UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

DWAYNE THORNTON,

Plaintiff,

v. Case No: 8:15-cv-2647-T-36JSS

NATIONAL COMPOUNDING COMPANY, INC., FORT MYERS BEACH PHARMACY HOLDINGS, LLC, FORT MYERS BEACH PHARMACY, LLC, SOOTHE ENTERPRISES, LLC, SOOTHE PHARMACY, INC., SOOTHE COMPOUNDING PHARMACY, SOOTHE PERSONALIZED RX, SOOTHE NUTRITION AND SUPPLEMENTS, SOOTHE PHARMACY, SOOTHE PERSONALIZED HEALTH & NUTRITION, FRANK DESTEFANO, BRAD LONG, C.V. MCDOWELL MEDICAL, INC., ROBUSTO ENTERPRISES, LLC, EDUARDO LOPEZ, SOOTHE PERSONALIZED NUTRITION, LLC, C.V. MCDOWELL, LLC, MCDOWELL COMPANIES, INC., JACK L. STAPLETON, JACK H. STAPLETON, GREAT WHITE SHARK OPPORTUNITY FUND, L.P. and GREAT WHITE SHARK OPPORTUNITY FUND MANAGEMENT, LLC,

Defendants.
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ORDER

This matter comes before the Court on Defendants Robusto Enterprises, LLC, Eduardo Lopez, Great White Shark Opportunity Fund, L.P., and Great White Shark Opportunity Management Fund, LLC's Motion to Dismiss and Incorporated Memorandum ("Shark Defendants' Motion to Dismiss") (Doc. 108), C.V. McDowell Entities' Motion to Dismiss and

Incorporated Memorandum of Law ("C.V. McDowell Entities' Motion to Dismiss") (Doc. 110), Defendants Jack L. Stapleton and Jack H. Stapleton's Motion to Dismiss and Incorporated Memorandum of Law ("Stapleton Defendants' Motion to Dismiss") (Doc. 112), Defendant Brad Long's Motion to Dismiss and Incorporated Memorandum of Law (Doc. 127),[1] Plaintiff-Relator's Consolidated Opposition Brief in Response to All Defendants' Motions to Dismiss (Doc. 135), and Plaintiff United States' Consolidated Response to Defendants' Motions to Dismiss Complaint in Partial Intervention (Doc. 136). This action was filed as a *qui tam* suit by Relator Dwayne Thornton, who alleges that Defendants violated the False Claims Act, 31 U.S.C. §§ 3729, *et seq*. ("FCA") by engaging in a scheme for impermissible kickbacks in obtaining and filling prescriptions for compound pharmaceuticals whose cost was reimbursed by government healthcare programs. Doc. 75. The Relator alleged four counts under the FCA. The United States filed a Complaint in Partial Intervention, in which it named only some Defendants, alleged one count for violation of the FCA, and alleged two common law counts, including one for unjust enrichment and a second for payment by mistake. Doc. 104.

Defendants move to dismiss the claims in Relator's Second Amended Complaint that survived the Government's intervention, as well as the claims raised by the Government in its Complaint in Partial Intervention. Docs. 110, 112, 135. A hearing was held on the motions on May 31, 2019. The Court, having considered the motions and being fully advised in the premises

[1] This Motion to Dismiss was originally filed by Defendants National Compounding Company, Inc.; Fort Myers Beach Pharmacy Holdings, LLC; Fort Myers Beach Pharmacy, LLC; Soothe Enterprises, LLC; Soothe Personalized Nutrition, Inc.; Soothe Pharmacy, Inc.; Soothe Compounding Pharmacy; Soothe Personalized Rx; Soothe Nutrition and Supplements; Soothe Pharmacy; Soothe Personalized Health and Nutrition; Frank Destefano; and Brad Long. Doc. 127. With the exception of Long, these Defendants moved to withdraw their Motion to Dismiss. Doc. 155. Their motion to withdraw was granted, making Long the only remaining Defendant with respect to this Motion to Dismiss. Doc. 161.

will grant the Shark Defendants' Motion to Dismiss, grant-in-part and deny-in-part the C.V. McDowell Entities' Motion to Dismiss, and grant-in-part and deny-in-part the Stapleton Defendants' Motion to dismiss.

I. BACKGROUND[2]

A. The Schemes Alleged in Relator's Second Amended Complaint

Plaintiff alleges that the twenty-two Defendants knowingly submitted, or caused to be submitted claims to Medicare, Tricare, and other government programs to pay for compound pharmaceutical products, which were false because the claims were for prescriptions generated through kickbacks and illegal marketing practices, many of which were not wanted by the patients or medically necessary. Doc. 75. As part of this scheme, Relator alleges violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (1990).

The Relator served as the Vice President of Pharmacy Operations, and as Director of Operations/Pharmacy Services for Defendants Soothe Pharmacy, Inc., and other Defendants that used the name "Soothe", including National Compounding Company, Inc.; Soothe Compounding Pharmacy; Soothe Enterprises, LLC; Soothe Personalized Nutrition, LLC; Soothe Nutrition and Supplements; Fort Myers Beach Pharmacy, LLC; Soothe Personalized Health & Nutrition; Soothe Pharmacy; Fort Myers Beach Pharmacy Holdings, LLC; and Soothe Personalized Rx (the "Soothe Entities" or "Soothe Defendants")[3]. *Id.* ¶¶ 6, 13-20. Relator's tenure with the companies lasted

[2] The following statement of facts is derived from the Relator's Second Amended Complaint (Doc. 75), and The United States of America's Complaint in Partial Intervention (Doc. 104), the allegations of which the Court must accept as true in ruling on the instant Motions to Dismiss. *Linder v. Portocarrero*, 963 F.2d 332, 334 (11th Cir. 1992); *Quality Foods de Centro Am., S.A. v. Latin Am. Agribusiness Dev. Corp. S.A.*, 711 F.2d 989, 994 (11th Cir. 1983).

[3] Certain of these Defendants are simply fictitious names for other Soothe Entities.

from June 2014 until April 2015 and during most of that time, Relator reported to Defendant Brad Long. *Id.* ¶ 6. Relator classifies the "Soothe Defendants" and Long as the "pharmacy defendants."

Defendants C.V. McDowell Medical, Inc.; C.V. McDowell, LLC; and McDowell Companies, Inc. (the "McDowell Defendants") are companies that generate prescriptions for compound pharmaceutical products, which they then sell on a commission basis to pharmacies to fill orders. *Id.* ¶¶ 25-27. Defendant Jack L. Stapleton is the registered agent, owner, and managing member of C.V. McDowell Medical, Inc., is the managing member of C.V. McDowell, LLC, and is the registered agent and officer/director of McDowell Companies, Inc. *Id.* ¶ 28. Defendant Jack H. Stapleton is an authorized member of C.V. McDowell, LLC. *Id.* ¶ 29.

Defendant Robusto Enterprises, LLC ("Robusto") also generates prescriptions for compound pharmaceutical products, which it sells on a commission basis to pharmacies to fill orders. *Id.* ¶ 31. Robusto is managed by David Chessler (who is not a party to this case), who also manages Defendants Great White Shark Opportunity Fund Management, L.P, and Great White Shark Opportunity Fund Management, LLC (the "Great White Defendants"), which are also companies that generate prescriptions for compound pharmaceutical products that are sold on a commission basis to pharmacies to fill orders. *Id.* ¶¶ 31-33. Defendant Eduardo "Eddie" Lopez is also a manager of Robusto, and held himself out as a representative of the "Great White Shark Opportunity Fund" when communicating with the Soothe Defendants and working to generate prescriptions for compound pharmaceutical products which were sold on a commission basis to pharmacies to fill orders. *Id.* ¶ 34. Relator classifies the McDowell Defendants, the Stapletons, Robusto, the Great White Defendants, and Lopez as the "representative groups."

Relator alleges that the representative groups work on commission and obtain a percentage of any prescription order for compound pharmaceutical products, which may be worth thousands

of dollars. *Id.* ¶¶ 43, 45. Relator explains that the Anti-Kickback Statute prevents the representative groups from providing business to pharmacies through a commission structure, but that representative groups and the pharmacy defendants are doing so in violation of the Anti-Kickback Statute. *Id.* ¶ 55. Relator alleges that the representative groups would obtain prescriptions through several marketing efforts, including through call lists of people known to suffer from painful conditions, and seek to obtain such individuals' consent to obtain a prescription from a doctor for various medications. *Id.* ¶¶ 47-48.

Additionally, the representative groups would advertise these medications as being free of charge, despite the fact that a co-payment is required, and threaten to discontinue providing prescriptions to any pharmacy that attempted to collect co-payments. *Id.* ¶¶ 50-51, 54, 77-78. The pharmacies, therefore, would refill prescriptions even if patients did not make co-payments. *Id.* ¶ 79. Relator alleges that the knowing failure to collect a co-payment is an improper inducement to the patient to purchase the product. *Id.* ¶ 80.

Relator further alleges that the representative groups are violating the FCA and Anti-Kickback Statute by having doctor's offices fax prescriptions to the representative groups, who then would forward the prescription to pharmacies in order to ensure the representative groups obtained a share of the value of the prescription. *Id.* ¶ 57. The pharmacy defendants would then fill the prescriptions en masse. *Id.* ¶ 64. Additionally, pharmacies would transfer prescriptions from one pharmacy to another in exchange for a fee or percentage of the bill to a government program. *Id.* ¶ 72. Relator alleges that the representative groups and pharmacies would generate and fill prescriptions without medical necessity or documentation of medical necessity. *Id.* The Relator alleges that this scheme involves receiving or offering remuneration in violation of the Anti-Kickback Statute. *Id.* ¶¶ 73-74.

Relator also alleges that the representative groups do not obtain separate documentation for re-fills being requested or authorized. *Id.* ¶ 95. He alleges that the Robusto Enterprises Defendants would use a form with a box for refills that could be checked by anyone, making it impossible to be sure that the box was checked by an appropriate provider. *Id.* ¶ 96. Additionally, Relator alleges that the pharmacy defendants and representative groups did not bother to determine whether patients actually needed the medicine and did not require additional documentation to be sure patients needed refills. *Id.* ¶ 103. Through this scheme, the representative groups worked with the pharmacy defendants to maximize revenue as part of a fraudulent scheme to knowingly submit or cause to be submitted false claims to the United States. *Id.* ¶ 105.

Relator contends that he analyzed the Soothe Defendants' billing over a period of a year, and found that Flurbiprofen and Fluticasone were used as ingredients to drive up the costs of compounds with no medical reason. *Id.* at 118-20. Creams using these ingredients are expensive and billed to the patients' insurance, and most of the claims were paid for by TRICARE, a government healthcare program. *Id.* ¶¶ 127-28. When Relator raised this issue during his tenure with the Soothe Defendants, "he was told that if the doctor signs the prescription and it isn't hurting anyone, the government will not find out what happened." *Id.* ¶ 129. Indeed, Relator alleges that the amount of Fluticasone being used in prescriptions was unsafe and above recommended levels, but Defendant Brad Long contended that it was safe and effective. *Id.* ¶¶ 130-131. Relator attempted to have the Soothe Defendants lower the amount of Fluticasone in some formulas, but this alienated representative groups, and Brad Long "was able to get Soothe to continue to use Fluticasone in amounts that exceeded the manufacturers recommendations." *Id.* ¶ 132.

Relator included a "representative chart" in the Second Amended Complaint that shows examples of false claims submitted to the government through billing of prescriptions generated

by representative groups to TRICARE. *Id.* ¶¶ 135-36. The chart shows: (1) the representative group that generated the prescription; (2) the date the prescription was dispensed and billed to TRICARE; (3) the alias of the patient prescribed; (4) the quantity of the drug prescribed; (5) the drug prescribed; (6) the total amount billed to TRICARE; (7) the cost for the prescription; and (8) the percent of profit from the prescription. *Id.* Although in explaining the chart, Relator indicates that the amounts were billed to TRICARE, Relator then states that the representative groups "knowingly caused to be submitted the representative examples of false claims to TRICARE or other Government insurance programs, and they also knowingly caused to be submitted other similar false claims to TRICARE or other Government insurance programs through Soothe and other pharmacies." *Id.* ¶ 137.

Relator indicates that he tried to reform the practices while he was employed by the Soothe Defendants. *Id.* ¶ 141. For example, Relator showed Defendants Long and DeStefano examples of fraud and false claims, many of which involved patient complaints. *Id.* ¶ 143. One such complaint was demonstrated in e-mails between C.V. McDowell and Long, in which there was a discussion of patient complaints about not wanting, needing, or requesting the medications. *Id.* ¶ 144. Another patient complained on September 26, 2014, that C.V. McDowell would not stop calling her about a prescription refill that she did not want for a wound she did not have. *Id.* ¶ 145. Relator e-mailed C.V. McDowell (including Defendant Jack L. Stapleton) regarding wrongful prescriptions, and Stapleton responded to Relator that due to internal changes, increased restrictions, and filters implemented for Soothe, Relator would see a decline in such complaints. *Id.* ¶ 148. Relator continued to receive complaints, including that a complaint that the physician had not actually signed a prescription. *Id.* ¶ 149.

Relator also details a patient study that C.V. McDowell wanted Soothe to participate in that would generate many prescriptions and for which patients would have free or low cost co-pays. *Id.* ¶ 153. The Soothe Defendants declined to participate in the study because they were at risk of losing a major contract because patients were contacting their insurance companies (the Second Amended Complaint does not indicate what patients said to their insurance companies). *Id.* ¶ 155. Relator spoke with the Stapleton Defendants and C.V. McDowell on a phone call and advised them that their practices were illegal, and one of the Stapleton Defendants indicated that any violations were not serious. *Id.* ¶ 156.

The Relator's Second Amended Complaint contains four counts based on these alleged facts. Count I alleges violations of 31 U.S.C. § 3729(a)(1)(A) for submitting and/or causing the submission of False Claims to the United States. *Id.* ¶¶ 166-176. In Count I, Relator alleges that Defendants submitted false claims, or caused them to be submitted, by illegally transferring prescriptions en masse in exchange for a percentage of the transferred prescription, waiver, reduction, or arrangement for reduction of co-payments owed by patients, which violated the Anti-Kickback Statute and government regulations. *Id.* ¶ 169. Relator alleges that Defendants misrepresented to physicians the need for the prescriptions, and misrepresented to patients the co-payment obligations. *Id.* ¶ 171. As part of this scheme, Defendants routinely used pre-printed prescription pads to further their goals, which included using them to create automatic refills of prescriptions. *Id.* ¶ 172. Defendants also promoted specific prescriptions solely to increase the cost of those prescriptions. *Id.* Relator also alleges that the Defendants who generated prescriptions (the Representative Groups) routinely obtained commissions for prescriptions that they arranged to be filled, creating an illegal kickback scheme. *Id.* ¶ 170. The McDowell Defendants, Robusto, and Great White Defendants also sent prescriptions to doctors' offices,

which were then returned to these Defendants, who then sent them to the pharmacies to fill. *Id.* ¶ 173. The purpose of this procedure was to ensure these Defendants obtained commissions on the sale as part of their kickback arrangements that caused the submission of false claims to the Government by the Soothe Defendants and other pharmacies. *Id.* Additionally, Relator alleges that the Soothe Defendants did not maintain efforts to ensure a prescribing doctor comported with the laws of the state in which the prescription was filled, despite acting as a national provider of these pharmaceuticals. *Id.* ¶ 174.

Count II alleges violations of 31 U.S.C. § 3729(a)(1)(B) for using false statements. *Id.* ¶¶ 177-181. In Count II, Relator contends that to further their activities, Defendants created false records in the form of prescriptions material to supporting their false claims. *Id.* ¶¶ 178-79. Count III alleges violations of 31 U.S.C. § 3729(a)(1)(C) for conspiring to submit false claims. *Id.* ¶¶ 182-85. Finally, Count IV alleges a reverse FCA claim under 31 U.S.C. § 3729(a)(1)(G). *Id.* ¶¶ 186-92.

C. The United States' Complaint in Partial Intervention

The United States filed a Complaint in Partial Intervention against Defendants Brad Long; Frank DeStefano; CV McDowell, LLC; J&J Tel Marketing, LLC; Jack L. Stapleton; and Jack H. Stapleton ("Government's Complaint"). Doc. 104. Either Long, DeStefano, or both are officers or owners of the various Soothe Defendants. Doc. 75 ¶¶ 13-22. The United States has since settled its claims against Frank DeStefano.[4] Doc. 154. Under the FCA, once the Government intervenes, the relator has "the right to continue as a party to the action," subject to certain limitations, but the Government has "the primary responsibility for prosecuting the action . . . ." 31 U.S.C. §

[4] The Relator's claims against DeStefano that have not been superseded remain pending. Doc. 154.

3730(c)(1). Accordingly, the Relator's claims are superseded by the Government's Complaint to the extent that it intervened, and Relator's Second Amended Complaint survives only with respect to non-intervened claims. *United States v. Pub. Warehousing Co. K.S.C.*, 242 F. Supp. 3d 1351, 1357 (N.D. Ga. 2017); *see also* Relator's Consolidated Response to the Motions to Dismiss at 4-5 ("Relator's kickback claims against the Soothe Defendants and CV McDowell Defendants that allege false claims based on those same illegal commission arrangements are superseded by the Government's Complaint.").

The Government alleges that Long and DeStefano owned and were actively involved in managing and directing the daily operations at Soothe Compounding Pharmacy ("Soothe Compounding"), and that the Stapleton Defendants were actively involved in managing and directing operations of C.V. McDowell, LLC ("McDowell LLC") and J&J Tel Marketing, LLC ("J&J"), which are affiliate companies (collectively, "McDowell Companies"). Doc. 104 ¶¶ 7-8, 10, 12-13. The Government further alleges that the McDowell Companies utilized telemarketing to market topical compounded prescription creams and other pharmaceutical products directly to patients throughout the country, including to TRICARE beneficiaries. *Id.* ¶¶ 9-10.

The Government alleges a scheme under which Soothe Compounding entered into agreements with independent third-party marketers who were paid kickbacks to generate compounded drug prescriptions, which they were to arrange to be referred to Soothe, which would seek payment from the patient's insurance, including TRICARE. *Id.* ¶ 34. The marketers included McDowell LLC. *Id.* Long and DeStefano negotiated the agreements and oversaw the relationships. *Id.*

In March 2014, Soothe Compounding entered into an Independent Contractor Agreement ("Agreement") with McDowell LLC. *Id.* ¶ 35. Long, DeStefano, and the Stapleton Defendants

were involved in negotiating the arrangement. *Id.* ¶ 36. In the Agreement, the parties agreed to split revenue from prescriptions that McDowell LLC solicited and referred to Soothe Compounding. *Id.* ¶ 35. Specifically, Soothe Compounding would pay McDowell LLC fifty percent of the gross sales amount of all Soothe Compounding products ordered, purchased, and prescribed by physicians. *Id.*

Long and DeStefano also both negotiated other agreements. Among those agreements was a commission agreement between Soothe Enterprises, LLC, an entity related to Soothe Compounding, and Robusto Enterprises, under which Robusto Enterprises would receive seventy-five percent of the amount collected on claims attributed to Robusto Enterprises. *Id.* ¶ 37. Long and DeStefano also obtained an agreement between Soothe Compounding and the owner of another entity, Top Tier Medical, in which Soothe Compounding agreed to split all revenue from prescriptions that the owner was responsible for bringing to Soothe. *Id.* ¶ 39. The agreements with these entities explicitly indicated that their relationship to Soothe Compounding was as independent contractors, and no employment relationship existed. *Id.* ¶ 43

In essence, the marketing agreements were arrangements under which Long and DeStefano agreed to pay third parties for the referral of prescriptions to Soothe Compounding. *Id.* ¶¶ 44-45. For example, a Robusto Enterprises principal e-mailed Long and DeStefano on June 13, 2014, when the agreement was being drafted, stating "[o]our intentions are to start flowing business your way starting this Monday." *Id.* ¶ 45. Another Robusto Enterprises principal e-mailed Long and DeStefano about a person he believed could bring in 200-250 prescriptions in July, which Long stated "sound[ed] good." *Id.*

Various communications indicated marketers shifted business they generated to and from Soothe. *Id.* ¶ 48. An e-mail from Soothe Compounding to McDowell LLC indicated that various

migraine prescriptions could not be filled because the strength of a certain ingredient was absent from the prescriptions, and Jack H. Stapleton advised Soothe Compounding to disregard migraine patients sent to Soothe from McDowell LLC because they would be processed by another pharmacy. *Id.* The Government contends this is demonstrative of the role that marketers played in determining where prescriptions were referred, and also show that the marketers were third-party referral sources, and not employees of Soothe Compounding. *Id.* ¶ 49.

The Government alleges that the marketing companies would seek to obtain and refer prescriptions that would generate a high payment to the pharmacy and, therefore, a larger kickback for the marketer, regardless of whether a specific formulation was medically necessary. *Id.* ¶ 51. For example, DeStefano, on behalf of one of the Stapleton Defendants, asked Soothe Compounding employees about a formulation for a supplement compound, and the employees responded to DeStefano, Long, and Stapleton that they analyzed the formula and that they found one ingredient at the highest average wholesale price. *Id.* ¶ 52. Additionally, DeStefano wrote to Soothe employees that one of the Stapleton Defendants indicated an interest in expanding into wound and scar formulas, noted that wounds could be challenging for adjudications, and asked the employees to help the Stapleton Defendant out as much as they could in researching formulas. *Id.* ¶ 53. Long followed up on the e-mail by asking what formula would be recommended, and asking for information regarding the cost, average wholesale price, and adjudicated amount. *Id.* Along these lines, a couple weeks later, Jack H. Stapleton asked a Soothe Compounding official which wound creams had the highest payout, and the Soothe official provided information on the highest average wholesale price payout for all of their formulations. *Id.* ¶ 54.

Jack H. Stapleton also contacted Soothe Compounding officials regarding a migraine formula that McDowell LLC learned had a higher payout. *Id.* ¶ 55. Jack H. Stapleton asked for

Soothe Compounding's approval of the formula so that McDowell LLC could send Soothe Compounding migraine prescriptions with that formula. *Id.* Soothe Compounding responded that the formula was approved, but that one change would decrease reimbursement by a dollar or so. *Id.* Jack H. Stapleton also contacted Soothe Compounding to inquire whether a general wellness/metabolic formulation used by another client would have a higher average wholesale price than the one provided by Soothe Compounding. *Id.* ¶ 56.

Likewise, Lopez of Robusto Enterprises e-mailed Long, DeStefano, and another Soothe Compounding official a copy of a prescription pad that reflected a prescription formula, and asked their thoughts on the formulations and how they would be reimbursed. *Id.* ¶ 57. Lopez specifically asked how much pain and scar prescriptions "would come back at for a TriCare 240gm." *Id.*

Another method of increasing revenue was to generate multiple prescriptions per patient. *Id.* ¶ 59. McDowell LLC instructed its telemarketing sales agents to ask prospective patients about their interest in topical creams for a number of different common ailments, such as scarring, dry itchy skin, pain, and severe headaches. *Id.* ¶ 60. Similarly, Lopez e-mailed Long and DeStefano that maximizing overall reimbursement per patient would hopefully result in higher per patient revenue with little to no difference in the time it would take to bill. *Id.* ¶ 61.

The kickback schemes routinely resulted in the referral of unwanted or unnecessary prescriptions for compound drugs. *Id.* ¶ 62. Patients referred by McDowell LLC frequently contacted the pharmacy to complain that they did not want or need the medications they had been sent by Soothe Compounding. *Id.* Long and DeStefano were aware of these complaints, but benefitted from the profits Soothe Compounding made from the kickback schemes. *Id.*

The Government further alleges that Soothe Compounding submitted claims for TRICARE reimbursement for the prescriptions for compound drugs referred from McDowell LLC to Soothe

Compounding. *Id.* ¶ 64. The Government provided several sample claims (using aliases for the patients) submitted by Soothe Compounding to TRICARE for prescriptions referred to Soothe by McDowell LLC, and for which McDowell LLC received a kickback:

1. Patient A was a patient referred to Sooth by CV McDowell. Soothe filled prescription 114924 for a compounded medication for Patient A on or about June 20, 2014 and submitted a claim to TRICARE. TRICARE paid Soothe $5,552.88 for the prescription.

2. Patient B was a patient referred to Soothe by CV McDowell. Soothe filled prescription 116331 for a compounded medication for Patient B on or about June 25, 2014 and submitted a claim to TRICARE. TRICARE paid Soothe $9,001.33 for the prescription.

3. On July 2, 2014, Soothe sent a report to CV McDowell detailing prescriptions for which CV McDowell was credited that were filled between June 15, 2014 and July 1, 2014. That report included prescription 114924 for Patient A, totaling $5,552.88, and prescription 116331 for Patient B, totaling $9,001.33. Soothe reported that prescriptions credited to CV McDowell during this period (including the prescriptions for Patient A and Patient B) had generated a total of $384,026.65. On or about that same day, consistent with Soothe's agreement with CV McDowell, Soothe paid CV McDowell 50% of that amount: $192,013.

4. Patient C was a patient referred to Soothe by CV McDowell. Soothe filled prescription 131979 for a compounded medication for Patient C on or about October 1, 2014 and submitted a claim to TRICARE. TRICARE paid Soothe $9,892.64 for the prescription. On October 15, 2014, Soothe emailed a report to CV McDowell (copying both Long and DeStefano) detailing prescriptions for which CV McDowell was credited that were filled between October 1, 2014 and October 14, 2014. That report included prescription 131979 for Patient C, totaling $9,892.64. Soothe reported that prescriptions credited to CV McDowell during this period (including the prescription for Patient C) had generated a total of $581,628.59. On or about October 16, 2014, consistent with Soothe's agreement with CV McDowell, Soothe paid CV McDowell (through a CV McDowell affiliate called CCV Enterprises LLC) 50% of that amount: $290,814.

Id. ¶ 66. The Government also provided a chart of payments totaling more than $4.4 million made by Soothe Compounding to McDowell LLC. *Id.* ¶ 67. The chart includes the date of the payments and the amount of the payments. *Id.* The Government's Complaint also provides representative

patients and a chart of payouts from Soothe Compounding to Robusto Enterprises and to Top Tier Medical, which included claims submitted by Soothe Compounding to TRICARE. *Id.* ¶¶ 68-75.

The Government's Complaint further alleges that McDowell LLC had similar kickback schemes with other pharmacies, including World Health Industries Holding Company, Inc. and Opus Rx, LLC. *Id.* ¶¶ 77-82. With respect to Opus Rx, LLC, the Government alleges that an agreement also existed between that pharmacy and J&J. *Id.* ¶ 80. The Government includes in its allegations various terms of the agreements with these pharmacies, as well as prescriptions filled for specific TRICARE beneficiaries and the amount TRICARE paid for the prescriptions, which McDowell LLC or J&J were credited with obtaining for the pharmacies. *Id.* ¶¶ 77-79, 82.

Additionally, the Government provided allegations regarding McDowell LLC's practices. Specifically, the Government alleges that McDowell LLC's training materials instructed sales agents to "sell the patient on the Topical Creams" and not to "give up" during sales calls. *Id.* ¶ 83. On these calls, the sales agents would obtain information about patients' insurance and their primary care physicians. *Id.* ¶ 84. McDowell LLC would then seek to arrange for the patients' doctors to authorize prescriptions for these products which the patients purportedly agreed to accept. *Id.* ¶ 85. The prescriptions were then directed back to McDowell LLC, which would determine to which pharmacy it would send the prescription. *Id.* This method allowed McDowell LLC to direct prescriptions to pharmacies that agreed to pay kickbacks to McDowell LLC. *Id.*

The Government alleges that McDowell LLC would also use "telemedicine" providers, who would consult with and prescribe compound medications for patients McDowell LLC solicited. *Id.* ¶ 86. The "telemedicine" providers did not have a relationship with the patients and did not physically examine them. *Id.* The providers would return the prescriptions to McDowell

LLC, or send them to a pharmacy chosen by McDowell LLC, which ensured McDowell LLC would receive a kickback. *Id.*

These tactics by McDowell LLC resulted in the referral of unwanted prescriptions and the pharmacies that filled the prescriptions frequently received complaints from the patients that they did not want or need the medications, or that they were advised when they agreed to accept the medications that they would not have to pay anything. *Id.* ¶ 87.

McDowell LLC was advised of these complaints. *Id.* ¶¶ 88-93. For example, a pharmacy with which McDowell LLC had a kickback arrangement advised the Stapleton Defendants on April 11, 2014, that almost every patient for whom they filled prescriptions called back stating that they did not know what the prescription was or that they did not have issues related to the prescription. *Id.* ¶ 88. Similarly, Soothe Compounding contacted McDowell LLC on July 15, 2014, stating that a patient claimed he had no wound or need for the product. *Id.* ¶ 89. The Government provides various other specific examples of complaints being communicated to McDowell LLC and contends that the complaints show that patients were misled or coaxed into accepting medications that they did not want or need. *Id.* ¶¶ 90-93.

The Government alleges that Long and DeStefano were aware of the restrictions of the Anti-Kickback Statute, because they received training in it at previous jobs, and because a representative of Professional Compounding Centers of America ("PCCA") warned them that a pharmacy's production-based payments to non-employee marketers would violate the Anti-Kickback Statute if those marketers generated business for federal health care program beneficiaries. *Id.* ¶ 98. In fact, the PCCA representative e-mailed Long a document on April 17, 2013, discussing the Anti-Kickback Statute's restrictions on pharmacies paying commissions, bonuses, and other production-based compensation to an independent contractor to market or

generate Medicare business. *Id.* ¶ 99. The same document was subsequently provided to Long by an acquaintance of his with the subject line "FYI: article about paying 1099 employees." *Id.* ¶ 101.

The Government also alleges that McDowell LLC and J&J were aware of the prohibitions under the Anti-Kickback Statute. *Id.* ¶ 103. Specifically, the Government relies on certain marketing agreements signed by Jack L. Stapleton which state that McDowell LLC and J&J would provide services in compliance with the federal anti-kickback laws, specifically 42 U.S.C. § 1320a-7b, and would not pay remuneration to any person or entity in return for referrals or the writing of prescriptions. *Id.* ¶ 103. Additionally, on March 13, 2014, the chief executive officer of a compounding pharmacy to which McDowell LLC had been sending prescriptions sent a letter to Jack L. Stapleton regarding the termination of the pharmacy's marketing agreement with McDowell LLC. *Id.* ¶ 105. The pharmacy indicated that McDowell LLC failed to comply with applicable federal and state regulations as required by the agreement, that a large portion of the prescriptions referred by McDowell LLC were problematic and troubling, and that many patients and providers indicated that the prescriptions referred were never authorized. *Id.* The chief executive officer rejected McDowell's claim of entitlement to continuing revenue compensation, stating that this was prohibited by anti-kickback laws. *Id.* Similarly, another pharmacy notified McDowell LLC on January 30, 2015, that it was modifying marketing agreements to ensure compliance with federal and state anti-kickback statutes and regulations. *Id.* ¶ 106.

The Government's Complaint contains three causes of action. Count I is against all Defendants named in the Government's Complaint and alleges violation of section 31 U.S.C. § 3729(a)(1)(A). Doc. 104 ¶¶ 111-113. The Government alleges that Defendants knowingly caused to be made or presented claims for payment for compounded drugs for TRICARE patients that

were tainted by illegal kickback arrangements in violation of the FCA. *Id.* ¶ 112. Count II is against all Defendants and alleges a common law equitable cause of action to recover money paid by mistake by TRICARE for compounded drugs that were tainted by the kickback arrangements of which Defendants were a part. *Id.* ¶¶ 114-16. Count III is also against all Defendants and alleges a common law claim for unjust enrichment, based on the contention that Defendants were unjustly enriched at the expense of the United States by virtue of their kickback scheme. *Id.* ¶¶ 117-19.

II. LEGAL STANDARD

To survive a motion to dismiss, a pleading must include a "short and plain statement showing that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009) (quoting Fed. R. Civ. P. 8(a)(2)). Labels, conclusions and formulaic recitations of the elements of a cause of action are not sufficient. *Id.* at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Mere naked assertions, too, are not sufficient. *Id.* A complaint must contain sufficient factual matter, which, if accepted as true, would "state a claim to relief that is plausible on its face." *Id.* (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citation omitted). The court, however, is not bound to accept as true a legal conclusion stated as a "factual allegation" in the complaint. *Id.* Therefore, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* (citation omitted).

In addition to satisfying the general pleading requirements articulated in *Twombly* and *Iqbal*, an FCA complaint must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b), which places more stringent pleading requirements on cases alleging fraud. *United States ex rel.*

Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301 (11th Cir. 2002). "[U]nder Rule 9(b) allegations of fraud must include facts as to time, place, and substance of the defendant's alleged fraud." *Id.* at 1308 (citation and internal quotations omitted). The Rule 9(b) particularity requirement for fraud allegations exists to put defendants on notice as to the exact misconduct with which they are charged and to protect defendants against spurious charges. *Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001). The failure to satisfy Rule 9(b)'s pleading requirements amounts to a failure to state a claim under Rule 12(b)(6) and requires dismissal of the complaint. *See, e.g.*, *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005).

III. DISCUSSION

A. The False Claims Act

The FCA was enacted to recover money fraudulently taken from the government. *United States ex rel. Butler v. Magellan Health Servs., Inc.*, 74 F. Supp. 2d 1201, 1204 (M.D. Fla. 1999) (citing *United States ex rel. Marcus v. Hess*, 37 U.S. 537, 551 (1943)). The Act allows a private party to bring a civil action (known as *qui tam*) alleging fraud upon the government, and that party may share in the proceeds should he or she prevail. *Id.* at 1205-06. The *qui tam* action may be brought against 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;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); [or]
>
> * * *
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the

> Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

31 U.S.C. § 3729(a)(1) (2009). "Knowing" and "knowingly" "mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). Under the FCA, the term claim:

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
>
> > (i) is presented to an officer, employee, or agent of the United States; or
> >
> > (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
> >
> > > (I) provides or has provided any portion of the money or property requested or demanded; or
> > >
> > > (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and
>
> (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.

Id. at 3729(b)(2)(A).

Additionally, under the FCA, material "means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at 3729(b)(4); *see also Universal Health Care Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). "The materiality standard is demanding" and materiality "cannot be found where noncompliance is minor or insubstantial." *Universal Health*, 136 S. Ct. at 2003. For example, the

failure to comply with an express provision that is a condition of payment is relevant, but not dispositive; "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" could also be proof of materiality, but is not dispositive; and government payment of particular claims in full despite actual knowledge that certain requirements were violated is strong evidence that such requirements are not material. *Id.*

B. The Anti-Kickback Statute

The Anti-Kickback Statute "makes it a felony to offer, solicit, pay or receive any remuneration—or "kickback"—'for referring 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.' " *United States v. LifePath Hospice, Inc.*, No. 8:10-cv-1061-T-30TGW, 2016 WL 5239863, at *5 (M.D. Fla. Sept. 22, 2016) (quoting 42 U.S.C. § 1320a-7b(b)(1)). There are four elements that must be met for a defendant's conduct to meet the statute's four elements: "(1) knowingly and willfully; (2) paying something of value, directly or indirectly; (3) to induce the referral of individuals to the defendant for furnishing of services; (4) paid for by a Federal health care program." *Id.* (citing *United States v. Vernon*, 723 F.3d 1234, 1252 (11th Cir. 2013)).

C. TRICARE

TRICARE is a federal health care program, as defined by the Anti-Kickback Statute, that covers compounded drugs that are medically necessary and proven to be safe and effective. 32 C.F.R. § 199.4(g)(15) (2017). During the relevant time period, TRICARE reimbursed pharmacies for the ingredients in compound drugs. Doc. 104 ¶ 24. A pharmacy seeking reimbursement from TRICARE for the ingredients in a compound drug must comply with TRICARE's anti-fraud and

abuse provisions. *Id.* § 199.9(a)(4). Additionally, such a pharmacy must enter into a Provider Agreement with ESI, the TRICARE pharmacy benefits manager. Doc. 104 ¶ 28.

The Code of Federal Regulations provides examples of fraud, which include commission and kickback arrangements with independent contractors. *Id.* § 199.9(c)(12). Additionally, under ESI's Provider Agreements, which incorporate ESI's Provider Manuals, pharmacies must be aware of and comply with all state and federal law, including anti-kickback statutes. Doc. 104 ¶ 29. If a pharmacy commits fraud or abuse, that pharmacy may be excluded or suspended from participation in TRICARE. *Id.* §§ 199.9(b), (f).

The Government alleges that compliance with the Anti-Kickback Statute is a condition of payment by TRICARE, and that a pharmacy must not offer or pay anything of value to third parties in exchange for referring, recommending, or arranging for the referral of TRICARE patients for prescriptions to be filled by the pharmacy and reimbursed by TRICARE. Doc. 104 ¶ 30. The Government further alleges that the Defense Health Agency ("DHA") has exercised its authority to suspend providers under investigation for fraud and abuse, including the payment of kickbacks. *Id.* ¶ 31. Finally, the Government alleges that each compounded drug claim submitted by a pharmacy for reimbursement from TRICARE generally includes specific representations about the date of service, the patient on whose behalf payment is being sought, the provider who prescribed the medication, and the individual ingredients contained in the compounded drug. *Id.* ¶ 32.

D. Arguments for Dismissal of Relator's Claims

1. Shotgun Pleading

The Second Amended Complaint impermissibly lumps all Defendants together in the counts, and reincorporates each preceding count into each subsequent count. *See generally* Doc. 75. This makes the Second Amended Complaint an impermissible shotgun pleading. *Weiland v.*

Palm Beach Cty. Sheriff's Office, 792 F.3d 1313, 1321-22 (11th Cir. 2015) (stating that a complaint is a shotgun pleading where multiple claims are asserted against multiple defendants). For this reason alone, the court may require Relator to submit a more definite statement. *Anderson v. Dist. Bd. of Trs. Of Cent. Fla. Cmty. Coll.*, 77 F.3d 364, 367 n.3 (11th Cir. 1996).

It is impossible to discern from the Second Amended Complaint which actions are attributable to which Defendant. For example, Relator refers to the Great White Defendants in conjunction with Lopez and Robusto. Doc. 75 ¶ 35. There is no indication that these companies and this individual are the same entities, and that their actions could be attributed to each other. Moreover, it is impossible to discern from the representative chart of allegedly false claims whether the representative group who generated the prescription was one of the Great White Defendants, or Robusto, or Lopez when the representative group is listed as "ROBUSTO." This poses particular problems given the heightened pleading standard at issue in this case. Moreover, it creates substantially more work for Defendants and the Court in attempting to evaluate the Second Amended Complaint.

Accordingly, the Second Amended Complaint must be dismissed as a shotgun pleading. In the event that Relator chooses to amend the complaint and file a Third Amended Complaint, the pleading must attribute various acts to a specific Defendant. If one party's actions are attributed to another Defendant, Relator must explain why, and provide a factual basis for such attribution. Each count raised shall incorporate only the preceding factual allegations that are relevant to that specific count.

The Shark Defendants and Long contend that the Second Amended Complaint, which is Relator's third pleading, should be dismissed with prejudice against them. Doc. 108 at 24-26; Doc. 127 at 10. These Defendants argue that amendment is futile because Relator would include

more specific detail if such information was available. Doc. 108 at 25-26; Doc. 127 at 10. Defendants further contend that another amendment would allow Relator to bolster his own allegations with those in the Government's Complaint. *Id.* at 26.

Relator has not previously had the benefit of an Order by the Court prior to amending his previous pleadings. *Cf. RS Compounding*, 304 F. Supp. 3d at 1228 (denying the relator an additional opportunity to amend where she already had the benefit of a detailed order addressing the substantive issues of her claims). Amendment at this stage would not necessarily be futile. Accordingly, Relator will be granted an opportunity to amend his Second Amended Complaint.

2. Shark Defendants' Motion to Dismiss Count I—§ 3729(a)(1(B)

The Shark Defendants move to dismiss Count I because the Relator failed to plead a violation of section 3729(a)(1)(A) with specificity. Doc. 108 at 9. The Shark Defendants contend that Relator did not (1) allege the submission of claims with particularity because he provided no exact billing data and did not establish that he had sufficient knowledge of any defendant's billing practices or possess first-hand knowledge of claims being submitted; and (2) did not allege with particularity that medically unnecessary services were provided. *Id.* at 9-17.

To state a claim under 31 U.S.C. § 3729(a)(1)(A), a Relator must plead three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false. *United States v. KForce Gov't Sols., Inc.*, No. 8:13-cv-1517-T-36TBM, 2014 WL 5823460, at *7 (M.D. Fla. Nov. 10, 2014) (citing *United States ex rel. McGinnis v. OSF Healthcare Sys.*, No. 11-cv-1392, 2014 WL 2960344, at *6 (C.D. Ill. July 1, 2014)). To comply with Rule 9(b) in pleading a claim for violation of the FCA, "some indicia of reliability must be given in the complaint to support the allegation of" fraud. *Clausen*, 290 F.3d at 1311. To that end, the "plaintiff must plead

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." *Id.* at 1310 (citation omitted).

Rule 9(b)'s heightened pleading standard may be applied less stringently, however, when specific "factual information [about the fraud] is peculiarly within the defendant's knowledge or control." *Hill v. Morehouse Med. Assocs., Inc.*, No. 02-14429, 2003 WL 22019936, at *3 (11th Cir. Aug. 15, 2003) (quoting *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Blue Cross Blue Shield of Ga., Inc.*, 755 F. Supp. 1040, 1052 (S.D. Ga. 1990)). For example, the Eleventh Circuit has found that personal knowledge of the fraud obtained by being in a position to know that false claims were submitted to the government, with a factual basis for the alleged personal knowledge, is sufficient to satisfy Rule 9(b), even when certain documentary support is lacking. *United States v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005); *see also United States ex rel. Heater v. Holy Cross Hosp., Inc.*, 510 F. Supp. 2d 1027, 1036 (S.D. Fla. 2007) (stating that the Relator's personal experience with the defendant's billing process, which he obtained as an employee in the billing department, could provide the "indicia of reliability" required to survive a motion to dismiss where the documentation necessary to plead the case was peculiarly within the defendant's control). The Court has explained "that a Relator with direct, first-hand knowledge of the defendants' submission of false claims gained through her employment with the defendants may have a sufficient basis for asserting that the defendants actually submitted false claims." *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 704 (11th Cir. 2014). However, "a plaintiff-Relator without first-hand knowledge of the defendants' billing practices is unlikely to have a sufficient basis" for an allegation that a false claim was actually submitted to the government. *Id.* Thus, for example, a plaintiff who "did

not have any duties which gave her knowledge of or participation in [the] Defendants' actual submission of . . . claims or receipt of . . . payments," is unlikely to have sufficient knowledge. *United States es rel. Aquino v. Univ. of Miami*, 250 F. Supp. 1319, 1333 (S.D. Fla. 2017). "Additionally, a corporate outsider likely does not have the required access to learn enough about the defendants' billing practices." *Mastej*, 591 F. App'x at 704.

For a Relator to establish the indicia of reliability necessary based on personal knowledge, he or she "must explain the basis for her assertion that fraudulent claims were actually submitted." *Id.* It is not sufficient for the Relator to simply allege that he or she was aware of the defendants' billing practices, heard about certain billing practices in the rumor mill, or offer conjecture about the source of his or her knowledge. *Id.*

For example, in *Mastej*, the plaintiff alleged that he worked in the healthcare industry for over thirty years, holding many positions with different companies, including as a Medicare/Medicaid auditor with Michigan Blue Cross, a reimbursement specialist with Humana, and as the CEO of several hospitals and medical centers. *Id.* at 695. From 2001 to 2007, the plaintiff worked as one defendant's President of Acquisitions and Development. *Id.* In this role, the plaintiff "attended monthly operations meetings with Defendant HMA's CEO, Chief Operating Officer ("COO"), regional senior vice presidents, divisional vice presidents and corporate department heads." *Id.* Additionally, he would often attend "weekly case management meetings in which Medicare and Medicaid patients and billing were discussed." *Id.*at 595-96. Specifically, during these meetings, "every patient was reviewed, including how the services were being billed to each patient," which provided the plaintiff with familiarity with the payor mix at hospitals. *Id.* at 596.

In 2007, the plaintiff in *Mastej* began working for a subsidiary of his former employer, which was also a defendant in the action. *Id.* He worked there as the CEO for approximately eight months and his responsibilities included speaking with upper management on all aspects of management of the company, as well as negotiating physician contracts. *Id.* The plaintiff alleged that through his positions as President of Acquisitions and Development and CEO, he became "familiar with the operational aspects pertinent to the fraudulent schemes" alleged in the complaint alleging violation of the FCA, such as the services offered by the companies, the patient demand for those services, the staffing necessary to meet patient demand, the revenue generated, and the costs incurred. *Id.*

The Eleventh Circuit held that the plaintiff provided sufficient indicia of reliability for his personal knowledge of the alleged scheme, stating that "during 2007 [the plaintiff] was not a corporate outsider who only speculated that Defendants must have submitted or paid claims to the government." *Id.* at 707. The plaintiff "sufficiently articulated how he allegedly gained his direct, first-hand knowledge of Defendants' submission of false interim claims to the government and the government's payment of such claims." *Id.* Additionally, the Eleventh Circuit relied on the fact that the case turned on claims submitted to the government for referred Medicare patients, and the pertinent question was who referred the patient. *Id.* at 708. The case did not turn on the type of medical service rendered, the billing code, or what was charged for the service, so particularized medical billing or content was not as relevant as cases involving claims for reimbursement based on a false claim. *Id.*

a. Relator's Insider Status

Relator worked for the Soothe Defendants as Vice President of Pharmacy Operations and as Director of Operations/Pharmacy Services for approximately nine months. Doc. 75 ¶ 6. During

that time, he "analyzed the billing by Soothe over a period of a year." *Id.* ¶ 117. Relator also alleges that he "has direct and independent knowledge of the allegations in this disclosure," and that "[a]s a result of working for Soothe and attempting to improve its practices, [he] obtained direct knowledge of all the information contained" in the Second Amended Complaint. *Id.* ¶¶ 10, 40. The allegations demonstrate that he was aware of and spoke to Long and DeStefano about customer complaints regarding copayments, had authority to make policy regarding requirements for refills, reviewed prescriptions received by Soothe, had access to the formulas used by Soothe and what percentage of Soothe's revenue was generated by certain formulas, discussed formulas with the owners of Soothe, and was aware of which representative group generated the prescription. *Id.* ¶¶ 52, 81, 100, 108, 123-24, 130-31, 135-36.

The Relator in this case did not provide allegations as extensive as those in *Mastej* to demonstrate what his duties were or to what information he had access. But, as the Eleventh Circuit stated in that case, "whether the allegations of a complaint contain sufficient indicia of reliability to satisfy Rule 9(b)" is evaluated "on a case-by-case basis." *Mastej*, 591 F. App'x at 704. Here, the allegations that Relator was a corporate insider with access to billing records and information regarding prescription formulas, co-pays, and costs, provide indicia of reliability. Accordingly, the Court will examine Relator's claim in Count I under section 3729(a)(1)(A) through this lens.

b. Presentment Requirement

"Because the submission of an actual claim to the government for payment is the *sine qua non* of an FCA violation, a plaintiff-relator must plead the submission of a false claim with particularity." *Masej*, 591 F. App'x at 703 (internal quotations and citations omitted). To do so, "a relator must identify the particular document and statement alleged to be false, who made or

used it, when the statement was made, how the statement was false, and what the defendants obtained as a result." *Id.* (quoting *United States ex rel. Matheny v. Medco Health Sols. Inc.*, 671 F.3d 1217, 1225 (11th Cir. 2012)). A plaintiff is ordinarily required to provide exact billing data, including name, date, amount, and services rendered, or attach a representative sample claim to provide the necessary indicia of reliability that a false claim was actually submitted. *Id.* at 704. However, as discussed above, a plaintiff with first-hand knowledge that the defendant submitted false claims, gained through the plaintiff's employment with the defendant, may provide a sufficient basis for asserting that the defendant actually submitted a false claim. Relator had sufficient personal knowledge of Soothe's billing practices, which would include purported kick-backs to the representative groups, to provide indicia of reliability. The Court will examine Relator's allegations regarding submission of false claims with that in mind.

Relator contends that he alleged that false claims were presented to the government with specific examples in a representative chart contained in the Second Amended Complaint. Doc. 75 ¶ 136. The chart displays (1) which representative group generated the prescription, (2) the date the prescription was dispensed and billed to Tricare, (3) the alias of the patient prescribed, (4) the quantity of the drug prescribed, (5) the drug prescribed, (6) the total amount billed to Tricare, (7) the cost of the prescription, and (8) the percent of profit from the prescription. *Id.* ¶¶ 135-136. Relator further alleges that the representative groups that generated the prescription "knowingly caused to be submitted the representative examples of false claims to Tricare or other Government insurance programs, and they also knowingly caused to be submitted other similar false claims to Tricare or other Government insurance programs through Soothe and other pharmacies." *Id.* ¶ 137.

The Shark Defendants argue that the chart is not sufficient to provide specific examples because it shows only compounds dispensed by unidentified pharmacies without information on the alleged subsequent submission of reimbursement claims to the government. Doc. 108 at 11. Additionally, Defendants assert that because Relator alleges "the date the prescription was dispensed and thus billed to Tricare," and does not specify whether bills were submitted to Tricare or other government insurance programs, Relator is simply assuming certain information without having first-hand knowledge of such information. *Id.* Similarly, Relator alleged that the representative groups worked with numerous pharmacies, but the chart does not indicate what pharmacy filled the prescription. *Id.* at 12.

Additionally, Defendants contend that even if the dispensation date could be used in lieu of the date of a claim submission, the chart is not sufficient to qualify as exact billing data because it does not specify what entity submitted the claim to a government health care program. *Id.* Defendants rely on *Hopper*, in which the relator detailed an illegal scheme to cause the government to pay amounts that it did not owe, but failed to allege the existence of a single actual false claim, and provided no detail as to what entity was alleged to have presented a claim of any kind, let alone a false or fraudulent claim. *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009). Although the relator alleged that "pharmacies and other healthcare providers submitted claims to various state healthcare programs for reimbursement," and that "state agencies submitted claims to the federal government for payment," the Eleventh Circuit found this to be insufficient because the complaint did "not identify specific persons or entities that participated in any step of th[e] process," nor did it "allege dates, times, or amounts of individual false claims." *Id.*

Defendants also rely on *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:11-cv-00962-WSD, 2012 WL 8020674, at *13 (N.D. Ga. Aug. 29, 2012), to assert that the representative

chart is not sufficient. In *Omnicare*, the plaintiff provided spreadsheets that detailed "prescriptions filled by Defendants, including redacted patient information, drugs dispensed, date filled, and an indication of why the particular prescription was 'off-label', " which the Northern District of Georgia found insufficient to meet the particularity requirement because the spreadsheets did not offer information as to the subsequent submission of reimbursement claims for the defendants having filled the prescriptions. The district court later found the relator's amended complaint, which was accompanied by spreadsheets specifying the pharmacy location that filled each identified prescription, as well as detailed information on each prescription, was sufficient to meet the particularity requirement. *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:11-cv-00962-WSD, 2013 WL 2303768, at *6 (N.D. Ga. May 17, 2013). Relator contends that *Omnicare* is not similar to this case because the chart contained in the Second Amended Complaint contains the date, type, and amounts of false billings. Doc. 135 at 9.

The Court agrees with the Shark Defendants that certain information is omitted from the representative chart, such as who submitted the claim to the Government. However, the chart provides sufficient information, taken in conjunction with Relator's insider status and review of Soothe's billing records, to allege that false claims were presented to the Government.

However, as stated above, Relator submitted a shotgun pleading that describes various actions without clarifying which actions were attributable to which Defendant, and lumping all Defendants together in this and other claims. Accordingly, neither Defendants nor this Court can discern to which parties certain actions are attributable and the claim is due to be dismissed.

c. Allegations that Services were Not Medically Necessary

The Shark Defendants argue that Relator did not state a claim because he did not sufficiently allege for purposes of section 3729(a)(1)(A) that the claims submitted were false. Doc.

108 at 15-17. Generally, the Shark Defendants argue that Relator did not specifically allege that any claim for a medically unnecessary product or service was made because the Second Amended Complaint does not provide any basis for Relator's bald assertion that medically unnecessary prescriptions were dispensed. Doc. 108 at 15-17.

A claim may be false if it is based on a medically unnecessary product or service. *Mastej*, 591 F. App'x at 708. In such cases, "representative claims with particularized medical and billing content matter more, because the falsity of the claim depends largely on the details contained within the claim form—such as the type of medical services rendered, the billing code or codes used on the claim form, and what amount was charged on the claim form for the medical services." *Id.*

This Court has previously found that it is insufficient to allege that the relator received complaints from physicians about extra refills and the high costs of those refills if the relator did not identify the physician or the complaining patient's initials. *United States ex rel. Stepe v. RS Compounding LLC*, 304 F. Supp. 3d 1216, 1223 (M.D. Fla. 2018). The Court also noted in that case that the relator did not "identify any specific claims in which the dosage prescribed for a TRICARE or Medicare patient was unnecessarily high or the number of refills medically unnecessary." *Id.*

The Shark Defendants contend that the chart is insufficient because it does not indicate that the prescriptions were medically unnecessary, and the Second Amended Complaint contains nothing other than Relator's assertions that prescriptions were unnecessary, a matter on which Relator is not qualified to opine. Doc. 108 at 16-17.

Relator responds that because cost is a consideration for determining medical necessity under 32 C.F.R. § 199.2, the fraudulent scheme to craft formulas that maximize revenue without

advance in efficacy is sufficient to allege that the prescriptions were not medically necessary. Doc. 135 at 17. Relator alleges that Defendants prescribed excessive amounts of Fluticasone, which he objected to during his tenure with the Soothe Defendants and that this drug was chosen because of its high reimbursement price. Doc. 75 ¶¶ 121, 130, 131. Relator notes that the representative chart includes claims that include excessive Fluticasone prescriptions. Doc. 135 at 18-19; *see also* Doc. 75 ¶ 136. Additionally, Relator alleged that Defendants "did not bother to determine that the patients actually needed the medicine . . . ." Doc. 75 ¶ 103. The Court finds that the representative chart, and allegations regarding the scheme, are sufficient to allege that prescriptions were written in the absence of any medical necessity.

3. C.V. McDowell Entities' and Stapleton Defendants' Motion to Dismiss Count I—§ 3729(a)(1)(A)

The C.V. McDowell Entities and Stapleton Defendants argue, in case it is not superseded by the Government's Complaint, that Count I's claim that they "created false statements through the illegal transfer of prescriptions en masse in exchange for a percentage of the transferred prescription, the waiver, reduction or arrangement for the reduction of co-payments owed by patients in violation of the Anti-Kickback Statute ("AKS") and government regulations," Doc. 75 ¶ 169, must be dismissed. Doc. 110 at 16; Doc. 112 at 11. Defendants argue that Relator fails to connect the general allegations in the factual section of the Second Amended Complaint with any specific false claims that were actually submitted to a federal payor. Doc. 110 at 16. For the reasons explained above in connection with the Shark Defendants' Motion to Dismiss, Relator sufficiently alleged that false claims were presented to the government.

4. Shark Defendants', C.V. McDowell Entities', Stapleton Defendants', and Long's Motions to Dismiss Count II—§ 3729(a)(1)(B)

"To prove a claim under § 3729(a)(1)(B), a relator must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it was false, and (3) the statement was material to a false claim." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017).

The Shark Defendants, C.V. McDowell Entities, Stapleton Defendants, and Long argue that Relator failed to meet the pleading standard to state a claim under section 3729(a)(1)(B). Doc. 108 at 17-18; Doc. 110 at 16-17; Doc. 127 at 5-7. The Shark Defendants and Long argue that Relator failed to allege that he made or caused to be made a false statement, that any false statement was material, or that the Government paid a false claim. Doc. 108 at 18-22; Doc. 127 at 5-7. The C.V. McDowell Entities and Stapleton Defendants argue that this claim should be dismissed against them because Relator failed to allege that they had any role in the preparation of any claim forms for submission to federal payors. Doc. 110 at 16-17; Doc. 112 at 11.

Regarding the falsity requirement, this Court has explained that "[a] claim is considered false under the [FCA] if it is either factually or legally false." *United States v. Space Coast Med. Assocs., L.L.P.*, 94 F. Supp. 3d 1250, 1259 (M.D. Fla. 2015). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* (quoting *Prime v. Post, Buckley, Schuh & Jernigan, Inc.*, No. 6:10-cv-1950-Orl-36DAB, 2013 WL 4506357, at *8 (M.D. Fla. Aug. 23, 2013)). A legal falsity may be based on either an express certification or an implied certification. *Id.* Implied certification may be a basis for liability where the claim not only requests payment, but makes specific representations about the goods or services provided, and the defendant's failure to disclose noncompliance with material statutory, regulatory, or

contractual requirements makes those representations misleading half-truths. *Escobar*, 136 S. Ct. at 2001. In other words, implied certification may be a premise of liability where a party requesting payment "makes certain representations which are misleading because of the omission of violations of statutory, regulatory, or contractual requirements," regardless of whether the requirements were an express condition of payment, and the omission was material. *Marsteller for the use and Benefit of United States v. Tilton*, 880 F.3d 1302, 1313 (11th Cir. 2018).

At issue in this case are allegedly legally false claims, based on non-compliance with the Anti-Kickback Statute. Indeed, "[c]ourts 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. Keeler v. Eisai, Inc.*, No. 09-22302-CV-WILLIAMS, 2013 WL 12049080, at *13 (S.D. Fla. Feb. 1, 2013) (quoting *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 312 (3d Cir. 2011)). Alternatively, an implied certification theory has also been recognized "where compliance with the Anti-Kickback Statute is a prerequisite for payment." *Id.* (citing *McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005)). Here, Relator alleges that "Defendants knowingly made false statements and false certifications with full knowledge that these false statements and false certifications would be material to the United States' decision to pay." Doc. 75 ¶ 188.

Regarding the pleading standard of 9(b), Defendants rely on *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997). That case involved RICO claims that were required to meet the standard of Rule 9(b), and the Eleventh Circuit previously explained that the plaintiffs were required to allege: "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the

content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud." *Id.* The Eleventh Circuit held in that case the plaintiffs failed to meet that standard because (1) they lumped together all defendants in their allegations and, therefore, the complaint did not contain allegations with respect to the separate defendants, and (2) they did not specify the time, place, and manner in which specific predicate acts occurred. *Id.* at 1381.

Relying on this case, the Shark Defendants argue that Relator's allegations that Defendants' use of preprinted prescription pads and forms with check-boxes making it impossible for pharmacies to determine whether the prescription was approved by a physician constituted a false statement is not sufficient to meet the standard of Rule 9(b). Doc. 108 at 18-19. Defendants also contend that Relator failed to plead a false statement because Relator does not allege that the prescriptions were not approved by a doctor or how these actions made the prescriptions false statements. *Id.* Defendants further contend that the allegations that they failed to assure that prescriptions were from doctors licensed in the same state as the patients, and failed to follow state law, do not constitute a false statement because the allegations do not purport to specifically apply to Defendants, and do not specifically allege any incidences in which this actually occurred, or in what states these incidents occurred. *Id.* at 19. Finally, Defendants argue that the allegations that pharmacies filled prescriptions in violation of the Drug Benefit Manual and the Drug Enforcement Administration's Pharmacist's Manual does not meet the pleading standard. *Id.* at 19-20. Defendants contend that Relator fails to tie these allegations to them specifically and the FCA does not create liability for a health care provider's disregard of purported government regulations or improper internal policies. *Id.* at 20.

Relator responds that the claims presented to the government and the prescriptions upon which the claims were based are false records or statements. Doc. 135 at 22. Relator urges that he has met the required specificity based on the chart of representative examples. *Id.* Relator also contends that specificity was met with the following allegations:

> 57. Representative groups (including, but not limited to, the C.V. McDowell Defendants and the Robusto Enterprises Defendants) have the prescription faxed back to themselves for distribution to pharmacies to control the prescription and ensure they can obtain a share of the value of the prescription.
>
> 60. Forwarding a prescription interferes with the relationship between the patient, doctor and pharmacist and interferes with the ability of the pharmacist to be sure that the prescription is in fact ordered in the normal course of professional conduct as required for a valid prescription.
>
> 64. The actions taken by the pharmacies and the representative groups knowingly to fill prescriptions en masse and in fact generate the prescriptions in the first place, often without medical necessity or documentation of medical necessity violates the pharmacy responsibility to handle only valid prescriptions.
>
> 65. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the Controlled Substances Act, See 21 U.S.C. Subchapter I, Part C § 829.
>
> 94. Many of the actions taken by the pharmacies and the representative groups are so egregious as to run afoul of the general requirements for a valid prescriptions presented in the Drug Enforcement Administration's Pharmacist's Manual Section IX:
>
> > A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829**)**. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful,

> questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.
>
> 109. All Defendants were engaged in the practices described in this section and all the representative groups knowingly presented such prescriptions to Soothe directly, knowing that false claims for reimbursement from Tricare or other government health care payors would be submitted.
>
> 179. Each and every prescription created as a result of the Defendants' illegal practices to increase revenue such as waiving co-payments and transferring prescriptions creates a false record material to obtaining payment from a government program.

Doc. 75 ¶¶ 57, 60, 64-65, 94, 109, 179. Relator contends that these actions by Defendants were part of the illegal kickback scheme perpetrated by Defendants in violation of the Anti-Kickback Statute, meaning that Defendants had knowledge of false records. Doc. 135 at 23. Because Defendants did not advise the government that they were paying or receiving commissions in violation of the Anti-Kickback statute, and did not collect co-pays for the prescriptions in violation of the Anti-Kickback Statute, Relator contends that Defendants made false statements.

The Court agrees that Relator failed to allege that Defendants made false statements with the requisite specificity. Although Relator generally alleges that scheme that would result in false statements, Relator does not allege that Defendants falsely certified compliance in connection with these transactions. *Cf. Eisai*, 2013 WL 12049080, at *13 (finding that the relator did not meet the standard of Rule 9(b) where, even assuming payments constituted illegal kickbacks, he did not sufficiently allege that participants actually received payments or falsely certified compliance, and failed to connect the alleged scheme to particular instances of fraud or misrepresentation). The only allegations regarding certification are contained in paragraph 188, in which Relator states that false certifications were made. No factual allegations support this conclusion. Thus, regardless

of whether Relator pled the requisite materiality, which is discussed in conjunction with the C.V. McDowell Entities' Motion to Dismiss, Count II must be dismissed against the Shark Defendants, C.V. McDowell Entities, Stapleton Defendants, and Long.[5]

5. Shark Defendants', C.V. McDowell Entities', Stapleton Defendants', and Long's Motions to Dismiss Count IV—§ 3729(a)(1)(G)

Section 3729(a)(1)(G) is a "reverse" FCA claim, a term used because under this subsection, "liability results from avoiding the payment of money due to the government, as opposed to submitting to the government a false claim." *Space Coast Med. Assocs.*, 94 F. Supp. 3d at 1263. Under this subsection, a person is liable for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the government." 31 U.S.C. § 3729(a)(1)(G). To plead a claim under this provision, a relator must allege that the defendant owed a definite and clear obligation to pay money to the United States. *Space Coast Med. Assocs.*, 94 F. Supp. 3d at 1263.

"Importantly, to establish a reverse false claim cause of action, a relator must show that the defendant owed a definite and clear 'obligation to pay money to the United States at the time of the allegedly false statements.' " *RS Compounding LLC*, 304 F. Supp. 3d at 1226 (quoting *Space Coast Med. Assocs.*, 94 F. Supp. 3d at 1263). "[T]he duty to remit known overpayments is a clear obligation under the FCA." *Id.*

[5] Because this Count is due to be dismissed, the Court does not address whether Relator was required to allege that the government actually paid a false claim, which Relator argued was eliminated by Congress in the 2009 amendments to the FCA. Doc. 108 at 21-22; Doc. 135 at 28.

The Shark Defendants argue that Relator failed to allege that they used a false statement and, therefore, failed to state a claim. Doc. 108 at 22. The C.V. McDowell Entities and Stapleton Defendants move to dismiss Count IV because it fails to separate each defendant and fails to reference any knowing false record, statement, or concealment made by any specific entity. Doc. 110 at 15; Doc. 112 at 11. Long moves to dismiss Count IV because Relator failed to identify any obligation that he had to pay the government. Doc. 127 at 8-9.

Relator does not actually allege that any overpayments or payments on false claims were paid by the Government. Because of this, Relator has not alleged that overpayments or obligations to repay the Government existed. *RS Compounding LLC*, 304 F. Supp. 3d at 1226-1227. Accordingly, Count IV must be dismissed against the Shark Defendants, C.V. McDowell Entities, Stapleton Defendants, and Long.

6. Shark Defendants', C.V. McDowell Entities', the Stapletons', and Long's Motion to Dismiss Count III—§ 3729(a)(1)(C)

Section 3729(a)(1)(C) governs liability for conspiring to commit a violation of various subparagraphs of the FCA, including § 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G). "Complaints alleging a conspiracy to violate the [FCA] are also subject to Rule 9's heightened pleading standard." *LifePath Hospice*, 2016 WL 5239863, at *8. "A defendant is liable for conspiracy if the relator can prove two elements: (1) that the defendant conspired with at least one person to get a false or fraudulent claim paid by the government; and (2) that at least one of the conspirators performed an overt act to get a false or fraudulent claim paid." *Id.* (citing *United States ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc.*, 597 F. Supp. 2d 1280, 1289 (M.D. Fla. 2009)). To "conspire" for purposes of this section "requires a meeting of the minds 'to defraud the government.' " *Id.* (quoting *Breathe Easy*, 597 F. Supp. 2d at 1289).

This Court has "held that a failure to adequately allege the existence of a false claim is fatal to a conspiracy claim." *Id.* at *9 (compiling cases). The Court explained that "[b]ecause the existence of a false claim . . . is an element of a cause of action for conspiracy to violate the [FCA], the failure of a relator to sufficiently plead that claim's existence necessarily means that, as a matter of law, the relator cannot prevail." *Id.* Because Relator failed to state a claim for violation of the FCA against the Shark Defendants, CV McDowell Entities, Stapleton Defendants, or Long for reasons set forth above, his conspiracy claim must also fail.[6]

7. C.V. McDowell Entities' Motion to Dismiss CVMM and MCI

The McDowell Entities move to dismiss C.V. McDowell Medical, Inc. ("CVMM") and McDowell Companies, Inc. ("MCI") because the Second Amended Complaint contains no allegations directed at either party and neither entity was a party to a contract with any pharmacy. Doc. 110 at 17-18. The McDowell Entities further contend that CVMM is a defunct entity, voluntarily dissolved on June 8, 2015, that never entered into any contracts, never did any business, and never generated any revenue. *Id.* at 17. These entities were not named in the Government's Complaint and, therefore, all claims raised by Relator are still in effect.

Despite CMVV's dissolved status, it may be sued. *Grguric v. Little Mermaid S., Inc.*, No. 07-81219-CIV, 2008 WL 1766889, at *2 (S.D. Fla. Apr. 14, 2008) (stating that Florida law permits an aggrieved party to sue a dissolved corporation). However, for the reasons stated above in connection with the various counts of the Second Amended Complaint, no claim is stated against CVMM or MCI and, therefore, Counts I, II, III, and IV are dismissed against them.

[6] Great White Shark Opportunity Fund, L.P and Great White Shark Opportunity Fund Management, LLC also request to be dismissed because insufficient allegations tie these entities specifically to the alleged fraud. Doc. 108 at 23. Because all counts will be dismissed against them for the reasons set forth, the Court does not address this additional argument.

B. Motions to Dismiss Government's Complaint

1. The C.V. McDowell Entities and Stapleton Defendants' Motion to Dismiss all Claims for Failure to Sufficiently Plead Scienter

The C.V. McDowell Entities' Motion[7] to Dismiss focuses on the scienter requirement of the FCA. Additionally, the C.V. McDowell Entities move to dismiss the common law claims of unjust enrichment and payment by mistake on the basis that these claims are premised on their alleged noncompliance with the Anti-Kickback Statute and FCA, which the C.V. McDowell Entities argue the Government failed to sufficiently plead. Doc. 110 at 13-14. For the reasons set forth below, the Court finds that the Government's claim under the FCA is sufficiently pled. Accordingly, the Court will also deny the C.V. McDowell Entities' motion to dismiss the Government's unjust enrichment and payment by mistake claims.

As previously stated, section 3729(a)(1)(A) imposes liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Thus, a claim under this subsection of the FCA includes a scienter requirement. *Universal Health Servs.*, 136 S. Ct. 1989 at 1996. The scienter requirement may be established by showing that a defendant acted with actual knowledge, deliberate ignorance, or reckless disregard. 31 U.S.C. § 3729(b). Although Rule 9(b) applies to FCA claims, a relator may plead scienter generally. *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1055 n.13 (11th Cir. 2015). Because the heightened pleading standard does not apply to the scienter requirement, the plausibility standard of Federal Rule of Civil Procedure 8(a)(2) applies.

The C.V. McDowell Entities argue that the Government bases its scienter allegations on four alleged facts: (1) contract fragments contained in the Government's Complaint between the

[7] The Stapleton Defendants incorporate all arguments made by the C.V. McDowell Entities into their Motion to Dismiss. Doc. 112 at 11.

C.V. McDowell Entities and the Pharmacies;[8] (2) a letter response to a McDowell LLC demand for payment; (3) a flat fee contract with a pharmacy; and (4) a memorandum that McDowell LLC received from a pharmacy seeking to convert its marketing firms' personnel from independent contractors to employees.[9] Doc. 110 at 3-4. The C.V. McDowell Entities contend that none of these allegations satisfy the applicable pleading requirements.

With respect to the contracts, the C.V. McDowell Entities argue that because the contracts contain language requiring compliance with the Anti-Kickback Statute, but also contain an impermissible commission scheme, this is evidence that the McDowell Entities did not know the contracts violated the Anti-Kickback Statute. Doc. 110 at 4-6. The Government argues that this is a factual matter that should not be resolved on a motion to dismiss. Doc. 136 at 14. The Court agrees. The Court will not evaluate the factual matter of what knowledge or beliefs the C.V. McDowell entities could have gleaned from various contracts at the motion to dismiss stage. At this point, the Court could plausibly infer that the C.V. McDowell Entities simply included that as standard contract language, or included the language to demonstrate a lack of knowledge.

Next, the C.V. McDowell Entities challenge the Government's allegation that they were aware of the Anti-Kickback Statute's prohibitions because they entered into a flat-fee agreement with a compounding pharmacy that required McDowell LLC to comply with the pharmacy's policies and procedures, including compliance with the federal anti-kickback statute. Doc. 104 ¶ 104. In essence, the Government's allegation is that because McDowell LLC entered into one flat-

[8] The C.V. McDowell Entities rely on Exhibits 1-10 with respect to arguments related to these contracts, which they moved to file under seal. Doc. 110 at 4 n.2; Doc. 111. The Court denied the motion to seal and the C.V. McDowell Entities have not since filed the documents with the Court. Doc. 137. The Court relies only on what has been filed in ruling on the motion to dismiss.

[9] To the extent that the Stapleton Defendants adopt these arguments, *see* Doc. 112 at 12, the Court reaches the same conclusion as to the arguments' validity.

fee contract, it must have known that its commission-based contracts were unlawful, which the C.V. McDowell Entities argue is not a plausible inference. Doc. 110 at 7. The Court agrees that this is a stretch, but it is not the only basis on which the Government pled knowledge, which is discussed below.

The C.V. McDowell Entities also contend that the letter in which a pharmacy refused to remit continuing revenue payments to McDowell LLC after termination of their agreement, relied on by the Government to show knowledge, is not sufficient. Specifically, the C.V. McDowell Entities argue that their demand was not a demand for kickbacks, the pharmacy's letter contained only a vague mention of Anti-Kickback compliance without any explanation, and the situation—which involved a flat-fee contract—would not put McDowell LLC on notice that different contracts involved kickbacks on claims being submitted to TRICARE. Doc. 110 at 8.

In the letter at issue, a pharmacy that terminated its contract with McDowell LLC wrote that continuing revenue payments were "prohibited by anti-kickback laws," and stated that, contrary to McDowell LLC's representations in their agreement, McDowell LLC "appear[ed] to have little knowledge or appreciation for the regulatory requirements applicable to pharmacy practice . . . ." Doc. 110-11 at 3. It can reasonably be inferred from the letter that the C.V. McDowell Entities were knowledgeable about the Anti-Kickback Statute, and on notice that revenue-based referral arrangements were unlawful.

Additionally, the January 30, 2015 document relied on by the Government in its Complaint and attached to the Motion to Dismiss as Exhibit 12 raises an inference that the C.V. McDowell Entities had knowledge of the Anti-Kickback Statute. Doc. 104 ¶ 106; Doc. 110-12. In the document, a compounding pharmacy stated that it was "in the process of having the Rep Agreements modified so as to ensure compliance with the Federal and state Anti-Kickback Statutes

and regulations." Doc. 110-12 at 1. The compounding pharmacy explained that "in order to comply with these statutes and regulations . . . all representatives must be *bona fide* W-2 employees . . . ." *Id.* The compounding pharmacy further explained that doing so would allow the pharmacy "to compensate the reps for their performance on a commission basis, in a manner that ensures compliance with all applicable laws." *Id.* An inference can be made that these statements put C.V. McDowell on notice that its commission structure ran afoul of the Anti-Kickback Statute.

Finally, the C.V. McDowell Entities argue that because the contracts' compensation structures were perfectly lawful as applied to private insurers, and were problematic only with respect to federal payors, and the C.V. McDowell entities developed leads for private payors, the Government's Complaint does not plausibly allege that the C.V. McDowell Entities purposely targeted TRICARE. Doc. 110 at 10-11. Instead, the C.V. McDowell Entities contend that the Government's Complaint alleges only that TRICARE payments were an incidental share of their business, which they contend demonstrates a lack of intent to violate the Anti-Kickback Statute. *Id.*

The Government responds that the question is not whether the C.V. McDowell Entities were targeting TRICARE, but whether they were knowingly arranging for the referral of TRICARE patients in exchange for kickbacks. Doc. 136 at 19. Indeed, in the Government's Complaint, it alleges that because McDowell LLC's sales representatives were instructed to obtain physician and insurance information, the McDowell Entities knew that they were referring TRICARE patients to pharmacies. Doc. 104 ¶ 107. Moreover, the Government alleges that TRICARE patients were among those specifically sought out by McDowell LLC when it

purchased lead lists. *Id.* The Court agrees that these allegations are sufficient to plead that the McDowell entities had knowledge of the submission of false claims to the Government.

Based on the above, the Government's Complaint sufficiently alleges the FCA's scienter requirement with respect to the C.V. McDowell Entities, and their Motion to Dismiss on this basis is denied.

2. C.V. McDowell Entities', Stapleton Defendants', and Long's Motion to Dismiss For Failure to Plead Materiality

The C.V. McDowell Entities, Stapleton Defendants, and Long argue that the Government fails to meet the demanding materiality standard delineated by *Escobar*, 136 S. Ct. at 2003. In *Escobar*, the Supreme Court advised that the materiality standard was not met where noncompliance is "minor or insubstantial," or amounted to a "garden-variety breach[] of contract or regulatory violation[]." *Id.* at 2002-03. Instead, to be material, an omission must be significant enough that a government payor "would have attached importance to the violation in determining whether to pay the claim." *Id.*

In its Complaint, the Government alleges that the Defense Health Agency has previously exercised its authority to suspend providers for the payment of kickbacks. Doc. 104 ¶ 31. This weighs in favor of a finding of materiality. *Escobar*¸136 S. Ct. at 2003-04; *see also* Doc. 136 at 22 (listing cases in which courts have found non-compliance with the Anti-Kickback Statute to be material). Additionally, under 42 U.S.C. § 1320a-7(b)(7), entities may be excluded from participating in any federal health care program for engaging in fraud or obtaining kickbacks. Moreover, the Government's Complaint generally alleges a scheme under which Defendants obtained prescriptions for unnecessary medications at high volumes for profit at the expense of the Government. Common sense leads to the conclusion that violation of the Anti-Kickback Statute is material to the Government's decision to pay claims. *United States v. Triple Canopy, Inc.*, 857

F.3d 174, 178-79 (4th Cir. 2017) (stating that common sense led to the finding that omissions were material under the standard set forth in *Escobar*).

3. The Stapleton Defendants' Motion to Dismiss All Claims For Failure to Meet the Pleading Standard[10]

The Stapleton Defendants move to dismiss all claims against them for failure to meet the pleading standard and because the Government does not allege any facts that plausibly show scienter with respect to TRICARE claims. Doc. 112 at 11-2, 14-15. Jack L. Stapleton contends that the Government's Complaint does not tie him to any false claim or record.

Jack L. Stapleton argues that his e-mails and correspondences regarding customer complaints do not give rise to an inference that he knew the prescriptions were medically unnecessary because the allegations say little about his responses, whether any changes in business practices resulted, or how many complaints existed. *Id.* at 12. Jack H. Stapleton argues that the allegations regarding his e-mails about prescriptions and reimbursement rates, the allegations regarding his participation in negotiating the Soothe Compounding contract, and allegations regarding his managerial role are not sufficient to show awareness of the kickback scheme or scienter. *Id.* at 14-15.

The Government's Complaint sufficiently alleges that the Stapleton Defendants knowingly submitted false claims to the government. The Government's Complaint alleges that the Stapleton Defendants were advised in 2014 that patients complained about unwanted prescriptions. Doc. 104 ¶ 88. The previously-discussed letter in which a compounding pharmacy discontinued its relationship with McDowell LLC and refused to remit continuing payments was addressed to Jack

[10] The motion also seeks dismissal of the claims in the Second Amended Complaint. Because those claims are dismissed for other reasons, the Court addresses these arguments only in connection with the Government's Complaint.

L. Stapleton. *Id.* ¶ 105. Although the majority of the allegations relating to Jack H. Stapleton concern e-mails in which he discusses formulas and payouts for various prescriptions, *id.* ¶¶ 54-56, the Government's Complaint also alleges that Jack H. Stapleton was directly involved in negotiating the kickback arrangements and that the agreements provided that the companies would comply with federal anti-kickback laws, *id.* ¶¶ 36, 103. Although the Government's allegations regarding Jack H. Stapleton's knowledge are sparse, they are sufficient to withstand the Motion to Dismiss.

4. The Stapleton Defendants' Motion to Dismiss Because an Owner or Manager is not Liable for Corporate Acts

The Stapleton Defendants argue that because the allegations directed at them individually do not permit an inference of any purpose to violate the Anti-Kickback Statute, and an owner of officer of a company is not vicariously liable for corporate acts merely based on that individual's position or title, the claims against them must be dismissed. Doc. 112 at 13-16. However, for the reasons described above, the Government's Complaint specifically alleges claims against the Stapleton Defendants. Courts have held corporate officers liable for causing the submission of false claims resulting from schemes in which the corporate officers personally participated. *United States ex rel. Silva v. CICI Mktg., LLC*, 361 F. Supp. 3d 1245, 1253 (M.D. Fla. 2019). Accordingly, the Stapleton Defendants' Motion to Dismiss on this basis is denied.

5. The Stapleton Defendants' Motion To Dismiss for Lack of Nexus Between Them and Representative TRICARE Claims

The Stapleton Defendants argue that the Government fails to identify representative claims that they submitted or caused to be submitted to a federal payor. Doc. 112 at 16. This argument is, essentially, the same as that presented by the Shark Defendants in section III. D. 1, *supra*—that

a plaintiff is required to provide exact billing data with specific information regarding who submitted false claims, what those false claims were, and when they were submitted and paid.

The Government's Complaint alleges that the Stapleton Defendants utilized McDowell LLC and J&J to refer prescriptions to Opus Rx, and provides representative claims from which these companies received kickbacks. Doc. 104 ¶¶ 81-82. The representative claims include the pharmacy, the patient identifier, the date the prescriptions were filled, who referred the prescriptions, that the claims were submitted to TRICARE, and that the claims were paid by TRICARE. *Id.* ¶ 82. Accordingly, the Court finds that the Government adequately pleaded specific information regarding the submission of false claims.

ORDERED AND ADJUDGED:

1. Defendants Robusto Enterprises, LLC, Eduardo Lopez, Great White Shark Opportunity Fund, L.P., and Great White Shark Opportunity Management Fund, LLC's Motion to Dismiss and Incorporated Memorandum (Doc. 108) is **GRANTED**. All counts of Relator's Second Amended Complaint and Demand for Jury Trial (Doc. 75) are **DISMISSED without prejudice**.

2. C.V. McDowell Entities' Motion to Dismiss and Incorporated Memorandum of Law (Doc. 110) is **GRANTED-in-part** and **DENIED-in-part.** All counts of Relator's Second Amended Complaint and Demand for Jury Trial (Doc. 75) are **DISMISSED without prejudice** with respect to Defendants C.V. McDowell, LLC; C.V. McDowell Medical, Inc.; and McDowell Companies, Inc. The motion to dismiss the counts contained in The United States of America's Complaint in Partial Intervention (Doc. 104) is **DENIED**.

3. Defendants Jack L. Stapleton and Jack H. Stapleton's Motion to Dismiss and Incorporated Memorandum of Law (Doc. 112) is **GRANTED-in-part** and **DENIED-in-part.** All

counts of Relator's Second Amended Complaint and Demand for Jury Trial (Doc. 75) are **DISMISSED without prejudice** with respect to Defendants Jack L. Stapleton and Jack H. Stapleton. The motion to dismiss the counts contained in The United States of America's Complaint in Partial Intervention (Doc. 104) is **DENIED.**

4. Defendant Brad Long's Motion to Dismiss and Incorporated Memorandum of Law (Doc. 127) is **GRANTED-in-part and DENIED-in-part.** All counts of Relator's Second Amended Complaint and Demand for Jury Trial (Doc. 75) are **DISMISSED without prejudice**. The motion to dismiss Count II of the Government's Complaint (Doc. 104) is **DENIED.**

5. Relator shall have **FOURTEEN (14) DAYS** from the date of this Order to file a Third Amended Complaint, which cures the deficiencies addressed in this Order. Failure to file a Third Amended Complaint within the time provided will result in dismissal of Relator's Complaint against the Defendants named in the Motions to Dismiss discussed in this Order, without further notice.

DONE AND ORDERED in Tampa, Florida on July 1, 2019.

Charlene Edwards Honeywell

Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any