UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION	MDL NO. 1629
THIS DOCUMENT RELATES TO: THE GUARDIAN LIFE INSURANCE COMPANY OF AMERICA v. PFIZER, INC., et al., and AETNA, INC. v. PFIZER, INC., et al.	CIVIL ACTION NO. 04-cv-10981-PBS

MEMORANDUM AND ORDER

January 8, 2010

Saris, U.S.D.J.

I. INTRODUCTION

Plaintiffs Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals ("Kaiser"), Aetna, Inc. ("Aetna"), and Guardian Life Insurance Company ("Guardian"), collectively the Coordinated Plaintiffs, bring this case against Pfizer, Inc. and Warner-Lambert Company, alleging violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c) (Counts I-X); the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 (Count XI); the unfair competition statutes of other states (Count XII); the Pennsylvania Insurance Fraud Statute, 18 Pa. C.S. § 4117(a)(2) (Count XIII); and requesting restitution or disgorgement for unjust enrichment (Count XIV) related to the sales and marketing of the prescription drug

Neurontin. Plaintiffs allege that defendants Warner-Lambert and Pfizer engaged in a fraudulent scheme to promote and sell the drug Neurontin for "off-label" conditions. A condition is "off-label" if the Food and Drug Administration ("FDA") has not approved Neurontin for that condition.

Defendants moved for summary judgment in this action with respect to the Coordinated Plaintiffs, the "Class Plaintiffs," and the "Consumer Plaintiffs."[1] This opinion is restricted to the motion for summary judgment as it pertains to the Coordinated Plaintiffs. The motion was brought on four grounds: (1) that Plaintiffs have failed to create a triable issue of fact as to causation; (2) that Plaintiffs have failed to raise a triable issue of fact as to whether or not Neurontin is ineffective for the relevant off-label uses; (3) that Plaintiffs have failed to create a triable issue of fact as to whether Defendants misrepresented Neurontin's effectiveness with scienter; and (4) that Plaintiffs lack standing.

After a hearing and review of the briefs and extensive record, the motion for summary judgment [Docket No. 1689] as to Plaintiffs Guardian and Aetna is **ALLOWED**. With respect to

[1] The "Consumer Plaintiffs" are Carolyn Holloway, Lorraine Kopa, Jeanne Ramsey, Gerald Smith, Gary Varnam, and Jan Frank Wityk. The "Class Plaintiffs" are Harden Manufacturing Corporation, ASEA/AFSCME Local 52 Health Benefits Trust, and Louisiana Health Service Indemnity d/b/a Blue Cross Blue Shield of Louisiana.

Plaintiff Kaiser, the motion is **DENIED**.

II. BACKGROUND

The factual predicate for this case stems from Parke-Davis's allegedly fraudulent marketing campaign of the prescription drug Neurontin for off-label indications, or indications not approved by the Food and Drug Administration ("FDA").[2] The Court has written extensively about the facts of this case and assumes the parties' familiarity with these background facts. See, e.g., In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 257 F.R.D. 315 (D. Mass. 2009); In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 433 F. Supp. 2d 172 (D. Mass. 2006). Defendants' motion for summary judgment involves particular questions of causation and efficacy, requiring a closer examination of the facts related to those issues.[3]

A. Causation

The Defendants argue that there is no evidence that their alleged fraudulent marketing caused injury to the Coordinated Plaintiffs. Plaintiffs contend that, had they known the truth about Neurontin's lack of efficacy for off-label indications, they would have taken steps to limit the number of Neurontin prescriptions written to plan members and paid for by the plans

[2] Parke-Davis was acquired by Pfizer in 2000.

[3] The facts as recited here generally make all reasonable inferences in favor of the non-moving party and, unless noted, are undisputed.

themselves. Each Coordinated Plaintiff ascribes to different business practices and philosophies, and it is most useful to discuss them individually.

1. Kaiser

Kaiser is one of the largest health maintenance organizations in the United States and is a nonprofit, integrated healthcare provider that contracts for medical services from one of the regional Permanente Medical Groups ("PMG"). Kaiser is organized into eight regions, each of which has its own Pharmacy and Therapeutics ("P&T") Committee. (Coordinated Third Party Payor ("TPP") Pl.'s Resp. Def.'s Statement of Undisputed Material Facts ("Pl.'s Resp. Def.'s SOF") ¶ 79.) These P&T committees, which are largely comprised of PMG physicians, determine which drugs are placed on Kaiser's formulary. (Id.) Kaiser's formulary restrictions are advisory to physicians, following the plan's philosophy that physicians are in the best position to make individual prescribing decisions for patients. (Id.) In order to prescribe a drug that is either not on the formulary or restricted by the formulary, PMG physicians need only check a box on the prescription form indicating that the drug is necessary for the care of a patient. (Pl.'s Counterstatement of Undisputed & Disputed Facts in Opp'n to Def.'s Mot. Summ. J. ("Pl.'s Counterstatement") ¶ 149.) However, despite this flexibility, a 2008 Kaiser internal review found that during the period from

1994-2008, at least 95% of prescriptions written by PMG physicians were in compliance with the Kaiser formulary. (Millares Decl. ¶ 5, June 12, 2009.)

For a drug to be placed on Kaiser's formulary, a PMG physician typically makes a proposal, which is then considered by the P&T committee. (Pl.'s Counterstatement ¶ 150.) Once such a request is made, a drug information specialist is assigned to prepare a drug monograph. (Id. ¶ 151.) This monograph is distributed to members of the P&T committee. In addition, there are physician consultants for various therapeutic categories that are asked to review the monograph and provide their recommendation for formulary status. (Id.)

Neurontin was added to Kaiser's formulary in September 1994 with a restriction limiting its use to, or in consultation with, a PMG neurologist. (Id. ¶ 153.) In 1997, Neurontin's formulary status was expanded to include prescriptions by PMG pain clinic physicians for the treatment of Reflex Sympathetic Dystrophy. In 1999, the P&T committee voted to expand restrictions to include prescriptions by psychiatrists for the treatment of bipolar affective disorder. (Id. ¶¶ 20, 22.) For each of these three changes to the Kaiser formulary, Kaiser's Drug Information Service ("DIS") prepared monographs summarizing the available studies and other information for Neurontin related to the particular indication in question. At the time of each P&T Committee vote, Kaiser alleges that its DIS did not have access

to studies known to Pfizer that showed Neurontin's negative or negligible effects in patients with RSD and bipolar disorder. (Millares Decl. ¶ 18, Mar. 26, 2009.)

After these formulary expansions, the DIS continued to gather information on Neurontin and circulate it to its physicians and committees. (Pl.'s Counterstatement ¶¶ 159-60.) For example, in 1998 a DIS employee sent a request to Parke-Davis for "information regarding the use of Neurontin (gabapentin) for the management of neuropathic and central pain." (Id. ¶ 160.) Parke-Davis responded by sending an eleven-page letter summarizing published reports on these indications. No negative studies were reported despite the fact that Parke-Davis was aware of several at the time. (Id. ¶ 161 (citing the 1996 Gorson trial, funded by Parke-Davis, that found Neurontin was no better than a placebo in the treatment of painful diabetic neuropathy).)

In addition, DIS has an Inquiry Department, which responds to requests from PMG physicians and pharmacists who have questions about the use of a specific drug for a specific patient. Often, DIS solicits advice and information from pharmaceutical companies when answering such inquiries. (Id. ¶ 162.) Kaiser alleges that in responding to requests for information from its Inquiry Department, Parke-Davis provided information that was "materially misleading." (Id. ¶ 163.)

In mid-2002, news reports began to surface that revealed what Plaintiffs allege to be the "extensive misinformation

campaign" regarding Neurontin that is at issue in this litigation. (Id. ¶ 165.) Kaiser's Southern California Region's Drug Utilization Action Team ("DUAT") and Northern California Drug Utilization Group ("DRUG") responded to the news by embarking on several campaigns to attempt to correct and mitigate the effect of the misinformation and to reduce utilization of Neurontin for indications where the evidence suggested other treatments were of equal or greater efficacy and lower cost than branded Neurontin. (Id.) DUAT and DRUG's efforts included the distribution to PMG physicians of a "Summary of Treatment Alternatives," paycheck stuffers, pharmafax messages, pocket cards with treatment recommendations, as well as continuing medical education programs. (Id. ¶ 167.) As of June 2004, Neurontin prescriptions to Kaiser members had dropped by 34% since the DUAT and DRUG initiatives began in mid-2002. (Id. ¶¶ 168-69.)

Kaiser has also produced statements from two PMG physicians stating that, had they known of Pfizer's allegedly fraudulent marketing practices, they would have acted to change Neurontin's status on the Kaiser formularies. For example, Dr. Dale Daniel, the Chairperson of Kaiser's Southern California P&T Committee stated:

> Had I known at the time that Neurontin was no more effective and did not have a better safety profile than existing, less expensive treatments for neuropathic pain and other off-label indications, I would not have recommended that Neurontin be included on the Formulary

except as limited to its FDA-approved indications. (Daniel Decl. ¶ 9, June 12, 2009; see also Weider Decl. ¶ 9 (PMG pain specialist stating "Had I known at that time that Neurontin was no more effective and did not have a better safety profile than existing, less expensive treatments for reflex sympathetic dystrophy and neuropathic pain, I would not have recommended . . . the expansion of the formulary status of Neurontin in 1997 or again in 1999.").)

2. Aetna

Aetna is a third-party payor that provides health payment benefits to more than 13 million people across the country. (Pl.'s Counterstatement ¶ 170.) Aetna has a P&T committee that reviews drug classes and makes decisions concerning what is covered on the formulary. The committee examines the safety, efficacy and labeled indications for a drug, and also looks at available information about a drug's off-label uses. (Id. ¶ 171.)

Aetna's formulary is organized by drug class. For example, Neurontin is in the anticonvulsant drug class. (Id. ¶¶ 172-73.) Aetna's focus is on cost-effective therapy, where "managing" a drug means to "put a formulary around the drug class and actually have some controls." (Id. ¶ 172.) In the case of anticonvulsants like Neurontin, Aetna determined that it would not manage these drugs because a patient's need for treatment may

be based on subjective criteria.[4] (Id. ¶¶ 172-73.) When Aetna's P&T Committee makes a decision not to manage a drug, the result is that patients do not need pre-authorization to fill a prescription for that drug, and Aetna does not place limits on plan members' access to the drug.

In 2004, Aetna's P&T Committee made the decision to "manage" the anticonvulsant class of drugs by applying quantity limits. (Id. ¶ 174.) In particular, Neurontin was moved to non-preferred status in 2004, which meant that, depending on a member's plan design, it required either a higher co-pay or was not covered at all. (Id.) In 2006, Aetna decided to place "step edits" on Neurontin because generic versions of gabapentin were becoming available on the market.[5] (Id.)

---

[4] Epilepsy is considered to be a very serious condition that, when untreated, can have significant consequences for patients such as loss of driver's licenses and/or employment. In addition, when patients suffer a seizure or convulsion, they almost always need to go to the emergency room, which drives up health costs. Therefore, because epilepsy is difficult to treat and has potentially disastrous consequences for patients, TPPs were often reluctant to place any restrictions or prior authorization measures on the anticonvulsant class of drugs, including Neurontin. (See Pl.'s Counterstatement ¶¶ 81, 111-14.)

[5] Step edits are a type of restriction sometimes utilized by TPPs to ensure the appropriate use (e.g. on-label or appropriate off-label use) of a medication without enacting more restrictive "prior authorization" requirements. When step edits are placed around particular medications, a patient is required to try other, specified medications to treat a condition prior to receiving approval for the restricted medication. For example, when Aetna placed step edits around Neurontin, it may have required that a different anticonvulsant be prescribed to treat a condition prior to approving a patient's claims for Neurontin

Once these controls were placed on Neurontin, if a physician prescribed the drugs and coverage was denied, the physician had the ability to call Aetna's precertification unit and ask for an appeal of the decision. This is essentially a request for exception to the formulary's controls on a drug. (Id. ¶ 175.)

Aetna has produced a statement from its Head of Formulary Development & Pharmacy Clinical Policies, Michael Brodeur, stating that "Prior to January 2004, Aetna did not manage the drug class which included Neurontin. Had the facts concerning the manufacturers' misleading marketing campaign surfaced earlier, I believe this would have led Aetna to start to manage[] this drug class at a sooner date." (Brodeur Decl. ¶ 6, June 16, 2009.)

3. Guardian

Guardian is a mutual company that provides pharmacy benefit coverage to individuals and to both large and small employer groups. (Pl.'s Counterstatement ¶ 179.) Guardian relies on Medco, a prescription benefit manager, to administer its pharmacy benefit. (Id. ¶ 180.) Guardian relies entirely on Medco's P&T Committee to determine what drugs are placed on the formulary and thereby covered and paid for by Guardian. (Id.) Neurontin was on the formulary generated by Medco and in use for the benefit of Guardian's members. (Id.)

---

prescriptions.

Guardian's coverage philosophy for its pharmacy benefit program focuses on the need to provide members with broad coverage of medications with as little disruption in the process as possible. (Id. ¶ 181.) Despite the high utilization of Neurontin on its formulary, Guardian did not institute a coverage management protocol with respect to off-label use of Neurontin. (Id. ¶ 183.) Therefore, off-label prescriptions for Guardian members were reimbursed or paid for without restriction.

However, an Associate Actuary at Guardian's Medical SBU, which oversees, in part, the administration of Guardian's pharmacy benefit by Medco, stated, "Had the facts concerning the manufacturers' misleading marketing campaign surfaced earlier, I believe that Guardian would have more promptly intervened at an earlier date to curtail inappropriate usage, to the extent it could." (Fernando Decl. ¶ 6, June 15, 2009.)

B. Efficacy of Neurontin for Off-Label Indications

A core factual dispute in this case involves the efficacy, or lack thereof, of the prescription drug Neurontin for off-label indications such as bipolar disorder, neuropathic and nociceptive pain, migraine and other headaches, and use at doses greater than 1800 mg per day. Again, the Court emphasizes that the following rendition of the facts draws all reasonable inferences in favor of the Coordinated Plaintiffs for the purposes of summary judgment.

1. Bipolar Disorder

Plaintiffs have identified four clinical studies suggesting that Neurontin is no more effective than a placebo for treating either the manic or depressive symptoms associated with bipolar disorder. (See Class Pl.'s SOF Opp'n Def.'s Mot. Summ. J. ("Class Pl.'s SOF") ¶¶ 13-18.) The Pande Bipolar Trial, Frye Bipolar Trial, Guille Bipolar Trial and Vieta Bipolar Trial had essentially the same results, "with Neurontin failing to outperform placebo in improving bipolar symptom severity." (Id. ¶ 18.) In fact, one of Plaintiffs' experts, Dr. John Abramson, noted that the Pande trial "showed that Neurontin is significantly worse than placebo." (Id. ¶ 27.) In addition, Plaintiffs offer the testimony of Dr. Jeffrey Barkin, who reviewed all of the "double-blind, placebo-controlled trials" related to bipolar and found that the evidence "consistently shows lack of efficacy of gabapentin for the treatment of bipolar disorder."[6]

2. Neuropathic and Nociceptive Pain

Plaintiffs offer the following publications and/or clinical

[6] Defendants falsely assert that Plaintiffs' bipolar expert, Dr. Barkin, conceded the usefulness of Neurontin in treating bipolar disorder, when in fact the quoted excerpt of his deposition was a section where he had been asked to recite the conclusion of the published Vieta study, which was sponsored by Pfizer. Dr. Barkin independently examined the data collected in the Vieta study and came to the conclusion that Neurontin did not, in fact, outperform the placebo.

trials suggesting Neurontin is no more effective than a placebo in the treatment of neuropathic pain: (1) Gorson - Painful Diabetic Neuropathy Trial; (2) Reckless - Painful Diabetic Neuropathy Trial; (3) Serpell - Neuropathic Pain Trial; (4) POPP - Neuropathic Pain Trial; (5) Gilron - Neuropathic Pain Trial (see Gilron et al., Morphine, Gabapentin, or Their Combination for Neuropathic Pain, 352 New Eng. J. Med. 1324 (2005)); and (6) Dworkin Trial (see Dworkin et al., A Randomized, Placebo-Controlled Trial of Oxycodone and of Gabapentin for Acute Pain in Herpes Zoster, 142 Pain 209 (2009)). (Class Pl.'s SOF ¶¶ 212-26, 236-37.)

In 1996, a study entitled "A Double-Blind Placebo-Controlled Trial of Gabapentin for Treatment of Painful Diabetic Neuropathy" (the "Backonja trial"), which was sponsored by the Defendants, was completed. (Id. ¶ 214.) Defendants claim that the results of the Backonja trial show efficacy of Neurontin for the treatment of painful diabetic neuropathy. (Id. ¶ 216.) However, one of Plaintiffs' experts reviewed the data of the Backonja trial and found that the higher occurrence of side effects in study participants taking Neurontin resulted in the blind being broken for many of the patients associated with pain relief. (Id.) Denouncing the study as only "superficially favorable," Plaintiffs' expert biostatistician reviewed the Backonja trial data and found that the study "provides no basis of any clinical efficacy of gabapentin over placebo in reducing pain." (Id. ¶

215.) In fact, Defendants' own pain experts stated in 1998 "that patients with more severe AEs [adverse events] tend to believe that they are on a study drug (which would probably be a good guess) and therefore tend to have better efficacy data, thus unblinding and corrupting the study." (Id. ¶ 217.)

In 2001, Pfizer filed a supplemental new drug application seeking approval to market Neurontin as a treatment for neuropathic pain. The FDA informed Pfizer that the application would be "refused to file" but offered to have the application reviewed by an Advisory Committee of outside pain experts.[7] (Id. ¶ 227.) Pfizer determined that it would be in its best interest to "avoid an Advisory Committee [] review" of its data. (Id. ¶ 228.)

Defendants assert that Plaintiffs' expert, Dr. Thomas Perry, testified in his deposition that his meta-analysis of Neurontin neuropathic pain trials revealed statistically significant effects of treatment with Neurontin over placebos. (See James Decl. Ex. 43 at 219-21, Mar. 2, 2009.) Plaintiffs refute this characterization, stating that the quotes excerpted from Dr. Perry's deposition refer to anecdotal evidence as opposed to clinical trials.

[7] Upon submission of a new drug application, the FDA will review the submission to determine whether it is sufficiently complete to enable a substantive review; if not, the FDA will refuse to file it. See 21 C.F.R. § 814.42.

With respect to nociceptive pain, Plaintiffs have identified four clinical trials conducted by Pfizer, all of which showed that Neurontin did not outperform a placebo in treating nociceptive pain. (Id. ¶ 229.)

3. Migraine and Headache

Plaintiffs have put forth evidence that Defendants conducted three studies of Neurontin for the treatment of migraine that resulted in no statistically significant difference in the reduction of migraine attack frequency between the placebo and Neurontin. (Class Pl.'s SOF ¶¶ 468-71.) Plaintiffs' migraine expert, Dr. Douglas McCrory, reviewed the evidence on Neurontin's use in migraine and headache and concluded that "[i]n comparison with other widely used migraine preventive drugs, the estimated effect size for gabapentin not only fails to reach statistical significance, but also has a much lower magnitude of effect." (Id. ¶ 472 (citing Rona Decl. Ex. 478 at 1).)

Defendants claim that Dr. McCrory's report does not establish Neurontin's ineffectiveness for migraine because Dr. McCrory limited his opinions to the use of Neurontin for migraine prophylaxis.[8] However, Dr. McCrory stated that his review of the evidence was limited to migraine prophylaxis because there have

[8] In the context of the treatment of migraine patients, prescription medications are either used as a prophylaxis, to prevent the onset of migraine headaches, or as acute treatment when patients are suffering immediate migraine pain.

been no studies or trials conducted on the use of Neurontin for acute migraine treatment. (See Rona Decl. Ex. 481 at 3.)

4. Dosages Greater than 1800mg Per Day

Neurontin was approved by the FDA in 1993 to treat epilepsy at doses ranging from 900-1800mg per day. (Class Pl.'s SOF ¶ 563.) Plaintiffs offer evidence of one clinical trial, conducted by Defendants, that found no "dose-response relationship" for Neurontin in the treatment of epilepsy at dosages greater than 1800mg/day (Id. ¶¶ 564-65), and two additional trials, both sponsored by Defendants, suggesting that higher doses of Neurontin did not offer additional efficacy in the treatment of epilepsy. (Id. ¶¶ 566-67.) For the treatment of pain, Plaintiffs offer evidence of two trials conducted by Defendants that failed to demonstrate any enhanced efficacy of Neurontin at dosages above the FDA-approved limit. (Id. ¶¶ 568-70.) Plaintiffs point to four additional studies conducted where the evidence cannot support a finding of increased efficacy in the treatment of pain due to the failure to use "fixed-dose" groups, or groups that took the same dosage of Neurontin throughout the duration of the trial. (Id. ¶ 568.)

In 1997, Defendants submitted a supplemental New Drug Application to the FDA requesting "an increase in the effective dose range to include 3600 mg/day" and "an increase in the maximum recommended dose to 4800 mg/day." (Id. ¶ 576.) The FDA

rejected this application, writing "that the evidence from controlled trials fails to provide evidence that higher doses of Neurontin are more effective than those recommended." (Id. ¶ 577.)

In addition, Plaintiffs' dosage expert, Dr. Brian Alldredge, reviewed all "fixed-dose, parallel group" studies of Neurontin at higher dosages, and concluded that the evidence failed to establish a dosage-related effect at dosages above 1800 mg/day. (Id. ¶¶ 581-82.) Defendants challenge this conclusion by pointing to instances in Dr. Alldredge's deposition where he stated that some individual patients might be able to tolerate, or even require, dosages greater than 1800mg per day. (James Decl. Ex. 45 at 170.)

III. ANALYSIS

A. Standard of Review

Summary judgment is appropriate when "the pleadings, depositions, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant . . . would permit a rational fact finder to resolve the issue in favor of either party." Medina-Muñoz v. R.J. Reynolds Tobacco Co., 896 F.2d 5, 8

(1st Cir. 1990) (internal citations omitted). A material fact is one that has the "potential to affect the outcome of the suit under the applicable law." Sanchez v. Alvarado, 101 F.3d 223, 227 (1st Cir. 1996) (internal citations and quotation omitted). In order to defeat the entry of summary judgment, the nonmoving party must submit "sufficient evidence supporting the claimed factual dispute to require a choice between the parties' differing versions of the truth at trial." LeBlanc v. Great Am. Ins. Co., 6 F.3d 836, 841 (1st Cir. 1993) (internal citations and quotations omitted). In evaluating motions for summary judgment, however, the Court will not consider "conclusory allegations, improbable inferences, and unsupported speculation." Galloza v. Foy, 389 F.3d 26, 28 (1st Cir. 2004) (internal citation omitted).

B. Actionability of Half Truths Under RICO

As a preliminary matter, Defendants argue that they did not have a duty to disclose all negative trials involving Neurontin and therefore did not commit fraud. This argument has no merit.

To make a claim under the RICO Act, a plaintiff must allege "racketeering activity" within the meaning of RICO. 18 U.S.C. § 1962(c). In this case, the Coordinated Plaintiffs have alleged that Defendants engaged in a pattern of racketeering activity involving acts of mail fraud and wire fraud. (See, e.g., Third Coordinated Amended Complaint ¶ 235 [Docket No. 583].) The First Circuit has said that "the locus classicus of fraud is a seller's

affirmative false statement or a half truth, i.e., a statement that is literally true but is made misleading by a significant omission." Bonilla v. Volvo Car Corp., 150 F.3d 62, 69 (1st Cir. 1998) (citing Emery v. Am. Gen. Fin., Inc., 71 F.3d 1343, 1348 (7th Cir. 1995)); see also United States v. Autuori, 212 F.3d 105, 119 (2d Cir. 2000) ("[A]n omission can violate a fraud statute only in the context of a duty to disclose; but a fiduciary duty is not the sine qua non of fraudulent omissions. . . . A duty to disclose can also arise in a situation where a defendant makes partial or ambiguous statements that require further disclosure in order to avoid being misleading."); United States v. Keplinger, 776 F.2d 678, 697 (7th Cir. 1985) ("[O]missions or concealment of material information can constitute fraud cognizable under the mail fraud statute, without proof of a duty to disclose the information pursuant to a specific statute or regulation."); United States v. Townley, 665 F.2d 579, 585 (5th Cir. 1982) ("[U]nder the mail fraud statute, it is just as unlawful to speak 'half truths' or to omit to state facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading.").

In addition, pharmaceutical manufacturers, who have "superior access to information about their drugs, especially in the postmarketing phase as new risks emerge," are under a special duty to investigate and report adverse effects of their drugs. Wyeth v. Levine, 129 S. Ct. 1187, 1202, 1219 (2009) ("After the

FDA approves a drug, the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug."); see also 21 C.F.R. § 314.80 (placing responsibility for post-marketing surveillance of drugs on the manufacturer).

The Coordinated Plaintiffs have presented evidence that Defendants communicated half truths that are actionable under the RICO statute. (See, e.g., Class Pl.'s SOF ¶¶ 59-62, 73-74, 84-89, 104, 106, 112-13, 123-25, 136-38, 163-70, 250, 260-69, 273, 316-22.) This evidence includes instances of Defendants suppressing negative information while submitting for publication in monographs positive information about off-label indications. For example, in 1998, Defendants responded to a request for information from Kaiser regarding Neurontin's use for pain management by summarizing positive published reports on that indication, while failing to report negative studies known to Defendants at that time, such as the 1996 Gorson trial. (Pl.'s Counterstatement ¶¶ 160-61.) In addition, Kaiser's Drug Information Service contacted Pfizer multiple times requesting information about off-label uses of Neurontin, and Pfizer's responses were materially misleading. In 2000, Pfizer forwarded to DIS several cases in response to a physician inquiry about the role of Neurontin for the treatment of migraine, but failed to disclose the negative findings of its European studies on migraine and Neurontin. (Id. ¶ 163.) In 2001, Pfizer responded

to a request for information about the maximum dosage of Neurontin in the treatment of bipolar disorder by stating that 3600mg/day "is the recommended maximum dose." (Id.) Pfizer's response failed to indicate that clinical evidence did not support increased efficacy at that dose. (Id.)

C. Causation

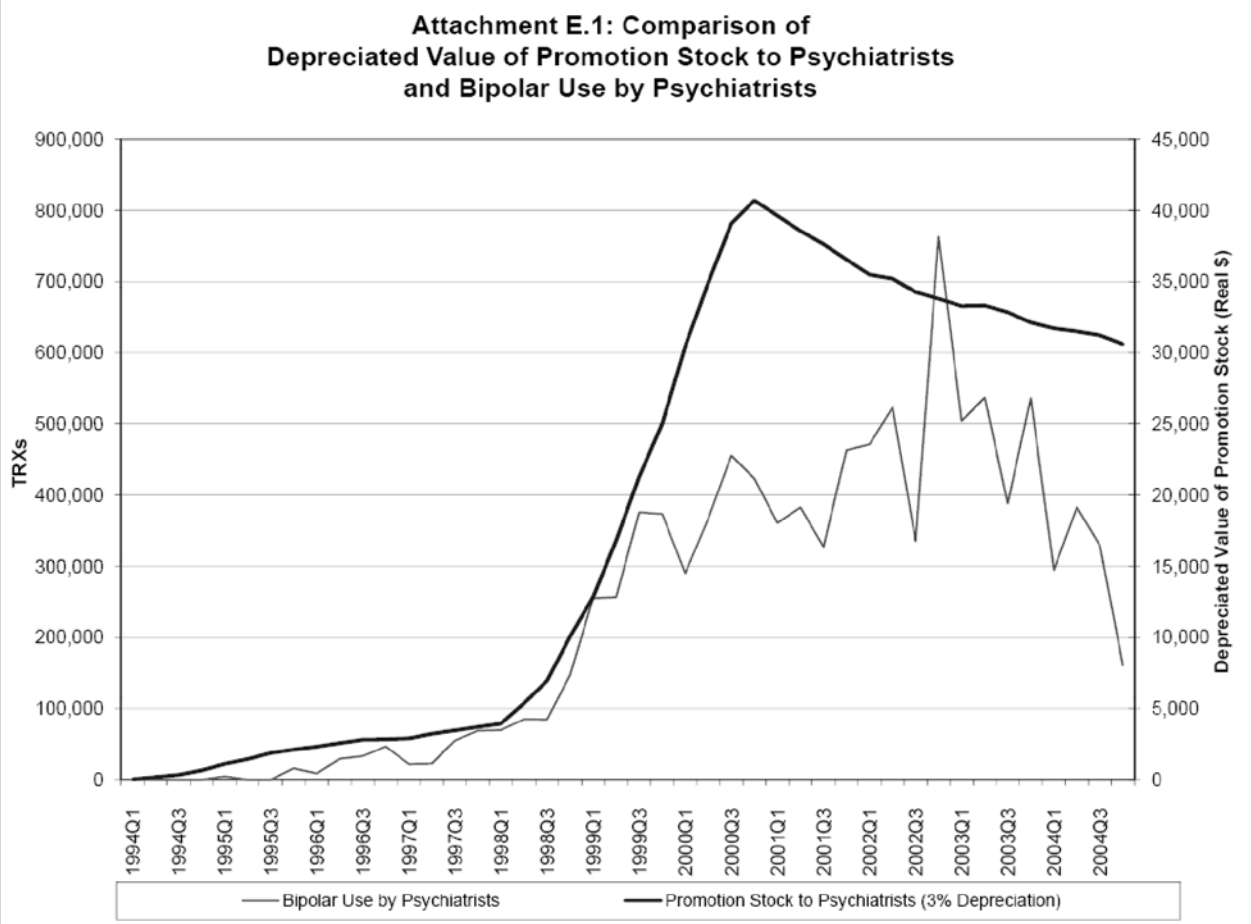
One of Defendants' principal arguments in support of their motion for summary judgment is that the Coordinated Plaintiffs have not raised a triable issue of fact as to causation. For their RICO claims, Plaintiffs must show both that Defendant's mail or wire fraud in violation of the racketeering statute was a "but for" cause of his injury as well as a proximate cause. See, e.g., George Lussier Enterprises, Inc. v. Subaru of New England, Inc., 393 F.3d 36, 51 (1st Cir. 2004) ("Section 1964(c) [of the RICO Act] requires that the defendant's specified acts of racketeering were the proximate cause of the plaintiffs' injuries.") (citing Holmes v. Secs. Investor Prot. Corp., 503 U.S. 258, 268 (1992)). However, the Supreme Court recently held that "first-party reliance" is not an element of a cause of action under RICO. "[T]he fact that proof of reliance is often used to prove an element of the plaintiff's cause of action, such as the element of causation, does not transform reliance itself into an element of the cause of action." Bridge v. Phoenix Bond & Indem. Co., 128 S. Ct. 2131, 2144 (2008). Still, a RICO

plaintiff who alleges injury "by reason of" a pattern of mail fraud cannot prevail "without showing that someone relied on the defendant's misrepresentations." Id. (emphasis in the original).

1. Aggregate Evidence

Plaintiffs have presented evidence, largely through the report of their expert, Dr. Meredith Rosenthal, that shows that Pfizer's marketing of Neurontin for off-label indications caused a sharp increase in the number of prescriptions that the Plaintiffs paid for or reimbursed. (See Rona Decl. Ex. 79.) The charts produced by Dr. Rosenthal offer a visual and compelling depiction of Plaintiffs' evidence. Chart C.3, reproduced here, shows a sharp increase in off-label prescriptions for Neurontin, beginning around 1996. During the same time period, Neurontin on-label prescriptions as an adjunctive epilepsy therapy remain roughly static.

Attachment C.3: Neurontin On- and Off-Label Use



(Id. at 48.) Dr. Rosenthal's report also details Pfizer's expenditures on marketing of Neurontin during the same time period. Dr. Rosenthal found a high correlation between Pfizer's promotional marketing and off-label prescriptions for Neurontin. As an example, Dr. Rosenthal's Chart E.1 shows the correlation between promotional efforts for psychiatrists and bipolar use of Neurontin by psychiatrists.

(Id. at 59.) If Plaintiffs can prove that Pfizer engaged in a fraudulent marketing campaign by suppressing material adverse information about Neurontin's efficacy for off-label uses, Dr. Rosenthal's report would support a jury finding that it is more likely true than not true that the Coordinated Plaintiffs did, in fact, suffer harm as a result of Defendants' fraudulent marketing of Neurontin. For example, in the psychiatric area, the Plaintiffs argue that the fraudulent marketing caused virtually all the off-label prescriptions, in areas such as bipolar use. Hartman Decl. at 9-10, Aug. 11, 2008 (Docket No. 1457 Ex. G)).

While Plaintiffs' position has strong intuitive appeal, trial courts have almost uniformly held that in a misrepresentation action involving fraudulent marketing of direct claims to doctors, a plaintiff TPP or class must prove through individualized evidence that the misrepresentation caused specific physicians, TPPs, or consumers to rely on the fraud, and cannot rely on aggregate or statistical proof. See Southern Ill. Laborers' & Employers Health & Welfare Fund v. Pfizer, Inc., No. 08-cv-5175, 2009 WL 3151807, at *6 (S.D.N.Y. Sept. 30, 2009) (dismissing complaint on the ground that plaintiffs failed to allege that physicians, Pharmacy Benefit Decision Makers or Third Party Payors relied on misrepresentations of Lipitor's efficacy); In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 2:06-cv-5774, 2009 WL 2043604, at *26 (D.N.J. July 10, 2009) ("TPP plaintiffs may not establish the requisite proximate cause

through aggregate proof or generalized allegations of fraudulent conduct and resulting harm."); In re Actimmune Mktg. Litig., 614 F. Supp. 2d 1037, 1052 (N.D. Cal. 2009) (granting a motion to dismiss where plaintiffs did not "allege what specific information the individual plaintiffs or their physicians had about the drug [and] the extent to which they relied upon that information"); Ironworkers Local Union No. 68 v. AstraZeneca Pharms., 585 F. Supp. 2d 1339, 1344 (M.D. Fla. 2008) (granting a motion to dismiss a TPP's RICO claim for failure to show proximate cause, where "establishing that Plaintiffs' injuries were caused by Defendants' misconduct would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit."). The Second Circuit reached a similar conclusion, despite evidence of widespread fraudulent marketing of cigarettes to consumers, stating that "not every wrong can have a legal remedy . . . at least not without causing collateral damage to the fabric of our laws." McLaughlin v. Am. Tobacco Co., 522 F.3d 215, 219 (2d Cir. 2008) (denying class certification in a civil RICO claim regarding allegedly fraudulent marketing of "light" cigarettes to consumers and stating that "reliance on the misrepresentation . . . cannot be the subject of general proof") (internal citations omitted).

As stated earlier, Plaintiffs have presented substantial evidence that Defendants engaged in a widespread fraudulent off-

label marketing campaign to promote Neurontin which increased off-label sales of Neurontin. Still, despite over a decade of Neurontin-related litigation, which I have presided over as the multi-district litigation judge,[9] no evidence has been presented of any doctor who states that she relied on a misrepresentation or omission in prescribing Neurontin for an off-label indication. Many doctors have not met with Pfizer sales representatives or attended its "educational seminars. Even those that have been detailed deny reliance, even in the psychiatric areas where there is strong evidence that Neurontin is no better than a placebo for bi-polar disorder. While each of the Coordinated Plaintiffs can prove through aggregated proof that the fraudulent marketing campaign likely caused them injury, they cannot prove which doctor's prescriptions were caused by Defendants' alleged fraudulent misrepresentations or omissions and which were not. Plaintiffs must provide a damages model that segregates damages caused by unlawful conduct from damages caused by lawful conduct. See Hood ex rel. Mississippi v. Eli Lilly & Co. (In Re Zyprexa Products Liability Litigation), ___ F. Supp.2d ___, 2009 WL 4260857, at *3, *35 (E.D.N.Y. December 1, 2009) (granting partial summary judgment in favor of pharmaceutical company in a "structural class action" case brought by a state Medicaid

[9] I also presided over the initial whistle-blower suit filed in 1996. United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001).

program because "reliance, loss-causation, and injury are inappropriate for aggregation, due to the need to prove these elements on an individualized basis"). See also U.S. Football League v. Nat'l Football League, 842 F.2d 1335, 1378-79 (2d Cir. 1988) ("A plaintiff's proof of amount of damages thus must provide the jury with a reasonable basis upon which to estimate the amount of its losses caused by . . . lawful factors."); Farley Transp. Co., Inc. v. Santa Fe Trail Transp. Co., 786 F.2d 1342, 1352 (9th Cir. 1985) (holding that plaintiff's "utter failure to make any segregation between damages attributable to lawful competition and that attributable to the unlawful scheme to deviate from the tariff rate requires reversal of the verdict . . . ."); MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1162-63 (7th Cir. 1982) ("When a plaintiff improperly attributes all losses to a defendant's illegal acts, despite the presence of significant other factors, the evidence does not permit a jury to make a reasonable and principled estimate of the amount of damage.").

To prevail, a TPP must demonstrate that it relied on a misrepresentation or omission, or provide a reliable methodology to calculate the percentage of the doctors who prescribed Neurontin based on Defendants' alleged fraud. Accordingly, the Coordinated Plaintiffs cannot rely solely on Dr. Rosenthal's report as the silver bullet to establish causation.

2. Direct Injury

A third-party payor claiming injury based on misrepresentations or omissions relied on by the TPP rather than physicians or patients, can "recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices." Desiano v. Warner-Lambert Co., 326 F.3d 339, 349 (2d Cir. 2003) (involving an action by TPPs against a pharmaceutical company for alleged misrepresentations made directly to the TPPs about the drug Rezulin); see also Southern Ill. Laborers' & Employers Health & Welfare Fund, 2009 WL 3151807, at *7 ("In Desiano, the plaintiffs, who were health insurers, alleged that the defendant, pharmaceutical company Warner-Lambert and its affiliates, made misrepresentations about anti-diabetes drug Rezulin's safety directly to the plaintiffs.").

Accordingly, in order to show causation, the Coordinated Plaintiffs must present evidence that they were directly harmed by misrepresentations or omissions relied on by the TPP. Of the three Coordinated Plaintiffs, only Kaiser has provided sufficient evidence of causation.

a. Kaiser

As a more hands-on third-party payor, Kaiser argues that, due to Pfizer's fraudulent misrepresentations about and withholding of certain negative studies for these indications, the recommendations of its Drug Information Service (DIS) were

tainted. Because DIS drug monographs for Neurontin, prepared by Kaiser and used by Kaiser's P&T committee, directly influenced Kaiser's decision to expand its formulary, a reasonable inference can be drawn that Kaiser was directly injured by Pfizer's misrepresentations about Neurontin. Notably, Kaiser's preparation of drug monographs gathered all publicly available data and publications regarding Neurontin, and therefore Kaiser directly relied on the "half truths" put forth by Pfizer through publications, monographs, and other communications to Kaiser and to the general public.

In addition, Kaiser's DIS had direct communications with Pfizer both through its information-gathering activities and its Inquiry Department service for physicians and members. (Pl.'s Counterstatement ¶¶ 159-63.) Kaiser alleges that, had Pfizer not made misrepresentations regarding Neurontin's effectiveness for certain off-label indications, DIS's activities would have highlighted problems with Neurontin such that Kaiser could have responded sooner and thereby reduced its payments and reimbursements for Neurontin. These activities represent direct interaction between Kaiser and Pfizer, providing the evidence of causation alluded to by the Desiano court.

Finally, Kaiser has shown that it was able to reduce its payments for Neurontin through an information campaign with more complete data regarding off-label uses of Neurontin that was initiated in 2002 after news reports of Pfizer's fraudulent

activities began to surface. (Id. ¶¶ 167-69.) These campaigns resulted in a 34% drop in Neurontin prescriptions to Kaiser members by June 2004. (Id. ¶¶ 168-69.) The reduction in Neurontin prescriptions after Kaiser learned the truth about Pfizer's misrepresentations and took action is strong evidence of a causal link between Pfizer's misrepresentations and Kaiser's alleged injuries.

For these reasons, Kaiser has provided evidence allowing a reasonable inference of causation to be drawn in its favor. Accordingly, the Defendant's summary judgment motion with respect to Kaiser on the issue of causation will be denied.

b. Aetna and Guardian

Prior to 2004, Aetna and Guardian had no formulary controls around Neurontin. Although Neurontin was listed as an anti-epileptic drug on Aetna's formulary, coverage was not restricted to prescriptions by neurologists, for example, as it was on Kaiser's formulary. Likewise, the evidence shows that, despite high utilization of Neurontin on its formulary, neither Guardian nor its prescription benefit manager Medco undertook any studies of the drug or placed any controls around off-label use of Neurontin. Neither TPP has submitted evidence suggesting that it had direct communications with Pfizer or relied on fraudulent representations in any of the off-label marketing campaigns.

There is no evidence in the record that Guardian or Aetna at

any point directly relied on Pfizer's "half truths," communicated through its alleged manipulation and withholding of studies that suggested Neurontin's ineffectiveness for off-label indications. Rather, their causation argument is wholly dependent on individualized proof that their members' prescribing physicians relied on defendants' misrepresentations.[10] Because the Court has concluded that the evidence provided in support of this theory, namely the aggregate evidence presented in Dr. Meredith Rosenthal's report, is legally insufficient to effectively segregate damages caused by Defendants' misrepresentations from damages caused by other sources, Guardian and Aetna cannot rely solely on the aggregate evidence to prove causation. Accordingly, the motion for summary judgment with respect to Guardian and Aetna will be allowed.

D. Injury to Business or Property under RICO

Defendants argue that summary judgment should be granted because the Coordinated Plaintiffs have failed to create a triable issue of fact regarding their alleged injuries. A showing of injury is generally necessary for the purposes of Article III standing, see Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985), but the RICO statute sets forth additional

[10] Third-party reliance is permissible to prove causation in a RICO case. See Bridge, 128 S. Ct. 2144 ("[I]t may well be that a RICO plaintiff alleging injury by reason of a pattern of mail fraud must establish at least third-party reliance in order to prove causation.").

requirements for a showing of injury. See DeMauro v. DeMauro, 115 F.3d 94, 96 (1st Cir. 1997) ("There is plainly a case or controversy under Article III; but the statutory precondition of injury to business or property must also be met.").

Plaintiffs argue that their injury is based on the fact that there were "cheaper and more optimal alternatives" to Neurontin for off-label indications. In Desiano, the Second Circuit explicitly acknowledged as valid the plaintiff TPPs' argument that the defendant pharmaceutical company's "fraud directly caused economic loss to them as purchasers, since they would not have bought Defendants' product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations." 326 F.3d at 349 (emphasis added). The court went on to offer a hypothetical to further underscore its holding:

> Consider, for example, a hypothetical in which a defendant drug company markets a "new," much more expensive drug claiming it is a great advancement (safer, more effective, etc. than metformin - the standard diabetes drug) when in fact the company is simply replicating the metformin formula and putting a new label on it. In other words, the only difference between metformin and the "new" drug is the new name and the higher prescription price (paid almost entirely by the insurance company). In that case, the "new" drug would be exactly as safe and effective as metformin, and thus there could be no injury to any of the insurance company's insured. Nevertheless, the insurance companies would be able to claim - precisely as they do here - that the defendants engaged in a scheme to defraud it, and that the company suffered direct economic losses as a result.

Id. at 349-50. See also District 1199P Health & Welfare Plan v.

Janssen, L.P., No. 06-3044 (FLW), 2008 WL 5413105, at *8 (D.N.J. Dec. 23, 2008) (holding that RICO injury based on overpayment for pharmaceuticals requires "'allegations that Defendants' drug was on some level inferior and therefore worth less than what Plaintiffs paid for it.'" (quoting Maio v. Aetna, Inc., 221 F.3d 472, 488 (3d Cir. 2000))); In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 2:06-cv-5774 (SRC), 2009 WL 2043604, at *18 (D.N.J. July 10, 2009) (agreeing with the Janssen court and dismissing plaintiffs' claims because they "failed to adequately plead that any . . . TPP beneficiaries 'received inadequate [or] inferior [drugs] . . . .'").

The Court finds that Kaiser has presented sufficient evidence to support its RICO claim that Neurontin was ineffective for the off-label indications (see supra Part II(B)) and that there were "cheaper and more optimal" alternatives to Neurontin. For example, in one of Kaiser's responses to interrogatories during the discovery process in this case, it provided a chart of cheaper and more optimal drugs for each off-label indication at issue. (See Nussbaum Decl. Ex. 146, at ¶ 4; id. Ex. 150 at 6.) In addition, Plaintiffs have provided information about a study, conducted by the University of North Carolina at Chapel Hill and funded in part by Pfizer, titled "Prescribing for Better Outcomes." (Nussbaum Decl. Exs. 4-5, June 18, 2009.) The study not only concluded that "no scientifically acceptable clinical trial evidence supports use of either gabapentin or topiramate in

bipolar mood disorder, either as monotherapy or as adjunct to other therapies," but also that "[r]esearch supports use of three antiepileptic drugs - (1) carbamazepine, (2) valproic acid/valproate and (3) lamotrigine [-] in achieving and maintaining remission for outpatient adults with primary diagnoses of bipolar I disorder." (Id. Ex. 5.)

E. Scienter

Defendants argue that Plaintiffs have failed to create a triable issue of fact as to whether they misrepresented Neurontin's effectiveness with scienter.

Plaintiffs have submitted abundant evidence outlined above that Defendants engaged in off-label marketing of Neurontin for multiple indications, all while they were in possession of studies showing that Neurontin was not more effective than a placebo in treating these indications. (See Class Pl.'s SOF ¶¶ 19-32; Coord. Pl.'s Counterstatement ¶¶ 25, 55, 59-60, 81-85, 91, 97-104, 123.) Such evidence raises a genuine issue of material fact with respect to scienter.

IV. CONCLUSION

Pfizer's Motion for Summary Judgment [Docket No. 1689] as to Plaintiffs Guardian and Aetna is **ALLOWED** with respect to Counts I-XIV. With respect to Plaintiff Kaiser, the motion is **DENIED**.

PATTI B. SARIS

United States District Judge