UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION	MDL NO. 1629
THIS DOCUMENT RELATES TO: HARDEN MANUFACTURING CORPORATION; LOUISIANA HEALTH SERVICE INDEMNITY COMPANY d/b/a BLUE CROSS/BLUE OF LOUISIANA; INTERNATIONAL UNION OF OPERATING ENGINEERS, LOCAL NO. 68 WELFARE FUND; ASEA/AFSCME LOCAL 52 HEALTH BENEFITS TRUST; GERALD SMITH; and LORRAINE KOPA, on behalf of themselves and all others similarly situated, v. PFIZER, INC. and WARNER-LAMBERT COMPANY.	CIVIL ACTION NO. 04-cv-10981-PBS

MEMORANDUM AND ORDER

December 10, 2010

Saris, U.S.D.J.

I. INTRODUCTION

Plaintiffs Harden Manufacturing Corporation ("Harden"), Louisiana Health Service Indemnity Company d/b/a Blue Cross/Blue Shield of Louisiana ("BCBSLA"), International Union of Operating Engineers, Local No. 68 Welfare Fund ("Local No. 68"), ASEA/AFSCME Local 52 Health Benefits Trust ("ASEA"), Gerald Smith and Lorraine Kopa, collectively the Class Plaintiffs, bring this case against Pfizer, Inc. and Warner-Lambert Company on behalf of themselves and all others similarly situated, alleging violations

of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c) (Claims 1-2); the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 et seq. (Claim 3); and making claims for common law fraud (Claim 4) and unjust enrichment (Claim 5).

Defendants moved for summary judgment [Docket No. 1689] 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.

In January of this year, the Court issued an opinion with respect to the Coordinated Plaintiffs in this case allowing in part and denying in part defendants' motion for summary judgment. See In re Neurontin Mktg. & Sales Practices Litig., 677 F. Supp. 2d 479 (D. Mass. 2010). In the time since defendants' motion for summary judgment was filed, the Court also held a bellwether trial in the case brought by Kaiser Foundation Health Plan, one of the Coordinated Plaintiffs. (See Jury Verdict, Docket No. 2760.) On November 3, 2010 the Court issued Findings of Fact and Conclusions of Law in that case. Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc., __ F. Supp. 2d __, 2010 WL 4325225 (D. Mass. Nov. 3, 2010). The Court made findings regarding Neurontin's efficacy for off-label indications, among other

things.[1]

After a hearing and review of the extensive record, the Court **ALLOWS** the defendants' motion for summary judgment with respect to all Class Plaintiffs except individual consumer plaintiffs Gary Varnam and Jan Frank Wityk.

II. BACKGROUND FACTS

This Court has written extensively about the facts of this case and assumes the parties' familiarity with the facts. See In re Neurontin, 677 F. Supp. 2d at 485; Kaiser, 2010 WL 4325225. Those facts relevant to causation will be described more fully here.[2]

A. Individual Consumer Plaintiffs

1. Gary Varnam

Gary Varnam suffers from bipolar disorder and received numerous prescriptions for Neurontin over a period of more than three years. (See Class Pl.'s Statement of Disputed and Undisputed Material Facts in Opp'n to Def.'s Mot. Summ. J. ("Pl.'s SOF") ¶ 193.) Varnam testified that Neurontin was "completely ineffective in treating my bipolar disorder" and "gave me no benefit." (Id.)

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[1] However, the Court reserves judgment as to which issues are governed by the doctrine of issue preclusion.

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

Varnam was first prescribed Neurontin by Dr. John Arness in February 2001, after asking if there were alternatives to Tegretol, a medication that requires patients to undergo frequent blood and liver function testing. (Id. ¶¶ 193-94.) Dr. Arness testified that he learned Neurontin could be used to treat bipolar disorder 10 or 15 years ago "[t]hrough readings and association with other doctors." (James Decl., Ex. 9 at 23.) He also testified that he had prescribed Neurontin to at least 10 to 20 patients with mild bipolar symptoms and that "the anticonvulsants are widely known and widely accepted as a treatment for bipolar disorder, and Neurontin is in that category." (Id. at 23-24.) Medical records kept by Dr. Arness indicated that Varnam was "feeling good and wants to continue [Neurontin]" during the time period in question. (Id. at 39, 42.) In addition, Dr. Arness stated that he could not recall being detailed on Neurontin by a Parke-Davis or Pfizer sales representative between 2000 and 2008. (Id. at 65.)

Plaintiffs have submitted evidence that Dr. Arness was detailed in September 1999 by a Parke-Davis sales representative, Laurie Winslow, with whom he discussed Neurontin's use for psychiatric disorders. (Pl.'s SOF ¶ 195 (citing Rona Decl., Ex. 376).) Later that month, Dr. Arness received a Medical Information Request or "Dear Doctor" letter from Parke-Davis concerning "treatment of bipolar depression and mood disorder." (Rona Decl., Ex. 86.) This letter described favorable evidence

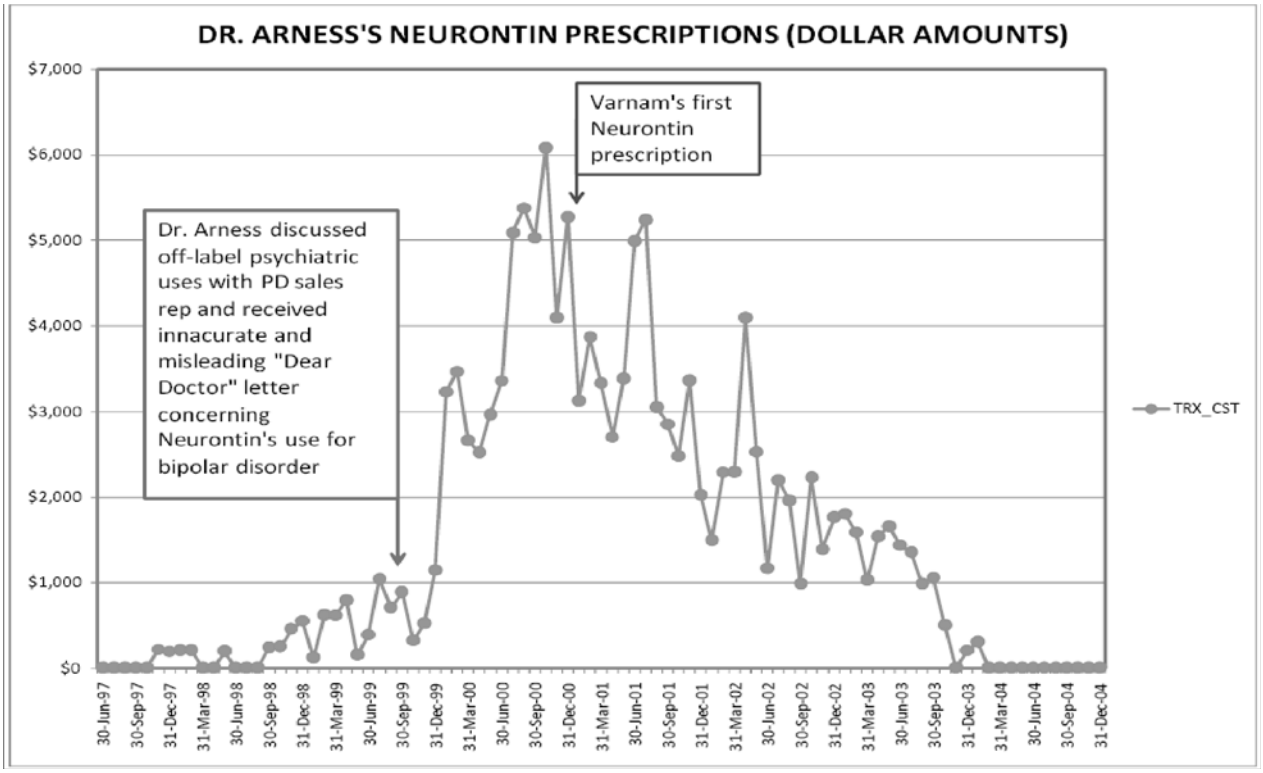
about Neurontin's use for mood disorder, including an article published in February 1996 in Progress in Neuro-Psychopharmacology and Biological Psychiatry by three members of Parke-Davis's department of Central Nervous System Clinical Research and Development. This article, titled "Effect of Gabapentin (Neurontonin® [sic]) on Mood and Well-Being in Patients with Epilepsy," (the "Dimond article") claimed that five epilepsy trials studying Neurontin showed that Neurontin had beneficial effects on mood. See Kaiser, 2010 WL 4325225, at *13. However, in 1992 the FDA examined the same five epilepsy trials as part of its medical statistical review of Neurontin, and determined that, for some patients, Neurontin increased the risk of depression, with or without suicidal ideation. See id. at *4.

The Dear Doctor letter also omitted information about the negative results of three double-blind, randomized controlled trials ("DBRCTs") studying the use of Neurontin to treat bipolar disorder. First, it omitted the negative results of a bipolar trial conducted by Dr. Atul Pande, a Parke-Davis employee. The Pande trial, the results of which were available to the defendants by July 1998, found that a placebo outperformed Neurontin in treating patients' mania, and showed no statistically significant difference between Neurontin and placebo for use in treating depression. Second, the letter omitted the Frye trial, which was an independent crossover study conducted between 1997 and 1999 that compared Neurontin to the

drug Lamotrigine and placebo in the treatment of refractory, or difficult to treat, bipolar disorder. The Frye trial found that Lamotrigine outperformed both Neurontin and placebo, and that there was no statistically significant difference between Neurontin and placebo. Interim results of the Frye trial were presented, in part, at meetings of the American Psychiatric Association in 1997 and 1998. Finally, the letter omitted the negative results of the Guille trial, which was also a DBRCT that compared Neurontin to placebo in treating refractory bipolar disorder. The trial investigators found no significant difference between Neurontin and placebo for treatment of either mania or depression. Defendants received the results of the Guille trial in May 1999. See Kaiser, 2010 WL 4325225, at **34-35. (See also Pl.'s SOF ¶¶ 14-16.)

Prior to receiving this letter, Dr. Arness's Neurontin prescriptions averaged a cost of $289 per month. In the two years after he received this letter, the average cost of his prescriptions increased to $3,486 per month, an 1100% increase. The change in Dr. Arness's prescription behavior is detailed in a chart provided by Plaintiffs.

(Id. ¶ 199.)



Varnam was subsequently treated by Dr. Beverly Grimm, who continued to prescribe Neurontin for ten months before taking him off the drug. (Id. ¶ 201.)

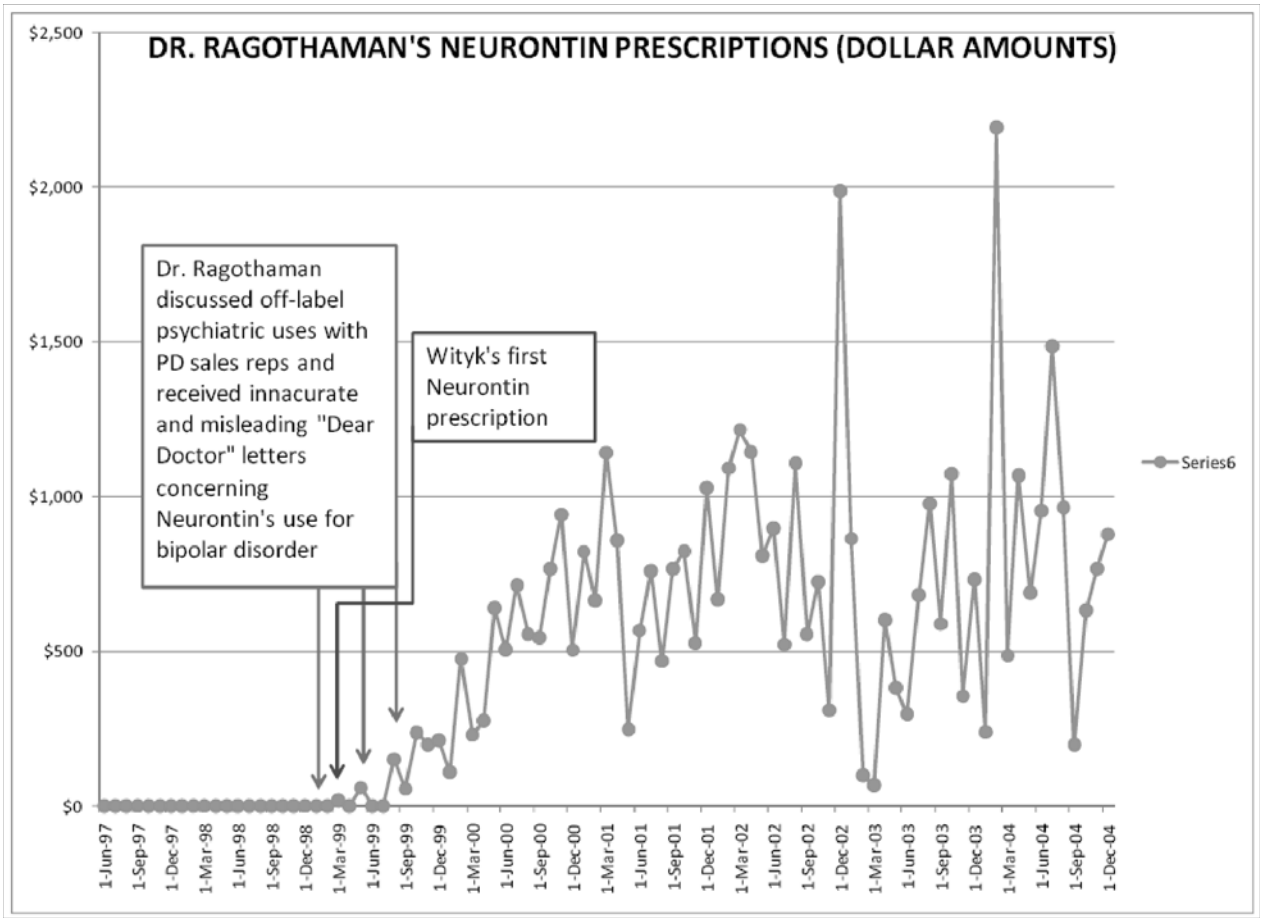
2. Jan Frank Wityk

Jan Wityk also suffers from bipolar disorder, and her psychiatric symptoms included bouts of suicidal thoughts. (Id. ¶ 202.) Wityk took Neurontin for several years, but she testified that she "never got better." (Id.) In December 1997, Wityk was treated by Dr. Nagaveni Ragothaman, who suggested various drugs as potential treatments, including Zoloft and Ativan. Neurontin was not one of the drugs discussed, and at that point in time,

Dr. Ragothaman had never prescribed Neurontin. (Id. ¶ 203.)

Dr. Ragothaman testified that she did not recall having been detailed on Neurontin or attending continuing medical education events at which Neurontin's off-label uses were discussed. (James Decl., Ex. 13 at 88-93.) However, plaintiffs have presented evidence that Dr. Ragothaman was detailed at least three times by Parke-Davis representatives in 1999. On February 4, 1999, Dr. Ragothaman discussed Neurontin's use in treating bipolar disorder with Parke-Davis sales representative Steve Alberti. On February 11, 1999, Dr. Ragothaman received the same Dear Doctor letter that Dr. Arness received. (Pl.'s SOF ¶ 206.) The letter omitted the negative data from the Pande clinical trial, which was known to the company for a year prior to sending the Dear Doctor letter. In September, 1999, Dr. Ragothaman received another Dear Doctor letter that failed to include the negative data from the Frye and Guille studies.

In March 1999, Dr. Ragothaman prescribed Neurontin to Wityk. (Id. ¶ 209.) After receiving the Dear Doctor letters, Dr. Ragothaman's prescriptions for Neurontin increased dramatically, as shown by the chart below. She continues to prescribe Neurontin to bipolar patients who suffer comorbid anxiety symptoms. (Ex. 13 at 31, 87-88.)



(Id. ¶ 208.)

Wityk was subsequently treated by Dr. Jerrold Gray, who continued to prescribe Neurontin to her and increased her daily dosage. (Id. ¶ 210.) Dr. Gray continued prescribing Neurontin to Ms. Wityk based on his "independent medical judgment that that was an appropriate treatment for her at that time" and on the fact that "she thought clearly that it was helping with her mood stability." (James Decl., Ex. 14 at 54, 57.) In addition, Dr. Gray made the following statement: "I do not remember receiving any specific information about Neurontin from a drug rep. I've seen thousands of drug reps. It is possible that a drug rep

provided information to me about Neurontin, but I would not make a decision solely upon a recommendation from a drug rep." (Id. at 109.)

However, Wityk testified that Dr. Gray told her "that the drug reps were pleased with the off-label success of Neurontin for people with bipolar disorder . . . [a]nd that I should give it some consideration and thought to changing medications as the drug representatives had seen amazing results." (Pl.'s SOF ¶ 210.) Wityk went on to state that, after telling Dr. Gray that Neurontin was not helping her condition, Dr. Gray increased her dosage, telling her that "he had discussed the fact that I was not getting better on the Neurontin with the drug, specifically with the drug representative who told him that they just need to continue to titrate me to a higher dose." (Id. ¶ 211.) This testimony, however, is disputed and likely inadmissible as hearsay.[3] Wityk's medical records indicate "patient reports significant benefits from the Neurontin but continues to have at least mild mood swings," and that she needed to be reassured that Dr. Gray would continue to prescribe her Neurontin after he

[3] Plaintiffs claim that these statements are not hearsay because they are not offered for the truth of the matters asserted, but only to establish that Dr. Gray was exposed to Defendants' marketing practices. This argument is unpersuasive. Plaintiffs offer the statement to prove that a Pfizer sales representative made a fraudulent statement to Dr. Gray regarding high doses of Neurontin, and that Dr. Gray relied on that statement in prescribing Neurontin to Wityk.

suggested the addition of Seroquel to her medication regimen. (James Decl., Ex. 14 at 74, 78-79.)

In September 2001, Dr. Gray discontinued prescribing Neurontin to Wityk, and Wityk claims that "Neurontin was ineffective for the entire time that [she] was on it." (Pl.'s SOF ¶ 211.)

3. Jeanne Ramsey

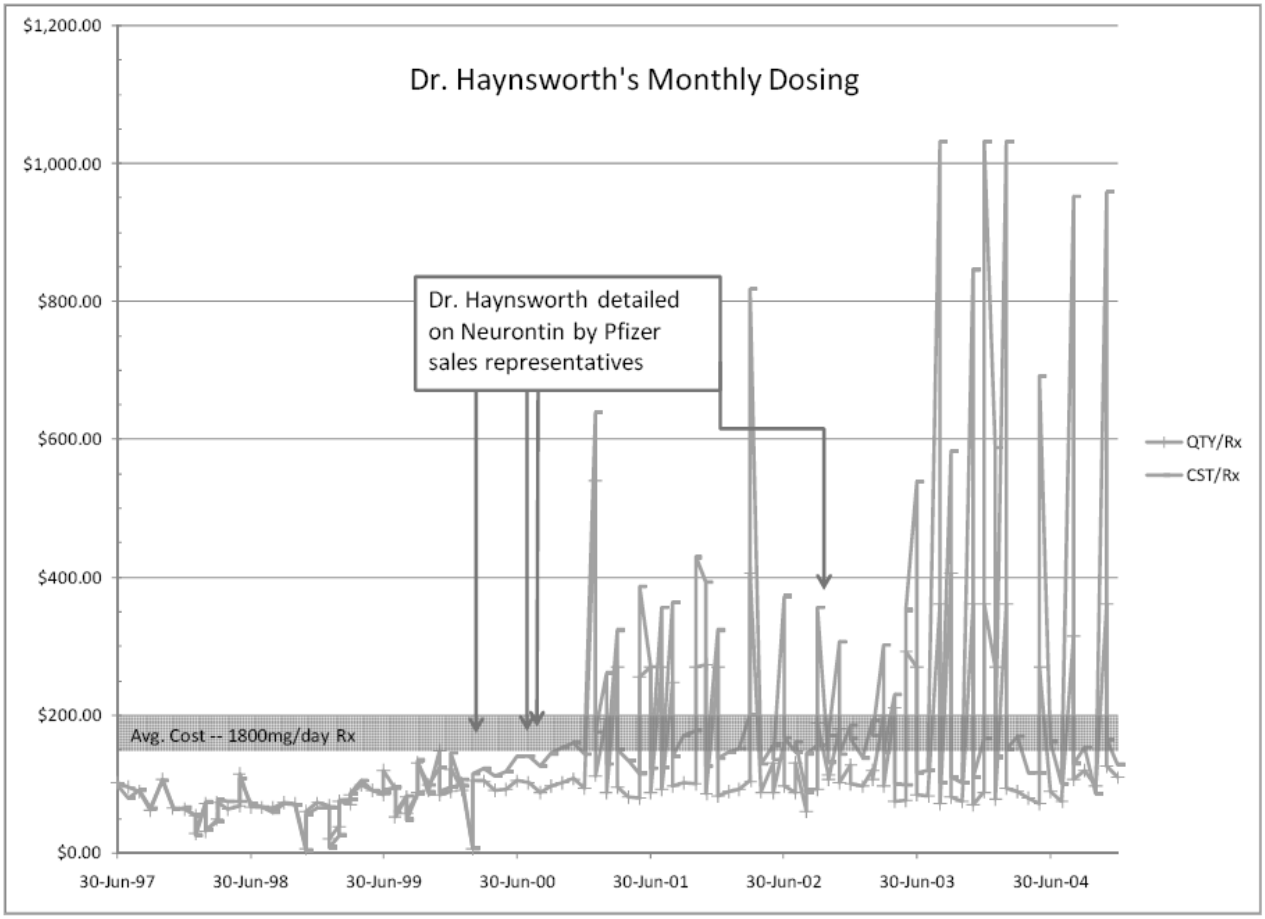
Jeanne Ramsey's claims are based on allegedly fraudulent marketing of Neurontin for doses greater than 1800 mg/day, which is the maximum dose recommended by the FDA. (Pl.'s SOF ¶¶ 694-705.) Ramsey suffered from Reflex Sympathetic Dystrophy (RSD), a chronic neuropathic pain condition, and was prescribed Neurontin at various doses during 2000. During this time period, she sought treatment from two doctors: Dr. Rick Waldo and Dr. Robert Haynsworth.

Dr. Waldo testified that he first prescribed Neurontin to Ramsey for neuropathic pain based on his independent medical judgment, which was informed by information in the clinical literature and conversations with neurologists. (James Decl., Ex. 18 at 29, 43.) Although Dr. Waldo does generally remember being detailed on Neurontin (specifically after it went generic), he does not recall ever discussing Neurontin's off-label uses with a sales representative. (Id. at 87-89.)

Dr. Haynsworth, a pain specialist, also prescribed Neurontin

to Ramsey. At the time Ramsey first visited Dr. Haynsworth, she had already been prescribed Neurontin at a dose of 900 mg/day. (James Decl., Ex. 19 at 43-44.) Dr. Haynsworth increased her dose to 2400 mg/day on March 31, 2000. (Id. at 51.) He based this decision on "the scientific literature and [his] experiences and [his] judgment." (Id. at 45.) By May 23, 2000, Ramsey reported an 80% reduction in her pain, and Dr. Haysworth increased her dose to 3200 mg/day. (Id. at 50-51.) Later during 2000, Ramsey experienced weight gain as a side effect of Neurontin and reduced her daily dose to 1200 mg. She then reported that her pain had returned. (Id. at 54-55.) Dr. Haysworth testified that he thought Neurontin was an effective treatment for Ramsey "[b]ecause it seemed like when she stopped it, she got worse." (Id. at 128.) Dr. Haysworth stated that he does not meet with pharmaceutical sales representatives. (Id. at 15, 127 (stating that "we have sales reps come by all the time, but . . . I don't talk to them").)

Plaintiffs claim that Dr. Haynsworth was in fact detailed on Neurontin on multiple occasions during this time period by Parke-Davis representatives. (Pl.'s SOF ¶¶ 695-97.) Plaintiffs have offered evidence that Dr. Haynsworth began prescribing more Neurontin after these detail visits.



(Id. ¶ 705.) There is no evidence that Ramsey's other doctor, Dr. Waldo, was detailed on Neurontin in 2000.

4. Gerald Smith

Gerald Smith suffered from severe headaches and neuropathic pain. He took Neurontin over a period of two years and claims that his headaches never got better. (Pl.'s SOF ¶ 455.) Smith was prescribed Neurontin by neurologist Dr. Kylene Huler. Dr. Huler wrote in a letter to another doctor on August 14, 2001 that, after he began taking Neurontin, Smith's "physical symptoms [had] improved to a degree where he was able to get himself off

of his medication." (James Decl., Ex. 2.) Dr. Huler testified that she prescribed Neurontin to Smith based on her clinical experience with using the drug off-label. (James Decl., Ex. 3 at 65.) She continued to prescribe the drug because it was helping to resolve Smith's physical symptoms by eliminating painful tingling on the thighs and reducing the intensity of his headaches by 50%. (Id. at 66-67, 70.)

Dr. Huler stated that no sales representative from Parke-Davis or Pfizer had ever discussed off-label uses of Neurontin with her, but that she did request literature about the use of Neurontin to treat off-label conditions like post-herpetic neuralgia and migraine. (Id. at 86-87, 169.) Dr. Huler continues to prescribe Neurontin to patients because "it works and it's very safe," and it does not interact with other medications. (Id. at 40.)

Plaintiffs offered evidence that Dr. Huler was detailed hundreds of times by various Parke-Davis and Pfizer representatives from 1996 through 2004. (Rona Decl., Ex. 423.) One sales representative wrote that "She is the Pfizer Queen (Zoloft, Neurontin) and she said as much." (Pl.'s SOF ¶ 457.)

5. Lorraine Kopa

Lorraine Kopa suffered chronic neck and back pain after a car accident. She took Neurontin for six months but claims it did not alleviate her pain. (Pl.'s SOF ¶ 458.) Kopa was treated

by Dr. Vithalbahai Dhaduk, who stated that he prescribed Neurontin to Kopa after several other treatment options had failed. (James Decl., Ex. 5 at 84-85.) He testified that he based his decision to prescribe Neurontin on his clinical experience, which included

> using Neurontin in a [sic] comorbid conditions with partial epilepsy and the migraine, as well as comorbid condition with the partial epilepsy and the neuropathic pain, Neurontin was helping the patients to control or relieve the neuropathic pain, in addition to helping the seizures, and was relatively safe and patients were able to tolerate the medicine.

(Id. at 86.) At the time of his deposition, he stated that he continues to prescribe Neurontin for pain. (Id. at 39, 49.)

Dr. Dhaduk has met with sales representatives about Neurontin and has attended Neurontin-related events, but he testified that these meetings and events were all related to on-label uses of Neurontin. (Id. at 111-15, 124-26, 142-43, 180-81.) Plaintiffs point out that Dr. Dhaduk has served as a Neurontin speaker for Pfizer and has been paid for that work. (Rona Decl., Ex. 425 at 131-32, 135.) Defendants also paid Dr. Dhaduk to attend their conferences and consultant meetings. (See James Decl., Ex. 5 at 127-28.)

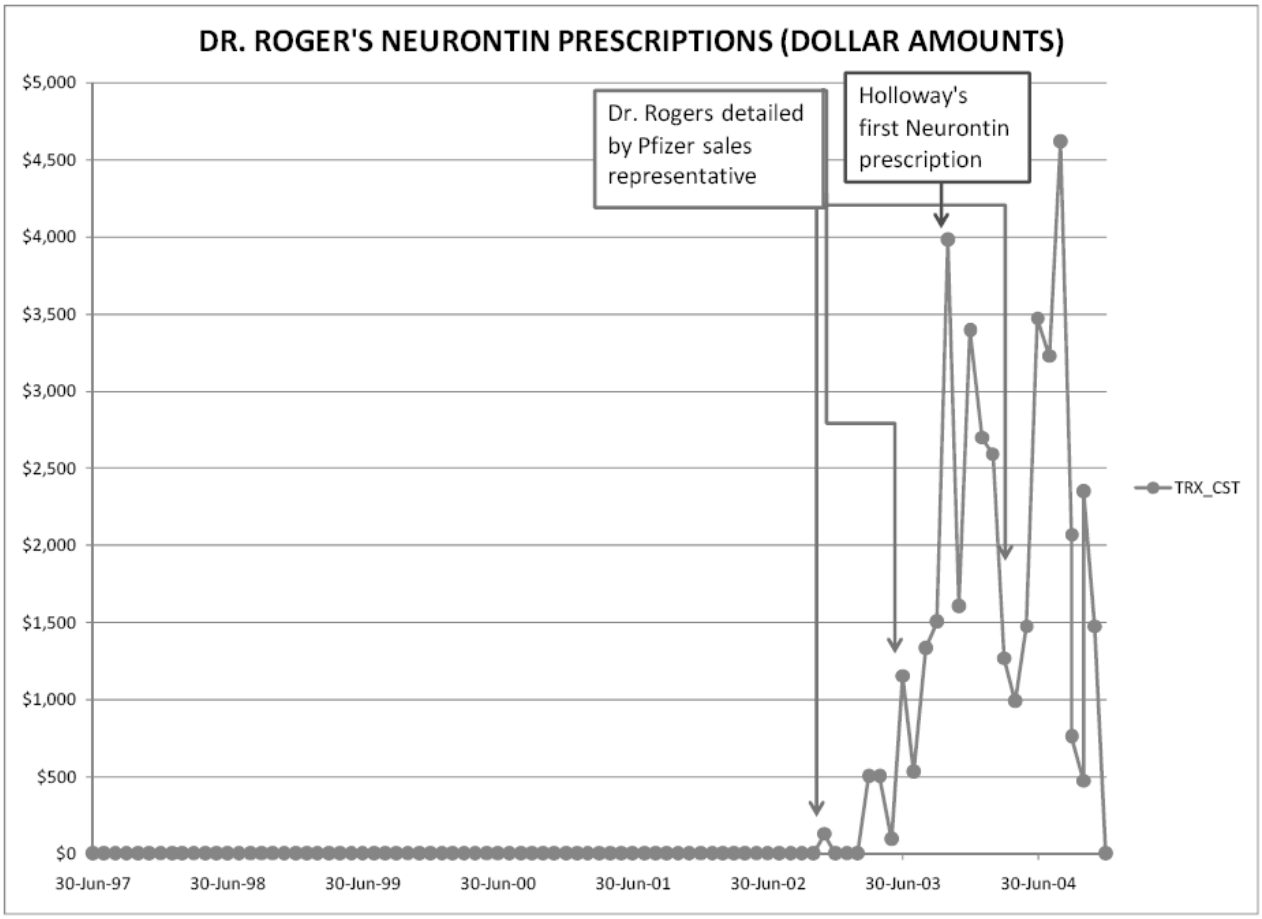
6. Carolyn Hollaway

Carolyn Hollaway suffered from nociceptive pain, specifically chronic back pain resulting from a car accident. The accident caused inflammation and pain in her lower back, for

which Dr. Greg Rogers prescribed her Bextra (another Pfizer drug later removed from the market) and Neurontin. (Pl.'s SOF ¶ 465.) Hollaway claims that Neurontin was not effective for relieving her back pain. (Id.)

Dr. Rogers testified in his deposition that his clinical experience plays a "tremendously important" role in his prescription decisions and that, for some of his patients, Neurontin has had "tremendous benefits." (James Decl., Ex. 6 at 27-28, 35-36.) Dr. Rogers related one of his early experiences with Neurontin in 1994 or 1995 when he prescribed Neurontin to a patient to treat seizures and found that some of her other symptoms also improved. (Id. at 42-44.) After beginning to take Neurontin, Hollaway reported to Dr. Rogers that her symptoms had improved. (Id. at 62-63, 119-20; see also James Decl., Ex. 7.)

Dr. Rogers testified that no sales representative had ever initiated a conversation with him about off-label uses of Neurontin, but that he had asked for information about off-label uses. (James Decl., Ex. 6 at 94-96.) Although Dr. Rogers testified that he had been prescribing Neurontin since 1994 or 1995, plaintiffs claim that he had never prescribed Neurontin before November 2002, the same month that he was first detailed by a Pfizer sales representative. (See Rona Decl., Exs. 433-34.) Plaintiffs allege that the following chart shows the changes in Dr. Rogers's Neurontin prescription behavior.



(Pl.'s SOF ¶ 467.)

B. <u>Class TPP Plaintiffs</u>

1. Blue Cross Blue Shield of Louisiana ("BCBSLA")

BCBSLA is a nonprofit mutual company that in 2003 covered over one million lives in Louisiana. BCBSLA used a pharmacy benefit manager ("PBM") to process claims for prescription medications. (Pl.'s SOF ¶ 711.) From 1995 through 1998, Paid Prescriptions, Inc. and National Rx Services, Inc. of Texas were the PBMs for BCBSLA. From 1998 through 2004, Merck-Medco served as the PBM. (<u>Id.</u> ¶¶ 711-12.)

BCBSLA maintains an open formulary, meaning that "they pay for all FDA approved drugs regardless of the formulary status of the drug." (Id. ¶ 719.) Neurontin was listed as a "preferred drug" on the BCBSLA formulary between 1998 and 2004, and was not reviewed during that time period. (Id. ¶¶ 721, 723, 738.) "BCBSLA has never considered excluding any drugs based on efficacy because it presumes that a drug is efficacious for its FDA approved indication." (Id. ¶ 752.) Pfizer representatives such as Jennifer Comeaux, Cher Rezor, and Paula Roads directly marketed to BCBSLA during the relevant time period. Plaintiffs claim that BCBSLA "relies on all information it receives from drug manufacturers, including published data, sales and marketing information to be complete and truthful," but they do not claim that BCBSLA relied on any specific fraudulent representations or omissions from Pfizer in choosing to keep Neurontin on the preferred tier of its formulary. (Id. ¶ 755.)

Plaintiffs provided information about twenty-one physicians in Louisiana who wrote Neurontin prescriptions that were paid for by BCBSLA. (See id. ¶¶ 780-801.) Each physician was detailed on Neurontin, often for off-label indications, by sales representatives for Parke-Davis and Pfizer. In all of these cases, the physician either began prescribing Neurontin for the first time or drastically increased her prescriptions after these details. (Id.)

For example, Dr. Timothy Best, a Lake Charles neurologist,

was regularly detailed on Neurontin beginning in the fall of 1999. Sales representatives left "articles about off-label uses, cookies, and invitations to CME programs and meetings." During the four years after these Neurontin details began, his Neurontin prescriptions for BCBSLA patients increased fourteen-fold. (Id. ¶ 784.)

In addition, Dr. Carolyn Baker, a Baton Rouge neurologist, was regularly detailed on Neurontin beginning in March of 1999. Defendants' call notes indicate that she was invited to CMEs as well as speaker's bureaus, given samples and "sweets." Her prescriptions for Neurontin steadily increased from 1999 through 2002. (Id. ¶ 783.)

2. ASEA/AFSCME Local 52 Health Benefits Trust ("ASEA")

ASEA is a health benefits trust formed in November 2000 that began providing health benefits to certain Alaskan government employees and their dependents in July 2001. (Def.'s Statement of Facts Supp. Mot. Summ. J. ("Def.'s SOF") ¶ 99.)

ASEA has provided information about four physicians who wrote Neurontin prescriptions that were paid for by ASEA. Each physician was detailed by Pfizer or Parke-Davis sales representatives and subsequently began writing Neurontin prescriptions or changed their prescription behavior to describe Neurontin more often. (Pl.'s SOF ¶¶ 802-05.)

3. Harden Manufacturing Corporation ("Harden")

Harden is a self-insured, Alabama-based furniture manufacturer with roughly 600 employees. (Def.'s SOF ¶ 102.) Over the relevant time period, only twenty of Harden's insureds were prescribed Neurontin. (Id. ¶ 103.) Plaintiffs do not dispute that "Harden has not approached the prescribing doctors to these twenty insureds to determine whether any of these prescriptions was caused by defendants' alleged misconduct rather than by the exercise of the prescribing physician's independent medical judgment." (Id. ¶ 105; see also Pl.'s Resp. Def.'s SOF ¶ 105.)

4. International Union of Operating Engineers, Local No. 68 Welfare Fund ("Local No. 68")

Plaintiffs have not provided any factual information about Local No. 68.

III. DISCUSSION

A. Legal Standard

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. Causation

One key issue is whether the Class Plaintiffs have raised a triable issue of fact as to causation. For their RICO claims, plaintiffs must show both that defendants' mail or wire fraud in violation of the racketeering statute was a "but for" cause of their injuries as well as a proximate cause. See, e.g., George Lussier Enters., 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)). First-

party reliance, or reliance by the Class Plaintiffs themselves, is not required to prove RICO causation. See Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 659 (2008) ("[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.") (internal citation omitted).

1. Individual Consumer Plaintiffs

Plaintiffs argue that they have put forth powerful evidence of a correlation between detailing visits and increased Neurontin prescriptions for off-label indications by individual physicians. Many of the treating physicians, with the exception of Dr. Huler and Dr. Rogers, testified that they did not recall ever receiving information from sales representatives about off-label uses for Neurontin. This evidence creates a triable issue of fact as to whether the treating physicians prescribed Neurontin as a result of off-label promotion. Plaintiffs must show more than a correlation between off-label promotion and prescriptions, though. While off-label marketing is prohibited by the FDCA, there is no statutory private cause of action. See Food, Drug, and Cosmetic Act, 21 U.S.C. § 337(a). Therefore, in order to survive summary judgment, plaintiffs must present evidence to show that their treating physicians relied on fraudulent off-label marketing that could form the basis of a RICO violation.

After the trial in the Kaiser case, the Court found that "the pervasive nature of the publication fraud" by Pfizer "infected the nationwide sources of information available to all physicians." Kaiser, 2010 WL 4325225, at *32. The Court found that plaintiffs established causation through direct reliance by Kaiser on fraudulent direct misrepresentations as well as fraudulent suppression of studies in the published literature. Specifically, Pfizer made misrepresentations about Neurontin's efficacy, which Kaiser relied on in making drug formulary decisions, producing drug monographs about the use of Neurontin for off-label indications, and answering physician inquiries. These formulary decisions and drug monographs in turn caused physicians treating Kaiser members to prescribe more Neurontin. Kaiser buttressed its argument by presenting evidence that physicians treating its members have a 95% compliance rate with its drug formularies. Accordingly, if Kaiser had not expanded Neurontin's formulary status and published positive drug monographs, physicians would likely have prescribed less Neurontin for off-label indications and used more effective, less expensive medication instead. Therefore, the Court found that the defendants' fraud caused Kaiser to pay for Neurontin prescriptions, rather than cheaper, more optimal alternatives.

In this case, plaintiffs must show that the defendants' alleged fraud caused the treating physician to prescribe Neurontin when he or she otherwise would have used alternative

treatments. The treating physicians for each of the individual consumer plaintiffs have testified that they prescribed Neurontin to the plaintiffs based on their independent medical judgment. Indeed, they deny any unsolicited off-label detailing by defendants' sales representatives and state that their knowledge about Neurontin's efficacy for off-label indications was informed by their clinical experience with the drug along with information received from trusted colleagues. Dr. Haynsworth, who treated Jeanne Ramsey, when asked whether or not his prescribing behavior would change if he had DBRCT evidence that Neurontin was not effective for neuropathic pain, testified that

> [I]f – some of the studies come out with maybe not a great effect, a significant effect, but not a great effect. But if I had that patient on Neurontin and they come in and their pain was a nine on a scale of zero to 10 and now it's down to a one and they say their pain is better, I'm going to keep them on Neurontin.

(James Decl., Ex. 19 at 91-92 (Haynsworth Dep.).)

Only two doctors received fraudulent materials from Pfizer. Dr. Arness and Dr. Ragothaman received "Dear Doctor" medical information letters from defendants that discussed the misleadingly positive Dimond article as evidence of Neurontin's efficacy for treating bipolar disorder, but omitted the negative results of the Pande, Frye, and Guille trials. At the Kaiser trial, Pfizer produced no reliable scientific evidence that Neurontin was effective in treating bipolar disorder. Intentional omission of the negative clinical trials could

constitute fraud. Defendants point out that no doctor testified that he would not have prescribed Neurontin to a patient if he been aware of these negative trials. Still, a fact-finder could reasonably infer that a doctor would not prescribe a drug if she were aware of overwhelmingly and uniformly negative evidence about its efficacy in treating bipolar disorder. The receipt of the "Dear Doctor" letters by the treating physicians for Gary Varnam and Jan Frank Wityk, both of whom suffered from this mental disease, creates a triable issue of fact as to causation.

With respect to the remaining individual consumer plaintiffs, there is no evidence that their treating physicians received or read misleading or fraudulent publications about Neurontin's use for off-label indications. While the consumer plaintiffs have presented evidence that their treating physicians may have relied on off-label marketing in making prescription decisions, there is no admissible, nonhearsay evidence in the record that those physicians relied on fraudulent off-label marketing, with the exception of the treating physicians for Gary Varnam and Jan Frank Wityk. To be sure, plaintiffs present a compelling argument that there was no legitimate basis for detailing psychiatrists to sell them Neurontin since there was no reliable scientific evidence suggesting that Neurontin was effective in treating bipolar disorder. Still, there is no evidence as to what the detailers said to any of the doctors, or what any of the doctors read, except the ones who were sent "Dear

Doctor" letters. Accordingly, there is no genuine issue of material fact as to causation in the case of Jeanne Ramsey, Gerald Smith, Lorraine Kopa, or Carolyn Hollaway, and the defendants' motion for summary judgment will be allowed as to these plaintiffs.

2. Class TPP Plaintiffs

In the Court's order on the defendants' Motion for Summary Judgment against the Coordinated Plaintiffs (Kaiser, Aetna, and Guardian), the Court noted its concern that "[w]hile 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." In re Neurontin, 677 F. Supp. 2d at 495. The evidence is disputed as to whether the Class TPP plaintiffs have, in fact, suffered harm as a result of defendants' off-label marketing. However, the Class TPP Plaintiffs have put forth no evidence as to which, if any, doctors were tainted by misleading information like "Dear Doctor" letters or other marketing material. There is no evidence in the record that any of the Class TPP Plaintiffs communicated directly with Pfizer in the development or evaluation of a drug formulary.

On the issue of causation, the Class Plaintiffs point to the analysis of Dr. Meredith Rosenthal. Dr. Rosenthal used national

data, correlated with information about Pfizer's promotional spending, to determine the percentages of Neurontin prescriptions that were "caused" by Pfizer's fraud. While this analysis demonstrates the likelihood of some injury, particularly in the area of bipolar disorder, it does not suffice to demonstrate the extent of harm caused by the fraud, as opposed to run-of-the-mill off-label detailing. Most courts have rejected such aggregate proof. The Second Circuit recently held, in a class action regarding sales and marketing of the drug Zyprexa, that where "[p]laintiffs allege an injury that is caused by physicians relying on [a pharmaceutical company's] misrepresentations," the injury cannot be shown by generalized proof. UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 133-36 (2d Cir. 2010); see also In re Neurontin, 677 F. Supp. 2d at 494-95; 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.").

Because the Class TPP Plaintiffs have not directly relied on misrepresentations by defendants, and because they have presented no evidence as to how many or which physicians who prescribed Neurontin to their members relied on fraud, they cannot establish causation.

IV. ORDER

The motion for summary judgment [Docket No. 1689] is **ALLOWED** with respect to all Class Plaintiffs except Gary Varnam and Jan Frank Wityk.[4]

/s/ PATT B. SARIS
PATTI B. SARIS
United States District Judge

[4] Gary Varnam and Jan Frank Wityk are plaintiffs who are named as class representatives in the class action complaint originally filed with this Court. Accordingly, this Court may retain jurisdiction over the plaintiffs' cases that have survived summary judgment. The parties shall inform the court whether the cases should be transferred pursuant to 28 U.S.C. § 1404. Any such motions shall be filed by January 15, 2011.