UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, and WISCONSIN, THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA, and THE DISTRICT OF COLUMBIA, *ex rel.* MICHELE CLARKE, TRICIA MULLINS, and KRISTI WINGER SZUDLO,	*	
Plaintiffs,	*	Civil Action No. 13-cv-11785-IT
v.	*	
AEGERION PHARMACEUTICALS, INC., MARC BEER, MELANIE DETLOFF, WILLIAM DULL, GREG FENNER, MARK FITZPATRICK, CRAIG FRASER, JAMES FRIGGE, DANIEL RADER, DAVID SCHEER, MARK SUMERAY, and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,	*	
Defendants.	*	

MEMORANDUM AND ORDER

March 31, 2019

TALWANI, D.J.

Pending before the court is Defendants Marc Beer, Melanie Detloff, William Dull, Greg Fenner, Mark Fitzpatrick, Craig Fraser, James Frigge, Daniel Rader, David Scheer, and Mark

Sumeray's Joint Motion to Dismiss (the "Joint Motion") [#147] all remaining claims in Relators Michele Clark, Tricia Mullins, and Kristi Winger Szudlo's Second Amended Complaint [#69]. For the following reasons, Defendants' Joint Motion [#147] is ALLOWED as to claims against David Scheer, but is otherwise DENIED.

I. Background

a. Factual Background[1]

Relators Clarke, Mullins, and Szudlo are former sales representatives at Aegerion Pharmaceuticals, Inc. ("Aegerion"). Second Am. Compl. ¶¶ 8-10 [#69]. Defendants Beer, Detloff, Dull, Fenner, Fitzpatrick, Fraser, Frigge, and Dr. Sumeray are former employees of Aegerion; Defendant Scheer was on Aegerion's Board of Directors. Id. ¶¶ 11-21.

In 2000 or 2001, Dr. Daniel Rader, an employee of the University of Pennsylvania (UPenn), approached Bristol-Meyer Squibb Company about donating a drug it had been developing to UPenn. Id. ¶¶ 19, 22, 36-39. Bristol-Meyer Squibb did so, and Dr. Rader began to develop the drug through the Food and Drug Administration's ("FDA") orphan drug program. See id ¶¶ 40-42. The orphan drug program incentivizes innovation of drugs for patient populations below 200,000 in the United States by allowing a cheaper and easier FDA approval process that does not require the same evidence of safety and efficacy as for non-orphan drugs. Id. ¶ 41.

From June 2003 to February 2004, Dr. Rader conducted a study of the drug on six individuals with Homozygous Familial Hypercholestrolemia ("HoFH"). Id. ¶ 42. HoFH is a life-

[1] To survive a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), Relators' Second Amended Complaint [#69] must "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550. U.S. 544, 570 (2007). The court accepts all factual allegations in Relators' Second Amended Complaint [#69] as true and draws all reasonable inference in favor of Relators. See Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009).

threatening genetic lipid disorder inherited from both parents.[2] Id. ¶ 30. The FDA and others in the scientific community estimate only one in one million people in the United States, or approximately 300 people, have the disorder.[3] Id. ¶¶ 2, 32. Dr. Rader proposed expanding use of the drug beyond the HoFH population, but the FDA informed Dr. Rader and UPenn "that the expanded use of the product in the additional groups of patients shifts the risk-benefit profile of the development program" in an adverse direction. Id.

Dr. Rader recruited a former colleague, Defendant David Scheer, to incorporate Aegerion in 2005 for the purpose of commercializing the drug. Id. ¶ 46. UPenn granted Aegerion the exclusive right to "research, develop, commercialize, make, have made, offer for sale and sell" the drug, which Aegerion renamed AEGR-733. Id. ¶¶ 49, 52. Dr. Rader was a member of Aegerion's Scientific Advisory Board as early as 2007 and Aegerion sold him a significant amount of stock at a fraction of its value. Id. ¶¶ 51-52.

Aegerion acknowledged in a statement filed with the Securities and Exchange Commission that the HoFH patient population was approximately 300 people, but also claimed that the drug has the potential to treat a much larger population with "severe refractory hypercholesterolemia,"[4] or approximately 30,000 people. Id. at ¶ 50, 54. Aegerion renamed

[2] People suffering from HoFH have limited or no ability to remove from their blood the "bad cholesterol" low-density lipoproteins ("LDL-C"). Id. ¶ 28, 30. If untreated, people with HoFH have extremely high LDL-C levels, typically between 500mg/dL and 1,000 mg/dL. Id. ¶ 30. Patients with HoFH develop atherosclerosis, or narrowing and blockage of the arteries, as early as age ten. Id. HoFH patients are at extremely high risk of cardiovascular problems and many are at risk for serious cardiac events starting in their 20s. Id. If left untreated, life expectancy of people with HoFH is 33 years. Id. Historically, HoFH has been difficult to treat because traditional "high cholesterol" treatments are ineffective. Id. ¶ 33.

[3] Heterozygous familial hypercholesterolemia, or HeFH, is inherited from one but not both parents. Id. ¶ 35. The prevalence of HeFH is far more widespread than HoFH and is accepted to be around 1 in 500. Id.

[4] Patients with "severe refractory hypercholesterolemia" are patients with high cholesterol who did not respond to other cholesterol-reducing treatments. Id. ¶ 54.

AEGR-733 Lomitapide, commercially known as Juxtapid, and Dr. Rader proposed to the FDA that his FDA Phase III clinical trial of Juxtapid be expanded to the "severe refractory hypercholesterolemia" patient population. Id. The FDA told Dr. Rader that if he wished to do so, he would need to expand his then-current trial beyond the thirty-six subjects being proposed and conduct a second–and possibly additional–trials in high risk HeFH patients, as there was "uncertainty regarding the long-term consequences of Lomitapide-associated hepatic steatosis." Id. ¶ 54, 57. Aegerion decided not to conduct the additional trial proposed by the FDA due to "financial constraints," and instead decided to remain with the smaller HoFH population. Id. ¶¶ 54, 57-58.

In October 2007, the FDA formally granted Juxtapid an orphan drug designation for the treatment of HoFH. Id. ¶ 56. In May 2010, the FDA expressed concern to Aegerion executives about potential "off-label use" of Juxtapid. Id. ¶ 58. Aegerion agreed to implement post-approval supply constraints to protect against this risk. Id.

In September 2010, Aegerion appointed a new CEO, Defendant Marc Beer. Id. at 59. Aegerion's Chief Medical Office abruptly resigned, and his position remained vacant until July 2011. Id. at ¶¶ 59, 65. Late in 2010, Aegerion announced at a conference that it had adopted a new estimate that the number of adult patients with HoFH in the United States was 3,000 patients instead of 300 patients. Id. ¶ 60. Dr. Rader endorsed this number, even though it was contrary to his prior assertions. Id. ¶¶ 61-62. Dr. Rader and Aegerion attempted to introduce this proposed new "functional" HoFH population to the FDA, but the FDA responded that this expanded "functional HoFH" definition too closely resembled the "severe refractory heterozygous FH population" for which Aegerion had not sought approval, "and expand[ed] the target population almost 10-fold." See id. ¶¶ 54, 57, 62.

In July 2011, Aegerion recruited Defendant Dr. Mark Sumeray as its Chief Medical Officer. Id. ¶ 65. In February 2012, Aegerion submitted to the FDA a New Drug Application for Juxtapid limited solely to HoFH. Id. ¶ 66. In December 2012, the FDA approved Juxtapid for use in patients with HoFH. Id. ¶ 72. Aegerion initially priced Juxtapid at $235,000 for a year's therapy and increased that price to $329,587 for a year's therapy by June 2014. Id. ¶ 163.

Despite receiving approval for the use of Juxtapid in a limited population, Aegerion[5] trained their sales representatives—including Relators—to aggressively market the drug as an off-label solution for a much larger swath of the public, including individuals with HeFH or simply with high cholesterol, and regularly pushed the inflated assertion that there were 3,000 potential HoFH patients. See, e.g. id. ¶¶ 75-81, 83-91, 93, 95-103, 105-07, 109-10, 114, 134. This off-label marketing scheme included instructing its sales staff that genetic testing was a threat to Juxtapid sales, and they should not mention HoFH when speaking with doctors and patients. See id. ¶¶ 76-79, 83, 84, 98, 99. Aegerion directed sales staff to ask doctors misleading questions to make them think the drug was suitable for patients with "severe refractory lipids," id. ¶ 76, 91, 98, 107-110; see also id. ¶¶ 87, 99, and to tell doctors that: there was "no definition" of HoFH, id. ¶¶ 76, 77, 78, 99, 107; doctors could determine who had HoFH without genetic testing, id. ¶ 100; the disease was not one in one million but rather one in 265, and the one in a million figure was outdated, see id. ¶¶ 76, 81, 84, 90, 91, 102-104, 114; and, Aegerion would not engage them as speakers unless they prescribed Juxtapid, see id. ¶¶ 96, 98, 105, 106. Aegerion also told sales staff to go to patients' homes to obtain consent form signatures and suggested that sales people complete medical forms themselves, id. ¶ 80. Aegerion encouraged its sales staff to "data mine" patient databases of medical practices for candidates matching Aegerion's definition

[5] The roles of each Defendant alleged in the Second Amended Complaint [#69] are addressed later in this memorandum.

of the "functional equivalent of HoFH." Id. ¶¶ 83, 85, 86, 88, 89. The sales team further set up a so-called "hunting" competition amongst sales staff, aggressively placing pressure on the staff to track down potential Juxtapid patients using this expanded use of the drug. See id. ¶¶ 93-95.

In July 2013, Defendant Beer announced that Aegerion would no longer report metrics other than sales of Juxtapid. Id. ¶ 120. By the late 2013, about a year after the launch of Juxtapid, Aegerion had 374 Juxtapid patients, over ninety of whom were Medicare patients (24%). Id. ¶¶ 121, 149, 150.

Relators filed their initial Complaint in this *qui tam* action under seal on July 26, 2013.

In November 2013, the FDA sent Aegerion a letter warning that Defendant Beer's public statements "provide evidence that Juxtapid is intended for new uses, for which it lacks approval and for which its labeling does not provide adequate directions for use," making it in violation of the Federal Food and Drug and Cosmetic Act. Id. ¶ 134. The FDA instructed Aegerion to correct the false impressions made by instituting a "comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages." Id.

On January 9, 2014, Aegerion announced that it was under investigation by the United States Attorney's Office in Boston, and that it was working on responding to a subpoena. Id. ¶ 135. Defendants Beer and Fraser resigned effective immediately. Id. ¶ 137.

On May 12, 2016, Aegerion announced that it would pay $40 million over five years to the United States to settle allegations of off-label marketing. Id. ¶ 138.

b. Procedural History

Relators' initial sealed Complaint [#3], brought on behalf of the United States and various states, alleged that Aegerion's off-label marketing scheme caused false claims for reimbursement to be submitted to the government, in violation of the federal False Claims Act

("FCA"), 31 U.S.C. § 3729, et seq., and various state analogs. Relators filed a sealed Amended Complaint [#12] on March 18, 2014, adding Defendants Beer, Fenner, and Fraser. On September 2, 2017, the court granted Relators leave to file their Second Amended Complaint adding Defendants Detloff, Dull, Fitzpatrick, Frigge, Rader, Scheer, Sumeray, and the Trustee of Pennsylvania. See Elec. Order [#64].

On September 22, 2018, the United States gave formal notice that the United States, Relators, and Aegerion had reached a settlement agreement to resolve the claims against Aegerion, and that the United States was therefore intervening as to Defendant Aegerion. Notice of Intervention [#63]. Once this notice was filed, the case was unsealed. See docket.

Relators filed the operative Second Amended Complaint [69] on September 27, 2017. The United States subsequently filed a Stipulation of Dismissal as to Aegerion Pharmaceuticals, Inc. [#98], and the court entered a corresponding Order of Dismissal [#103]. The United States and the Plaintiff States subsequently declined to intervene as to the individual Defendants. Notice of Election to Decline Intervention [#99]; Notice of Election [#110].[6] Relators dismissed their claims as to Dr. Rader and UPenn, Stipulation of Dismissal as to Defendants Daniel Rader and the Trustees of the Univ. of Pennsylvania [#141]; Order of Dismissal [#142], and their state claims. Assented to Motion for Voluntary Dismissal of State Claims [#169]; Order of Dismissal [#171].

The Joint Motion to Dismiss [#147] on behalf of the remaining Defendants followed. The

[6] The United States noted that a *qui tam* action "'may be dismissed only if the court and the Attorney General give written consent to the dismissal . . ..'" Notice of Election to Decline Intervention 1 [#99] (quoting 31 U.S.C. § 3730(b)(1)). The government thus requested that, "should either the Relators or the Defendants propose that this action be dismissed, settled or otherwise discontinued, this Court solicit the written consent of the United States before ruling or granting its approval." Id. The Plaintiff States made a similar request. Notice of Election 2-3 [#110].

court first address the common arguments raised as to all remaining Defendants, before turning to arguments raised on behalf of individual Defendants.

II. Joint Motion to Dismiss – Counts 1 and 2

In Count 1, Relators allege that the Defendants' marketing scheme caused health care providers to submit claims for Juxtapid coverage to Medicare and other government healthcare programs for unapproved use and non-medically accepted indications, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). Second Am. Compl. ¶¶ 2, 200-204 [#69]. In Count 2, Relators allege that the Defendants have knowingly made, used, or caused to be made or used, false records or statements which were material to false or fraudulent claims, in violation of 31 U.S.C. § 3279(a)(1)(B). Id. ¶¶ 205-209.

a. Rule 9(b)

Defendants first argue that Relators have failed to identify a specific patient who was prescribed Juxtapid for an off-label use where the government was billed, or even where the claim was submitted to the government for payment, and therefore fail to meet the particularity requirement required under Fed. R. Civ. P. 9(b). Joint Mem. 7-9 [#152]. Moreover, Defendants argue that the "indirect claim" standard does not apply in this case because Relators failed to plead with specificity that any third parties submitted Juxtapid claims, and even if any such claims were submitted by third parties, that the Defendants induced submission of such claims. Id. at 9-10. Finally, even if the indirect claim standard does apply, Defendants assert that Relators have failed to provide enough facts to support any inference of fraud "beyond possibility." Id. at 11-13.

Federal Rule of Civil Procedure 9(b) requires claims of fraud to be stated with particularity in order to give defendants sufficient notice of plaintiffs' claims, to protect

defendants from damage to their reputation by meritless claims, to discourage "strike suits," and to prevent the filing of suits that seek to use the discovery process as a fishing expedition. United States ex rel. Nargol v. Depuy Orthopaedics, Inc., 865 F.3d 29, 38 (1st Cir. 2017); Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996). The rule does so by requiring that, "[i]n alleging fraud . . . a party must state *with particularity* the circumstances constituting fraud." Fed. R. Civ. P. 9(b) (emphasis added). This requirement includes "set[ting] forth the 'who, what, when, where, and how' of the alleged fraud." United States ex rel. Ge v. Takeda Pharm. Co. Ltd., 737 F.3d 116, 123 (1st Cir. 2013) (citations omitted). To meet rule 9(b)'s particularity requirement, a relator's allegations must identify particular false claims for payment that were submitted to the government, and include at least some details, such as: dates, content, identification numbers, amounts, services billed, individuals involved, and the length of time between the fraud and the claim submission. Id. (citing United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232-33 (1st Cir. 2004), *abrogated on other grounds by* Allison Engine Co. v. U.S. ex rel. Sanders, 553 U.S. 662 (2008)).

The First Circuit has recognized a distinction between complaints alleging direct submission of false claims and those alleging that defendants induced third parties to file false claims. United States ex rel. Duxbury v. Ortho Biotech Prod., L.P., 579 F.3d 13, 29 (1st Cir. 2009); see also United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007). In the "indirect claim" cases, the First Circuit has applied a "more flexible standard" under which "a relator [can] satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility,' without necessarily providing details as to each false claim." Duxbury, 579 F.3d at 29. Instead, in these indirect claim cases, a claim that does not provide particular details of false claims "may nevertheless survive by alleging particular details

of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted. Id. (quoting United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009)). "[W]hile there is no 'checklist of mandatory requirements' that each allegation in a complaint must meet to satisfy Rule 9(b)," Lawton ex rel. United States v. Takeda Pharm. Co., Ltd., 842 F.3d 125, 131 (1st Cir. 2016) (quoting Karvelas, 360 F.3d at 233), "the evidence necessary to achieve this inference generally requires the relator to plead, inter alia, the 'specific medical providers who allegedly submitted false claims,' the 'rough time periods, locations, and amounts of claims,' and 'the specific government programs to which the claims were made,'" id. (quoting United States ex rel. Kelly v. Novartis Pharms. Corp., 827 F.3d 5, 13 (1st Cir. 2016)).

The allegations in the complaint show that Relators asserted both direct and indirect claims. Specifically, Relators have alleged that "Defendants' aggressive off-label marketing . . . caused patients, pharmacies and others (including Aegerion sales representatives, like Defendant Detloff) to claim Medicare payments for Juxtapid used in unauthorized and/or unacceptable ways." Second Am. Compl. ¶ 146 [#69]; see also id. ¶ 1 ("This case arises from Defendants' scheme to aggressively off-label market Aegerion's core drug, Juxtapid, *and cause false claims to be submitted* to . . . government healthcare programs . . . .") (emphasis added). Accordingly, Relators assert that Aegerion both induced third parties and directly submitted false claims to the government for reimbursement.

To the extent that Relators seek relief for claims directly submitted by Aegerion sales representatives, the more exacting standard under Rule 9(b) applies. And, because Relators fail to allege the details of any specific false claim directly submitted by Aegerion or the Defendants for reimbursement from the government, any direct claims against the Defendants are

insufficient to state a claim. As to Relators' indirect claims, however, the court must apply the more flexible pleading standard. After doing so, the court finds that Relators have adequately pled a fraudulent scheme and reliable indicia that lead to a strong inference that false claims were submitted.

Unlike in Rost, Relators have provided at least some factual or statistical evidence to strengthen the inference of fraud beyond a possibility. Relators have alleged that the Aegerion knew—and that it is accepted in the scientific community—that there are approximately 300 patients in the United States with HoFH, but that approximately one year after Juxtapid's launch, Aegerion reported 374 Juxtapid patients, over ninety of whom were Medicare patients (24%). Second Am. Compl. ¶¶ 121, 149, 150 [#69]. Moreover, there were 622 Medicare Part D claims for Juxtapid in 2013, 1,992 in 2014, 2,511 in 2015, and 992 in 2016. See Decl. of Benjamin Towbin in Support of Defs.' Joint Mot. to Dismiss ¶ 6 [#152-4].[7] The Second Amended Complaint further alleges that Aegerion announced that it would settle allegations of off-label marketing for $40 million dollars in 2016, Second Am. Compl. ¶ 138 [#69], and that Relators entered into a Settlement Agreement with Aegerion, which Relators have incorporated by reference into the Second Amended Complaint, see id. at 8 n.2, that provided further evidence that Aegerion engaged in a fraudulent off-marketing scheme, and that "Aegerion knowingly caused false of fraudulent claims for Juxtapid to be submitted to the Federal health care programs."[8]

[7] Defendants have asserted that the court can take judicial notice of the exhibits attached to their memorandum because they are referenced in the complaint and are publicly available government documents. Joint Mem. 4 n.5 [#152]. Relators notified the court at the hearing on this motion that they have no objection to the court's consideration of these exhibits.

[8] Defendants argued at the hearing on this motion that they were not parties to the Settlement Agreement and do not agree to the factual basis underlying that settlement. Defendants may

Relators' other allegations add to the inference of fraud. Chart A contains redacted information about fifteen patients covered by government healthcare programs that were prescribed Juxtapid by March 2013. Id. ¶ 153. The chart includes patients' (redacted) dates of birth, their referral dates, prescription details, insurance providers, shipment dates, and—for some of the patients—their LDL levels, cholesterol drug history, and whether they previously received apheresis.[9] Id. Chart B, entitled "Juxtapid Patients Likely Covered by Government Healthcare Programs," provides much of the same information included in Chart A for fourteen more patients. Id. ¶ 159.[10]

Relators allege that average LDL-C levels for patients who been previously treated for HoFH is between 300-700 mg/dL, and for untreated patients is between 500-1,000 mg/dL. Id. ¶¶ 30, 157. Yet, Chart A shows that at least some Juxtapid patients covered by government healthcare programs had LDL-C levels significantly below these levels. Id. ¶ 153. Further, some of those with reduced LCL-C levels were neither on cholesterol medication nor previously had

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certainly address the underlying facts during this litigation, and the court makes no factual determination at this time. At this procedural juncture, the court considers the Settlement Agreement only to the extent that it makes the inference that Aegerion caused the submission of false claims more plausible.

[9] LDL apheresis is a procedure for individuals with mortally high cholesterol, which, according to Dr. Rader, involves "physical purging of the blood to remove LDL cholesterol. Patients have the 3-4-hour procedure involving two intravenous lines every one to two weeks. This procedure is very taxing on patients and treats the symptoms of the disease as opposed to the disease mechanism itself, and it is also costly. While apparently beneficial, the apheresis treatment merely delays the progress of the disease." SAC ¶ 33 [#69].

[10] At the hearing on this motion, Relators' counsel stated that they have the names of patients and doctors referenced in Charts A and B but did not include them in the complaint in order to maintain those individuals' confidentiality. Although the court could require Relators to amend their complaint to add this information, the court will not require Relators to do so in the interest of patient confidentiality. The court notes, as it did at the hearing, that this evidence can be addressed on summary judgment.

apheresis. Id.

Given these allegations, the complaint satisfies Rule 9(b) purposes of protecting Defendants from meritless claims, discouraging strike suits, and preventing fishing expeditions. Coupled with Relators' allegations outlining Defendants' targeting of individuals covered by government programs, see id. ¶¶ 140, 149-152, and detailing the manner in which Aegerion employees promoted the drug, the court finds that Relators have provided adequate factual or statistical allegations at this stage to strengthen the inference of fraud beyond possibility.

b. Subjective Medical Judgments

Next, Defendants jointly argue that the claims submitted for reimbursement were based on the doctors' independent medical judgments of the patients' medical necessity and Relators therefore have failed to plead with particularity that claims for reimbursement were false. According to Defendants, Juxtapid could be prescribed by doctors if they complied with the Juxtapid Risk Evaluation and Mitigation Strategy (REMS), which Defendants state only requires that doctors find that the patient has a "clinical or laboratory diagnosis consistent with HoFH." Defendants argue that Relators have not alleged enough facts to show that any of the health care providers' REMS certifications were false, and thus have not sufficiently plead any false claims. Joint Mem. at 13-18 [#152].

For support, Defendants point to United States ex rel. Nowak v. Medtronic, Inc., in which the court stated that the relators could not demonstrate that a claim was false or fraudulent where "[e]ach individual health care provider's medical judgment is an essential element" of relator's claim." 806 F. Supp. 2d 310, 354 (D. Mass. 2011). Nowak's holding, however, is a narrow one and applies only in the context of medical devices, where claims for Medicare reimbursement are judged under a "reasonable and necessary standard." Id. at 318-19, 354. The Nowak court

specifically distinguished that case from cases involving off-label drug use. Id. at 354 ("Nowak's reasoning, however, omits out an important step in the analysis in the *medical device* context. . . . The categorical approach for *off-label drug use* . . . is inapplicable here." (first emphasis in original, second emphasis added)). Nowak is inapposite. Nor does the Defendants' reliance on United States ex rel. Jones v. Brigham & Women's Hosp., 678 F.3d 72 (1st Cir. 2012), better serve them. Jones concerned a grant proposal that relied on scientific data alleged to be false. Id. While acknowledging that "scientific judgments . . . about which reasonable minds may differ cannot be false," id. at 87, the court held that it was a matter for the jury to decide whether the scientist at issue had falsified data, id. at 96.

Neither the First Circuit nor any court in this district has found that claims for coverage of drugs cannot be false if supported by the judgment of the prescribing doctor. And, Relators claim here is that the Defendants used their off-label marketing scheme to mislead doctors about how to diagnosis HoFH, thereby corrupting the diagnosis process itself. See Second Am. Compl. ¶ 83 [#69]. As in Jones, the court finds that there is a genuine issue about whether the information Defendants gave to medical prescribers, which led to prescriptions for off-label use, was misleading.

c. Causation

Defendants next argue that even if Relators have sufficiently pled that there were off-label Juxtapid prescriptions that resulted in false claims, they have not pled with particularity that the Defendants' off-label promotion caused any of the false claims to be submitted. Joint Mem. at 18-19 [#151].

Relators must show that at least some subset of claims made for government reimbursement were false as a result of Defendants' actions. See Ge, 737 F.3d at 124; see also

D'Agostino v. ev3, Inc., 845 F.3d 1, 8 (1st Cir. 2016) ("[D]efendant's conduct must include not just materiality but also causation."). Here, Relators have alleged numerous efforts made by Aegerion salespeople to expand the definition of HoFH and mislead doctors into prescribing Juxtapid to patients who do not have HoFH, or even a diagnosis consistent with HoFH. The court need not repeat its analysis here. Relators' allegations provide sufficient indicia of reliability that Aegerion's off-label marketing scheme caused fraudulent claims for Juxtapid to be submitted to federal health care programs.

d. Materiality

Defendants challenge the sufficiency of Relators' allegations that their purportedly fraudulent representations were material to the government's decision to pay any claims for reimbursement for Juxtapid. Joint Mem. 21-25 [#152]. Relying on the Supreme Court's 2016 decision in Universal Health Services, Inc. v. United States ex rel. Escobar, Defendants say that the complaint fails scrutiny under Federal Rules of Civil Procedure 8 and 9(b) because the government was aware of Relators' allegations as of 2013 yet continued to reimburse Juxtapid claims through 2016. Id. at 21-25 (citing 136 S. Ct. 1989, 2003-04 (2016) ("[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.")).

As the First Circuit stated on remand in Escobar, "mere *awareness of allegation*s concerning noncompliance with regulations is different from *knowledge of actual noncompliance*." United States ex rel. Escobar v. Universal Health Services, Inc., 842 F.3d 103, 110 (1st Cir. 2016) (emphasis added). There is no indication that from 2013 through 2016, while the government paid claims for Juxtapid, the government had "actual knowledge" of "actual noncompliance," rather than mere awareness of allegations of noncompliance. Moreover, as this

court has previously recognized, actual knowledge may not be determinative of materiality as there may be other reasons why the government continues to pay these claims. See United States ex re. Williams v. City of Brockton, No. 12-cv-12193, 2016 WL 7429176 (D. Mass. Dec. 23, 2016) (Talwani, J.).

e. Public Disclosure

As a final argument pertaining to summary dismissal of Counts 1 and 2, the Defendants contend that Relators' allegations stem from information that was publicly available, and therefore Relators' claims must be dismissed pursuant to the public disclosure bar on *qui tam* actions, 31 U.S.C. § 3730(e)(4)(A). Joint Mem. 25-28 [#152]. Furthermore, Defendants assert that none of the Relators are an "original source" of the publicly available information, and therefore this exception to the public disclosure bar under 31 U.S.C. § 3730(e)(4)(A)(iii) does not apply. Id. at 28-30.

Under the public disclosure bar, the court shall dismiss a *qui tam* action or claim if the same allegations were publicly disclosed: in a federal criminal, civil, or administrative hearing in which the government is a party; in a congressional, Government Accountability Office, or other Federal report, hearing, or investigation; or from the news media. 31 US.C. § 3730(e)(4)(A). "That bar is designed to foreclose qui tam actions in which a relator . . . attempts to free-ride by merely repastinating previously disclosed badges of fraud. . . . [T]he bar seeks to prevent 'parasitic' suits." United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 53 (1st Cir. 2009) (internal citations omitted). An exception to the public disclosure bar applies if the relator was the "original source" and voluntarily disclosed to the government the information on which the false claim allegations are based, or if the relator provided "knowledge that is independent of and materially add to the publicly disclosed allegations." 31 U.S.C. § 3730(e)(4)(A), (B).

Relators' claims are not barred by public disclosure. Although Aegerion made public its inflated estimate of the prevalence HoFH population, these statements do not by themselves constitute the false claims alleged in the Second Amended Complaint. Rather, it is Aegerion's alleged internal off-label marketing scheme and efforts to convince doctors to prescribe Juxtapid for non-HoFH patients, and the resultant false claim submissions, that make up Relators' claims. "[T]here is no public disclosure when the 'essential background information' is publicly available but no allegation of fraud . . . has been made publicly available." Novak, 806 F. Supp. 2d at 328. Relators may not be the original source of Aegerion's publicly disclosed statements, but they allegedly were the original source of the off-label marketing scheme and purportedly false claim submissions, the information upon which the false claim allegations are based. See Second Am. Compl. ¶ 26.

The Defendants added in the Second Amended Complaint, which was filed after the case was unsealed, also raise the public disclosure bar specifically as it pertains to Relators' allegations against them. See David Scheer's Mem. in support of Joint Mot. to Dismiss ("Scheer Mem.") [#151]; Melanie Detloff and James Frigge's Mem. in support of Joint Mot to Dismiss ("Detloff/Frigge Mem.") [#154]; William Dull's Mem. in support of Joint Mot. to Dismiss ("Dull Mem.") [#159]; Mark Fitzpatrick's Memorandum in support of Joint Mot to Dismiss ("Fitzpatrick Mem.") [#155]; Mark Sumeray's Memorandum in support of Joint Mot. to Dismiss ("Sumeray Mem.") [#156]. But the information that Relators have provided as it pertains to individual Defendants is their alleged involvement within Aegerion in the scheme, during a period of time when Relators, who were employed by Aegerion between 2012 and 2014, claim first-hand knowledge. Second Am. Compl. ¶¶ 4, 8-10, 69, 75-76, 81, 83-84, 92-93, 97-99, 104-105, 149, 153, 159 [#69]. Moreover, Relators allege that they provided the government with a

copy of their Second Amended Complaint on or about July 27, 2017, id. ¶ 26, and they sought leave from this court to file their Second Amended Complaint on September 15, 2017, a week before the case was unsealed. The court does not find any of the claims against the Defendants barred by public disclosure.

Accordingly, for the foregoing reasons, the court declines to summarily dismiss Count 1 and 2 of the Second Amended Complaint.

III. Joint Motion to Dismiss – Count 3: Conspiracy

Count 3 alleges that the Defendants conspired to commit a breach of the FCA, in violation of 31 U.S.C. § 3729(a)(1)(C). Second Am. Compl. ¶¶ 210-213 [#69]. To prove a defendant is liable for conspiring to defraud the government by getting a false or fraudulent claim allowed or paid, a relator must show that "the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; and one or more conspirators performed any act to effect the object of the conspiracy." United States v. Presidents & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 196. (D. Mass. 2004).

Defendants contend that there can be no conspiracy where all Defendants allegedly were acting as agents of Aegerion, and therefore could not have conspired as Aegerion—including its agents—cannot conspire with itself. Joint Mem. 19-20 [#152]. Moreover, the Defendants assert that Relators' allegations fail to plead any particular facts to show the existence of any agreement between the parties, let alone an agreement to defraud the government. They argue that the conspiracy claims therefore must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). Id. at 19-21.

The Supreme Court has referred to the doctrine that a corporation cannot conspire with its own employees or agents as "antitrust law's intracorporate conspiracy doctrine." Cedric Kushner

Promotions, Ltd. v. King, 533 U.S. 158, 166 (2001). "Outside of the antirust context, the scope of the intracorporate conspiracy doctrine is far from settled." Commonwealth ex rel. Fleming v. South Bay Mental Health Center, Inc., 334 F. Supp. 3d 394, 403 n.4 (D. Mass. 2018). In Cedric Kushner Promotions, for example, the Supreme Court found an individual to be a separate entity under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c), from the closely held corporation of which he was president and sole shareholder. The Supreme Court found no consistency with "antitrust law's intracorporate conspiracy doctrine[,]" noting that that doctrine "turns on specific antitrust objectives." The First Circuit, in turn, has shown resistance to extending the doctrine outside of the antitrust context. See Stathos v. Bowden, 728 F.2d 15, 20-21 (1st Cir. 1984) ("We doubt that this 'intracorporate' exception should be read broadly. The cases employing it have rested in large part on precedent drawn from the antitrust field.").

In the FCA context, one court in this district, while not resolving the issue, has noted that "it is questionable whether [the doctrine] would apply . . . ." Presidents & Fellows of Harvard Coll., 323 F. Supp. 2d at 198 n. 40. Other district courts have concluded that the doctrine does apply. See Fleming, 334 F. Supp. 3d at 403 (applying the intracorporate conspiracy doctrine in the FCA context); United States ex re. Hagerty v. Cyberonics, Inc., 95 F. Supp. 3d 240, 269 (D. Mass. 2015) (same).

The court does not need to reach the issue here because, in this case, Relators have alleged that Dr. Rader, a non-Aegerion employee, was a part of this conspiracy. See Second Am. Compl. at 8 n.3; ¶¶ 205-209 [#69]. Relators allege that Dr. Rader conspired with the Aegerion employees, and that he was intimately involved in the FDA process and expanding use of Juxtapid to those with "functional HoFH." Id. at ¶ 62. Although Dr. Rader is alleged to have been a member of Aegerion's Scientific Advisory Board, Dr. Rader was not an employee of

Aegerion and is alleged to have acted as an independent decisionmaker. His alleged interest in the financial success of Aegerion—increased value in the stock that he held and potentially increased royalty payments to his separate employer, UPenn, see id. ¶¶ 51-52, 124- 133—is distinct from the company's financial interest. And, the fact that Dr. Rader has been dismissed from this action does not change his inclusion as part of the alleged conspiracy. See, e.g., United States ex rel. Head v. Kane Co., 798 F. Supp. 2d 186, 201 (D.D.C. 2011) ("[I]t is well-settled that 'all co-conspirators need not be joined to permit any one or more to be held liable for an unlawful conspiracy.'" (quoting Ass'n for Intercollegiate Athletics for Women v. Nat'l Collegiate Athletic, 558 F. Supp. 487, 498 (D.D.C. 1093))).

Moreover, as previously noted, the Second Amended Complaint sufficiently pleaded facts that the Defendants worked in concert to devise and implement Aegerion's off-label marketing scheme, and that marketing scheme caused false claims to be made to the United States government. Accordingly, Relators' conspiracy claim (Count III) has been adequately plead such that it survives this motion to dismiss.\

IV. The Individual Defenses

Each Defendant individually argues that the Second Amended Complaint must be dismissed as to that Defendant. The court examines those individual arguments not addressed above.

a. David Scheer

Defendant Scheer is President of Scheer & Company, Inc., a venture capital firm. Second Am. Compl. ¶ 20 [#69]. The complaint alleges that Dr. Rader recruited Defendant Scheer to establish Aegerion in order to commercialize Juxtapid, id. ¶¶ 43-48, and that Defendant Scheer served on Aegerion's Board of Directors from 2004 through 2016, id. ¶¶ 20, 196. Defendant

Scheer argues that Relators fail to allege with particularity any link between him and the alleged fraud, that any act by him was material to the submission of any false claim, that he entered into an agreement to defraud the government, or that he had actual knowledge or a reckless disregard of any false claim. Scheer Mem. at 5-10 [#151]. Finally, he says he is not responsible for Aegerion's misconduct simply because of his position as a member of the Board. Id. at 8-10.

The Second Amended Complaint outlines Defendant Scheer's prior entrepreneurial endeavors, and his role in establishing and attracting investors to Aegerion prior to it having obtained the rights to develop and sell the drug. Second Am. Compl. ¶¶ 43-49 [#69]. Relators also include a number of conclusory allegations regarding Scheer's overall plan and intentions. See, e.g., id. ¶¶ 62 ("expanding the target population tenfold was precisely what Dr. Rader, Scheer, Beer and other Defendants intended"); id. ¶ 196 ("Defendant Scheer conspired with the other Individual Defendants to establish Aegerion as a company ostensibly serving the needs of the HoFH population, but all the while the goal of the conspiracy was to sell Juxtapid in the off-label market. . . . Scheer would have known that Aegerion could not have achieved its peak sales, in excess of the entire patient population in the United States, without trespassing into off-label marketing"). However, the only allegation potentially tying him to the off-label marketing scheme itself, or even alleging any action by Defendant Scheer after the launch of Juxtapid, is that he attended a Juxtapid launch party in Cabo San Lucas, where he "would have heard [Defendant] Fraser make the presentation on "The Art of Not Defining HoFH," and he "knew that glowing financial predictions ultimately depend on sales for off-label use"); Id. ¶ 77 (internal quotation marks removed). Relators allege no facts that Defendant Sheer directed, implemented, participated or conspired in the alleged marketing scheme.

The Complaint further alleges that Defendant Scheer traded Aegerion stock for a net gain of $1,696,000. Id. ¶ 199. But the allegation that Defendant Scheer sold Aegerion stock does not provide a sufficient connection between him and the alleged fraud. See id. ¶ 199. "A relator does not satisfy the requirements of Rule 9(b) merely by pleading "fraud by hindsight." D'Agostino, 153 F. Supp. 3d at 532 n.9 (quoting Gross v. Summa Four, Inc., 93 F.3d 987, 991 (1st Cir. 1996)); cf. United States v. St. Michael's Credit Union, 880 F.2d 579, 602 (1st Cir. 1989) (noting the prejudicial danger of guilt by association).

Although Relators have a sufficiently alleged that Aegerion employees caused the submission of false claims generally, and that Defendant Scheer benefitted from those submissions, Relators have failed to allege facts showing a connection between Defendant Scheer and the off-label marketing scheme. Accordingly, Relators allegations against Defendant Scheer do not meet even the more-relaxed standard for indirect claims under Fed. R. Civ. P. 9(b). Accordingly, the Joint Motion to Dismiss [#147] is ALLOWED as to all claims against Defendant Scheer.

b. James Frigge and Melanie Detloff

Defendants Frigge and Detloff were former top selling Aegerion sales representative. Second Am. Compl. ¶¶ 13, 18 [#69]. They argue that the allegations against them are not sufficiently particular to meet to satisfy the requirements of Federal Rule of Civil Procedure 9(b). Detloff/Frigge Mem. at 1-9 [#154].

The Second Amended Complaint alleges that Defendant Detloff presented "best practices" for recruiting Juxtapid patients by going to patients' homes to get them to sign consent forms and attempting to recruit those patients' family members while there. Second Am. Compl. ¶ 80 [#69]. Relators further allege that Defendant Detloff personally filled out a statement of

medical necessity form, id. ¶¶ 80, 146, 168, and was listed as the salesperson on three Medicare patients on Chart A, one of whom was 64 years old, id. ¶ 153. As to Defendant Frigge, Relators allege that Defendant Frigge sent medical providers a misleading letter that Aegerion has "a drug in final review with the FDA for patients with *a form of Familial Hypercholesterolemia*," as opposed to identifying HoFH, and that Aegerion was working with Dr. Rader "to identify the appropriate patient population." Id. ¶¶ 67-68 (emphasis added). Relators further allege that Defendant Frigge participated in the internal sales "hunt," which purportedly encouraged Aegerion sales staff to market Juxtapid for off-label use. Id. ¶¶ 93-94.

When looking at the allegations against Defendants Detloff and Frigge in the context of the entire Second Amended Complaint, the court finds that Relators allegations against the two sales representatives satisfy the requirements of Rule 9(b). Defendant Frigge argues that because the letter he allegedly sent to medical providers states that the drug is for "*a form* of Hypercholesterolemia," it is therefore truthful and cannot serve as the basis of a false claim. Detloff/Frigge 6-7 [#154] (citing United States ex rel. Jones v. Brigham and Women's Hosp., 750 F. Supp. 2d 358, 366 (D. Mass. 2010), *vacated and remanded*, 678 F.3d 72 (1st Cir. 2012)). But whether this language was intended to mislead is a genuine issue of material fact better left for the jury. Cf. Jones, 678 F.3d at 96 ("[C]onstruing all facts in favor of Relator, we conclude that Jones generated a genuine issue of material fact as to whether the Defendants acted knowingly when allegedly making false representations in the Application.").

Defendant Detloff makes a similar argument, averring that she made no misstatements in furtherance of the alleged off-label marketing scheme. Detloff/Frigge Mem. 7-8 [#154]. However, as with Defendant Frigge's letter, there is a genuine issue as to whether her statements were intended to encourage the off-label marketing scheme.

Relators have alleged enough facts showing Defendants Detloff and Frigge's knowledge and participation in the off-label marketing scheme to satisfy Rule 9(b)'s particularity requirement. Accordingly, the Joint Motion is DENIED as to Defendants Frigge and Detloff.

c. Mark Fitzpatrick

Defendant Fitzpatrick was Aegerion's Chief Financial Officer from May 2011 to June 2015. Second Am. Compl. ¶ 15 [#69]. Relators state that Defendant Fitzpatrick was on an investor call when Defendant Beer told investors that Aegerion would no longer offer metrics other than sales, id. ¶ 120, and, as CFO, knew the predicted revenue that Aegerion had expected to collect and Aegerion's actual revenue, see id. ¶ 174. Defendant Fitzpatrick also presented the company's financial information at quarterly investor calls, including one stating expectations for "U.S. growth" in July 2014 (when the market was presumably already saturated). Id. ¶ 176.

Defendant Fitzpatrick argues his participation in quarterly investor calls during which the company's financial condition was discussed is insufficient to show that he had knowledge, or was deliberately ignorant, of the truth or falsity of Juxtapid claims. Fitzpatrick Mem. 1-8 [#155]. Accordingly, Defendant Fitzpatrick argues that the Second Amended Complaint must be dismissed against him pursuant to Rules 12(b)(6) and 9(b). Id. at 6-8.

Although a close call, the Second Amended Complaint has alleged enough to survive a motion to dismiss. Although Defendant Fitzpatrick may have been one step removed from the off-label marketing and sales itself, his intimate knowledge of the company's financial situation, the company's rapid growth beyond what would be possible but for the off-label marketing, and his participation in the investor call at which Defendant Beer announced that Aegerion would no longer offer non-sales metrics, is sufficient to show a willful blindness to the fact that Juxtapid was being marketed and sold for off-label use. And, unlike the allegations against Defendant

Scheer, Relators allege at least some affirmative act that Defendant Fitzpatrick took in the operation of Aegerion during the time that the off-label marketing scheme was taking place from which a reasonable juror could infer his knowledge and participation in the scheme.

Accordingly, the Joint Motion [#147] is DENIED as to Defendant Fitzpatrick.

d. Mark Sumeray

Defendant Sumeray served as Aegerion's Chief Medical Officer from the summer of 2011 through February 2016. Second Am. Compl. ¶ 21 [#69]. Relators have alleged that Defendant Sumeray told investors on several occasions that the HoFH population in the U.S. was 3,000 instead of 300, and that there "may be a more significant population of [HoFH] patients in need of therapy then we had initially anticipated." Id. ¶¶ 130, 189-192.

Defendant Sumeray argues that the Second Amended Complaint is void of allegations that he participated in the marketing of Juxtapid or did anything other than attend meetings where others purportedly made false statements having nothing to do with marketing. Sumeray Mem. 1-4 [#156]. He contends that any statements that he made were qualified statements that by their nature cannot be false, and the allegations against him lack the precision necessary to show the falsity of the claims, or any knowledge thereof, under Federal Rules of Civil Procedure 9(b) and 12(b)(6). Id. at 4, 7.

Despite these contentions, Defendant Sumeray's statements that the HoFH population may not just be larger than originally anticipated, but ten-fold what Aegerion originally said to be the actual population of HoFH patients in the United States, lead to the natural inference that he was both aware of and participating in the company's strategy to inflate this number to increase sales. These inflated estimates were pivotal to the alleged off-label marketing scheme.

Accordingly, because Relators have sufficiently pled Defendant Sumeray's involvement in the alleged fraud, the court DENIES the Joint Motion [#147] as to Defendant Sumeray.

e. Craig Fraser

Defendant Fraser, an Aegerion employee from October 2011 to August 2015, was Aegerion's President in charge of U.S. Commercial and Global Manufacturing and Supply Chain and Chief Operating Officer ("COO"). Second Am. Compl. ¶ 17 [#69]. The Second Amended Complaint includes various allegations that Defendant Fraser actively participated in the off-label marketing and sales scheme that resulted in false claim submissions. Relators alleged that: Defendant Frasier stated to Relator Clark that "3750 is our target @ label *and off label*," id. ¶ 69 (emphasis in original); Defendant Fraser made a presentation entitled "The Art of Not Defining HoFH" at the Juxtapid Launch Meeting in January 2013, id. ¶ 76; Defendant Fraser instructed sales representative to use misleading techniques to try to convince doctors to prescribe Juxtapid for patients without HoFH, see id. ¶¶ 76, 93, 100-101; he further instructed the Aegerion sales force to push the theory that the definition of HoFH was debatable, id. ¶ 99; Defendant Fraser was present during Defendant Detloff's "best practices" presentation, id. ¶ 80; he encouraged sales representatives to "data mine" for Juxtapid candidates by ignoring the FDA-approved indication, id. ¶ 85; and Defendant Fraser engaged in a competition with other executives during which he obtained prescriptions for Juxtapid for patients for both on and off-label use, id. ¶ 178.

Defendant Fraser argues that none of the facts alleged tie him to any false claims submitted to the government for reimbursement. Fraser Mem. 2 [#157]. But this argument states no more than the joint argument discussed and rejected above. The Joint Motion [#147] is DENIED as to claims against Defendant Fraser.

f. Marc Beer

Defendant Beer is Aegerion's former CEO before his departure in July 2015. Second Am. Compl. ¶ 12 [#69]. Defendant Beer argues that that Relators did not point to any specific directions he gave to the Aegerion sales team to promote Juxtapid for off-label use, and therefore fail to meet Rule 9(b)'s heightened standard for fraud allegations. Beer Mem. 3-5 [#158]. He asserts the Second Amended Complaint must therefore be dismissed as to the claims against him.

As to Defendant Beer specifically, Relators alleged that the off-label marketing scheme began once Defendant Beer became CEO of Aegerion, see Second Am. Compl. ¶¶ 59-60 [#69], and that Defendant Beer promoted Dr. Rader's "functional" HoFH theory, see id. ¶¶ 59-64. Defendant Beer made numerous public appearances at which he alleged that the estimate of patients with HoFH was 3,000 as opposed to 300, id. ¶¶ 81, 91, 102-104, 106, 114, intentionally misinterpreted scientific data at an investor conference, id. ¶¶ 109, 110, and only provided investors with revenue amounts rather than number of sales of Juxtapid, id. ¶ 120. Moreover, Relators contend that Defendant Beer placed pressure on the sales representatives to aggressively sell Juxtapid and to "data mine" for Juxtapid candidates by ignoring the FDA-approved indication, id. ¶¶ 85-86, 92-94, tracked the number of Juxtapid claims paid by government healthcare programs, while refusing to disclose that information, id. ¶ 148, and intentionally sought out medical practices with a high number of Medicare and Medicaid patients, see id. ¶¶ 152-153.

Relators have asserted particularized allegations against Defendant Beer sufficient to survive a motion to dismiss pursuant to Rule 9(b) or 12(b)(6). Relators sufficiently allege that Defendant Beer was intimately involved with, and participated in, the off-label marketing scheme. Accordingly, the Joint Motion to Dismiss [#147] is denied as to Defendant Beer.

g. William Dull

Defendant Dull is the former Director of the Southeast Region sales territory and Vice President of Global Marketing for Aegerion. Second Am. Compl. ¶ 14 [#69]. Relators allege that Defendant Dull was present while Defendant Detloff made her "best practices" pitch, which outlined many of practices used in Aegerion's off-label marketing scheme. Id. ¶ 80. Defendant Dull is alleged to have encouraged the practice of data mining databases for potential Juxtapid patients and encouraging the sales team to target large practices to perform these searches. Id. ¶ 89. He is also alleged to have taken a lead role in at least one training session of the Aegerion sales team meetings at which the "best practices" presentation was made. Id. ¶ 170.

Defendant Dull argues that the allegations against him are inadequate, as a matter of law, to show that he had the requisite scienter to participate in the conspiracy, and that Relators have failed to show that his actions caused false claim submissions or were material to the payment of those claims. Dull Mem. at 1-3 [#159].

Based on the allegations in the Second Amended Complaint and the inferences to be drawn from them, Defendant Dull was at the very least deliberately indifferent to the off-label marketing scheme occurring in his presence, and at worst was an active participant in the alleged conspiracy. Therefore, the Joint Motion to Dismiss [#147] is DENIED as to Defendant Dull.

h. Greg Fenner

Defendant Fenner was National Sales Director during his employment at Aegerion from July 2012 to March 2017. Second Am. Compl. ¶ 15 [#69]. Defendant Fenner argues that the Second Amended Complaint fails to allege with particularity that he caused the submission of false claims, and that he acted with the requisite state of mind for false claims to be submitted. Fenner Mem. 1-5 [#160].

The allegations specific to Defendant Fenner in the Second Amended Complaint are that he was present during Defendant Detloff's "best practices" presentation, Second Am. Compl. ¶ 80 [#69]; that he presented HoFH as more prevalent than was supported by accepted literature and urged against genetic testing as a means of diagnosing HoFH, id. ¶ 81; that he presented a PowerPoint presentation at the Aegerion National Sales meeting, of which the "Lessons Learned" included "not defining HoFH patients," "case based selling," "REMS not an impediment," and "EMR patient mining," id. ¶ 83; see also id. ¶ 85. He is further alleged to have set out the bonus incentive for the sales "hunt," id. ¶¶ 93-95, and cautioned sales rep that they must choose speakers that "believe in *our* definition of HoFH" to give speeches about HoFH, id. ¶ 96. Defendant Fenner is alleged to have put action to his words, telling one doctor that Aegerion could not engage him as a speaker unless he prescribed more Juxtapid. Id. ¶ 105. The Second Amended Complaint also includes allegations that Defendant Fenner told Relator Szudlo that the term HoFH was a faux pas when speaking to doctors' offices, and that she should talk to doctors using misleading generalities about the use of Juxtapid. Id. ¶¶ 97-99.

The Second Amended Complaint thus sufficiently alleges that Defendant Fenner was not only well informed and aware of the off-label marketing scheme but was pushing the scheme to the sales team. Given these allegations, his mental state while taking these actions is a question for the jury. See Karvelas, 360 F.3d at 228 (Rule 9(b) does not require a qui term relator to "plead with particularity allegations concerning defendants' knowledge, reckless disregard, or deliberate ignorance on the submission of false claims. The characterization of a state of mind, after all, does not lend itself to detailed pleading.").

Accordingly, the court DENIES the Joint Motion to Dismiss [#147] as to claims against Defendant Fenner.

V. Conclusion

For the reasons set foregoing reasons, the court ALLOWS in part and DENIES in part the Joint Motion to Dismiss [#147]. Because the Second Amended Complaint [#69] does not sufficiently allege that Defendant Scheer was a participant in the off-label marketing of Juxtapid that caused the submission of false claims for reimbursement from government health care providers, the joint motion to dismiss is ALLOWED as to Defendant Scheer. All claims against Defendant Scheer are DISMISSED.[11] The joint motion to dismiss is otherwise DENIED.

IT IS SO ORDERED.

Date: March 31, 2019

/s/ Indira Talwani
United States District Judge

[11] Because of the continuing proceedings against the other Defendants, this interlocutory order does not amount to a final judgment. Fed. R. Civ. P. 54(b). In light of the United States' and the Plaintiff States' requests as to any dismissal, see Notice of Election to Decline Intervention [#99], Plaintiff States' Notice of Election to Decline Intervention [#110], the court anticipates that, unless this order is subsequently revised, judgment as to Defendant Sheer will enter with prejudice as to the Relators and without prejudice as to the United States and the Plaintiff States.