UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. DAVID FRANKLIN,	)	
Plaintiff,	)	
v.	)	CIVIL ACTION NO. 96-11651-PBS
PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY and PFIZER, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER

August 22, 2003

SARIS, U.S.D.J.

I. INTRODUCTION

In this qui tam action, Relator Dr. David Franklin brings a claim under the False Claims Act, 31 U.S.C. §§ 3729 et seq., alleging that Defendant Parke-Davis (Franklin's former employer) promoted the drug Neurontin for uses not approved by the Food and Drug Administration, resulting in federal reimbursement payments for Neurontin prescriptions that were ineligible under Medicaid. Parke-Davis moves for summary judgment. The government, which has not intervened, has filed a Statement of Interest. After hearing, Parke-Davis's motion is **DENIED**.

II. DISCUSSION

In its earlier opinion on Parke-Davis's motion to dismiss, the Court canvassed the history of this suit, the complaint's factual allegations, and the relevant law. United States v. Parke-Davis, 147 F. Supp.2d 39 (D. Mass. 2001). Presuming familiarity with that opinion, the Court here will limit the discussion to the select legal and factual issues upon which summary judgment turns.

1. Double-Falsehood Requirement under the FCA?

The False Claims Act ("FCA") imposes liability on any person who, inter alia:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or] (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government

31 U.S.C. § 3729(a).

Parke-Davis argues that it can only be held liable under the FCA if Relator proves that Parke-Davis intentionally made a material false statement that led to the filing of a false claim. Under Parke-Davis's interpretation, the FCA contains a double falsehood requirement: An FCA plaintiff must prove a false statement that led to a false claim. Parke-Davis contends that

Relator has failed to show that Parke-Davis made any material false statements.

Parke-Davis's legal argument is inconsistent with the text of the FCA. While § 3729(a)(2) contains a double-falsehood requirement ("knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government") (emphasis added), FCA liability under § 3729(a)(1) arises when a defendant "knowingly presents, or causes to be presented . . . a false or fraudulent claim" (emphasis added). Thus, there is no double falsehood requirement under § 3729(a)(1): One will suffice. See Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000) ("Section 3729(a)(1) . . . requires only the presentation of a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement.'"); United States ex rel. Fallon v. Accudyne Corp., 921 F. Supp. 611, 627 (W.D. Wis. 1995) ("The primary distinction between a claim under section 2 and a claim under section 1 is that section 2 requires an affirmative false statement. To provide any distinct meaning to section 1 it is clear that no such express false statement is required.").

Because Relator has not limited his FCA claim to § 3729(a)(2), he need not show two falsehoods to prevail. 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. Though such evidence would be probative as to whether Parke-Davis caused to be presented false Medicaid claims, truthful off-label marketing (ineligible for federal safe harbors) and financial incentives like kickbacks would suffice.

To be sure, the Court's earlier opinion on Parke-Davis's motion to dismiss focused on allegations of false statements under § 3729(a)(2):

> Defendant argues that an impermissible off-label promotion [i.e., a promotion that violates the Food and Drug Administration's ("FDA's") strictures on off-label marketing] does not necessarily include a false statement or fraudulent conduct. For example, it points out, off-label promotion of a drug might simply consist of a representative of a pharmaceutical company distributing the finding of one doctor's experience with an off-label use of a particular drug to other physicians. However, Relator alleges more than a mere technical violation of the FDA's prohibition on off-label marketing. The gravamen of Relator's claim is that Parke-Davis engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid. Thus, the alleged FCA violation arises - not from unlawful off-label marketing activity itself - but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct. Cf. United States ex rel. Marcus v. Hess, 317 U.S. 537, 543-44, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (payments under government contract that was executed as a result of collusive bid constituted actionable false claims). A much closer question would be presented if the allegations involved only the unlawful - yet truthful - promotion of off-label uses to physicians who provide services to patients who are

> covered by Medicaid, as well patients who are not, without any fraudulent representations by the manufacturer.

Parke-Davis, 147 F. Supp.2d at 52 (emphasis added). With the benefit of a more fulsome factual record, it is now apparent that the "much closer question" can no longer be ducked. Under § 3729(a)(1), the only issue is whether Parke-Davis "caused to be presented" a false claim, and § 3729 does not require that the "cause" be fraudulent or otherwise independently unlawful.

2. Existence of a False Claim

Parke-Davis contends that Relator cannot prove the sine qua non of a False Claims Act violation: the existence of a false claim. In the early phases of this litigation, "Defendant d[id] not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA." Parke-Davis, 147 F. Supp.2d at 51. Now Parke-Davis argues that forty-two state Medicaid programs permit reimbursement for off-label, non-compendium drug prescriptions, and that therefore claims for Medicaid reimbursement for off-label Neurontin prescriptions in those states were not false claims. Parke-Davis contends that the Medicaid statute gives states the discretion to provide reimbursement for such prescriptions; in particular, Parke-Davis points to 42 U.S.C. § 1396r-8(d)(1)(B): "A state may exclude or otherwise restrict coverage of a covered outpatient drug if - (i) the prescribed use

is not for a medically accepted indication . . . ." Parke-Davis argues that the language "may exclude or otherwise restrict" indicates that states have the option not to exclude (i.e., may provide) coverage for drugs for which the prescribed use is not for a medically accepted indication.

Relator contends that Parke-Davis is wrong as to the scope of Medicaid coverage in the forty-two states. Indeed, Relator argues that the Medicaid statute does not authorize states to provide such broad coverage. Relator emphasizes that the Medicaid statute allows states to "exclude or otherwise restrict coverage of a covered outpatient drug," 42 U.S.C. § 1396r-8(d)(1)(B) (emphasis added), implying that states are given discretion only within the category of "covered outpatient drugs." The Medicaid statute defines this category to exclude drugs for which the prescribed use is not a medically accepted indication. Parke-Davis, 147 F. Supp.2d at 45 ("Covered outpatient drugs do not include drugs that are 'used for a medical indication which is not a medically accepted indication.'") (quoting 42 U.S.C. § 1396r-8(k)(3)). Thus, in Relator's view, § 1396r-8(d)(1)(B)(i) is simply superfluous, giving states the discretion to exclude drugs that are not covered by Medicaid to begin with. Basic rules of statutory construction, however, disfavor this interpretation. See, e.g., United States v. Flores, 968 F.2d 1366, 1371 (1st Cir. 1992)

("Courts should not lightly read entire clauses out of statutes, but should, to the exact contrary, attempt to give meaning to each word and phrase.").

It is not clear which side gets the better of the statutory-tail-chases-cat debate. The Court would appreciate an amicus brief from federal officials, providing the federal government's understanding of the extent to which the Medicaid statute empowers states to provide coverage of off-label, non-compendium prescriptions. Cf. Meyer v. Holley, 537 U.S. 280, 123 S.Ct. 824, 830 (2003) ("[W]e ordinarily defer to an administering agency's reasonable interpretation of a statute.") (citing Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-45 (1984)).

The debate may be immaterial. If the Medicaid statute gives states the discretion to cover off-label, non-compendium prescriptions, and a state exercised its discretion to cover such prescriptions, then an off-label Neurontin prescription in that state would not be a false claim. On the other hand, if the Medicaid statute does not give states the discretion to cover off-label, non-compendium prescriptions, but a state misconstrued the statute and authorized coverage of such prescriptions, an FCA action against Parke-Davis in that state would likely fail, as it would be difficult to establish Parke-Davis's scienter.

In any event, even Parke-Davis concedes that eight states do

not provide reimbursement for off-label drug prescriptions not included in a medical compendium, and in those states, a Medicaid-reimbursement request for an off-label, non-compendium prescription constitutes a false claim. Thus, at best Parke-Davis's argument goes to the amount of damages, and does not provide a basis for summary judgment of no liability under the FCA. At this juncture, the Court declines to do a state-by-state analysis of Medicaid coverage.

Parke-Davis also raises a factual argument about why Relator cannot show a false claim: Parke-Davis points out that the Medicaid reimbursement claim forms for prescription drugs do not require the claimant to list the indication for which the drug is being prescribed. Thus, Parke-Davis argues, Relator cannot show that any Medicaid claim sought reimbursement for an off-label, non-compendium use. But the Relator has provided analysis linking patients' treatment histories to Neurontin prescriptions that generated reimbursement claims; Relator contends this analysis demonstrates that many reimbursement claims must have been for off-label, non-compendium indications, given the patients' treatment histories. Parke-Davis has submitted expert testimony contesting the reliability of comparing data from pharmacy claim forms with diagnosis data from patient medical-services claim forms. Relator's expert evidence suffices to survive summary judgment.

3. Causation

The text of § 3729(a)(1) requires a causal connection between Parke-Davis's actions and the false claims at issue. Parke-Davis contends that the Relator must show that Parke-Davis "either exerted 'control over' or otherwise directly influenced, the submission of a false claim." (Mem. of Law in Supp. of Defs.' Mot. for Summ. J., Docket No. 297, at 18.) Parke-Davis argues that Relator cannot meet this standard, as the causal chain includes several links: Parke-Davis markets Neurontin to doctors, who prescribe it for their patients, who take the prescriptions to their pharmacists, who file claims for Medicaid reimbursement.

But Parke-Davis misstates the legal standard for causation. The FCA does not provide a special definition for causation, and neither the Supreme Court nor any Circuit Court of Appeals has grafted such a special definition on the FCA. Absent an FCA-specific definition of causation, the Court will apply common-law tort causation concepts, which Judge Campbell of the First Circuit has summarized:

> Causation in tort law is generally divided into two concepts: causation in fact, or actual causation, and proximate or legal causation. See W. Page Keeton et al., Prosser & Keeton on Torts §§ 41-42 (5th ed. 1984). The terms for these two concepts are sometimes confused, as are the concepts themselves. Regardless of the terminology, however, there are two questions that must be answered to determine if a defendant's conduct "caused" a plaintiff's injury. The first question is whether there was in fact some causal

> relationship between the conduct and the outcome. The Restatement expresses this test as whether the defendant's conduct was a "substantial factor" in producing the harm. Id. The second question is whether the circumstances and causal relationship are such that the law will impose liability on the defendant. Sometimes this is expressed as a foreseeability test, see Keeton, supra, § 42, at 273. Cf. Restatement (Second) of Torts, § 431(b)(1965) (different terminology).

Rodriguez-Cirilo v. Garcia, 115 F.3d 50, 54 (1st Cir. 1997) (Campbell, J., concurring).

Whether Parke-Davis's conduct was a substantial factor in causing the presentation of false Medicaid claims is a question of fact. Relator has produced enough evidence on this score to create at least a genuine issue of material fact. In particular, Relator has produced circumstantial evidence (e.g., the rates of off-label prescriptions before and after physician conferences hosted by Parke-Davis) and direct evidence (the "Verbatim" market-research reports recording doctors' state of mind after marketing meetings).

Parke-Davis also disputes that Relator can reliably extrapolate the prescription activities of a small sample of ten doctors to the off-label prescription rates of over 3000 physicians in fifty states, and, as discussed above, Parke-Davis challenges the reliability of the underlying data used to determine whether a prescription is for off-label uses. But the Court will defer the daunting task of determining whether a reliable statistical method exists for measuring nation-wide

damages.

As for proximate or legal causation, the Court has already held that Parke-Davis could have foreseen false Medicaid claims being filed, even with the intervening links in the causal chain:

> Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that - as a matter of law - Relator's allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks the chain of legal causation. See [United States ex rel.] Cantekin [v. Univ. of Pittsburgh], 192 F.3d [402], 416 [(3rd Cir. 1999)] (applying intervening cause analysis to claim under the FCA). Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. See id. Accord D. Dobbs, et al., Prosser and Keeton on Torts § 44, at 303-04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable intervening forces] will not supercede the defendant's responsibility."); Restatement (Second) of Torts § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's . . . conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."). In this case, when all reasonable inferences are drawn in favor of the Relator, 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.

Parke-Davis, 147 F. Supp.2d at 52-53.

While it is now clear that Relator's theory of the case is not limited to a "scheme of fraud," the Court holds that Relator has presented evidence showing that it was foreseeable that Parke-Davis's conduct (including non-fraudulent promotion of off-

label Neurontin uses) would ineluctably result in false Medicaid claims. Cf. United States ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 416 (3rd Cir. 1999) ("It is a basic principle of tort law that once a defendant sets in motion a tort, the defendant is generally liable for the damages ultimately caused, unless there are intervening causes.").

Parke-Davis places heavy reliance on United States ex rel. Kinney v. Hennepin County Medical Center, Civ. Action. No. 971680 (RHK/JMM), 2001 WL 964011 (D. Minn. Aug 22, 2001). Kinney dealt with "claims to Medicare and Medicaid for the payment of ambulance services that [the realtor] allege[d] were false because the ambulance transports were not 'medically necessary.'" Id. at *1. One of the defendants, a group of doctors that provided services to the defendant ambulance service, was alleged to have caused the false claims by "having its physicians falsely certify [the] ambulance runs as 'medically necessary' when they did not meet the either the Medicare or Medicaid criteria for medically necessary." Id. at *8. The court rejected this causation argument. See id. at *10. A critical factor was that the ambulance service's computerized accounting system automatically coded ambulance runs as "medically necessary," and that the physicians' determinations were irrelevant. See id. Here, in contrast, Relator has provided evidence that Parke-Davis's actions were not irrelevant, but rather played a key role

in setting in motion a chain of events that led to false claims.

The instant case is closer to United States ex rel. Pogue v. Diabetes Treatment Centers of America, 238 F. Supp.2d 258 (D.D.C. 2002). In that case,

> The Fourth Amended complaint describe[d] a twelve year fraudulent scheme in which [defendant] DTCA ran diabetes centers in various hospitals, and appointed doctors to serve as medical directors. Relator alleges the doctors were paid not for their nominal services as medical directors, but on a per-patient basis for referring their patients to the DTCA centers, in violation of the Stark laws' prohibition of self-referral. See 42 U.S.C. § 1395nn. The hospitals in which the centers were housed paid DTCA a per-patient fee, which Relator alleges was a kickback of the type prohibited by the Anti-Kickback laws. See 42 U.S.C. § 1320a-7b(b). Then the hospitals submitted reimbursement claims to Medicare for the care provided to the patients.

Pogue, 238 F. Supp.2d at 267. According to the relator, the reimbursement claims were false because they impliedly certified compliance with the Anti-Kickback and Stark laws. Id. at 261. Defendant DTCA "argue[d] that even if implied certification is a legitimate basis for Relator's claims, it cannot be held liable because it did not submit claims for Medicare reimbursement and did not certify compliance with healthcare statutes and regulations." Id. at 266. The court rejected this argument, stating, "An argument that the presentation of the claims was the work of another is unavailing as a means to avoid liability under the False Claims Act." Id. Cf. United States v. Mackby, 261 F.3d 821, 824-26, 828 (9th Cir. 2001) (affirming FCA liability of

owner/managing director of physical-therapy clinic who instructed the clinic's billing company to use an improper code on Medicare reimbursement claim forms; stating, "[A] person need not be the one who actually submitted the claim forms in order to be liable"); United v. Krizek, 111 F.3d 934, 935-37, 942 (D.C. Cir. 1997) (where psychiatrist's wife submitted invalid Medicare and Medicaid reimbursement claims, stating, "[W]e note that [the psychiatrist] is no less liable than his wife for these false submissions. . . . Dr. Krizek delegated to his wife authority to submit claims on his behalf. In failing 'utterly' to review the false submissions, he acted with reckless disregard."); see generally United States v. Neifert-White Co., 390 U.S. 228, 233 (1968) (holding that because the FCA is a remedial statute, it should not be given a cramped reading).

4. FCA Claim Based on Anti-Kickback Violations

The government attempts to resuscitate a claim the Court dismissed, namely, that Parke-Davis's alleged violation of the Medicaid Anti-Kickback provision, 42 U.S.C. § 1320a-7b(b), caused false claims, because Medicaid claimants impliedly certify that their claims have not been tainted by kickbacks.

The Court agrees with the government that recent caselaw supports implied-certification FCA claims in the healthcare context, including kickback-based claims. See, e.g., United States ex rel. Augustine v. Century Health Servs., Inc., 289 F.3d

409, 415 (6th Cir. 2002) (in Medicare-reimbursement context, stating, "[A] number of courts have held that a false implied certification may constitute a false or fraudulent claim even if the claim was not expressly false when it was filed. Instead, liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned. We adopt this theory of liability . . . ."); Mikes v. Straus, 274 F.3d 687, 700 (2nd Cir. 2001) (holding that claimants of Medicare reimbursement implicitly certify that they have complied with statutes or regulations that expressly require compliance as a prerequisite to Medicare payments); Pogue, 238 F. Supp.2d at 266 (affirming earlier holding that Medicare claimants impliedly certify compliance with Anti-Kickback laws, stating that "the developing law has supported [the court's] finding that violations of the Anti-Kickback and Stark laws can support a claim under the False Claims Act").

But while the Government's brief was persuasive on several points, the Government is (still) not a party to this suit, and the Court declines to use the Government's brief to revive Relator's claim. Evidence of kickbacks is relevant, however, to Relator's more clear-cut claim under § 3729(a)(1): Parke-Davis "caused to be presented" claims for reimbursement for off-label prescriptions that were ineligible for coverage under Medicaid.

ORDER

Defendant Parke-Davis's Motion for Summary Judgment (Docket No. 292) is **DENIED**.

PATTI B. SARIS
United States District Judge