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UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA and the STATES OF ARKANSAS, CALIFORNIA, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN ex rel. FRANK SOLIS, Plaintiffs, vs. MILLENNIUM PHARMACEUTICALS, INC., SCHERING-PLOUGH CORP., Defendants.	2:09 - CV - 3010 MCE JFM UNITED STATES' STATEMENT OF INTEREST REGARDING CERTAIN ISSUES RAISED IN DEFENDANTS' MOTIONS TO DISMISS THE RELATOR'S SECOND AMENDED COMPLAINT PURSUANT TO F.R.CIV.P. 12(B)(6)

I. INTRODUCTION

The United States respectfully submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments made by the defendants in their motions to dismiss the relator's Second Amended Complaint. The United States remains a real party in interest in this matter, even though it has not intervened in the action. *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715, 720 (9th Cir. 1994). The False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, is the United States' primary tool used to redress fraud on the government. The United States has a substantial interest in the development of the law in this area and in the correct application of the law in this, and similar, cases.

The United States takes no position on the defendants' arguments seeking dismissal for failure to plead fraud with particularity under F.R.Civ.P. 9(b), or for failure to establish jurisdiction under F.R.Civ.P. 12(b)(1) due to the public disclosure bar. Rather, the United States submits this Statement of Interest to set forth its position with respect to the following issues: 1) an FCA violation arising from kickbacks does not require the relator to plead a false certification, or to plead the absence of defenses; 2) causation under the FCA is simply common-law tort causation; 3) the fact that a good or service is reimbursed as part of a "bundled" DRG rate does not preclude FCA liability; and 4) the First Amendment is not implicated here and poses no limitation on off-label marketing claims under the FCA.

II. DISCUSSION

A. An FCA Violation Arising From Kickbacks Does Not Require The Relator To Plead A False Certification, Or To Plead The Absence Of Defenses

The defendants misconceive the elements of a violation of the FCA predicated on a violation of the Anti-Kickback Statute (AKS). Because an entity submitting a claim that results from a kickback violates a condition of payment, it is not necessary to allege a false certification, either express or implied. Also, even if this Court is inclined to reach the certification issue, an implied certification of compliance with the AKS is not limited to only the certifying entity's

own conduct, as defendants claim. Finally, at this stage of the litigation, it is not necessary for the relator to plead around any defenses that the defendants might raise.

1. Because a Claim That Is Tainted By A Kickback Violates A Condition Of Payment, It Is Not Necessary To Allege A False Certification, Either Express Or Implied

To establish a violation of the FCA predicated on a violation of the AKS, the relator need only show that defendants knowingly provided doctors with honoraria to induce them to write prescriptions for drugs that were reimbursable under federal programs, and that the doctors thereafter wrote prescriptions that were in fact paid for by a federal program. *See* 42 U.S.C. § 1320a-7b(b)(2), (g); *United States ex rel. Wilkins v. United Health Group, Inc.,* 659 F.3d 295, 313 (3d Cir. 2011). Compliance with the AKS is a material condition of payment under Medicare. *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 392 (1st Cir. 2011); *Wilkins*, 659 F.3d at 313; *United States ex rel. McNutt v. Haleyville Medical Supplies*, 423 F.3d 1256, 1259-1260 (11th Cir. 2005); *United States v. Rogan*, 459 F.Supp.2d 692, 717 (N.D.Ill.2006) ("Falsely certifying compliance with the Anti-Kickback Statute in a Medicare cost report is actionable under the FCA"), *aff'd* 517 F.3d 449 (7th Cir. 2008). The government is not required to pay for medical services tainted by kickbacks because in such circumstances the government has no assurance that the services were provided in the best interests of the patient rather than motivated by the financial interests of the hospital or the physician.

In 2010, the AKS was amended to state expressly that compliance with the AKS is a condition of payment and that claims submitted in violation thereof are also violative of the FCA. Dkt. 116 at 7-8. As the above case law shows, however, that amendment merely clarified existing law. Further, even before the 2010 amendment, this condition was (and continues to be) clearly established in the provider agreements that all physicians and hospitals must sign in order to participate in Medicare and the standard Hospital Cost Report that hospitals must also execute as a precondition of its eligibility. *Hutcheson*, 647 F.3d at 381-82. Moreover, even prior to the 2010 amendment, by making the payment of kickbacks a felony and specifying that this

prohibition covers items "for which payment may be made in whole or in part under a Federal health care program," 42 U.S.C. § 1320a-7b(b), the AKS itself effectively made compliance with its terms a condition of payment under federal health care programs because the government does not ordinarily pay for illegal services or goods.

Because compliance with the AKS is a fundamental condition of payment in federally-funded health insurance programs, claims seeking payment for services induced by kickbacks are "false" (*i.e.*, the services are not what the government bargained for and are ineligible for payment), and the FCA imposes liability where a defendant knowingly causes such a claim to be presented. *See Hutcheson*, 647 F.3d at 392. Because claims tainted by kickbacks are inherently "false" within the meaning of the FCA, it is not necessary for the court to consider whether the complaint in this case states a claim under either an express or implied certification theory of liability. The defendants' contention that the relator's kickback allegations must be made to fit into one or the other of these categories, Dkt. 116 at 118-19, is therefore erroneous. *Hutcheson*, 647 F.3d at 392.

2. An Implied Certification Need Not Be As To A Defendant's Own Conduct

Even if this court were to require that the relator plead an implied certification, the defendants err in arguing that the certification must be as to the defendant's own conduct. Dkt. 113-1 at 19. First, outside the context of pharmaceutical-marketing cases, it is a commonplace that a non-submitting party can be liable under the FCA for causing a third party to submit a false claim for payment to the government. *See United States v. Bornstein*, 423 U.S. 303 (1976) (holding that claims submitted by an innocent prime contractor were "false" within the meaning of the FCA due to fraudulent acts of subcontractor); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (holding subcontractor liable under FCA where its bid-rigging scheme caused contractor to present inflated claims to government); *United States v. Rivera*, 55 F.3d 703, 707-09 (1st Cir. 1995); *Mason v. Medline Indus., Inc.*; 731 F.Supp.2d 730, 738 (N.D. Ill. 2010). Along similar lines, in *United States ex rel. Hendow v. University of Phoenix*, the Ninth Circuit found that FCA liability could attach when representations were made in two stages – the

defendant college represented its eligibility to participate in the federal student aid program via a "phase-one" submission to the government, while the specific claims for student aid were submitted in "phase-two" submissions by students, who were not named as defendants. 461 F.3d 1166, 1173-74 (9th Cir. 2006), *citing United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005). This is because the FCA holds liable not just entities that submit false claims but also those that *cause* the submission of false claims by others. 31 U.S.C. § 3729((a)(1)(B); *United States v. Mackby*, 261 F.3d 821, 827 (9th Cir. 2001) ("a person need not be the one who actually submitted the claim forms in order to be liable"). Defendant Millennium noted in its reply to the government's previous statement of interest that the cases cited by the government on this point involved "factual falsity" rather than "legal falsity," but this is an irrelevant distinction for this point, because the "causes to be made or used" clause of § 3729((a)(1)(B) does not distinguish between factual and legal falsity. Indeed, those terms appear nowhere in the False Claims Act.

Moreover, as the *Hutcheson* court found, the FCA does not require any "certification" at all, let alone one as to a defendant's own conduct:

> The categorical limitation Blackstone advances does not appear in the text of the statute and is inconsistent with both the statutory text and binding case law.
> ...
>
> When the defendant in an FCA action is [not the entity that submitted the claim], the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent.

Hutcheson, 647 F.3d at 389. Defendant Millennium suggests that *Hutcheson* is inconsistent with precedent from this Circuit, Dkt. 116 at 8, but *Hutcheson* explicitly relied in part upon Ninth Circuit precedent in rejecting a limitation on FCA liability for non-submitting entities. *Id.* at 385, *citing Hendow*, 461 F.3d at 1172 ("[s]o long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach"). The *Hendow* court expressly recognized that false claims liability

may arise from separate submissions by different parties, even when one of those parties has no knowledge of any alleged wrongdoing. "The University 'uses' its phase-one application (and the resulting certification of eligibility) when it makes (or 'causes' a student to make or use) a phase-two application for payment. No more is required under the statute." *Id.* at 1174. That court further noted that,

> in amending the False Claims Act in 1986, Congress emphasized that the scope of false or fraudulent claims should be broadly construed: [E]ach and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim.

Id. at 1170-71, *citing* S.Rep. No. 99–345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274.

As support for their argument that the relator must allege a certification by a defendant as to its own conduct, the defendants rely upon *Ebeid*, 616 F.3d at 998, but that case does not articulate such a rule. The *Ebeid* court simply never reached the issue, because the defendant there was the party submitting the certification; thus, that court's reference to relator having to allege that "the *defendant* explicitly undertook to comply with a law, rule or regulation" should not be taken to exclude from liability cases where the defendant is a non-submitting party. *Id.* Such a reading would be inconsistent with *Hendow* as well as with *Bornstein* and *Marcus* (and *Ebeid* clearly stated that its opinion was consistent with *Hendow*). 616 F.3d at 998.

3. <u>It Is Not Necessary For The Relator To Plead The Absence Of Defenses</u>

Defendants also err in seeking to impose additional pleading requirements beyond the basic elements of a cause of action – in effect calling upon the relator to plead the absence of defenses, which F.R.Civ.P. 12(b)(6) does not require. Dkt 113-1 at 15-16. There is no requirement that the relator prove the negative – that the prescriptions would not have been written absent the kickbacks – just as there is no requirement that the relator prove that the sole purpose of the kickbacks was to induce prescription writing. *See United States v. McClatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000) (to establish an AKS violation, plaintiff need only show

that "one purpose" of the kickback was to induce referrals); *see also United States v. Kats*, 871 F.2d 105, 108 (9th Cir.1989) (jury instruction in criminal case alleging violation of AKS was proper, stating that government need only prove that remuneration was one purpose of the kickbacks, and not the only purpose). Even if there were such substantive requirements, it would not be something that the relator would have to allege at the pleading stage. *See also Wilkins*, 659 F.3d at 313 ("[T]o survive a Rule 12(b)(6) motion, [plaintiff] need not allege a relationship between the alleged AKS violations and the claims [defendant] submitted to the Government. Rather, [a complaint is sufficient if plaintiff] plead[s] that [defendant] knowingly violated the AKS while submitting claims for payment to the Government ...."). Defendant Schering characterizes this argument as implicating F.R.Civ.P. 9(b), but the issue is not whether the relator has alleged these facts with sufficient specificity, but rather that he is not obliged to allege them at all at this stage of the litigation.

Similarly, while fair market value may be relevant to evaluating the defendants' defenses to liability, Dkt. 113-1 at 15-16, it is not the relator's obligation to plead the absence of that defense at this stage of the case. As defendant Schering itself notes, the element of the AKS at issue is "(2) offering or paying remuneration," 42 U.S.C. § 1320a-7b(b)(2)(B), and the statute does not say "remuneration in excess of fair market value."[1]/ *See, e.g.*, *United States v. Shaw*, 106 F.Supp.2d 103, 121-22 (D. Mass. 2000) (motion to dismiss criminal indictment for violation of AKS denied; government not obliged to allege absence of defenses in indictment).

[1] Defendant Schering cites *United States v. Ctr. for Diagnostic Imaging, Inc.*, wherein the district court dismissed certain kickback claims upon the finding that "Without alleging the fair market value of those services, plaintiffs have failed to plausibly allege that the 'discounted' services constituted remuneration." 787 F. Supp. 2d 1213, 1223 (W.D. Wash. 2011). However, *Ctr. for Diagnostic Imaging* based its ruling on *United States ex rel. Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678-79 (N.D. Ill. 2006), a case that was decided at summary judgment upon a full factual record. For this reason, *Ctr. for Diagnostic Imaging* is not a useful guide to this Court in addressing these issues.

B. Causation Under The FCA Is Simply Common-law Tort Causation

In suggesting that the action of physicians defeats the element of causation in this case, the defendants set forth an erroneously restrictive view of causation that is found nowhere in the FCA. Causation under the FCA is governed by the common law standard of reasonable foreseeability. *See United States ex rel. Franklin v. Parke-Davis (Parke-Davis I)*, 147 F. Supp. 2d 39, 53 (D. Mass. 2001); *see also United States ex rel. Simpson v. Bayer Corp.*, 2013 WL 4710587, at *14 (D.N.J. 2013) ("[t]he operative Complaint sufficiently alleges causation in light of Simpson's allegations, particularly those regarding Bayer's illegal kickback scheme engineered to induce medical providers to prescribe Trayslol and Avelox, which would inevitably cause false claims to be submitted to the government by healthcare providers"), *citing United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243–244 (3d Cir. 2004). The actions of an intermediary break the chain of causation only where they are unforeseeable. *United States ex rel. Franklin v. Parke-Davis (Parke-Davis II)*, 2003 WL 22048255 at *5 (2003 D. Mass.). On this point, the *Parke-Davis I* court found that "the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." 147 F. Supp. 2d at 52-53. In other words, the very reason a pharmaceutical company employs sales representatives is in the hope of influencing prescriber behavior.

The *Parke-Davis II* court further noted that, "[w]hether [a defendant's] conduct was a substantial factor in causing the presentation of false Medicaid claims is a question of fact." 2003 WL 22048255 at *5. Defendant Schering's argument as to causation is thus a question of fact and not an appropriate basis for dismissal of the case. Defendant Millennium's reliance on *United States ex rel. Polansky v. Pfizer, Inc.*, Dkt. 116 at 13, *citing* 2009 WL 1456582 at *9-10 (E.D.N.Y. 2009), is misplaced, as that court characterized its dismissal as being pursuant to F.R.Civ.P. 9(b) and thus based upon the sufficiency of that particular complaint, rather than a generalized rule that a physician's specialized knowledge always breaks the chain of causation.

Similarly, at most, defendant Schering's causation argument goes to the sufficiency of the relator's complaint under F.R.Civ.P. 9(b).

Additionally, defendant Schering mistakenly suggest that causation, in connection with the off-label marketing claims, requires relator to show that the defendants made *false* statements in their marketing to providers. Dkt. 113-1 at 13. That argument improperly conflates falsity and causation. The question of whether a claim is false depends only on whether the claim was eligible for payment in light of applicable law. *See United States ex rel. Oliver v. The Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 2000). As noted above, the causation inquiry is whether it was reasonably foreseeable that the defendants' conduct or statements would influence the submission of those false claims, and there is no additional requirement that the defendant also make a false statement in doing so. Indeed, the FCA has multiple liability provisions, and whereas § 3729(a)(1)(B) requires proof of a false statement in addition to a false claim, § 3729(a)(1)(A) does not. *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 at *1-2 (D. Mass. August 22, 2003) ("Under § 3729(a)(1), Relator is not required to present evidence that Parke–Davis lied to physicians about Neurontin's off-label efficacy or safety to induce them to prescribe Neurontin for uses ineligible under Medicaid").

The defendants further err in essentially seeking to read into the FCA a second causation requirement, suggesting that the relator must allege that the defendants played a meaningful role in the actual presentment of those false claims by the providers to the government. Dkt. 113-1 at 14. No such requirement is found in the FCA, and such a requirement would be contrary to *Bornstein*, *Marcus*, *Hendow*, and *Hutcheson*, *supra*, which allowed a relator to predicate liability upon presentment made wholly or partly by innocent third parties. As the court stated in *United States ex rel. Bidani v. Lewis*:

> Compliance with the AKS is thus central to the reimbursement plan of Medicare. To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place. Reimbursing a claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact.

264 F.Supp.2d 612, 615 (N.D. Ill. 2003).

C. The Fact That A Good Or Service Is Reimbursed As Part Of A Bundled DRG Rate Does Not Preclude FCA Liability

Defendant Millennium squarely mis-states the government's argument on the issue of materiality, saying that "the Government has agreed that 'the element of materiality is defeated' for off-label uses administered in an inpatient setting." Dkt. 116 at 10. In fact, what the government said in its prior statement of interest is "The defendants argue that the element of materiality is defeated in this case by the fact that inpatient use of Integrilin is reimbursed under the DRG system." Dkt. 98 at 8. The actual position of the United States in addressing materiality was to emphasize the limitations on the defendants' argument. Significantly, the defendants' materiality argument has no relevance to the relator's kickback claims, as explained by the *Hutcheson* court:

> If kickbacks affected the transaction underlying a claim, as Hutcheson alleges, the claim failed to meet a condition of payment. Blackstone's argument that Medicare would excuse these violations because of a bureaucratic mechanism or because of an implicit medical necessity requirement impermissibly cabins what the government may consider material. Neither the Provider Agreement nor the Hospital Cost Report forms speak of such exceptions recognized by Medicare. We find Hutcheson's allegations sufficient to show, for purposes of this motion to dismiss, that the kickbacks were capable of influencing Medicare's decision as to whether to pay the hospital and physician claims.

Hutcheson, 647 F.3d at 394-95; *see also Main*, 426 F.3d at 916 ("[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork"). Thus, the DRG argument is an insufficient basis for dismissal of kickback claims, whether inpatient or outpatient. As to inpatient claims incorporating payment for drugs prescribed as a result of off-label marketing, the fact that a drug is part of a bundled DRG payment does not automatically defeat materiality. In some circumstances, the administration of a particular drug or use of a particular medical device may constitute the core purpose of the inpatient visit, in which case the circumstances underlying the use of the drug or device may be material to the payment decision. At one extreme, if an expensive technological medical device were central to a patient's treatment and were to

constitute a substantial part of the cost of an inpatient procedure, it might well be material to a payment pursuant to that DRG code. Conversely, a simple surgical wrapping might not be.

Finally, this argument has no bearing on materiality as to outpatient claims, which are not reimbursed as part of a DRG code.

D. The First Amendment Is Not Implicated Here And Poses No Limitation On Off-Label Marketing Claims Under The FCA

Finally, the government submits that the defendants err in arguing that the First Amendment requires a showing that the statements by the defendants to providers in the course of any alleged off-label marketing were themselves fraudulent. Dkt. 113-1 at 15. The FCA provides independent and distinct bases for liability for false claims and false statements, respectively. *Compare* 31 U.S.C. § 3729(a)(1)(A) *with* § (a)(1)(B). Liability under Section 3729(a)(1)(A) does not require proof that a defendant made a false statement; it requires only proof that the defendant presented or caused the presentment of a false claim. *Compare United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007) (separately analyzing false statement allegations under then-section 3729(a)(2)). Because off-label promotion by a pharmaceutical company can be *evidence* of that defendant's having caused physicians to submit false claims, the First Amendment is not implicated, even where the defendant's promotional message is factually true. *See Wisconsin v. Mitchell*, 508 U.S. 476, 488-89 (1993) ("The First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent."); *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004) (explaining in FDCA context that "th[e] use of speech to infer intent, which in turn renders an otherwise permissible act unlawful, is constitutionally valid"). Nothing in *United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012), is to the contrary; indeed, that court expressly stated that "we assume, without deciding, that such use of evidence of speech is permissible." *Id.* at 162 n.9. Further, *Caronia* was a criminal prosecution under the Food, Drug, and Cosmetic Act,

whereas the gravamen of a civil FCA action such as this is the submission of uncovered, false claims to federal healthcare programs.[2]/

CONCLUSION

As noted above, the United States of America takes no position on the defendants' motions pursuant to F.R.Civ.P. 9(b) or 12(b)(1). If the Court reaches the remaining arguments in the motions to dismiss, the United States respectfully requests that the Court consider its views as to the issues herein.

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[2] Nor does *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011), support dismissal. That case established the standard of review for a particular state statute involving a different form of pharmaceutical marketing, and it evaluated the statute in question based upon the evidentiary record adduced at trial in that matter. *Sorrell* did not contemplate dismissal at the pleading stage.