

United States District Court
For the Northern District of California

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

STROM ex rel. UNITED STATES OF AMERICA,

Plaintiff,

v.

SCIOS, INC. ET AL.,

Defendants.

No. C 05-3004 CRB

ORDER DENYING MOTION TO DISMISS

This case involves allegations by the United States that Defendants Scios Inc. and Johnson & Johnson (collectively, “Defendants”) fraudulently caused thousands of doctors to submit false claims for reimbursement under Medicare and other federally organized health programs.¹ The United States argues that this scheme violated the False Claims Act (“FCA”), 31 U.S.C. § 3729(a)(1). Defendants move to dismiss under Rule 12(b)(6) for failure to state a claim and under Rule 9(b) for failure to make allegations with sufficient particularity. As to the 12(b)(6) arguments, Defendants contend that the claims submitted by doctors to Medicare were not actually false, and that the False Claims Act should not be used to second guess decisions made by doctors. As to the 9(b) arguments, Defendants contend

¹ While the vast majority of claims at issue in this case were submitted to Medicare, the Complaint also alleges fraud with regard to claims submitted to the TRICARE program, 10 U.S.C. § 1071 *et seq.*, and the Federal Employee Health Benefits Program, 5 U.S.C. § 8901 *et seq.* The parties do not dispute that the relevant standards for off-label coverage are materially similar, and Defendants’ motion addresses all claims together. Therefore, this order discusses all claims generally as “Medicare” claims.

1 that the Complaint fails sufficiently to specify the details of the individual claims and that the
2 claims were extrapolated from an insufficiently precise algorithm. Further, Defendants argue
3 that the Complaint fails to allege a causal link between Defendants' actions and the
4 submission of some of the claims to Medicare and other federal programs.

5 Plaintiff's complaint seeks relief based on a relatively novel theory. While a few
6 district courts across the country have considered analogous complaints, there is little circuit-
7 level authority. For the reasons explained below, Defendants' motion to dismiss is DENIED.
8 While Defendants' arguments may gain more traction at the summary judgment stage or at
9 trial, at present the Complaint sufficiently alleges a cause of action under the FCA.

10 BACKGROUND

11 Because this case comes before the Court on a motion to dismiss, we begin by
12 summarizing the extensive allegations contained in the Complaint. As described below, the
13 material allegations revolve around whether or not Defendants induced doctors to prescribe
14 their drug – Natrecor – for a use that was not medically accepted. Natrecor was certified by
15 the FDA as effective when used for episodes of “acutely decompensated congestive heart
16 failure,” but Plaintiff alleges that Defendants recklessly encouraged doctors to prescribe the
17 drug for non-acute episodes. Plaintiff argues that use of this drug for non-acute episodes was
18 not medically accepted, and therefore was not eligible for reimbursement under Medicare or
19 other federal health care programs.

20 Scios developed a drug called Natrecor in the 1990s “for the short-term treatment of
21 patients with acutely decompensated congestive heart failure (‘ADHF’). Decompensation
22 means that the patient’s lungs have accumulated fluid.” Comp. ¶ 39. In August 2001, based
23 on the results from a recent clinical study, the FDA approved Natrecor for a limited use. The
24 FDA-approved label read as follows:

25 Natrecor (nesiritide) is indicated for the intravenous treatment of patients with acutely
26 decompensated congestive heart failure who have dyspnea at rest or with minimal
27 activity. In this population, the use of Natrecor reduced pulmonary capillary wedge
28 pressure and improved dyspnea.

Id. ¶ 43 (emphasis added). In the context of Medicare reimbursement, use of Natrecor for the
purpose listed on the label constitutes “on-label” coverage. Medicare coverage for the use of

1 Natrecor for any other purpose constitutes “off-label” coverage. While Medicare does
2 indeed cover off-label uses of drugs in some contexts, the Medicare Benefits Policy Manual
3 provides that the coverage “of an outpatient drug for an off-label use occurs only where the
4 use is medically accepted, taking into account the major drug compendia, (*e.g.*, Drugdex,
5 American Hospital Formulary Service, and U.S. Pharmacopeia-Drug Information),
6 authoritative medical literature, and/or accepted standards of medical practice.” *Id.* ¶ 30. As
7 Defendants explain, this “medically accepted” terminology clarifies the applicable statutory
8 language, which provides coverage for uses that are “reasonable and necessary.” *See* 42
9 U.S.C. § 1395y(a)(1)(A); *see also Nat’l Med. Enters. v. Bowen*, 851 F.2d 291 (9th Cir. 1988)
10 (“The [Medicare] Manual is a guide for intermediaries in applying the Medicare statute and
11 reimbursement regulations and does not have the binding effect of law or regulation.”).

12 A short time after Natrecor’s approval, Scios started what was known as “the FUSION
13 I trial.” *Id.* ¶ 48. The name “FUSION I” was derived from the study’s full name:
14 “Management of Heart Failure after Hospitalization with Follow Up Serial Infusions of
15 Nesiritide in an Outpatient Setting.” *Id.* (emphasis added). As explained more thoroughly
16 below, Plaintiff alleges that this outpatient use of Nesiritide constitutes an “off-label” use of
17 the drug because it was not limited to “acute” episodes of congestive heart failure. Further,
18 Plaintiff alleges that such a use was not reasonable and necessary. “FUSION I was a pilot
19 study designed only to assess the ability of a patient with chronic congestive heart failure to
20 tolerate . . . the safety of serial infusions . . . and thus was not a study that could be used to
21 determine the efficacy of the serial infusions.” *Id.* According to the Complaint, despite the
22 fact that the FUSION I study was not designed to assess the efficacy of outpatient use of
23 Nesiritide, Scios announced in a widely disseminated press release that “[d]ata from the
24 FUSION I study suggests that the Natrecor-treated patients show improvements in clinical
25 status with longer life expectancy and a lower frequency of hospitalizations compared to the
26 group of patients receiving standard care.” *Id.* ¶ 51. Plaintiff alleges that, because of the
27 limited nature of the FUSION I study, such a claim was scientifically unsupported.

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1 The Complaint alleges that this press release, in conjunction with the various other
2 marketing activities described below, shows that Defendants were encouraging a use of the
3 drug that was not authorized by the FDA. This is so, explains the Government, because an
4 outpatient use of the drug is inherently inconsistent with the “acutely decompensated
5 congestive heart failure” that is listed on the FDA label.

6 By definition, an acute episode of decompensated [congestive heart failure] with
7 dyspnea at rest or with minimal activity is an emergency situation that does not occur
8 on a scheduled basis. . . . Defendants knew that outpatient infusions would generally
9 not be for the acutely decompensated patients described in Natrecor’s label, except in
the rare circumstance when an acutely decompensated patient with dyspnea at rest or
with minimal activity sought care from a doctor’s office or clinic instead of a hospital
or emergency room.

10 Id. ¶ 57-58. Because these outpatient infusions would generally not occur in emergency
11 situations, Plaintiff contends that use of the drug in such a context almost always constitutes
12 an off-label use. Id. ¶ 58.

13 Plaintiff further alleges that Defendants were aware that outpatient use constituted an
14 off-label use. “At Scios’s October 2003 National Sales Meeting, Cox noted that half of the
15 Natrecor business was coming from the outpatient segment, and that Natrecor would
16 ultimately go from an acute medication to a chronic medication. He further noted that the
17 outpatient serial dose of Natrecor used for FUSION I was not within the label.” Id. ¶ 60.

18 Similarly,

19 at Scios’s April 2002 National Sales Meeting, Scios Marketing Director George
20 Mahaffey stated that intermittent infusions were not on label, and characterized the
21 FUSION I study as off label. In a February 10, 2003 public conference call by Scios
22 and J&J regarding their acquisition agreement, George Schreiner, Scios’s Vice
23 President and Chief Scientific Officer, said that the outpatient use of Natrecor which
24 was being studied in the FUSION I trial ‘of course is not currently within label but we
25 are conducting the appropriate studies to potentially make it eligible for label
26 extension.

27 Id. ¶ 61.

28 As noted above, Plaintiff also alleges that Defendants went to great efforts to market
Natrecor for these off-label uses despite the absence of medical evidence supporting its
efficacy for such uses. “A draft of the Natrecor 2003 Business Plan (reviewed by Scios CEO
Richard Brewer) listed as one of Scios’s 2003 objectives: ‘Achieve 2% penetration of the
patients treated serially via outpatient infusion for CHF by year-end 2003,’ and as one of its

1 long-term objectives: ‘Develop the outpatient infusion market and achieve at least 15%
2 penetration of the estimated 145k patients treated with serial outpatient infusion by 2007.’
3 Id. ¶ 63. “On June 6, 2002, Kim Hillis, Scios’s Director of Sales, wrote to the sales
4 management with her thoughts on the areas where Scios’s marketing, clinical, and sales
5 efforts should be directed to achieve \$1 billion in annual sales of Natrecor. Outpatient
6 infusion was the first area Hillis listed.” Id. ¶ 65. Defendants pursued these objectives
7 despite the fact that “the off-label use was unsupported by *any* credible study showing that
8 the serial outpatient infusions had any benefit for patients.” Id. ¶ 5.

9 As for particular marketing efforts, Plaintiff alleges that Defendants relied on a variety
10 of marketing strategies to promote use of Natrecor in the outpatient context. First,
11 “Defendants encouraged health care providers to start outpatient infusion clinics that used
12 Natrecor. For example, Defendants paid grant funds and provided other resources to health
13 care providers to use in starting outpatient infusion clinics.” Id. ¶ 71. Moreover,

14 [i]n approximately late 2002 or early 2003, at a sales management meeting in Dallas,
15 management was told to direct the sales representatives to ‘[a]ggressively pursue
16 business’ in the outpatient infusion market. During a sales representative training
17 session in February 2004, Defendants discussed separate sales goals for ‘Acute CHF’
18 sales, and ‘Outpatient’ sales, and their plan to continue marketing Natrecor for
19 outpatient use by ‘establish[ing] a growing prescriber and advocate base that will
20 drive Natrecor as the preferred management strategy in the outpatient setting.’

21 Id. ¶ 74.

22 In addition to simply focusing sales resources on expanding the outpatient market,
23 Defendants also paid health care professionals to encourage further use of Natrecor in
24 outpatient contexts. “From 2003 to 2005, Defendants paid over \$100,000 to a nurse at South
25 Bay. This nurse made promotional speeches relating to the outpatient use of Natrecor; she
26 trained other health care providers on the outpatient use of Natrecor; and her name appears as
27 author on various publications relating to the outpatient use of Natrecor, including, *inter alia*,
28 ‘Nesiritide in an Outpatient Infusion Clinic Setting - Case Studies of 17 patients’” Id. ¶
76. Moreover, “Defendants paid numerous other health care professionals who authored
articles, made promotional speeches, and taught continuing medical education courses that
promoted the outpatient use of Natrecor.” Id. ¶ 77. The Complaint lists a series of examples

1 at paragraphs 78 through 80. The complaint further alleges that Defendants encouraged this
2 use of Natrecor “for serial infusions despite the lack of any scientific evidence to support the
3 efficacy of such treatment.” Id. ¶ 81.

4 Next, the Complaint alleges that “Defendants also encouraged scheduled outpatient
5 infusions of Natrecor through their Centers of Excellence (later renamed Commitment to
6 Excellence) Program.” Id. ¶ 82.

7 Under this program, Defendants sent health care practitioners who were potentially
8 interested in starting outpatient infusion clinics to existing outpatient clinics that used
9 Natrecor, in order to observe and learn. For example, prior to opening their own
10 outpatient clinics, doctors and nurses from New York and Rhode Island visited South
11 Bay to meet with the South Bay nurse and see how the South Bay clinic operated. At
12 least three of the doctors who met with the nurse and then opened their own outpatient
13 clinic each subsequently submitted claims to Medicare totaling more than \$500,000
14 for serial, outpatient infusions of Natrecor. In a November 19, 2003 presentation to
15 J&J officials, Scios officials acknowledged that Natrecor outpatient infusions were
16 due in part to the Centers of Excellence program.

17 Id. ¶ 82. Defendants also “hired a company called Ingenix to ghostwrite articles about
18 Natrecor, including its outpatient use, and arranged to submit them for publication in
19 journals. Ingenix wrote the articles and Defendants selected the doctors and nurses to place
20 their names on the articles as ‘authors.’” Id. ¶ 84.

21 The Complaint further alleges that Defendants were well aware of the frequency with
22 which heart failure patients – Natrecor’s customers – were covered by Medicare. “A
23 presentation at the August 2001 Natrecor launch National Sales Meeting by Scios Vice
24 President of Sales and Marketing Tom Feldman noted that ‘[o]ver 80% of the [congestive
25 heart failure] patient population is over 65 years old.’ That same presentation noted that
26 Medicare paid for 72.98% of the claims for [congestive heart failure] diagnosis code (ICD-9)
27 428.0, and stated that [congestive heart failure] is the ‘[s]ingle largest expense for
28 Medicare.’” Id. ¶ 91. Because such a large number of Natrecor recipients were covered by
Medicare, “Defendants established a reimbursement team, headed by Christopher Panarites,
to handle reimbursement issues and the Medicare Contractors’ local coverage determinations
(‘LCDs’) regarding Natrecor. The main objective of Mr. Panarites’s job was to maintain
unrestricted access to Natrecor in the outpatient setting.” Id. ¶ 94.

1 The Complaint notes that Scios, “without any scientific support for the efficacy of the
2 serial infusions, urged Medicare Contractors to cover serial outpatient infusions.” Id. ¶ 106.
3 In particular, the Complaint explains that “Scios routinely touted both the safety and alleged
4 efficacy results of the limited FUSION I study to the Medicare Contractors in an effort to
5 support coverage.” Id. As a result, “Five Medicare Contractors (three in the New York
6 region) issued Local Coverage Determinations (‘LCDs’) allowing limited coverage for the
7 outpatient serial use of Natrecor” Id. “A number of other Medicare Contractors
8 specifically denied coverage for this use.” Id. On May 17, 2005, a number of these
9 Contractors “submitted a formal request to [the Centers for Medicare & Medicaid Services]
10 for a National Coverage Determination (‘NCD’) on Natrecor, noting that ‘the specific reason
11 for our NCD request focuses on the ‘off-label’ use of intravenous Nesiritide’” Id. ¶ 106.
12 In March of 2006, the Centers for Medicare & Medicaid Services (“CMS”), which
13 administers the Medicare Program, determined that Medicare coverage would be unavailable
14 for this off-label use. The CMS explained that

15 Much of the reported research on the use of nesiritide for the intermittent treatment of
16 chronic heart failure appears in abstracts and has not yet been published as full peer-
17 reviewed journal articles. In general, abstracts do not provide sufficient information
18 for us to evaluate the strength of the reported findings critically. . . . The published
19 articles . . . supporting the off-label use of nesiritide for chronic heart failure are
20 hampered by methodological shortcomings, including small sample size and the lack
21 of long term outcome data.

19 Id. ¶ 114.

20 The Complaint asserts two causes of action: presentation of false claims to the United
21 States government in violation of the False Claims Act, and Unjust Enrichment. As to the
22 False Claims Act claim, the Complaint specifically alleges that “Scios and J&J knowingly
23 caused to be presented false or fraudulent claims for payment or approval to the United
24 States for the scheduled, serial use of Natrecor that were not covered by the federal health
25 care programs.” Id. ¶ 122. As to the claim for Unjust Enrichment, the Complaint relies upon
26 the presentation of false claims to argue that “Scios and J&J were unjustly enriched at the
27 expense of the United States in an amount to be determined which, under the circumstances,
28 in equity and good conscience, should be returned to the United States.” Id. ¶ 125.

DISCUSSION

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2 Defendants move to dismiss. First, they argue that the United States has failed to
3 satisfy the pleading requirements of the False Claims act. This is so, they contend, because
4 the Complaint does not allege that the claims submitted to Medicare violated any bright-line
5 rule. The conduct alleged, argue Defendants, is better regulated by means other than the
6 False Claims Act. For the reasons explained more thoroughly below, this motion is
7 DENIED. The Complaint sufficiently alleges that Defendants’ reckless misrepresentation of
8 scientific evidence caused doctors to submit claims for treatment that were not reasonable
9 and necessary, and hence were not eligible for reimbursement under Medicare.

10 Second, Defendants argue that Plaintiff fails to plead the FCA cause of action with
11 sufficient particularity, and ask this Court to dismiss the Complaint under Rule 9(b). This
12 argument, too, is DENIED.

13 **1. Statutory Background and Applicability to Pharmaceuticals**

14 Before addressing the specific arguments made by Defendants, it will be helpful to
15 outline both the provisions of the False Claims Act, and a case that has addressed its
16 application to the pharmaceutical context.

17 The Complaint proceeds under one section of the False Claims Act. That section,
18 codified at 31 U.S.C. § 3729(a)(1)(A), provides that any person who “knowingly presents, or
19 causes to be presented, a false or fraudulent claim for payment . . . , is liable to the United
20 States government for a civil penalty of not less than \$5,000 and not more than \$10,000, . . .
21 plus 3 times the amount of damages which the Government sustains because of the act of that
22 person.” *Id.* A person “knowingly” presents a false claim when that person “has actual
23 knowledge of the information[,] acts in deliberate ignorance of the truth or falsity of the
24 information[,] or acts in reckless disregard of the truth or falsity of the information.” *Id.* §
25 3729(b)(1)(A)(i)-(iii).

26 A small number of district court orders from across the country have addressed the
27 pleading requirements of this act in the pharmaceutical context. Among the most famous of
28 these is United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001).

1 In Parke-Davis, the relator alleged that the defendant had engaged in a fraudulent scheme to
2 promote the sale of Neurontin for off-label uses. The complaint alleged that this scheme
3 caused the submission of false claims to Medicaid. The defendant argued *inter alia* that the
4 complaint was an attempted “end-run around the enforcement provisions of the FDCA by
5 creating a cause of action for money damages.” Id. at 51. While the court agreed that the
6 FCA could not be converted into a private right of action to remedy all violations of
7 regulatory law, it concluded that “the FCA *can* be used to create liability where failure to
8 abide by a rule or regulation amounts to a material misrepresentation[] made to obtain a
9 government benefit. Thus, the failure of Congress to provide a cause of action for money
10 damages against a pharmaceutical manufacturer for marketing off-label drugs does not
11 preclude an FCA claim where the manufacturer has knowingly caused a false statement to be
12 made to get a false claim paid or approved by the government” Id. (citations omitted).

13 The defendant also argued that the complaint had not “accounted for the independent
14 actions of the physicians who wrote the off-label prescriptions and the pharmacists who
15 accepted and filled the off-label prescriptions.” Id. at 52. The court rejected this argument,
16 noting that “[u]nder black letter law . . . such an intervening force only breaks the causal
17 connection when it is unforeseeable.” Id. (citing *Dobbs, et al., Prosser and Keeton on Torts*
18 § 44, at 303-04 (5th ed. 1984)). In the context of that case, “when all reasonable inferences
19 are drawn in favor of the Relator, the participation of doctors and pharmacists in the
20 submission of false Medicaid claims was not only foreseeable, it was an intended
21 consequence of the alleged scheme of fraud.” Id. at 52-53.

22 The district court declined to dismiss the case.

23 **2. Defendants’ Arguments Under Rule 12(b)(6)**

24 Defendants’ memorandum in support of dismissal under Rule 12(b)(6) urges this
25 Court to conclude that “the False Claims Act only applies where there is a bright line rule.”
26 Mot. at 7. Defendant goes on to cite to a variety of cases for the proposition that “the False
27 Claims Act has historically been applied in cases involving patently obvious falsehoods.” Id.
28 Indeed, Defendants surely are correct that the “archetypal *qui tam* FCA action . . . [is] filed

1 by an insider at a private company who discovers his employer has overcharged under a
2 government contract.” Id. (quoting United States ex rel. Hopper v. Anton, 91 F.3d 1261,
3 1266 (9th Cir. 1996)).

4 However, Defendants overstate their claim. Defendants repeatedly urge this Court to
5 require an allegation of “an objective lie” that a defendant “knows to be false,” Mot. at 7, but
6 Defendants fail to cite or acknowledge the statutory definition of “knowing.” In contrast to
7 Defendants’ implications, the FCA defines “knowing” to include a defendant who “acts in
8 deliberate ignorance of the truth or falsity of the information” and a defendant who “acts in
9 reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729. This
10 statutory definition broadens the reach of the FCA beyond what Defendants suggest is its
11 outer limit. While Defendant is correct that FCA cases frequently rely on the word “lie,” it is
12 clear that this term is used to address the falsity of a claim, rather than whether the defendant
13 has actual knowledge of falsity. Adopting the latter as the benchmark for FCA claims would
14 directly conflict with the statutory language, and this Court therefore rejects the invitation to
15 do so.

16 Given this broader definition of “knowing,” Plaintiff has succeeded in stating a claim
17 under the FCA. In sum, the Government alleges that Defendants’ marketing activities
18 created the market for the outpatient use of Natrecor, and that Defendants encouraged such a
19 use even though they had no credible evidence that Natrecor was effective in that context.
20 Because Defendants had no evidence supporting the efficacy of Natrecor in the outpatient
21 context, Plaintiff effectively alleges that they acted in reckless disregard of the truth when
22 they encouraged submission of such claims to Medicare. See 31 U.S.C. § 3729(a)(1)(A)
23 (extending liability to parties who “caused to be presented” a false claim for payment).
24 “Reckless disregard” satisfies the “knowing” element of an FCA action. See 31 U.S.C.
25 § 3729(b)(1).

26 Further, Plaintiff alleges that the drug was not, in fact, effective when used for the off-
27 label purpose. Because the statute permits reimbursement only for “reasonable and
28 necessary” treatments, 42 U.S.C. § 1395y, a prescription of Natrecor in a context where it is

1 not “reasonable” or “necessary” would be statutorily ineligible for reimbursement. This
2 satisfies the FCA’s requirement of a “false” statement.²

3 As to evidence of Defendants’ reckless disregard, Plaintiff points first to the FUSION
4 I study, which was allegedly the central piece of evidence used by Defendants to support
5 outpatient use of Natreacor. The Complaint alleges that this study “was not a study that could
6 be used to determine the efficacy of the serial [outpatient] infusions.” Comp. ¶ 48. Plaintiff
7 alleges that the truth of the matter is that Natreacor is simply not effective in the outpatient
8 setting: a later study, properly designed to isolate the efficacy of the drug, “did not show any
9 significant benefits of serial outpatient Natreacor infusions in comparison to standard care.”
10 Id. ¶ 54. Therefore, alleges Plaintiff, use of Natreacor in that setting could not be “reasonable
11 and necessary” as required by Medicare.

12 Defendants suggest that they are shielded from liability because there was no clear
13 evidence demonstrating that Natreacor was not suited to outpatient use, and further because a
14 number of regional Medicare Contractors authorized reimbursement for outpatient use of
15 Natreacor. This argument both overstates the FCA’s “knowledge” requirement and
16 understates the breadth of Plaintiff’s allegations. First, as to whether there was “clear
17 evidence” demonstrating that Natreacor was not suited to outpatient use, such evidence is
18 unnecessary. While Defendants are correct that such evidence would establish that
19 Defendants “had actual knowledge” that Medicare would not pay for outpatient uses of
20 Natreacor, the FCA simply does not require “actual knowledge.” As discussed above, the
21 FCA also penalizes those who act in “deliberate ignorance of the truth or falsity of the
22 information” and in “reckless disregard of the truth.” The fact that Defendants are alleged to
23 have strenuously supported the efficacy of Natreacor, even when there was no scientific proof
24 supporting those claims, sufficiently establishes allegations of “reckless disregard of the
25 truth.”

26
27 ² This is not to say, as Defendants suggest, that this Court is “second-guess[ing] doctors’
28 considered medical opinions.” Mot. at 10. Rather, this Court acknowledges that the Complaint
alleges that doctors did not, in fact, make considered medical judgments. Instead, the Complaint
alleges that doctors prescribed Natreacor for outpatient use only because they were induced to do
so by Defendants’ misrepresentations.

1 Second, as to whether the Contractors' authorization of off-label reimbursement
2 absolves Defendants, Plaintiff alleges that the only reason those Contractors authorized
3 reimbursement was because of Defendants' misrepresentations. In particular, the Complaint
4 alleges that "[i]n 2004 and 2005, Scios, without any scientific support for the efficacy of the
5 serial infusions, urged Medicare Contractors to cover serial outpatient infusions. For
6 example, Scios routinely touted both the safety and alleged efficacy results of the limited
7 FUSION I study to the Medicare Contractors in an effort to support coverage." Comp. ¶ 106.
8 As explained above, Plaintiff separately alleges that this FUSION I study did not in fact
9 support the efficacy of outpatient use of Natreacor. In other words, Plaintiff alleges that the
10 Contractors were duped in the same way that doctors were duped: they were told that certain
11 medical evidence existed, when in fact it did not. Making inferences in favor of the non-
12 moving party, as is required at this stage, Plaintiff has sufficiently alleged a violation of the
13 False Claims Act.

14 **3. Defendants' arguments under Rule 9(b)**

15 Defendants also argue that the Complaint is insufficiently particular under Rule 9(b)
16 of the Federal Rules. "[C]omplaints brought under the FCA must fulfill the requirements of
17 Rule 9(b)." Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001). Specifically,
18 Defendants argue that the complaint is inadequate for two reasons: (1) "the Complaint as a
19 whole fails to identify the allegedly false claims with the particularity courts have required,
20 instead using a formula to lump together all the prescriptions written during a six-year
21 period;" and (2) "the Complaint fails to allege a causal connection of any sort between Scios
22 and Natreacor prescriptions written months after Scios directed its sales force to limit
23 promotion to hospital use." Mot. at 11-12.

24 **a. Failure to sufficiently identify the false claims**

25 Defendants make two arguments with regard to the identification of the false claims.
26 First, Defendants argue that the Complaint itself does not specify the details of the thousands
27 of claims that are alleged to have violated the FCA. Instead, the Complaint alleges a total
28 estimate of the number of claims, and alleges that all these claims were submitted because of

1 Defendants' misrepresentations. Plaintiff submitted a database containing the details of the
2 claims themselves, such as claim numbers, to Defendants in separate filing.

3 Second, Defendants argue that the algorithm used by Plaintiff to identify false claims
4 is insufficiently accurate, and at most can be said to identify claims that "were *probably* false
5 rather than identifying particular claims that actually *were* false." *Id.* at 12. While this
6 algorithm is not mentioned in the Complaint, it is explained in a letter submitted to
7 Defendants, and was used to compile the total number of allegedly false claims. This
8 probabilistic approach to defining claims, argue Defendants, is insufficient.

9 Because this Court concludes that the Complaint on its face is sufficiently particular,
10 this order does not address the adequacy of the algorithm.

11 Defendants contend that the allegations in the Complaint do not specify the details of
12 the claims themselves, such as the names of the doctors or the date of the treatment, and
13 therefore the Complaint is insufficiently particular. However, there appears to be a split of
14 authority – none of it controlling – as to the proper approach to determining particularity in
15 this context. Some courts, as Defendants argue, require the details of the claims themselves
16 be pleaded with particularity, even if the fraudulent scheme itself is alleged with great
17 particularity.³ Other courts, however, focus on the allegations of fraudulent conduct and the
18 scheme of misrepresentations, rather than on the details of the individual claims.⁴

19
20 ³ See, e.g., United States ex rel. Duxbuty v. Ortho Biotech Prods., 579 F.3d 13, 30 (1st
21 Cir. 2009) (finding a complaint to be sufficiently particular, albeit a "close call," where it
22 provided "information as to the dates and amounts of the false claims"); United States ex rel.
23 Rost v. Pfizer, Inc., 253 F.R.D. 11 (D. Mass. 2008) (explaining that after being dismissed for
24 insufficient particularity, an amended complaint was adequately plead where it listed the 200
claims in addition to the drug codes used); United States ex rel. Serrano v. Oaks Diagnostics,
Inc., 568 F. Supp. 2d 1136, 1143 (C.D. Cal. 2008) ("[T]he Ninth Circuit requires some specifics,
such as the time, place, nature of the false statement, as well as the identities of the parties to the
misrepresentation be present to comply with Rule 9(b) pleading standards.").

25 ⁴ See, e.g., United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 49 (D.
26 Mass. 2001) ("[W]here the alleged scheme of fraud is complex and far-reaching, pleading every
27 instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims
28 under the FCA have not placed the bar so high as to require pleading with total insight."); United
States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1049 (S.D.
Tex. 1998) (holding relator satisfied Rule 9(b) by alleging the "basic framework, procedures,
the nature of fraudulent scheme, and the financial arrangements and inducements among the
parties and physicians that give rise to Relator's belief that fraud has occurred"); United States

1 This Court concludes that, given the purposes of Rule 9(b), the specifics of all claims
2 are unnecessary at the pleading stage. The gravamen of this action concerns fraudulent
3 inducement of doctors, and the Complaint provides exhaustive allegations relating to this
4 fraud. In this context, the specifics of the claims themselves are somewhat less important.
5 Instead, the case concerns the marketing activities of Defendants and whether they acted in
6 reckless disregard of the truth. The allegations in the Complaint put defendants on sufficient
7 notice of the nature of the action, and given the immense number of claims at issue, requiring
8 them to be listed one-by-one in the Complaint is ungainly and unfair. While Plaintiff
9 undoubtedly bears the burden of proof as to damages, Plaintiff need not conclusively meet
10 this burden at the pleading stage.

11 This approach is in keeping with the purpose of Rule 9(b). The Ninth Circuit has
12 explained that, in order to comply with Rule 9(b), allegations of fraud must be “specific
13 enough to give defendants notice of the particular misconduct which is alleged to constitute
14 the fraud charged so that they can defend against the charge and not just deny that they have
15 done anything wrong.” Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993). This
16 standard has been met here. Plaintiff has alleged a thorough and complex series of actions
17 which, if true, constitutes a violation of the False Claims Act. Indeed, Defendants do not
18 argue that allegations regarding their conduct are insufficiently particular. Instead,
19 Defendants focus on the fact that the individual claims for reimbursement are not identified.
20 However, allegations of that nature are by no means necessary in order to Defendants to
21 formulate their defense. Plaintiff is clear as to the wrongs it believes Defendants to have
22 committed. While there may indeed be factual disputes as to which claims, if any, were the
23 result of Defendants’ fraudulent activity, it is not Plaintiff’s burden to prove such causation at
24 the pleading stage. Given the tremendous burden to fully identify such claims at the pleading
25 stage, and the fact that Defendants have been fully apprised of what “is alleged to constitute
26 the fraud charged,” id., dismissal is not warranted.

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28 es rel. Pogue v. Am. Healthcorp., Inc., 977 F. Supp. 1329, 1332-33 (M.D. Tenn. 1997)
(permitting relator to omit allegations concerning each instance of fraudulent conduct).

b. Failure to allege causation for claims submitted after March 2006

Defendants come close to conceding that claims submitted after March of 2006, when Medicare officially denied coverage for outpatient use of Natrecor, were “false” for purposes of the FCA. Mot. at 15; see also Comp. ¶ 110. However, Defendants argue that “the Complaint fails to plead the requisite causal nexus between *any* of Scios’ alleged promotional activities and the submission of *any* particular claim.” Mot. at 15. Specifically, with regard to post-March 2006 claims, Defendants explain that “nowhere in the Complaint’s 34 pages is there a single allegation that Scios engaged in outpatient promotion *after* the summer of 2005.” Id. While Defendants are correct, they miss the point of the Complaint. Even though the Complaint itself explains that Scios “terminate[d] the use of any promotional material or programming that directly conflicts with” a specialists’ panel recommendation that off-label use not be prescribed in July of 2005, Comp. ¶ 104, the broader allegations suggest that the only reason any doctor prescribed Natrecor was because of Defendants’ earlier promotion. In other words, while Defendants’ termination of promotion is a step in the right direction from Plaintiff’s perspective, the Complaint alleges that after many years of promotion, Defendants were not able to un-ring the bell. The Complaint alleges that Defendants’ actions created the market for off-label use of Natrecor, and so alleges that all such uses can be traced back to Defendants’ actions. Subsequent attempts shift course on their own do not absolve Defendants for earlier allegedly fraudulent activity.

4. Unjust Enrichment

The motion also seeks dismissal of Plaintiff’s unjust enrichment claim. However, the motion does not present an independent basis for this conclusion. Instead, the motion argues that because the FCA claim fails, so too must the claim for unjust enrichment. Because this Court disagrees with Defendants’ analysis of the FCA claim, their argument as to unjust enrichment must be rejected.

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Conclusion

For the reasons stated above, the motion to dismiss is DENIED.

IT IS SO ORDERED.



Dated: Dec. 23, 2009

CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

United States District Court
For the Northern District of California