UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. DAVID FRANKLIN, Plaintiff, v. PFIZER, INC. and PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY, Defendants.	)	Civil Action No. 96-11651-PBS

UNITED STATES' STATEMENT OF INTEREST IN OPPOSITION TO DEFENDANT PARKE-DAVIS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The United States respectfully submits this Statement of Interest in Defendants' Motion for Summary Judgment. The United States' interest in this matter is three-fold. First, the United States remains the real party in interest in this matter, even where it has not intervened in the action. Second, if proved true at trial, Relator's case would show that Defendants engaged in a scheme to defraud federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals -- judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor. Third, because the False Claims Act, 31 U.S.C. § 3729, et seq. (the "FCA") is the United States' primary tool against fraud upon the government, it has a keen interest in the development of the law in this area and in the correct application of that law in this case and similar cases pending in several courts. The issue of violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), forming the basis for violations of the FCA is the subject of several recent decisions discussed herein. It is of particular importance to the United States because it goes to one of the core purposes of the FCA – addressing corruption in government programs and procurement. In healthcare kickback cases, even where it has not intervened, the United States has repeatedly and successfully asserted that AKS violations give rise to FCA liability.[1]

Defendant's Motion for Summary Judgment is premised on the characterization of this case as one involving evidence merely of non-false, non-fraudulent off-label promotion of

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[1] See, e.g., U.S. ex rel. Thompson v. Columbia/HCA,125 F.3d 899, 903 (5th Cir. 1997); U.S. ex rel Barrett v. Columbia/HCA, 2003 WL 757713 (D. D.C. 2003) (holding that a violation of AKS can give rise to an FCA claim); U.S. ex rel Bidani v. Lewis, 2003 WL 925998 (N.D. Ill. 2003) (same); U.S. ex rel Pogue v. Diabetes Treatment Centers of America, 238 F.Supp.2d 258 (D. D.C. 2002) (same). The government has also twice obtained consent decrees enjoining companies from submitting claims to Medicare or Medicaid for patients referred pursuant to a kickback scheme. The defendants paid significant sums to resolve their FCA liability. See Shalala v. Radiation Care, No. 1:94-CV-3339-RCF, 1995 U.S. Dist. LEXIS 749 (N.D. Ga. 1995); Shalala v. T² Medical, No. 1-94-CV-2549-ODE, 1994 WL 686949 (N.D. Ga. 1994).

prescription medications with the possible addition of a few false statements to doctors made by the Relator himself. That is not this case. The evidence in this case supports a finding that Defendants (hereinafter collectively referred to as "Parke-Davis") engaged in a fraudulent scheme, involving many false statements to doctors and the United States Food and Drug Administration ("FDA"), advanced by payment of illegal kickbacks, and resulting forseeably in the submission of false and/or fraudulent statements and claims to federally-funded Medicaid programs across the country.[2] As such, this case provides sufficient evidence to support a finding that Parke-Davis violated the FCA.

ARGUMENT

I. RELATOR HAS PROVIDED EVIDENCE OF FALSE STATEMENTS AND FRAUDULENT CONDUCT GIVING RISE TO FCA VIOLATIONS.

In this case, Parke-Davis boldly asserts that the Plaintiff can offer no evidence of false statements and bases its Motion for Summary Judgment on the absence of evidence of false statements.[3] Parke Davis is wrong. Relator has presented evidence of an illegal off-label marketing scheme that is rife with false statements and fraudulent conduct all of which had one

[2]Parke-Davis also argues that whether its off-label promotional activities violated the FDCA is irrelevant to this summary judgment motion. Defs' Mem. at 6 & n.2. Parke-Davis seeks to give the impression that its off-label promotional activities did not violate the FDCA because the activities were permissible under certain safe harbors provided by FDAMA and FDA guidelines. Defs' Brf. at 16 & n.8. However, whether its activities fell within those safe harbors is an intensive factual issue. See 21 U.S.C. § 360aaa et seq. (FDAMA), and 62 Fed. Reg. 64074-99 (1997)(FDA Guidance regarding Continuing Medical Education). Parke-Davis has not established the extensive factual basis necessary for these safe harbors, much less that these facts are uncontroverted. To the contrary, as discussed below, there is substantial evidence in this case that Parke-Davis's activities at issue in this case fell outside any safe harbors and violated the FDCA's prohibition against off-label marketing. Such conduct is relevant to an examination of Parke-Davis' overall promotional scheme (including the provision of kickbacks to induce off-label scripting), which rendered the off-label claims fraudulent under the FCA.

[3]See, e.g., Def. Mem. at 16 ("Relator has provided no evidence, however, that any of these activities involved false statements, i.e., that these activities were anything more than the communication of accurate information regarding Neurontin's off-label use"); id. at 14 ("Relator cannot identify any reference in the approximately 80 boxes of documents produced in this case to a false statement made by Warner-Lambert to a physician or to anyone else").

intended purpose and result -- increasing sales and, therefore, the claims for off-label uses of Neurontin submitted to Medicaid.

As discussed below, the reimbursement systems, on which manufacturers like Parke-Davis rely to pay for their products, in turn rely on the flow of accurate information and the unbiased professional medical judgment of physicians and pharmacists. Parke-Davis' illegal conduct caused the pharmacists to submit claims that as a result were (unknowingly) false and/or fraudulent representations that the supplies or products billed were procured in accordance with all laws and regulations governing Medicaid and thus eligible for reimbursement. The entire scheme was a fraudulent one. It was designed to and did promote Neurontin off-label not just using accurate statements, but also with false and fraudulent statements and conduct, including kickbacks falsely labeled as "consulting" payments to subvert the independent decision making process of the physician upon both the patients and the reimbursement system rely. These critical and at a minimum disputed facts undermine the lynchpin of Defendant's argument -- the lack of false or fraudulent conduct causing claims upon the public fisc. For this reason alone, Parke-Davis' Motion for Summary Judgment fails.

Relator's evidence of both false statements, and fraudulent conduct includes:

A. False statements to doctors about off-label uses of Neurontin, which, in documents created at the time, the doctors identified as something they relied upon in increasing their prescribing of Neurontin. See Relators Separate Statement of Disputed Material Facts and exhibits ("Exhs.") cited therein ("Sep. Stat.") at paragraphs 285-88.

B. False statements to doctors in the form of purportedly independent medical education, including an extensive program on uses of such drugs for pain, which was created by a company that was in partnership with Parke-Davis, to promote off-label uses of Neurontin, with materials that falsely denied the financial affiliation between Parke-Davis and the sponsors and/or faculty. See Exhs. 55, 61, 175, 178, 181-83; Sep. Stat. 393-395.

C. Payments (kickbacks) to doctors –falsely labeled as "consulting" fees -- combined with Olympics tickets and trips to Puerto Rico, Florida and elsewhere, for which the purpose was to induce the doctors to both prescribe Neurontin off-label and recommend its use to others off-label rendering these claims ineligible for payment. See, e.g., Exhs. 168, 170-173, 179-80; Sep. Stat. 78-82, 113-15, 146-7.

D. False statements to the FDA denying the existence of Parke-Davis' off-label marketing activities in order to be able to continue them and avoid an enforcement action, which could stop Medicaid payments for Parke-Davis for this drug. See Exh. 156, Sep. Stat. 388-392.

A. Relator Has Provided Evidence of Parke-Davis' False Statements and Material Omissions to Doctors.

Relator's evidence, including the doctors' reports of Parke-Davis' sales representatives visits, as well as his own statements, and the recorded teleconference and voicemail statements, show a concerted scheme to convey false and materially misleading information to doctors about the safety and efficacy of Neurontin. Numerous examples of such specific false statements are set forth in the Relator's Separate Statement of Undisputed Facts at 152-241, 285-89, and discussed in Relator's Opposition at pp. 42-55 and therefore will not be repeated here.

B. Relator Has Provided Evidence of False Statements and Material Omissions About the Financial Independence of Off-Label Programs Funded by Parke-Davis.

Parke-Davis also made and/or caused to be made false statements to doctors and others about the financial independence and unbiased nature of thousands of presentations about Neurontin and its off-label uses. As noted by the FDA in a 1997 warning letter to another drug manufacturer, "[m]aterials presented as educational in nature are more fully accepted and integrated into research participants' personal belief systems than material clearly identified as promotional." See 1997 FDA Warning Letter to Schering, Exh. 165 (stating that the drug company's failure to disclose and/or disguise of the promotional nature of an event involving claims not supported by adequate and well-controlled studies rendered them misleading in

violation of the FDCA). Parke-Davis influenced the content of purportedly independent medical education, which explicitly disclaimed any such influence, and concealed and made false statements about the payments that it had made to doctors who acted as speakers and faculty for such education. See, e.g., Sep. Stat. 393, Exhs. 61, 175-178, 181-83. For example, Parke-Davis joined into an undisclosed partnership with a company known as Physicians World whereby Parke-Davis employees were transferred to Physicians World to run Parke-Davis' speakers' bureau. Exhs. 55, 177. At the same time, a division of Physician's World, known as Professional Post-Graduate Services, purported to be an independent medical education provider that created a program on anti-convulsants for pain. In fact, the program was actually a massive promotion of Neurontin for pain, and Parke-Davis staff planned and participated in each stage of the development. Parke-Davis involvement included planning and participating in the first meeting assessing the need for such a program, as well as each of the curriculum planning meetings and teleconferences, the creation of "study groups" and dinner meetings carrying out the program, and the recruitment of doctors to participate and the provision of speakers for each activity. Exhs. 43, 51, 59, 175-178, 181-83. This program was provided to thousands of doctors around the country. Id. In each of instance, the materials falsely stated that they were in created in compliance with ACCME guidelines, which prohibited such content control by Parke-Davis as condition of program, and required disclosure of all such financial affiliations. Id. The materials did not, however, disclose the relationship between Physicians World and Parke-Davis, nor did they disclose the known substantial financial and other affiliation between Parke-Davis and each of the faculty members, all of whom were paid consultants to Parke-Davis -- and several of whom had received many thousands of dollars in speaker payments and /or grants from Parke-

Davis. Id. & Exh. 61. To the contrary, by the listing of each of these faculty, there was an asterisk listing "no significant financial or other affiliation reported" – even while affiliations with other drug companies were listed. Exhs. 175, 178. Moreover, both Physicians World and Parke-Davis knew of the affiliation of these faculty with Parke-Davis -- each was a paid consultant on the advisory board organized by Parke-Davis and Physicians World in the fall of 1995, and several were regular speakers for Parke-Davis. Exhs 51, 59, 61. One physician in particular was a regular Neurontin speaker who had received payments from Parke-Davis of more than $10,000 and served on numerous so-called "advisory boards" "consultant meetings" and "speaker bureau" panels. Id.

C. Relator Has Provided Evidence of Kickbacks Paid by Parke-Davis to Doctors in Violation of the Anti-Kickback Statute

The payments of kickbacks in the form of lavish trips, tickets and other payments to doctors, often disguised as "education" or payments for "consulting services" is conduct which is by its nature fraudulent and designed to deceive. Examples of such kickbacks paid by Parke-Davis to doctors include:

1. **August 1996 Atlanta Olympics**: This five day- four night sham "advisory board meeting" at the Chateau Elan Resort and Winery, came complete with Olympics tickets for each attending doctor and his or her spouse, motorcoach travel to the Olympics, all meals and use of the resort, winery and spa facilities, and a $750 payment to the doctors. Parke-Davis termed this a "$3mm investment" and a program that was to be, at best "50/50 business & fun." The public agenda for the meeting listed only 10.5 hours of "business meetings" but the internally circulated agenda at the meeting listed one of the three sessions as devoted entirely to off label "Non-Epileptic" uses of Neurontin. Exhs. 168, 170-173, 179-80.

2. **April 1996 Jupiter Beach Resort Sham "Consultants Meeting"**: This three day, two night event in Palm Beach, Florida included airfare, accommodations, all meals for the doctor and a guest, and a cruise on the Yacht the "Gonzo", as well as a $250 payment to each doctor. Again the agenda included explicitly off-label topics. Doctors were targeted for the meeting based upon their prescribing practices and Parke-Davis sought to track their prescribing after the event to determine the impact on their prescribing. Sep. Stat. 78-82, Exhs. 49-54, 61.

3. **January 1997 Puerto Rico "Speakers' Bureau":** This three day, two night event at the El Conquistador Resort in Fajardo, Puerto Rico included accommodations and all meals for the doctor and a guest, as well as airfare and a $250 payment to each doctor. Again the meeting included explicitly off-label topics, even though the stated purpose of the meeting was to train doctors to speak on behalf of Parke-Davis on Neurontin, and Parke-Davis reported to the FDA in the summer of 1997 that it only trained and paid such doctors to speak on-label. See Sep. Stat. 113-115, 120-122, Exhs. 61, 81, 156.

D. Relator Has Provided Evidence of Parke-Davis' False Statements to the FDA:

In a July 1997 statement to the FDA -- in response to the FDA's specific inquiry about off-label promotion -- Parke-Davis made material false statements to the FDA on a number of issues – including (1) whether it had paid speakers to speak off-label; (2) whether it had solicited participants to listen to presentations on off-label via teleconference series; and (3) whether it had paid any remuneration to the participants in its teleconferences. Exhs. 155-56. The true facts were reported to Parke-Davis at the highest levels, including in some instances to its attorneys, well before that time. See Exh. 75 (testimony of sales rep. S. Spencer that she was required to recruit doctors and given a quota as an example of the off-label marketing); Exhs. 74, 81, 174; Sep. Stat. 388-392. Parke-Davis made these false statements to the FDA knowing that if it admitted to these off-label activities and the FDA initiated enforcement action, Parke-Davis risked not only being required to immediately stop its off-label promotion and correct its off-label message, but also its ability to sell and/or receive reimbursement of Neurontin. See generally 21 U.S.C. §§ 331-335(b); 42 U.S.C. § 1320(a)(7); Exh. 165 (1997 FDA Warning

Letter). Thus, Parke-Davis made material false statements that would have a natural tendency to influence agency action in response to the FDA's specific questions on these topics. Their falsity sought to avoid enforcement action and evade detection so that Parke-Davis could continue its fraudulent scheme and induce federal and state health funding of its misbranded drugs.

II. DEFENDANTS MISSTATE THE ELEMENTS OF AN FCA VIOLATION.

Section (a)(1) of the FCA provides that "any person" "is liable to the United States" who "knowingly . . . causes to be present . . . a false or fraudulent claim for payment." 31 U.S.C. § 3729(a)(1). In this case, Defendants' liability under the section (a)(1) of the FCA is premised upon causing fraudulent claims to be submitted to the United States for payment with the requisite knowledge. The claims were fraudulent because they were the intended end-result of Defendants' unlawful and fraudulent off-label, kickback-laden marketing scheme. Moreover, FCA section (a)(1) does not require a false statement be made as part of this unlawful and fraudulent scheme. A false statement is only required by section (a)(2), which is an alternative, not the sole, theory of liability in this case.

Defendants improperly attribute misstatements of FCA law in their memorandum to this Court's decision on the Motion to Dismiss. See, e.g. Defendants Mem. 11-13. As this Court explained, however, the FCA does not require a literally false statement but reaches "all fraudulent attempts to cause the Government to pay out sums of money." U.S. ex rel Franklin v. Parke-Davis, 147 F. Supp.2d 39, 50-51 (D. Mass. 2001) (citations omitted). This Court already

rejected Defendants' claim to the contrary, stating:

> Finally, Defendant argues that Relator's claim fails because he does not allege that false statements made by Parke-Davis to doctors were material to the government's decision to pay the claim for off-label prescriptions of Neurontin. "Liability under the FCA, however, is not limited only to false statements or claims made directly by the Defendant to the government. The Act reaches beyond claims which might be legally enforced, to all fraudulent attempts to cause the government to pay out sums of money." Neifert-White Co., 390 U.S. at 233 (internal quotations omitted). Relator has adequately alleged that Parke-Davis knowingly caused the submission of these false claims through a fraudulent course of conduct in violation of 31 U.S.C. § 3729(a).

Id. at 53; see also Cook County v. U.S. ex rel. Chandler, 123 S.Ct 1239, 1245 (2003) (noting that "Congress wrote [the FCA] expansively, meaning "to reach all types of fraud, without qualification, that might result in financial loss to the Government") (citations omitted).

Likewise, Parke-Davis incorrectly cites this Court's decision and Blusal Meats v. U.S., 638 F.Supp. 824 (S.D.N.Y. 1986), for the proposition that it is an element of the FCA that "Defendants intentionally and knowingly made a material false statement." See Def. Mem. at 11. The FCA does not require proof that a defendant acted "intentionally," and this Court did not so state. To the contrary, as the plain language of the FCA makes clear, the requisite knowledge includes "reckless disregard," "deliberate ignorance" and "actual knowledge." The FCA further specifically states that "no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b). Blusal Meats is inapplicable. The case was decided under the FCA before the 1986 Amendments, which specifically clarified that no proof of specific intent to was required and added the reckless disregard and deliberate ignorance standard. 31 U.S.C. § 3729(b) (1986).

III. TO PROVE LIABILITY, RELATOR NEED SHOW ONLY THAT A FALSE CLAIM WAS *CAPABLE* OF INDUCING PAYMENT, NOT THAT THE GOVERNMENT *ACTUALLY* RELIED ON THE FALSEHOOD IN MAKING PAYMENT.

The False Claims Act requires at most only material false or fraudulent statements or claims, caused with the requisite knowledge. Actual reliance is not required. Consistent with the language of the FCA, and the cases expressly defining "materiality" in similar circumstances, materiality is established when the conduct is capable of inducing reliance by the United States. See Kungys v. U.S., 485 U.S. 759, 770-71 (1988) (plurality) (observing that "most common formulation" of materiality is whether information has a "natural tendency to influence, or was capable of influencing," the decision of the agency); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776 (4th Cir. 1999); U.S. ex rel. Berge v. Trustees of Univ. of Alabama, 104 F.3d 1453, 1459 (4th Cir. 1997).

Proof of reliance is one way for a Relator, or the government, to prove that a false or fraudulent claim caused actual damages. Reliance, however, is not a prerequisite for liability. U.S. v. Calhoun, 97 F. 3d 518, 532 (11th Cir. 1996) ("A statement can be material even if it is ignored or never read by the agency receiving the misstatement. False statements must simply have the capacity to impair or pervert the functioning of a government agency"). Every federal appellate court to have considered the issue, including the First Circuit, has held that liability may lie under the FCA even in the absence of proof of measurable, monetary damages. See U.S.

v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995).[4] The FCA reaches even *unsuccessful attempts* to defraud the United States. See Neifert-White, 390 U.S. at 232 (holding that FCA extends to all fraudulent attempts to cause the United States to pay out sums or money); U.S. ex rel. Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991) (finding that even if no payment is made on the claim and even if the United States cannot prove actual damages, it may recover civil penalties); S. Rep. No. 99-345, at 8 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5273 ("[Civil penalties] may be recovered from one who submits a false claim though no payments were made on the claim").

IV. RELATOR NEED NOT, BUT HAS PROVIDED EVIDENCE FROM DOCTORS THAT THEY RELIED UPON PARKE-DAVIS' FALSE AND/OR FRAUDULENT STATEMENTS IN INCREASING THEIR ORDERS FOR NEURONTIN.

Defendant repeatedly claims that the Relator cannot prevail under the FCA because he cannot provide evidence in the form of a doctor who says "I relied upon the false statements about safety and effectiveness." This argument is wrong as a matter of fact and law.

First, Relator has provided evidence of physician reliance that includes statements by doctors that they received a message from a Parke-Davis sales call; the message was false and/or materially misleading; and the doctor stated at the time that he or she would increase his or her prescribing as a result. See Sep. Stat. 275-89.

Defendants suggest that only by deposing the doctors could Relator provide such evidence. As the evidence submitted by Relator demonstrates, this is not the case. In addition,

[4] See also U.S. v. Hughes, 585 F.2d 284, 286 n.1 (7th Cir. 1978) ("A false claim is actionable under the Act even though the United States has suffered no measurable damages from the claim"); U.S. ex rel. Schwedt v. Planning Research, 59 F.3d 196, 199 (D.C. Cir. 1995); Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 183 (3d Cir. 2001); Harrison, 176 F.3d at 785 n.7 (4th Cir. 1999); U.S. v. Ridglea State Bank, 357 F.2d 495, 497 (5th Cir. 1966); Varljen v. Cleveland Gear, 250 F.3d 426, 429 (6th Cir. 2001); Bly-Magee v. California, 236 F.3d 1014, 1017 (9th Cir. 2001); Fleming v. U.S., 336 F.2d 475, 480 (10th Cir. 1964), U.S. v. Killough, 848 F.2d 1523, 1533-34 (11th Cir. 1988).

although physician statements can support Relator's claims, neither the absence of such admissions nor self-serving physician denials cannot defeat those claims, especially on summary judgment. One would not expect doctors many years after the fact to remember, let alone to admit, that a particular false statement by a sales representative caused them to write more prescriptions, much less that a payment to the doctor, or a trip to Florida or the Olympics influenced their ordering of Neurontin. Nor has Parke-Davis provided any statements of doctors that this was not the case. Relator's contemporaneous evidence of the doctors' statements and increased prescriptions indicates otherwise. See Sep. Stat. 275-89.

In addition, the causal link between Parke-Davis' fraudulent scheme to induce Neurontin referrals and the foreseeable resultant claim for such Neurontin referrals can be established by circumstantial evidence such as that the doctors attended an event, or accepted a payment, or received the false or fraudulent presentation, and then increased their prescriptions for Neurontin off-label. See VLT Corp. v. Unitrode, 130 F.Supp.2d 178 (D. Mass. 2001) (Saris, J.) ("[There is no requirement under § 271(b) that the causation element of inducement be proven by direct evidence of reliance. That fact, like any other fact, may be demonstrated though circumstantial, rather than direct, evidence"). See also Moleculon Research Corp. v. CBS, 793 F.2d 1261, 1272 (Fed.Cir.1986) ("It is hornbook law that direct evidence of a fact is not necessary"). "Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence." Moleculon Research, 793 F.2d at 1272 (quoting Michalic v. Cleveland Tankers, 364 U.S. 325, 330 (1960)). See generally Basic v. Levinson, 485 U.S. 224 (1988) (holding in securities fraud context, that even where, unlike here, reliance is an element of a fraud claim as under 10(b)(5), proof of causation can be established by evidence other than

evidence of actual reliance by each investor on the false statement -- which would render proof nearly impossible in a real world situation). The Court in Basic v. Levinson noted:

> There is, however, more than one way to demonstrate the causal connection. Indeed, we previously have dispensed with a requirement of positive proof of reliance, where a duty to disclose material information had been breached, concluding that the necessary nexus between the plaintiffs' injury and the defendant's wrongful conduct had been established.
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> Presumptions typically serve to assist courts in managing circumstances in which direct proof, for one reason or another, is rendered difficult. . . . Requiring a plaintiff to show a speculative state of facts, i.e., how he would have acted if omitted material information had been disclosed, would place an unnecessarily unrealistic evidentiary burden on the Rule 10b-5 plaintiff who has traded on an impersonal market.

Id; see also Affiliated UTE Citizens v. U.S., 406 U.S. 128, 153-56 (1972) (holding that positive proof of reliance on failure to disclose is not a prerequisite to recovery where facts withheld were material in sense that a reasonable investor might have considered them important in the making of this decision); see generally, St Louis Convention and Visitors Comm'n v. Nat'l Football League, 154 F.3d 851, 863 (8th Cir. 1998) (holding that Plaintiff may rely on circumstantial evidence to establish causation for antitrust claims); Group Health Insurance v. Philip Morris, 188 F.Supp.2d 1122, 1128 (D. Minn. 2002) (holding that causal nexus and reliance component in consumer protection claim may be established by "circumstantial evidence" and "need not include direct evidence of reliance by individual consumers of defendants' products"); Blue Cross & Blue Shield of New Jersey v. Philip Morris, 178 F.Supp.2d 198, 251-52 (E.D.N.Y. 2001) (rejecting argument that demonstrations of causation and injury require individual proof in mass tort action); Falise v. American Tobacco, 94 F.Supp.2d 316, 335 (E.D.N.Y.2000) ("Where, however, the fraudulent scheme is targeted broadly at a large proportion of the American public the requisite showing of reliance is less demanding. Such sophisticated, broad-based fraudulent

schemes by their very nature are likely to be designed to distort the entire body of public knowledge rather than to individually mislead millions of people").[5]

Here, Relator offers expert analysis that prescriptions by particular doctors increased following their attendance at particular events -- including the Jupiter Beach Resort "consultants" meeting, which included payments to the attending doctors. Sep. Stat. 309-387. Parke-Davis targeted high prescribers for this event and sought to track the physicians after the program and payments to see the impact on prescribing. Exhs. 49, 53-54, Sep. Stat. 80-82. Thus, there is evidence that Parke-Davis funded these boondogles, and the various financial inducements included therein, for the purpose of influencing prescribing and recommending of Neurontin off-label in order to increase such sales and such sales did increase. Id. & Sep. Stat. 243-68, 309-87. A reasonable trier of fact could conclude based upon such evidence that Parke-Davis' own plans worked as intended. See generally U-Haul Int'l. v. Jartran, 793 F.2d 1034, 1041 (9th Cir. 1986) ("The expenditure by a competitor of substantial funds in an effort to deceive consumers and influence their purchasing decisions justifies the existence of a presumption that consumers are, in fact, being deceived. He who has attempted to deceive should not complain when required to bear the burden of rebutting a presumption that he succeeded"); FTC v. Brown & Williamson

[5]Under other federal statutes, including the FTC Act and Lanham Act, a showing of individual reliance is not required. See McGregor v. Chierico, 206 F.3d 1378, 1388 (11th Cir. 2000); FTC v. Figgie Int'l., 994 F.2d 595, 605-6 (9th Cir. 1993). See also Boston Athletic Ass'n v. Sullivan, 867 F.2d 22, 34 (1st Cir. 1989) (in case alleging that t-shirts with the words "Boston Marathon" confused purchasers into thinking that the shirt was an "official" shirt of the event, "we think it fair to presume that purchasers are likely to be confused."). Under the Lanham Act, "[o]nce it is shown that a defendant deliberately engaged in a deceptive commercial practice, we agree that a powerful inference may be drawn that the defendant has succeeded in confusing the public." Resource Developers v. Statute of Liberty-Ellis Island Found., 926 F.2d 134, 140 (2d Cir. 1991). "It is well established that if there is proof that a defendant intentionally set out to deceive or mislead consumers, a presumption arises that customers in fact have been deceived." Cashmere & Camel Hair Mfrs. Institute v. Saks Fifth Ave., 284 F.3d 302, 315-16 (1st Cir. 2002) ("Common sense and practical experience tell us that we can presume, without reservation, that consumers have been deceived when a defendant has explicitly misrepresented a fact that relates to an inherent quality or characteristic of the article sold. To presume as much requires neither a leap of faith nor the creation of any new legal principle").

Tobacco, 778 F.2d 35, 42 (D.C. Cir. 1985) (holding that the defendant's large expenditures in its deceptive advertising campaign "strongly supports public reliance because advertising expenditures presumptively have the effect intended").

This connection is particularly evident when the wrongful conduct at issue involved payments and other remuneration to prescribing doctors, thereby corrupting the decision making process by which drugs are chosen for patients. As has been noted by the Supreme Court, "[A]n impairment of impartial judgment can occur in even the most well-meaning men when their personal economic interests are affected by the business they transact on behalf of the Government." U.S. v. Mississippi Valley Generating, 364 U.S. 520, 549-50 (1961). "In this conflict of interest, the law wisely interposes. It acts not on the possibility that, in some cases, the sense of that duty may prevail over the motives of self-interest, but it provides against the probability in many cases, and the danger in all cases, that the dictates of self-interest will exercise a predominant influence, and supersede that of duty." U.S. v. Carter, 217 U.S. 286, 308-09 (1910).

Relator has provided evidence (1) that off-label prescriptions by the attending physicians increased following such events and/or the physicians' receipt of payments, (Sep. Stat. 309-387) (2) that such off-label prescriptions increased substantially during the time period of Defendants' fraudulent scheme, (Sep. Stat. 243-68), and (3) that Defendants' own conduct was intended to lead to that result (Sep. Stat. 58-74). This evidence is more than sufficient to create an issue of fact as to whether the scheme caused off-label prescriptions to be written for Medicaid patients and the resulting claims for reimbursement of those drugs.

V. PARKE-DAVIS HAS NOT DEMONSTRATED THE ABSENCE OF A GENUINE DISPUTE OF MATERIAL FACT AS TO WHETHER IT CAUSED FALSE OR FRAUDULENT CLAIMS TO BE SUBMITTED TO MEDICAID.

As this Court has recognized, the FCA is directed not merely at those who submit false claims but also at those who "cause" false or fraudulent claims to be submitted. See, e.g., 31 U.S.C. § 3729(a)(1), (2). Contrary to Defendants' claim, the Supreme Court has long held that a wrongdoer need not have had a direct connection to the United States or control over the ultimate submission of the claim to the government to be liable under the FCA. See U.S. ex rel. Marcus v. Hess, 317 U.S. 537, 544-45 (1943). In Hess, the United States alleged that it was defrauded when the defendant electrical contractors conspired to rig the bidding process for certain local Public Works Administration projects, which were partially funded by the United States. The Hess Court concluded that the "[FCA] provisions, considered together, indicate a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." Hess, 317 U.S. at 544-45; see also U.S. v. Bornstein, 423 U.S. 303, 309 (1976) ("It is settled that the [FCA] . . . gives the United States a cause of action against a subcontractor who causes a prime contractor to submit a false claim to the Government."); Murray & Sorenson v. U.S., 207 F.2d 119, 123-24 (1st Cir. 1953) (holding causation established by scheme to cause inflated bid to be submitted to contractor for passing on to local government for submission to

federal government, even in absence of any false documents containing fraudulent or fictitious statements or entries).[6] The First Circuit in Murray explained:

> The fact that the claims in this case were not presented directly to the government, but were made to it indirectly through the contractors, does not prevent recovery under the [FCA]. . . . In this case there was the secret tip given by Hanson to Sorenson that the latter could raise his bid on behalf of the corporate defendant for faucets to a price higher than would otherwise have been submitted.

Id. The analysis is the same no matter how many hands the inappropriate charge passed through before its submission to the government. A seventh level subcontractor who, with the requisite knowledge, causes a false claim by passing an ineligible charge through five innocent intermediary contractors to the prime contractor, who submits it to the government, is thus liable under the FCA because the ultimate submission of the ineligible charge by the prime contractor was "reasonably foreseeable." See U.S. ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 411-17 (3rd Cir. 1999) (holding that failure of researcher to reveal pharmaceutical manufacturer funding in grant application stated FCA claim). As stated in Cantekin, 192 F.3d at 416, "[i]t 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," citing Keeton, et al., Law of Torts § 44 (5th ed. 1984).

Moreover, courts looking at fact patterns similar to this one have consistently found FCA liability where, as here, a defendant, by paying kickbacks or otherwise violating Medicare and Medicaid requirements, caused false claims to be submitted by innocent third parties.

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[6] See also U.S. v. Mackby, 261 F.3d 821, 827-28 (9th Cir. 2001) (defendant liable for instructions causing false claims by billing staff); U.S. v. Krizek, 111 F.3d 934, 942 (D.C. Cir. 1997) (defendant liable for false claims by spouse); U.S. v. Lagerbush, 361 F.2d 449, 449 (3d Cir. 1966) (government contractor's employee liable for false representations to contractor that resulted in false claims); U.S. v. Island Park, 888 F. Supp. 419, 440 (E.D.N.Y. 1995) (defendant's conduct caused false claims to the government by an innocent mortgagee).

For example, in U.S. ex rel Pogue v. Diabetes Treatment Centers of America, 238 F.Supp.2d 258 (D. D.C. 2002), the Court specifically rejected the argument that a violation of the AKS, such as those alleged here, did not cause a false claim to be submitted because the claim was submitted by someone other than the defendant. In that case, the allegation was that the Defendant Diabetes Treatment Centers of America ("DTCA"), a contractor operating diabetes treatment centers in hospitals, paid kickbacks to physicians for referrals to DTCA and the hospitals. Id. at 261. DTCA, however, did not bill Medicare. Instead, the hospitals, which had DTCA operated treatment centers, paid DTCA a per-patient fee. The hospitals then billed Medicare for the care provided to the patients, whose admission relator alleged DTCA induced by their payments to doctors. The Court explained that the fact that DTCA did not bill Medicare directly, but caused the doctor to refer to DTCA, and the hospital, which in turn billed Medicare, did not affect DTCA's liability under the FCA, stating:

> DTCA argues 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. Under the plain language of the [FCA], liability attaches to one who "causes to be presented" a false claim. 31 U.S.C. § 3729(a)(1). An argument that the presentation of the claims was the work of another is unavailing as a means to avoid liability under the [FCA]. See United States v. Raymond & Whitcomb, 53 F.Supp.2d 436, 445 (S.D.N.Y. 1999) (submission of a false claim by a participant in a venture extends that false claim to all parties). . . . Likewise, DTCA's claims that it cannot violate the Stark laws because it is not an entity to which those laws appl[y] must fall. Regardless [of] whether the facts reveal that DTCA may be directly liable under the Stark laws, if DTCA caused a claim to be presented by an entity that *is* covered by the laws, such as the defendant physicians, it may be liable under the False Claims Act.

238 F. Supp.2d at 266; see also U.S. ex rel. Goodstein, et al. v. McLaren Regional Medical Center, slip op., Case No. 97-CV-72992-DT at 10 (E.D. Mich. Jan 3, 2001) (enclosed as Ex. A) (holding FCA claim stated by allegation of engaging in prohibited financial and referral

relationship even though the physician defendants had not submitted any of the hospital claims). As noted by the Court in Pogue, it is not the number of intermediaries in the causation chain which limits FCA liability, but the existence of the requisite knowledge. The Court explained:

> This is not to say that DTCA will automatically be held liable if Relator's allegations are ultimately proven. The [FCA] includes a scienter requirement; the violation must have been made "knowingly," which can be proven by actual knowledge, deliberate ignorance, or reckless disregard. 31 U.S.C. § 3729(b).

Id.[7] Here, likewise, Parke-Davis knowingly caused doctors to refer patients to a Parke-Davis drug, which patients purchased at pharmacies, which submitted the resulting claims to the government. See Sep. Stat. 301-308. The resulting claims for payment were not just the reasonably foreseeable result of this scheme, they were the intended result necessary for Parke-Davis to increase its sales and continue to be paid.

Similarly, in U.S. ex rel McCready v. Columbia/HCA, 2003 WL 912738 (D.D.C. 2003), the court rejected the argument of one defendant that it did not submit the challenged claims for Medicare reimbursement or even benefit from their submission. In that case, the Milestone health care management company was alleged to have conspired with a hospital to keep patients at the hospital before they were transferred to the rehabilitation center managed by Milestone. Id. at 1. The Court rejected Milestone's motion to dismiss on the theory that it neither benefitted from keeping the patients at the hospital, nor submitted claims for those hospital stays, stating:

> That Milestone did not gain from the scheme in this way does not negate Milestone's alleged participation in and responsibility for the fraud, however. The complaint adequately implicated Milestone by naming specific Milestone employees who facilitated and participated in the scheme to retain patients in the hospital past their recommended discharge.

[7]Parke-Davis has not moved for summary judgment on the issue of knowledge.

Id. at * 3; see also U.S. v. F.E. Moran, 2002 WL 2003219, *8 (N.D. Ill.) (rejecting argument that summary judgment should be granted because two defendants had no direct contractual relationship with the government and received no federal funds). The situation here is quite similar. Although Parke-Davis did not submit the ultimate claim to Medicaid, it participated in a fraudulent scheme to cause claims that are not eligible for reimbursement (e.g. those tainted by kickbacks and fraudulent off-label marketing) to be submitted. The fact that the claims were submitted to the government by an unknowing third party pharmacy in no way decreases Parke-Davis' liability for causing the improper (kickback-driven) off-label prescription's submission.

In support of its argument that the Relator has not established causation, Parke-Davis cites only U.S. v. Kinney, 2001 WL 964011 (D.Minn.). In that case, however, the alleged false statement, by the remaining defendant in the case, was shown as a matter of undisputed fact to have no effect on the billings to the government. The undisputed evidence was that the defendants doctor's practice (HFA) sometimes signed forms indicating medical necessity and sometimes did not, but that either way, the hospital billed Medicare without ever checking whether the forms were signed or medical necessity was indicated. Thus, the doctor's statements simply did not cause the false billing -- the false billing occurred regardless of what the doctors did. 2001 WL 964011, *3 (noting that the undisputed evidence was that the false billing "code was entered into the HCMC computer system [by the hospital] regardless of whether the 'medical necessity' block on that particular run sheet had been signed"). The Court in Kinney explained:

> Unlike Hess, there is no evidence here that the HFA emergency room physicians' signatures on ambulance run sheets set in motion a chain of events that resulted in claim forms being submitted to Medicare for ALS-Minor ambulance runs. As Kinney has established, the claim forms identified the disputed ambulance services according to HCPCS and revenue codes that were appropriate only for "medically necessary" ambulance services; those codes were selected, however, as the result of HCMC's actions, not the signatures of HFA physicians on ambulance run sheets. Accordingly, Hess is also distinguishable.

Id. at *9.[8] There is no comparable lack of a direct causal link here. Here, either through false and misleading statements, illegal remuneration or both, Parke-Davis caused doctors to prescribe Neurontin for non-medically indicated purposes. Some of those prescriptions were, forseeably, and with the knowledge of Parke-Davis, reimbursed by Medicaid. Sep. Stat. 301-03. Parke-Davis intended its off-label promotion scheme to cause these prescriptions. Parke-Davis even sought to track the doctor's prescribing before and after specific events to make sure that the promotion scheme was working. See, e.g., Exh. 54, Sep. Stat. 82. Such evidence is more than sufficient to permit a reasonable trier of fact to conclude that Parke-Davis' fraudulent scheme caused the submission of claims to the government.

VI. VIOLATIONS OF LAW GIVE RISE TO AN FCA CLAIM WHERE, AS HERE, COMPLIANCE WAS A PREREQUISITE TO PAYMENT.

The legal premise of Defendants' argument remains the incorrect assertion that FCA liability can only be premised on an express certification of fact that is literally false. The overwhelming weight of federal case law establishes that the appropriate inquiry for a court considering whether the violation of a statute, regulation, or contract provision gives rise to FCA liability is whether a nexus exists between compliance with that statute, regulation, or contract

[8]It is also interesting to note that the plaintiff in Kinney did not even sue HFA, the physician practice, until after his suit against the county hospital, which allegedly knowingly submitted the false claims, had been dismissed. Although the Court in Kinney dismissed the county hospital from the case on the ground that a municipality is not a person under the FCA, 2001 WL 964011, the Supreme Court recently held to the contrary – that a municipality is a person and can be held liable under the FCA. Chandler, 123 S.Ct at 1244.

provision, and the defendant's claim for payment, i.e., whether compliance is a prerequisite to payment or the right to retain payment. Thus, when a party violates applicable statutory, regulatory, or contractual provisions, FCA liability will attach if compliance affects entitlement to payment. "'[T]he key inquiry is whether the claim in question has the practical purpose and effect, and poses the attendant risk, of inducing wrongful payment. . . . If compliance with the statute or regulation was a condition for payment, then the FCA is implicated." U.S. ex rel. Bidani v. Lewis, 1998 WL 1820753, *8-9 (N.D. Ill. 1998) (citations omitted).

A. False Representations of Entitlement Violate the FCA.

FCA liability exists based on the knowing violation of a statute, regulation, or contract provision that constitutes a prerequisite to payment. In these cases, liability attaches whether or not there is an express certification. Many parties and courts use the short-hand term "implied certification" to describe cases in which no express certification is submitted. See, e.g., U.S. ex rel. Augustine v. Century Health Services, 289 F.3d 409, 415 (6th Cir. 2002). In both express and implied certification cases, presentment of the claim falsely represents an entitlement to payment that is forfeited by the violation of an applicable statute, regulation or contract.

The plain language of the FCA establishes that liability may attach for the submission of a false claim even in the absence of an express false statement. While 31 U.S.C. § 3729(a)(2) premises liability on the "use of a false record or statement to get a false or fraudulent claim paid," § 3729(a)(1) only requires the submission of, or causing the submission of, a "false or fraudulent claim for payment or approval" without the additional element of a false record or statement. See Shaw v. AAA Engineering & Drafting, 213 F.3d 519, 531-32 (10th Cir. 2000) (highlighting distinction between sections (a)(1) and (a)(2)).

The legislative history of the 1986 FCA amendments indicates that Congress intended the FCA to apply whenever a defendant "knowingly" caused a claim that is ineligible for payment, even if the defendant provided the product or service requested by the government. See S. Rep. No. 99-345 at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274 ("claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program" and a false claim "may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specifications, statute, or regulation").

Consistent with the statute and its legislative history, for over 50 years, federal courts have held that claims caused by defendants who broke the law to obtain the opportunity to bill the government violate the FCA, regardless of whether the claimant expressly certified compliance with the prohibition. For example, the Supreme Court has held that bid rigging to obtain a contract renders the claims submitted under the fraudulently procured contract false. Hess, 317 U.S. at 543-44; see also Murray & Sorenson, 207 F.2d at 124 (FCA liability established by bid rigging, even though no evidence of false statement or certification presented); U.S. v. CFW Construction, 649 F. Supp. 616, 618 (D.S.C. 1986) (all claims under contract tainted by rigged bids were false under FCA). Other federal courts similarly have imposed FCA liability on defendants who caused the submission of claims while engaged in prohibited kickback or other financial conflicts of interest.[9] In none of these cases did the absence of an

[9] See U.S. v. TDC Mgmt., 288 F.3d 421, 426 (D.C. Cir. 2002) (ombudsman's claims triggered FCA liability because they failed to disclose conflicts of interest deemed "information critical to the decision to pay," despite the absence of a specific contractual prohibition or disclosure requirement); U.S. v. General Dynamics, 19 F.3d 770 (2d Cir. 1994) (FCA claim stated by allegation of payment of kickbacks by the subcontractor to the prime contractor, and the inclusion of those kickbacks in the prime contractor's cost data); U.S. v. Killough, 848 F.2d 1523 (11th Cir. 1988) (FCA liability based on the illegal payment of kickbacks in exchange for the award of certain federal contracts); U.S. v. A and C Invs. 513 F. Supp. 589 (N.D. Ill. 1981) (holding FCA claim stated by allegations that

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express certification of compliance prevent liability from attaching; in each, the relevant inquiry was the existence of a nexus between compliance and payment.

B. Billing the Government Is An Implicit Certification of Compliance with Laws, Regulations or Contract Terms That Are Prerequisites to Payment.

Courts have repeatedly held that FCA liability can be premised on such "implied certifications" of compliance with law, regulation or contract terms. See Shaw, 213 F.3d at 531-2. This implied certification theory has been explicitly recognized by at least six Courts of Appeals, including the First Circuit, as well as by numerous district courts. See Scolnick v. U.S., 331 F.2d 598 (1st Cir. 1964) (imposing FCA liability based upon mere cashing of check to which payee was not entitled, without any representation to obtain check); Murray & Sorenson, 207 F.2d at 124 (1st Cir. 1953) ("[I]n this case there was an implied false representation that the bids were at a figure which the corporate defendant would have submitted in competition"); Century Health, 289 F.3d at 414-415 (6th 2002) (implicit false certification of continuing compliance with Medicare requirements actionable under FCA); Mikes v. Straus, 274 F.3d 687, 699-700 (2nd Cir. 2001) (endorsing theory where violated provision was a condition of payment); U.S. ex rel. Siewick v. Jamieson Science & Eng'g., 214 F.3d 1372, 1376 (D.C. Cir. 2000) ("Courts have been ready to infer certification from silence, but only where certification was a prerequisite to the government action sought"); Shaw, 213 F.3d at 531-33 (defendant's submission of monthly invoices to the government for photography services despite failure to comply with environmental provisions in contract impliedly certified that contractor had complied with the terms of the contract "even absent an affirmative or express false statement"); Ab-Tech

[9] (...continued)
defendants paid bribes to government employee in connection with housing contract, and by then submitting claims under the tainted contract).

Construction v. U.S., 31 Fed Cl. 429, 434 (Fed Cl. 1994), aff'd., 57 F.3d 1084 (Fed. Cir. 1995) (claims court decision expressly endorsing theory and finding FCA violation for seeking payment when defendant failed to meet program eligibility requirements, affirmed without opinion).[10] Here, Parke-Davis knowingly caused the pharmacists to (unknowingly) impliedly or expressly represent entitlement to payment for Parke-Davis' drug where there was no such entitlement, and Parke-Davis thereby violated the FCA.

VII. CLAIMS SUBMITTED FOR OFF-LABEL NEURONTIN PRESCRIPTIONS BY DOCTORS WHO RECEIVED KICKBACKS FROM PARKE-DAVIS PROVIDE THE BASIS FOR FCA LIABILITY.

Claims submitted for patients referred to a particular drug as a result of kickbacks in violation of the AKS are actionable under the FCA. In its ruling on the Motion to Dismiss, this Court noted,

> While Defendant's payment of kickbacks may well be illegal, a claim under the FCA will fail unless Relator alleges that Parke-Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute.

[10] See also Bidani, 2003 WL 925998, *1; Barrett, 2003 WL 757713, *2-3; Pogue, 238 F.Supp.2d at 263-66; U.S. ex rel. Kneepkins v. Gambro Healthcare, 115 F. Supp. 2d 35, 42-43 (D. Mass. 2000) (holding failure to disclose violation of AKS, without explicit certification, stated claim under FCA); U.S. v. NHC Healthcare Corp., 115 F. Supp.2d 1149, 1155 (W.D. Mo. 2000) (holding provider could be held to have implicitly certified compliance with the standard of care in nursing home services, because that standard lay "at the core of the parties' agreement"); U.S. ex rel. Wright v. Cleo Wallace Centers, 132 F.Supp. 2d 913, 926 (D. Colo. 2000) (holding FCA liability stated based on Medicare claims for services rendered in facilities not licensed for those services "even without an affirmative or express false statement of such compliance."); BMY Combat Sys. v. U.S., 38 Fed. Cl. 109, 125 (Ct. Cl. 1997) ("Although [the contractor] did not make expressly false representations on the [invoices], [the contractor's] implied representations fall into the category of acts that constitute false or fraudulent claims"); U.S. ex rel. Pogue v. American Healthcorp., 914 F. Supp. 1507, 1509-13 (M.D. Tenn. 1996) (holding concealment of Medicare anti-fraud kickback violation while billing Medicare stated FCA claim); U.S. ex rel. Aranda v. Community Psychiatric Centers of Okla., 945 F. Supp. 1485, 1488 (W.D. Okla. 1996) (FCA claim stated by allegation that Medicaid claims implicitly certified compliance with applicable statutes, rules and regulations governing quality of care); U.S. v. Island Park, 888 F. Supp. 419, 439-40 (E.D.N.Y. 1995) (false statements or records not required for fraudulent course of conduct in mortgage program administration to be actionable). Moreover, the Ninth Circuit adopted the implicit certification theory without discussion in another case, U.S. v. McLeod, 721 F.2d 282, 284 (9th Cir. 1983), where it upheld an FCA violation based upon mere cashing of an erroneously issued government check.

In his Amended Complaint, Relator alleged exactly that – both explicit and implicit false certifications by doctors and pharmacists (unknowingly by pharmacists) and has now provided the evidence thereof. See Amended Complaint ¶¶ 24-50, 60-68.

In the hearing on the Motion to Dismiss the Amended Complaint, while dismissing Count II, which alleged a kickback theory based in part on false certifications by doctors concerning the doctors' services, this Court stated that the evidence of kickbacks was relevant and remained in the case as to whether there was a fraudulent scheme under the FCA as set forth in Count I, which includes kickbacks as one of the ways in which Defendants caused false claims for reimbursement for off-label prescriptions. The Court stated that the evidence of kickbacks "is very relevant as to whether there is a fraudulent scheme." January 9, 2002 Hearing p. 27. The Court also stated: "It is appropriate to do discovery into the kickback scheme because it is part of the fraudulent scheme alleged. . . ." Id. at 49. Thus, this Court kept in this case kickbacks as one of the types of fraudulent conduct engaged in by Defendants in support of their off-label promotion scheme.

A. Courts Hold Unanimously that FCA Remedies Apply to Violations of the AKS.

At least nine courts have ruled that the government may pursue an action under the FCA to redress violations of the AKS, including three new decisions in the last six months.[11] In the

[11] See U.S. ex rel. Thompson v. Columbia/HCA,125 F.3d 899, 903 (violation of the AKS, when combined with the false certification of compliance with applicable laws and regulations, may give rise to false claims under the FCA), on remand, 20 F. Supp. 2d 1017, 1046-48 (S.D. Tex. 1999) (because hospital's certification of compliance with AKS is a condition to payment, relator may pursue FCA claims; claims submitted in violation of Stark laws are false as a matter of law under the FCA); Bidani, 2003 WL 925998 (denying summary judgment on ground that, on its face, the AKS demonstrates that compliance with the statute is presumed and material when Medicare claims are paid); Barrett, 2003 WL 757713 (holding that a violation of AKS can give rise to cause of action under the FCA); Pogue, 238 F.Supp.2d 258 (holding that allegations of violations of AKS stated claim under FCA under implied certification theory); U.S. ex rel. Goodstein, et al. v. McLaren Regional Medical Center, slip op., Case No. 97-CV-72992-DT (E.D. Mich. Jan 3, 2001) (enclosed as Ex. A) (denying motion to dismiss government allegations that physician participants to kickback schemes caused hospital to submit false Medicare claims for the

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most recent of these decisions, U.S. ex rel Bidani v. Lewis, 2003 WL 925998 (N.D.Ill. 2003), the Court summarized:

> The government has entered a statement of interest in this case, arguing that since AKS is a critical provision of the Medicare statute, compliance with it is material to the government's treatment of claims for reimbursement. We agree. The AKS criminalized receiving remuneration intended to affect decisions to purchase supplies for which payment may be made under Medicare. 42 U.S.C. § 1320a-7b(b)(1). Those convicted under the AKS are barred from participating in the federal health care program. 42 U.S.C. § 1320a7(a)(1). 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. This situation exemplifies the "inducing wrongful payment" test for determining materiality contemplated in Luckey, supra.

Id. at *2. Similarly, the Court in a recent decision in Pogue noted that despite Defense counsel's claims to the contrary, no Circuit Court had ever rejected the theory of AKS violations as stating a basis for an FCA violation and that in fact no district court that had squarely addressed the issue had so held either.[12] 238 F.Supp.2d at 265-66. The Court in Barrett similarly stated:

> HCA argues that kickbacks cannot give rise to an FCA cause of action. This is contrary to existing precedent ... The cases stating that kickback claims state a cause of action under the FCA rely on precedent stating that FCA liability arises where information is concealed in the submission of a claim, that if known to the government, would affect the government's decision to pay on that claim. . . .

[11] (...continued)
referred services); Kneepkins, 15 F. Supp. 2d 35, 43 (D. Mass. 2000) (allegations that rebates offered in return for referrals violated the AKA were sufficient to state an FCA claim); U.S. ex rel. Gublo v. Novacare, Inc., 62 F. Supp. 2d 347, 355 (D. Mass. 1999) (relying on Thompson to permit relator to pursue FCA claims based on violations of the AKS and Stark laws); U.S. ex rel. Pogue v. American Healthcorp., 914 F. Supp. at 1513 (M.D. Tenn. 1996) (reinstating allegations that kickbacks rendered claims for referred items and services false or fraudulent under the FCA); U.S. ex rel. Roy v. Anthony, 914 F. Supp. 1504, 1506-07 (S.D. Ohio 1994) (denying motion to dismiss and permitting relator to proceed in an FCA case based on tainted patient referrals).

[12] While not specifically addressing condition of payment, one court recently dismissed a relator's kickback-based FCA allegations in a declined case. The court disposed of the relators' claim based on the absence of factual allegations, rather than the legal issue of nexus to payment. Citing law review articles by defense attorneys, and noting that neither party had fully briefed the issue, however, the court expressed concern at allowing "a qui tam plaintiff [to] use the FCA as a vehicle for pursuing a violation of the anti-kickback statute . . ." U.S. ex rel. Barmak v. Sutter, 2002 WL 987109 (S.D.N.Y. 2002).

> compliance with the [AKS] and Stark laws would affect the government's decision to pay. . . .

2003 WL 757713, *1. Likewise here, Parke-Davis' violation of the AKS in inducing the prescriptions would affect the government's decision to pay the prescriptions written by the doctors receiving the kickbacks from Parke-Davis. Allowing Parke-Davis to retain the benefit of the prescriptions illegally induced by its extensive scheme of kickbacks would be to enforce the tainted bargain and allow Parke-Davis to retain the benefit of the very prescribing it infected.

Moreover, the holdings in these cases accord with decades of case law interpreting the FCA in various contexts. The United States has routinely pursued wrongdoers under the FCA whose claims were rendered false or fraudulent by their violation of a related statute, rule, or regulation, including, significantly, statutes prohibiting kickbacks.[13] It is the violation of the statute, rule, or regulation that, when combined with the submission of a claim to the United States, gives rise to an FCA cause of action.

B. Under the Statutory Scheme, Violation of the AKS Affects a Provider's Entitlement to Medicaid Payment Such That Compliance With the AKS is a Prerequisite to Payment.

Moreover, the Social Security Act (SSA) itself establishes that compliance with the AKS is a prerequisite to a provider's right to receive or retain Medicaid payments. As such, FCA liability exists as a matter of law when a violation of the AKS results in the submission of a claim for payment under Medicare or Medicaid. A sufficiently direct nexus is also – and equally firmly – established by the general legal principle that providers who violate statutes that relate

[13] See, e.g., U.S. v. General Dynamics, 19 F.3d 770, 775 (2d Cir. 1994) (FCA claim based on violation of the Anti-Kickback Act of 1946); U.S. v. White, 765 F.2d 1469, 1479-80 (11th Cir. 1985) (FCA case based upon altered time cards submitted in violation of Truth in Negotiations Act (TINA); U.S. v. Rockwell Int'l, 795 F. Supp. 1131, 1132 (N.D. Ga. 1992) (FCA claim based on violation of TINA).

directly to the integrity of a government program involving government funds, like the AKS, are not entitled to payment from the federal fisc for the resulting claims.

1. The SSA Makes Compliance with the AKS a Prerequisite to Payment.

At the heart of the instant dispute is Relator's allegation that Defendants violated a critical provision of the Medicaid statute. See 42 U.S.C. § 1320a-7b.[14] Defendants engaged in conduct proscribed by a criminal statute that establishes a core term of Medicaid's reimbursement scheme. The link between the prohibited conduct (unlawfully inducing prescribers to order certain items) and the claims at issue in this litigation (claims to Medicaid for those very prescribed items) is apparent on the face of the AKS itself.

Conduct that violates the AKS is, by statutory definition, conduct intended to induce a referral or affect the decision to order items or services for which payment may be made under Medicaid or certain other Federal health care programs. The statute specifically focuses on paying off referral sources to obtain the opportunity to bill those Federal health care programs: it is only violated when one purpose of paying kickbacks is to induce another person to refer, arrange for, or recommend referrals for the provision of "any item or service for which payment may be made in whole or in part under a Federal [or, prior to 1996, Medicare or Medicaid] health care program." 42 U.S.C. § 1320a-7b(b) (emphasis added).

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[14] Most states also have their own criminal statutes that prohibit the payment and solicitation of kickbacks to induce patient referrals in language virtually identical to that of the federal AKS. See, e.g., Mass. Gen. Laws Ann ch. 118E § 41 (1993) (prohibiting kickbacks to induce Medicaid referrals); Mass. Gen. Laws Ann ch. 175H § 3 (1998) (prohibiting kickbacks to induce private insurance referrals); 18 N.Y.C.R.R. §§ 515.2(a) (2002) (prohibiting kickbacks to induce Medicaid referrals as an "unacceptable practice" and condition of participation); 515.5(a), (b) (prohibiting payment for services rendered in violation of a condition of participation); N.J. Stat. Ann. § 30:4D-17(c) (1997) (prohibiting kickbacks to obtain payment under Medicaid); Cal. Wel. & Inst. Code § 14107.2 (2001) (prohibiting kickbacks for referral of Medi-Cal business); Cal. Bus. & Prof. Code § 650 (2003) (prohibiting kickbacks between licensed professionals); Fla. Stat. Ch. 409.920 (2003) (prohibiting kickbacks for referral of Medicaid business); Fla. Stat. Ch. 456.054 (2001) (prohibiting kickbacks for referral of patients); Fla. Stat. Ch. 465.185 (2001) (prohibiting payment of kickbacks by pharmacies); Was. Rev. Code Ann. § 74.09.240 (2001) (prohibiting kickbacks to induce referrals of Medicaid patients).

Preserving the integrity of professional decision-making is a primary concern of the AKS. In addition to offering presumptively independent professional judgment to patients, physicians have, from the very infancy of the program, served as "gatekeepers" upon whose professional judgment Congress relied to determine whether a particular item or service provided to a beneficiary should be reimbursed by Medicaid. See 42 U.S.C. § 1395y(a)(1)(A) (covered services are those that are "reasonable and necessary for the diagnosis or treatment of illness or injury to improve functioning of a malformed body part"). Medicaid depends on the integrity of a provider's decision-making as a prima facie indication that the prescribing of any drugs, and the choice of provider accord with the proper diagnosis and are medically necessary and appropriate. This is particularly true in the area of off-label prescribing -- where the drugs prescribed by the doctor have not met the FDA requirements for proof of safety and efficacy. It is therefore vital in this system that the doctor's decision making process be untainted by self-interest or improper inducement. The structure of the program assumes that medical decision-making, including referrals and supplier ordering decisions, will reflect professional judgment rather than personal financial interest because kickbacks and their insidious influence have long been prohibited.

The Seventh Circuit observed, in a case involving orders for drugs, among other things:

> In prohibiting 'kickbacks,' Congress need not have spelled out the obvious truisms that, while unnecessary expenditure of money earned and contributed by taxpaying fellow citizens may exacerbate the result of the crime, kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed. . . . A compassionate people have established and paid for a program of care for the aged among them. Nothing in that program gave to its empowered and privileged conductors carte blanche to manipulate within its fixed costs, as defendants apparently recognized in mislabeling ('fees for consulting services') the payments and in funneling the payments through [the management company].

U.S. v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980).

The legislative history of the AKS reflects Congressional intent to address precisely these sorts of dangers: to prohibit "certain practices [that] have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and [that] contribute[d] appreciably to the cost of Medicare and Medicaid programs." H.R. Rep. No. 231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 5093 (emphasis added). Violations are punishable by up to a $25,000 fine and/or five years of imprisonment. See 42 U.S.C. § 1320a-7b(b). Married with the criminal provision is a growing list of other statutory provisions that establish that Congress intends to eliminate kickback-tainted claims from Medicare, Medicaid, and other Federal health care programs. Any party convicted under the AKS must be excluded (i.e., not allowed to bill for services rendered) from these Federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the AKS, the Secretary may exclude that provider from the Federal health care programs for a discretionary period (in which event he must direct the relevant State agency(ies) to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b). The enactment of these various provisions and amendments demonstrates Congress's continuing commitment to the fundamental principle that Federal health care programs will not tolerate the payment of kickbacks.

Moreover, state Medicaid programs often stress the importance of compliance with these laws by requiring providers to execute an explicit statement of compliance with applicable Medicare and Medicaid laws as a condition of participation in the program. See Sep. Stat. 296-98, Jeffrey Aff. ¶¶ 5-8; cf. Pogue, 238 F.Supp.2d at 264 (noting that medicare enrollment forms notify providers that compliance with the AKS is a condition of payment).

For the programs to function in the best interests of the public welfare – individual patient health as well as the continued fiscal viability of the programs – they must function free of the insidious effects of kickbacks and related financial conflicts of interest. The only logical conclusion to be drawn is that by prohibiting the practice of paying off referral sources for the opportunity to bill Federal health care programs, Congress intended to prevent the product of those practices – i.e., kickback-tainted claims – from entering the payment system.

Against this backdrop, any claim that the United States is willing and content to pay claims for services that are known to have resulted from the illegal payment of kickbacks blatantly contradicts the entire statutory scheme and the evidence that Congress never intended to subsidize providers for buying patient referrals with kickbacks. Cf. U.S. v. Acme Process Equip., 385 U.S. 138, 147 (1966) ("it is the 'inherent difficulty in detecting corruption which requires that contracts made in violation of . . . [the contractor Anti-Kickback Act] be held unenforceable, even though the party seeking enforcement ostensibly appears entirely innocent'") (quoting Mississippi Valley, 364 U.S. at 565). It would be fundamentally inconsistent for Congress to intend to prohibit providers from paying kickbacks in order to bill Medicare or Medicaid, and to prohibit proven perpetrators from billing Federal health care programs for a period of years while at the same time intending that Medicare or Medicaid pay the underlying claims that the perpetrator procured by means of the kickbacks. The fact that the kickback is effectuated by submission of the claim through an innocent pharmacist does not change the fact that claim was generated by fraudulent conduct rendering it ineligible for payment. In these circumstances, the FCA provides a remedy when, despite Congress's presumption that providers will obey the law, kickback-tainted claims are funneled into the reimbursement system.

2. Providers Who Pay Kickbacks Forfeit Their Entitlement to Collect or Retain Government Reimbursement.

Beyond the clear import of the AKS itself, long-established federal case law dictates that, when federal funds are at issue, non-compliance with statutes prohibiting actual financial conflicts of interest negates a claimant's right to payment by the United States. Thus, the solicitation or payment of bribes, and other less obvious financial incentives, nullifies any pre-existing duty of the United States to pay submitted claims for services that, but for the financial incentives, would have been reimbursable.

Courts on numerous occasions have refused to award breach-of-contract damages to contractors when their federal government contracts were tainted by a conflict of interest, regardless of why the contract was terminated. In the seminal case, Mississippi Valley, the Supreme Court considered a suit brought by a contractor seeking to recover the funds it had spent on a construction contract, before the United States had cancelled the contract. 364 U.S. at 523-24. The Court accepted the argument "that the contract was unenforceable due to an illegal conflict of interest" on the part of an individual who served contemporaneously as an agent of the government and an officer of a private bank which stood to benefit from the contract. Id. at 524.

The Court noted that the statute at issue did not specifically provide that contracts made in violation of the statutory prohibition were to be invalidated, but held nevertheless that the proper inquiry was "whether the sanction of nonenforcement is consistent with and essential to effectuating the public policy embodied in Section 434." Id. at 563.

Similarly, a few years later, the Supreme Court held that a contract is unenforceable when it is tainted by kickbacks. Acme, 385 U.S. 138 (1966). There, the United States had cancelled a procurement contract with plaintiff Acme because three of Acme's principal employees had

accepted kickbacks for awarding subcontracts, in violation of the Anti-Kickback Act, 41 U.S.C. § 51, a government procurement statute analogous to the AKS. Acme, 385 U.S. at 138-139. Despite the fact that the Anti-Kickback Act at issue in Acme on its face provided only two sanctions for violation of its provisions: a fine or imprisonment, the Court found that the Anti-Kickback Act "clearly expressed" Congress's hostility to kickbacks, and implied a civil remedy to hold the contract unenforceable. Id. at 143. Thus, even though the Anti-Kickback Act only explicitly provided the civil remedy of recovery of the amount of the kickback, the Supreme Court unanimously held that the Act implicitly authorized cancellation of the contract and payment under that contract. Id. at 147-48.[15]

Like the financial conflict-of-interest statute at issue in Mississippi Valley, the AKS does not require actual corruption or actual financial loss to the United States. The purpose of the law is "to insure honesty" and integrity, including the independent use of medical judgment, in the provision of medical services to Medicaid beneficiaries, and to prevent referring physicians "from advancing their own interests at the expense of the public welfare." See Mississippi Valley, 364 U.S. at 548 (citation omitted). Such referral relationships, and any resulting obligation of the Medicaid program to pay for services resulting from such tainted referral relationships, must – in accordance with Mississippi Valley and Acme – be held unenforceable, to avoid saddling the American public with "the type of infected bargain which the statute outlaws." Id. at 563.

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[15] See also TDC, 288 F.3d 421 (holding defendants liable under the FCA because they sought payment for claims submitted after they engaged in prohibited financial conflicts of interest on ground that once the defendants engaged in the conflicts of interest, the Program no longer had any value to the United States, and holding that the United States' damages were comprised of all amounts paid to TDC for contract performance after that point); U.S. v. Medico Indus., 784 F.2d 840 (7th Cir. 1986) (holding that the United States was entitled to cancel contract where former government employee violated 18 U.S.C. § 207 revolving door statute); K & R Eng'g. v. U. S., 616 F.2d 469 (Ct. Cl. 1980) (holding that contractor was not entitled to receive breach of contract damages from United States where government employee had accepted kickbacks from contractor in exchange for contracts, in violation of 18 U.S.C. § 208).

The prohibited kickbacks allegedly paid by the Defendants to various physicians and other referral sources were, like the kickbacks paid in Acme, designed to result in additional business for the party paying the kickbacks. The payment of kickbacks to the referring physicians thus creates a real conflict of interest, pitting those physicians' own financial interests in the kickback arrangements against the same physicians' independent medical judgment in determining what treatments are in the best medical interests of their patients. As in both Acme and Mississippi Valley, the resulting conflict of interest so infects the entire relationship as to necessarily render any resulting obligation of the United States unenforceable as a matter of law. Violation of the AKS forfeits the provider's entitlement to receive or retain Medicaid reimbursement for the referred services and products.

VIII. CLAIMS FOR PRESCRIPTIONS FOR NEURONTIN OFF-LABEL WRITTEN BY DOCTORS WHO HAVE ACCEPTED KICKBACKS ARE FALSE CLAIMS.

Claims submitted to Medicaid programs for the costs of prescriptions or orders written by doctors who received illegal kickbacks are false and/or fraudulent claims. Here, Relator has identified the doctors who received the illegal remuneration and in some cases the increased prescriptions thereafter. See Sep. Stat. 309-87. The issue of how many false or fraudulent claims were submitted and the overall financial impact is at least a disputed issue of fact, and primarily an issue of the extent of damages and penalties. See generally Bigelow v. RKO Radio Pictures, 327 U.S. 251, 265 (1946) ("The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created"); Janigan v. Taylor, 344 F.2d 781, 786 (1st Cir. 1965) ("It is more appropriate to give the defrauded party the benefit even of windfalls than to let the fraudulent party keep them").

Where, as here, the Plaintiff is able to identify the scheme to submit the false or fraudulent claims and the category of particular claims that were thereby rendered false or fraudulent, e.g. claims for reimbursement for off-label prescriptions following the kickback to the prescribing physician, there is evidence sufficient to survive summary judgment as to liability.

CONCLUSION

For the foregoing reasons, the Court should deny defendant Parke-Davis' Motion for Summary Judgment.

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I hereby certify that a true copy of the above document was served upon (each party appearing pro se and) the attorney of record for each other party by mail on

5/23/03

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