UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. DR. JESSE POLANSKY,	)	
Plaintiff,	)	No. 04-cv-0704 (ERK)(ALC)
v.	)	
PFIZER, INC.,	)	
Defendants	)	

UNITED STATES' STATEMENT OF INTEREST
IN RESPONSE TO DEFENDANT'S MOTION TO DISMISS
COUNTS I AND III THROUGH XIX OF THE FIFTH AMENDED COMPLAINT

The United States, real party in interest in this action, hereby moves to submit this Statement of Interest (Statement) pursuant to 28 U.S.C. § 517 to respond to certain arguments raised in defendant's Motion to Dismiss relator Polansky's Fifth Amended Complaint. The United States remains a real party in interest in this matter, even where it has not intervened in the action. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the United States' primary tool used to redress fraud on the government. As such, the statute should be read broadly to reach all fraudulent attempts to cause the government to pay out sums of money. *United States v. Neifert-White*, 390 U.S. 228, 233 (1968). Thus, the United States has a keen 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 submits this Statement to clarify the legal basis for an FCA claim predicated on allegations of off-label marketing by pharmaceutical manufacturers. First, claims for payment of items or services that are not eligible for reimbursement by federal health programs are "false claims." Second, a drug manufacturer may cause a provider to submit a false claim for reimbursement if that false claim was a reasonably foreseeable consequence of the drug manufacturer's conduct. Third, the identification of specific false claims is not an absolute prerequisite to satisfying the particularity requirement of Rule 9(b) in FCA cases. So long as the complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility, a court may conclude that Rule 9(b) is satisfied. Nonetheless, the United States submits that if the Court finds that relator's complaint fails to meet that test and is subject to dismissal under Rule 9(b), then it need not reach the other issues addressed herein.[1] The United States takes no position on whether relator has adequately plead facts that would state a cognizable claim under the FCA as properly interpreted.

I. CLAIMS FOR OFF-LABEL, NON-COVERED USES ARE FALSE CLAIMS.

Physicians are free to prescribe drugs for off-label uses. Nonetheless, as defendant concedes, federal health care programs do not cover *all* uses of *all* drugs. *See* Defendant's Brief in support of its Motion to Dismiss (Def. Br.) at 12. Rather, the programs at issue here generally cover drugs for "medically accepted indications," which, by statute, are defined as indications

[1] The United States does request that should the Court decide to dismiss Relator's Fifth Amended Complaint for failure to plead fraud with particularity, the dismissal should be without prejudice as to the United States. *See United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005).

that are FDA-approved or that are "supported by a citation" in a statutorily-recognized compendium. 42 U.S.C. § 1396r-8(k)(6).

By way of background, in order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services. If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. 42 U.S.C. §§ 1396b(a)(1), 1396d(b).

Under the Medicaid Drug Rebate Statute, federal financial participation is prohibited for a drug manufacturer's covered outpatient drugs unless there is a rebate agreement between the manufacturer and the Secretary under the statute. *See* 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396r-8(d).[2]

Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act (FDCA), 21

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[2] A State may restrict from coverage or exclude altogether certain drugs or classes of drugs or certain medical uses where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i). In addition, a State also may adopt a prior authorization program, maintain a formulary, impose limits on prescription quantities to discourage waste, and address instances of fraud or abuse by individuals. 42 U.S.C. § 1396r-8(d)(4)-(6).

U.S.C. §§ 355 and 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3). The statute defines "medically accepted indication" as a use that is FDA-approved or a use that is "supported by a citation" in certain statutorily-identified compendia. *Id.* at § 1396r-8(k)(6).[3] Thus, under this statutory scheme, an off-label use that is not "supported by a citation" in the compendia falls outside the definition of a covered outpatient drug under Medicaid, and Medicaid is free to deny payment for resulting claims for such an off-label use.[4]

Courts have held that when a drug is prescribed for a use that is not covered by federal programs, the resulting claim for reimbursement of that prescription is "false" under the FCA. *See United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 13-14 (D. Mass. 2008); *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003) (*Parke-Davis II)* ; *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001) (*Parke-Davis I*) ("[T]he 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."); *Strom ex rel. U.S. v. Scios, Inc.*, 676 F. Supp. 2d 884, 891 (N.D. Cal. 2009) ("Because the [Medicare] statute permits reimbursement only for 'reasonable and necessary' treatments, [an off-label prescription] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the

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[3] The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the Drugdex Information System. Id. at § 1396r-8(g)(1)(B)(i).

[4] Medicare Part D incorporates by reference the provisions of the Medicaid Drug Rebate Statute pertaining to "covered outpatient drugs." 42 U.S.C. § 1395w-102(e).

FCA's requirement of a 'false' statement."). Court have similarly found in other contexts that claims for services not covered by Medicare are false under the FCA. *See Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975).

This principle is consistent with a host of other situations in which courts have found FCA liability even though there may be nothing false on the face of the claims in question. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543-44 (1943) (bid rigging to obtain a contract renders the claims submitted under the fraudulently procured contract false); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (claim may be ineligible for payment where physician received a kickback for the billed service); *United States v. McLeod*, 721 F.2d 282, 284 (9th Cir. 1983) (deposit of a facially valid check to which defendant was not entitled is a false claim); *Scolnick v. United States*, 331 F.2d 598, 599 (1st Cir. 1964) (same); *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419, 440 (E.D.N.Y. 1995) (facially-accurate claims resulting from conduct that violated fair housing and non-discrimination provisions in HUD program were false within the meaning of the FCA).

When a claim is false because it is for a non-reimbursable item (*e.g.*, an off-label indication that is not otherwise covered by federal health programs), an analysis under a "certification theory" is simply inapposite. *See* Def. Br. at 19 (discussing false certification theory of liability). Whether the provider "certified" on the claim for payment that the prescribed usage was on-label or otherwise reimbursable is irrelevant. Rather, the core question for "falsity" under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable. This is an objective question and is not, as defendant argues, a "subjective interpretation of defendant's legal duties" that preclude a finding

of falsity. Def. Br. at 13. For that same reason, contrary to defendant's suggestion (Def. Br. at 11, 22), whether other information on the claim form is "truthful," such as the identity of the patient or the name of the drug used, has no bearing on the fact that a prescription was for a non-covered, non-reimbursable use and thus constitutes a false claim within the meaning of the FCA.

Accordingly, defendant also is incorrect in suggesting that the claim must contain a separate "conscious and deliberate 'lie'" in order to be a false claim. Def. Br. at 10. As is clear from the language of the statute, the FCA does not require proof of double falsity – a false claim *and* a false statement. The first two sections of the FCA provide independent and distinct bases for FCA liability. *Compare* 31 U.S.C. § 3729(a)(1) (liability for false claims) *with* (a)(2) (liability for false statements).[5] By its very terms, Section 3729(a)(1) only requires that the defendant presented or caused the presentment of a false claim, not that the defendant made a false statement or lied on the claim itself. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731-33 (1st Cir. 2007) (separately analyzing false statement allegations under Section 3729(a)(2)); *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003) (same). Accordingly, a case cited by Pfizer, *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006), was wrongly decided because it demanded a showing of "extra" false statements and failed all together to consider liability under Section (a)(1), which does not require proof of any false statement at all. The *Hess* court also erred on the issue of materiality, as the question as to whether a claim is even eligible for payment is obviously material to the Government's decision to pay that claim.

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[5] The FCA was recently amended and these sections were recodified as 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B).

Furthermore, in order for a statement to be "false" under section 3729(a)(2), it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." *W. Page Keeton, Prosser & Keeton on the Law of Torts* § 106, at 738 (5th ed. 1984); *see Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA). Thus, a statement urging a physician to prescribe a drug for an unapproved use could well amount to a half-truth and satisfy the false statement requirement of section (a)(2), where, for example, the drug sales representative fails to mention evidence that does not support the drug's safety or efficacy for the unapproved use or that the FDA has specifically denied approval for that indication.

Relator here has alleged that promoting Lipitor therapy for patients outside the risk categories and cutpoints set forth in the National Cholesterol Education Program Guidelines is unlawful off-label promotion, and that resulting claims outside those Guidelines did not qualify for reimbursement under federal health care programs. This court has already observed that advocacy by Pfizer for an off-label use of Lipitor may well have violated the FDCA, but the fact that Pfizer may have done so does not automatically translate into FCA liability if the resulting claims for such prescriptions are not false under the FCA. *United States ex rel. Polansky v. Pfizer, Inc.*, 2009 WL 1456582, at *6-7 (E.D.N.Y. May 22, 2009). Prescriptions claims for

Lipitor would be "false" if they were prescribed for unapproved uses that were not supported by a citation in one of the statutorily-identified compendia.[6]

The United States takes no position as to whether relator has adequately alleged facts to support his claim that the Lipitor claims at issue here are false; however, Pfizer's reliance on the fact that the label for Lipitor was changed in 2009 clearly is misplaced. Def Br. at 3. If a claim was false when it was submitted in 2004, a label change five years later does not transform that false claim into a reimbursable one. To hold otherwise would be to render federal health care program restrictions on coverage meaningless. It also would undermine the gatekeeping role of the federal government in protecting public health as well as the public fisc in ensuring that, based on the information available at the time, only indications that have been FDA-approved or are sufficiently supported by scientific literature as safe and effective are reimbursed.

II. FCA Pleading Requirements

Of course, if a relator is claiming that the defendant drug company *caused* the providers to submit these false claims, the relator must adequately allege such causation. The relator need not allege an express false statement to satisfy the causation element, though such evidence would be one way the relator could do so. Assuming that a relator has supported his allegations with sufficient facts, courts analyze causation based on general tort law principles when determining whether the company may be liable for causing the submission of false claims based on off-label marketing conduct. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192

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[6] As noted, the statutory definition of "medically accepted indication" refers to off-label indications that are supported (as opposed to listed) in the compendia. *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008) (citing CMS Release No. 141); *see* 42 U.S.C. § 1396r-8(k)(6).

F.3d 402, 415 (3d Cir. 1999) (discussing principles of causation); *Parke-Davis II*, 2003 WL 22048255 at *4-6. In *Parke-Davis II*, the court found that causation is satisfied where (a) the drug manufacturer's alleged off-label marketing was a "substantial factor" in producing the false claims and (b) it was "foreseeable" that the off-label marketing would result in false claims. 2003 WL 22048255 at *4-6. That court, like others presented with FCA cases based on allegations of off-label marketing, also found that the actions of health care providers are not an intervening force that breaks the chain of legal causation, particularly because influencing those actions is the goal of off-label promotion. *Id.* at *5 ("[T]he 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."); *see also Scios*, 676 F. Supp. 2d at 891 (denying a motion to dismiss and finding that the independent actions of physicians "only breaks the causal connection when it is unforeseeable" that a particular drug would be billed to a federal health care program). Indeed, the pharmaceutical industry would not employ the army of sales representatives who promote their products if these sales efforts had no effect on physician practices. Thus, the relevant question here is whether relator has sufficiently alleged that it was foreseeable that Pfizer's conduct would result in some false claims being submitted to federal health care programs.

Likewise, under the FCA, courts have held that a false claim is material if it "has a natural tendency to influence agency action or is capable of influencing agency action." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999).[7] Pfizer's argument that

[7] The FCA has also been recently amended to expressly define "materiality" in this fashion. *See* 31 U.S.C. § 3729(b)(4) (2009) (defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").

federal health care programs do not require certain information on claims forms that may have allowed the programs to prevent the payment of non-covered claims should be rejected because it runs counter to the courts' long-standing recognition that those who deal with the Government must "turn square corners" and cannot take advantage of government officials who may have too few resources to catch attempted fraud at its inception. *See, e.g., Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143 (1920); *Rogan*, 517 F.3d at 452 ("The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers"). The Government processes millions of claims for payment by federal health programs each year, and requiring it, as Pfizer apparently suggests, to examine every claim it pays for potential underlying misconduct is patently unreasonable.

III. Rule 9(b) Pleading Requirements

Defendant further asserts that relator has failed to identify specific claims and that regardless of whether relator has identified specific claims submitted to federal health care programs, he has failed to provide sufficient details about those claims. The United States takes no position on the sufficiency of relator's complaint; however, to the extent that defendant contends that relator's complaint must fail because it did not identify specific false claims or do so with sufficient particularity, defendant seeks to impose too rigid a pleading standard in FCA cases.

The allegation of a specific false claim is not an absolute prerequisite to pleading a viable FCA claim. Although FCA liability attaches to the claim for payment, whether specific claims must be identified for a complaint to satisfy Rule 9(b)'s particularity requirement will depend on

the circumstances of each case. *See Ebeid ex rel. U.S. v. Lungwitz*, 2010 WL 3092637, at *4-5 (9th Cir. Aug. 9, 2010); *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 31-32 (1st Cir. 2009); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009); *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849 (7th Cir. 2009); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 390-91 (D. Mass. 2008). Thus, in off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator "need not allege the details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" *See In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d at 390 (quoting *Rost*, 507 F.3d at 732). As this court has considered in examining relator's prior complaint in this action, in evaluating such matters on a case-by-case basis, the strength of the inference of fraud on the government may be measured by, for example, factual or statistical evidence tending to show fraud beyond possibility. *See Polansky*, 2009 WL 1456582, at *9; *see, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d at 390.

CONCLUSION

The United States submits this Statement regarding how to interpret and apply certain aspects of the Medicaid Act and the FCA. The United States takes no position on the sufficiency of the complaint herein.

Respectfully submitted,

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