligible for government reimbursement," he was in the same position as the relator in *Clausen* insofar as he "fail[ed] to provide the next link in the

FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describe[d]." *Id.* at 1359. As this Court has concluded previously, Relator has failed to proffer "facts as to time, place, and substance of the defendant's alleged fraud, specifically, the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Clausen,* 290 F.3d at 1310 (citations and internal quotation omitted).[23] Accordingly, Relator's claims must fail.

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[23] A line of decisions from the Eleventh Circuit - *Clausen, Corsello, Atkins,* and *Solvay* - make clear that this court has an important gatekeeping function where FCA claims are involved. Significantly, in *Clausen,* the Eleventh Circuit held that "[w]e cannot make assumptions about a False Claim Act defendant's submission of actual claims to the Government without stripping all meaning from 9(b)'s requirement of specificity or ignoring that the 'true essence of the fraud' of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme." 290 F.3d at 1312-13 & n.21. It reasoned that Rule 9(b) serves not only to give defendants notice of the fraud charges, but also protects them from frivolous suits. The danger in FCA cases in particular - which gives the relator a share of any recovery obtained on behalf of the government - is that lowering the pleading requirements would allow plaintiffs without knowledge of the fraud to bring baseless actions, "learn the complaint's bare essentials through discovery," and extract settlements, all while damaging the defendant's goodwill and reputation. *Id.* at 1313-14 & nn. 24-25 (citations omitted). In this case, Relator has made numerous attempts to bypass the pleading requirements, even making an unusual request to defer ruling on Eisai's motion to dismiss until after discovery and summary judgment because of supposed discovery violations. Yet, "[i]f Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion." *Clausen,* 290 F.3d at 1312-13 & n.21.

Indeed, the *Clausen* court was keenly aware of the hardship the decision might work upon relators given the circumstances in which such actions are brought. See *id.* at 1314. It noted that the relator - a corporate outsider - might have needed to "work hard to learn the details of the alleged schemes" if that was even possible, but that "neither the Federal Rules nor the Act offer any special leniency under these particular circumstances to justify Clausen failing to allege with the required specificity the circumstances of the fraudulent conduct he asserts in his action." *Id.* The Eleventh Circuit spoke more to Rule 9(b)'s "policy

Moreover, apart from the controlling decisions of *Clausen* and its progeny, the Court is not persuaded that Relator's complaint bears sufficient indicia of reliability that would warrant relaxation. Unlike the relator in *Hill,* Relator summarily states that he has "both personal and inside knowledge of Eisai's corporate endorsement of its national off-label marketing scheme of Ontak and Dacogen and other illegal conduct regarding the Subject Drugs." (Compl. ¶ 14.) But the basis for his knowledge underpinning his claims is often absent. For example, there is no indication of how he knows that doctors were paid to endorse off-label uses or the amount of money paid to them. Similarly, his belief that false claims were actually submitted apparently rests on his knowledge that doctors were sold drugs (as demonstrated through the GOERS report) and that unknown people at Eisai told him that those providers participate in Government programs. He concludes from this, but provides nothing to support, that they naturally must have sought reimbursement for some or all of those prescriptions. *(Id.* ¶ 240.) This gap illustrates Relator's difficulty; he was only a salesman and had no personal knowledge of what providers did after they were incentivized to prescribe Eisai's drugs, if that is true. The knowledge of that fact, however, is the crux of any FCA claim.

Most concerning, however, is that many of the details that were required to have been pleaded and should have been known to Relator are absent from the Complaint. At the very least, as a salesman, Relator should be familiar with Eisai's drug sales and marketing program. But he is unable to plead with particularity what was told to him by

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underpinnings" again in *Atkins* (a case where the government declined to intervene). 470 F.3d at 1360. It reiterated that 9(b) prevents spurious lawsuits and counseled that courts must be principled in not giving a plaintiff a "ticket" to discovery absent a suitable basis. *Id.* at 1359-60 (quotation omitted).

Eisai employees and what he told doctors when he met with them. He states, for example, that he "was directed" to make false statements about Ontak's effectiveness, but he cannot say who instructed him, when, or where. (Compl. ¶ 93.) And despite the fact that the information was not protected, in contrast to *Hill,* Relator has no documentation to illustrate the false nature of the claims. As Defendant observes, "[i]f Keeler were a genuine whistleblower with information about actual fraud, it would not have been difficult for him as a disgruntled former employee to satisfy these requirements." (Reply at 7.) Consequently, in light of the paucity of details, the Court has no basis to find that Relator's claims are more likely to be reliable rather than purely speculative or as the court in *Clausen* warned, spurious. 290 F.3d at 1313 n.24.

With that in mind, the remaining bases for relaxation are inapplicable. While the broad nature of a scheme may make pleading each instance impractical, Relator has not proffered representative samples of conduct and the Court must not lose sight of the purpose underlying Rule 9(b). *See United States ex rel Sanchez v. Lymphatx, Inc.,* 596 F.3d 1300, 1302-03 (11th Cir. 2010); *United States ex rel. Bledsoe v. Cmty Health Sys., Inc.,* 501 F.3d 493, 509-10 (6th Cir. 2007) ("We conclude that the concept of a false or fraudulent scheme should be construed as narrowly as is necessary to protect the policies promoted by Rule 9(b)."). In other words, a relator cannot segue into discovery simply by filing prolix but unsubstantiated claims. Moreover, to rely on the assertion that the information is exclusively in the hands of the defendant requires a relator to set forth a detailed factual basis for that belief, details which are missing here. *See Clausen,* 290 F.3d at 1314 n.25 (citations omitted).

IV. REMAINING STATE CLAIMS

Relator's remaining claims are brought pursuant to various states' false claims laws. Those claims are subject to the heightened pleading standard of Rule 9(b) and based on the foregoing, are subject to dismissal. *See United States ex rel. Rost v. Pfizer, Inc.,* 507 F.3d 720, 723, 731 (1st Cir. 2007) (affirming district court's dismissal of entire complaint, including counts brought under state statutes analogous to the FCA, since "[t]he heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court" (citations omitted)); *Hopper v. Solvay Pharms., Inc.,* 590 F. Supp. 2d 1352, 1363 (M.D. Fla. 2008), *aff'd* 588 F.3d 1318 (11th Cir. 2009).

V. CONCLUSION

In sum, Relator has failed to set forth a claim under even the minimal pleading requirements recognized by long-standing and well-established FCA precedent. While the repeated failure to cure deficiencies requires that this matter be brought to an end, the Court nevertheless emphasizes how limited its review of the alleged conduct has been and how many questions remain outstanding. *Clausen* and subsequent authority speak to a critical policy consideration of filtering out frivolous or harassing claims that are burdensome to defend against, balanced against the rights of litigants to access courts and to pursue their claims without having to prove them at the outset of litigation. Thus, we do not know if Mr. Keeler's allegations are actually true – indeed, for purposes of this motion, the Court has presumed them to be so to the extent they are properly supported.

It is similarly unknown whether another insider (with more knowledge of Eisai's activities) or the Government (with the benefit of claim submission records) could have pursued this case. *See Atkins,* 470 F.3d at 1360 n.17 ("We note, however, that the

government already possesses the claims - false or otherwise - a potential defendant has submitted for payment. The government can, therefore, access those claims on its own and evaluate any FCA liability that it believes should attach *before* determining whether to bring suit or intervene . . . when the government brings an FCA action or intervenes in a *qui tam* action, we may assume that it does not do so solely to use the discovery process as a fishing expedition for false claims."). And finally, there still may be other allegations that fall outside the FCA ambit altogether; that is not to say that Eisai may not be immune from action under other statutes by other parties. *See Clausen,* 290 F.3d at 1311 ("The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." (citation omitted)). What can be said is that Mr. Keeler has had the chance to litigate his assertions of fraud but has been unable to posit a sufficient link between Eisai, doctors, and Government programs to sustain a claim.

In light of the foregoing, it is hereby **ORDERED AND ADJUDGED** as follows:

(1) Defendant's Motion to Dismiss (DE 95) is **GRANTED**. The above-styled case is **DISMISSED WITH PREJUDICE.**

(2) Defendant's Motion to Unseal (DE 197) is **DENIED**. Any and all other pending motions are **DENIED AS MOOT.**

(3) The Clerk is directed to **CLOSE** this case for administrative purposes.

DONE AND ORDERED in chambers in Miami, Florida, this 31st day January, 2013.

KATHLEEN M. WILLIAMS
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 09-22302-CV-WILLIAMS

UNITED STATES OF AMERICA, *et al.,*
ex rel. Michael Keeler,

Plaintiffs,

vs.

EISAI, INC.,

Defendant.

ORDER

THIS MATTER is before the Court on Relator's Motion to Amend Order of Dismissal under Rules 60(a) and (b) and Rule 59(e) (DE 236). The motion seeks three things: (1) to clarify the Court's January 31, 2013 Order of Dismissal to state that the case is not dismissed with prejudice as to other parties in interest that might be able to make out a claim; (2) to revise that Order to state that the dismissal is without prejudice as to Mr. Keeler (since he may be able to join with others or the Government to provide missing information necessary to form a claim); and (3) to allow Relator leave to file a fourth amended complaint based on "rich," newly-discovered of fraud that he obtained in discovery and which "adds an extremely high indicia of reliability to Relator's allegations." Essentially, the motion is one for reconsideration and to amend the Complaint.

The Court has reviewed the motion and the record and concludes that under any standard, Relator's requests must be denied. As to the first, Relator has not shown how he has been affected by the Court's order to the extent it may affect other potential plaintiffs or relators. *See* Mot. at 5 (stating that the United States "should not be prejudiced if a relator's allegations are challenged under Rule 9(b)"). As to the remaining grounds - which raise similar issues - Relator has not shown that dismissal with prejudice was not warranted. *See Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014-15 (11th Cir. 2005) (holding that trial court did not err in denying relator's request to file an amended complaint where there was a repeated failure to cure deficiencies in three prior complaints).

Finally, as Mr. Keeler acknowledges in his reply, he has neither attached a proposed complaint for the Court to review in accordance with Local Rule 15.1 nor has explained how his allegations would withstand the scrutiny required by Federal Rule of Civil Procedure 9(b). In any event (and aside from the fact that, as Defendant sets forth, this motion is a totally inappropriate vehicle for the relief requested), allowing Mr. Keeler to use documents obtained in discovery to overcome pleading hurdles would circumvent the purpose of Rule 9(b). *See, e.g., United States ex rel. Karvelas v. Melrose-Wakefield Hosp.,* 360 F.3d 220, 229, 231 (1st Cir.2004) ("[A] qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery."). Indeed, in *United States ex. rel. Clausen v. Laboratory Corp. of Am., Inc.,* 290 F.3d 1301 (11th Cir. 2002), the Eleventh Circuit warned of a situation where "a plaintiff does not specifically plead

the minimum elements of their allegation, [and is able] to learn the complaint's bare essentials through discovery and may needlessly harm a defendants' goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are baseless allegations used to extract settlements." *Id.* at 1313 n.24 (citation omitted).

Accordingly, it is hereby **ORDERED AND ADJUDGED** that Relator's Motion (DE 236) is **DENIED**. Although Relator suggests that he may seek to re-file the motion, he is warned that having dismissed this action and denied reconsideration, the proper avenue for challenging the Court's rulings is an appeal. (*See* DE 256, at 1 ("[T]he Court will need to see and evaluate Relator's additional allegations and/or evidence in order to determine if it is proper to vacate or modify its Order.") Any further filings in this action may result in the imposition of sanctions.

DONE AND ORDERED in chambers in Miami, Florida, this 1st day of April, 2013.

KATHLEEN M. WILLIAMS
UNITED STATES DISTRICT JUDGE