UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION	
THIS DOCUMENT RELATES TO:	CIVIL ACTION NO. 04-cv-10739-PBS
KAISER FOUNDATION HEALTH PLAN, INC., et al.	
v.	
PFIZER, INC., et al.	

MEMORANDUM AND ORDER

July 27, 2011

Saris, U.S.D.J.

After a lengthy trial, a jury returned a verdict on RICO claims for plaintiff Kaiser on March 25, 2010 in the amount of $47,363,092. (Jury Verdict, Docket No. 2760.) Under the statute, the award on the RICO claims was trebled to $142,089,276. On November 3, 2010, this Court issued an opinion finding that defendants engaged in fraudulent business acts or practices under California's Unfair Competition Law and awarded plaintiffs $95,286,518 in restitution. In re Neurontin Mktg. & Sales Practices Litig., 748 F. Supp. 2d 34 (D. Mass. 2010). Judgment was entered on February 22, 2011 (Docket No. 3326).

Defendants have filed a Motion for New Trial and to Re-Open Evidence or, Alternatively, to Alter or Amend Judgment pursuant

to Fed. R. Civ. P. 59 (Docket No. 3362). The Court **DENIES** defendants' motion for new trial, and writes now only to address three of the issues raised therein.

I. DISCUSSION

A. Motion to Re-Open Evidence and Admit 2011 Cochrane Review

Defendants seek to re-open the evidence in order to submit an article issued by the Cochrane Collaboration titled "Gabapentin for chronic neuropathic pain and fibromyalgia in adults (Review)." (Docket No. 3362, Ex. A.) The Court previously found that "[t]he Cochrane Group is an international nonprofit organization that provides compilations of the most reliable scientific evidence available about the use of certain drugs to treat various indications." 748 F. Supp. 2d at 43 n.4. The new Cochrane report on the use of Neurontin to treat neuropathic pain finds that "Gabapentin provides pain relief of a high level in about a third of people who take it for painful neuropathic pain. . . . More conservative estimates of efficacy resulted from using better definitions of efficacy outcome at higher, clinically important, levels, combined with a considerable increase in the number of studies and participants available for analysis." (Docket No. 3362, Ex. A at 2.)

The authors concluded that results might vary among different neuropathic pain conditions, and that the amount of evidence for some conditions is "low, excluding any confidence

that it works or doesn't work." (Id. at 28.) Overall, the 2011 Cochrane report included 29 studies, five of which studied postherpetic neuralgia (which is an on-label indication for Neurontin), and eight of which studied painful diabetic neuropathy. (Id. at 7.) The 29 studies involved 3,571 participants. Approximately 75% of those participants were enrolled in studies of postherpetic neuralgia ("PHN"), painful diabetic neuropathy ("PDN"), or mixed neuropathic pain. Id. Accordingly, the authors wrote that "[t]hough gabapentin was tested in 12 different neuropathic pain conditions, only for three was there sufficient information to be confident that it worked satisfactorily, namely PHN, PDN, and mixed neuropathic pain, itself principally, though not exclusively, PHN and PDN." (Id. at 25.)

Defendants bring their motion pursuant to Fed. R. Civ. P. 59(e). "Rule 59(e) motions are granted only where the movant shows a manifest error of law or newly discovered evidence." Kansky v. Coca-Cola Bottling Co. of New Eng., 492 F.3d 54, 60 (1st Cir. 2007) (citing Marie v. Allied Home Mortgage Corp., 402 F.3d 1, 7 n.2 (1st Cir. 2005)). "An order for a new trial on the ground of newly discovered evidence requires proof of the following elements: (1) The evidence has been discovered since the trial; (2) The evidence could not by due diligence have been discovered earlier by the movant; (3) The evidence is not merely cumulative or impeaching; and (4) The evidence is of such nature

that it would probably change the result if a new trial is granted." Raymond v. Raymond Corp., 938 F.2d 1518, 1527 (1st Cir. 1991). "'[N]ewly discovered evidence' normally refers to 'evidence of facts in existence at the time of trial of which the aggrieved party was excusably ignorant.'" Rivera v. M/T Fossarina, 840 F.2d 152, 156 (1st Cir. 1988) (quoting Brown v. Pa. R.R. Co., 282 F.2d 522, 526-27 (3d Cir. 1960)). Examples of "newly discovered evidence" under Rule 59 that have been accepted by courts include: (1) newly located witnesses with personal knowledge germane to the case, see Compass Tech., Inc. v. Tseng Labs., Inc., 71 F.3d 1125, 1130-31 (3d Cir. 1995); (2) evidence belatedly disclosed by opposing party such that the movant did not have time to recognize it as useful evidence, see Alpern v. UtiliCorp United, Inc., 84 F.3d 1525, 1536-37 (8th Cir. 1996); and (3) evidence that a key witness committed perjury, see Krock v. Electric Motor & Repair Co., 339 F.2d 73, 75 (1st Cir. 1964); In re Vioxx Prods., 489 F. Supp. 2d 587, 591-92 (E.D. La. 2007).

After trial, the Court concluded that "Kaiser has proven that Pfizer fraudulently marketed Neurontin by showcasing positive information about Neurontin's efficacy in the published literature, while suppressing negative evidence from Pfizer-sponsored clinical trials about Neurontin's efficacy for bipolar disorder, neuropathic pain, migraine, or doses greater than 1800 mg/day." 748 F. Supp. 2d at 38-39. The Court also found that "Kaiser has proven that there is little or no scientifically

accepted evidence that Neurontin is effective for the treatment of bipolar disorder, neuropathic pain, nociceptive pain, migraine, or doses greater than 1800 mg/day." Id. at 39.

The new Cochrane report is related only to the Court's findings about the use of Neurontin to treat neuropathic pain. The findings regarding the other three indications (bipolar disorder, migraine, and high doses) are unrelated to this discussion.

As the Court acknowledged in its findings, the conclusion that Neurontin was not effective in the treatment of neuropathic pain was "a closer call" when compared to the three other indications, for which there was no scientific evidence of efficacy. Id. at 78. Two credible defense experts testified that they believed Neurontin was, for some patients, an effective treatment for neuropathic pain. Id. at 77-78. In addition, "some trials studying the use of Neurontin to treat diabetic peripheral neuropathy found that, using some secondary outcomes . . . Neurontin outperformed placebo." Id. However, after weighing all of the evidence, including 12 double-blind randomized controlled trials and testimony from three experts, the Court concluded that, "using the generally accepted standard of scientific efficacy followed by the FDA and the scientific community . . . there is insufficient reliable evidence of the efficacy of Neurontin with respect to the broad indication of neuropathic pain." Id. at 79.

At trial, defendants introduced the 2005 Cochrane report on the use of Neurontin for neuropathic pain into evidence, which found that "there is adequate evidence to support that there's efficacy of gabapentin for the treatment of neuropathic pain." Id. at 78. However, the Court found that the 2005 Cochrane report was not persuasive because defendants suppressed data from trials studying the use of Neurontin to treat neuropathic pain that had negative results. Id. Specifically, the authors of the 2005 Cochrane report did not have access to the unpublished Reckless and POPP trials, and they did not have access to the raw data for the Backonja, Gorson and Serpell trials. Id. The Court's conclusion was supported by the testimony of plaintiffs' expert, Dr. Kay Dickersin, who also published her findings based on discovery materials in this case in an article in November 2009 in the New England Journal of Medicine. Dr. Dickerson found that each of twenty-one clinical trials sponsored by the defendants exhibited some sort of bias or deviation from the truth. See Kay Dickerson, et al., "Outcome Reporting in Industry-Sponsored Trials of Gabapentin for Off-Label Use," 361 New Eng. J. Med. 1963 (2009). Significantly, the new 2011 Cochrane report was made possible by the release of previously suppressed trials and data that were disclosed during the Kaiser trial and discovery process.

The Court concludes that a new trial is not warranted for two reasons. First, the Cochrane report is not newly discovered

evidence that defendants could not have replicated before trial, but rather is a scholarly article that provides a meta-analysis of scientific studies, most of which were available during trial.[1] Pfizer could have performed a similar meta-analysis prior to the trial. Indeed, plaintiffs' expert, Dr. Thomas Perry, did perform a similar meta-analysis, albeit one that reached an opposite conclusion. Moreover, Dr. Robert Gibbons, a highly qualified biostatician who testified as defendants' expert in this trial, has previously provided the Court with similar meta-analysis testimony in the related products liability litigation that refutes the FDA's conclusion that gabapentin was associated with increased rates of suicide and suicidal ideation. See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 2011 WL 1048971 (D. Mass. Mar. 18, 2011).

Pfizer argues, though, that the Cochrane Group's opinion should be considered new evidence because it is a uniquely independent and respected publication which would have more persuasive force than a litigation-inspired expert report. This argument displays a certain amount of chutzpah. The previous

[1] One of the underlying studies was not in existence at the time of trial. See Wallace MS, et al., "Gabapentin extended-release tablets for the treatment of patients with postherpetic neuralgia: a randomized, double-blind, placebo-controlled, multicentre study," 30 Clinical Drug Investigation 765 (2010). This study, however, is not relevant because, as the Court explained in its Findings of Fact and Conclusions of Law, Neurontin has been approved by the FDA for the treatment of postherpetic neuralgia and plaintiffs do not contest that it is effective for that indication. See, e.g., 748 F. Supp. 2d at 78.

Cochrane report was unpersuasive to the Court precisely because defendants suppressed negative data while emphasizing positive data in the published literature. Pfizer itself did not provide the Cochrane Group with all available studies prior to the trial because it fraudulently suppressed these studies. Therefore, the Cochrane Group was unable to produce an opinion based on all of the neuropathic pain DBRCTs until after the trial, when the Cochrane Group obtained access to all available data and clinical trials on the use of Neurontin to treat neuropathic pain. The bottom line is that if it were not for Pfizer's fraudulent suppression of studies, the Cochrane Group likely would have published a reliable meta-analysis prior the trial, which may have tipped the balance in favor of Pfizer on the issue of neuropathic pain.

Alternatively, the Court is not convinced that the Cochrane article qualifies under the law as newly discovered evidence with respect to the efficacy of the drug. The parties have not identified any case law in support of the premise that a new scholarly article, which essentially represents an expert opinion, constitutes newly discovered evidence. While there is some case law that is relevant, the facts of those cases are so different that they provide little guidance. See Chilson v. Metro. Transit Auth., 796 F.2d 69, 72 (5th Cir. 1986) (holding, in an employment retaliation case where the plaintiff had criticized wasteful spending, that a post-trial internal audit

confirming plaintiff's allegations of wasted public funds was newly discovered evidence under the rule); Rosebud Sioux Tribe v. A & P Steel, 733 F.2d 509, 515-17 (8th Cir. 1984) (holding that a post-trial admission of perjury by a witness was "newly discovered evidence" under the rule since the perjury existed at the time of the trial although it was revealed only after trial); Kettenbach v. Demoulas, 901 F. Supp. 486 (D. Mass. 1995) (holding that a conversation recorded post-judgment constituted newly discovered evidence because the events that the recording purported to describe took place before the trial, and in fact were the basis for the action).

Knowledge about drug efficacy and safety is an iterative process. See, e.g., Daubert v. Merrell Down Pharms., Inc., 509 U.S. 579, (1993) ("[A]rguably, there are no certainties in science."); Bone Shirt v. Hazeltine, 461 F.3d 1011, 1026 (8th Cir. 2006) ("Science evolves, and scientific methods that were once considered unassailable truths have been discarded over time."); Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1316 (11th Cir. 2000) (noting that "new scientific evidence is continually emerging" and discussing the frequent conflicts between changing science and a court's interest in finality). The most eloquent discussion of post-trial emergence of new scientific evidence comes from the District of Columbia Court of Appeals.

Although science is a constantly evolving process, the

> law depends upon a high level of certainty once an outcome has been determined. A trial can be no more than a resolution of an immediate dispute on the basis of present knowledge; its outcome must turn upon the teachings of science as understood at the time of trial as best can be discerned through the presentations of the parties. Where scientific facts are at issue, it is not unexpected, given the nature of the process, that the passage of time will bring forth further scientific data and inquiry relating to the ultimate scientific fact at issue. To reopen the trial's determination of scientific truth, however, runs squarely into the fundamental principle of certainty.

Merrell Dow Pharms., Inc. v. Oxendine, 649 A.2d 825, 831 (D.C. 1994). Accordingly, the 2011 Cochrane report is not "newly discovered evidence" under the case law analyzing Rule 59(e).

Finally, Pfizer must show that "[t]he evidence is of such nature that it would probably change the result if a new trial is granted." Raymond, 938 F.2d at 1527. To calculate damages for neuropathic pain, the Court used the difference between the cost of Neurontin and the cost of cheaper and more optimal drugs that would likely have been prescribed by PMG physicians. Neurontin, 748 F. Supp. 2d at 69. Accordingly, even if the Court had considered the new Cochrane report, I would likely still have concluded that Kaiser suffered damages because there were cheaper and more optimal drugs that physicians could have prescribed to Kaiser members had Kaiser and the doctors been aware of Pfizer's suppression of negative information. Moreover, Pfizer fraudulently marketed Neurontin for the treatment of neuropathic

pain as a broad indication.[2] The authors of the Cochrane report made clear that they were only confident about their results with respect to PHN and PDN, and could not say whether Neurontin worked satisfactorily for other neuropathic pain conditions. See supra. Therefore, even if the 2011 Cochrane report did tip the balance in favor of Pfizer on the issue of efficacy, it would only do so with respect to PHN and PDN.

The Court concludes that the opinion offered in the Cochrane report is a "new" expert opinion about known pre-existing facts as opposed to "newly discovered" evidence. Accordingly, the Court declines to re-open the evidence in light of defendants' motion under Rule 59.

B. Admission of Plaintiffs' RICO Enterprise Exhibits

Pfizer also makes a Rule 59 motion for a new trial on the basis of the Court's admission of certain documents, which

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[2] Indeed, when Pfizer sought approval from the FDA in 2001 of Neurontin for the broad indication of neuropathic pain, the FDA stated:

> The general neuropathic pain indication cannot be granted for Neurontin based on the clinical trials in painful diabetic peripheral neuropathy (DPN) and post-herpetic neuralgia (PHN). These two conditions are distinct, pathophysiological states and, therefore, will be treated as two indications. In order for a general neuropathic indication to be granted, the sponsor must provide evidence that the underlying disease process is similar for DPN, PHN, and the pain of other neuropathic disorders and/or that the drug is effective for the neuropathic pain of all (or at least most) etiologies.

748 F. Supp. 2d at 46 (citing TX 200 at 4).

defendants claim was in error under Federal Rule of Evidence 403. These 111 exhibits were relevant to plaintiffs' allegations of RICO enterprises between Pfizer and two medical marketing firms.

Defendants objected strenuously to the admission of these exhibits during trial. (See, e.g., Docket Nos. 2604, 2631.) In response to Pfizer's objections, the Court required plaintiffs to explain how each document related to the RICO claims and why the document should be admitted. (Docket No. 2660.) After reviewing Kaiser's submission, the Court allowed the admission of documents, and also allowed Pfizer to introduce its own binder of documents, pursuant to Federal Rule of Evidence 106.

Pfizer also had an opportunity to make individual objections to any of the 111 exhibits that Kaiser sought to introduce. The Court noted that it expected Pfizer to make such objections:

> I'm assuming there might be parts that you'd move to strike or sanitize . . . . I'm going to allow [the documents] in short of your moving to strike certain sections of them. . . . [I]n other words, if there's a three-page email chain and they've only quoted from part of it, if you wanted to, I suppose I could strike the rest of it. But short of sanitizing them, I'm going to allow them in, subject to somebody in your team telling me something wasn't reference, because they put quotes from each one of them in the footnotes . . . which seemed pertinent.

(Trial Tr. vol. 16 at 9, Mar. 15, 2010.) Pfizer did not make any such individual objections or request any sanitization.

It is important to note that each of the documents admitted was authenticated and was a business record as defined by the rules of evidence. (Id. at 8.) Moreover, the exhibits were

relevant to an essential element of plaintiffs' case: the existence of a RICO enterprise. Pfizer's objection was premised on Rule 403, which states that "[a]lthough relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Pfizer's argument is that the documents would cause jury confusion because they were not introduced in connection with a witness's testimony.

As the Court noted during trial, plaintiffs provided context for these exhibits. Video depositions played during trial discussed Pfizer's relationships with the medical marketing firms, and the exhibits admitted document those relationships. (See id.) In addition, the Court took steps to avoid jury confusion as a result of the admission of these exhibits. Pursuant to Federal Rule of Evidence 1006, the parties were each allowed to provide the jury with a list of the documents they had admitted into evidence. In addition, both sides were permitted to identify important passages of each exhibit by using a colored sticky-note. The jury was instructed that the plaintiffs used green notes while the defendants used blue notes. (Id. at 10-11.) Plaintiffs also addressed the documents by showing them during their closing argument.

Courts that have excluded evidence on the basis of the risk

of jury confusion have often done so when the voluminous evidence offered was at best marginally related to the elements of the plaintiffs' claims. See, e.g., City of Long Beach v. Standard Oil Co. of Calif., 46 F.3d 929, 938 (9th Cir. 1995). The Court weighed the risk of jury confusion against the probative value of the evidence several times during the trial, and ruled under Rule 403 that the evidence was admissible. The Court finds that the admission of these exhibits was not a "manifest error of law" requiring a new trial under Fed. R. Civ. P. 59. The documents at issue here are central to plaintiffs' case, and the precautions taken by the Court to prevent jury confusion were sufficient.

C. Jury Instruction Regarding Kaiser's Premiums

During trial, the jury heard the following deposition testimony from Albert Carver, the Vice President of Pharmacy Strategy and Operations for Kaiser Foundation Health Plan:

> Q: If the cost of a prescription drug increases, would the premium then increase for the next period?
>
> A: Yes, that's correct.

(Carver Dep. Tr., 55-56 (played Mar. 22, 2010).) There was no other evidence regarding premiums for Kaiser members.

In Pfizer's closing argument, they argued "[T]o the extent that Kaiser paid more for sugar pills or paid for more Neurontin than it should have, that got passed on to the insureds, presumably years ago." (Trial Tr. vol. 20, 128, Mar. 23, 2010.)

Plaintiffs objected, and the Court instructed the jury: "[T]here's nothing in the record about whether or not the payment of premiums or increases might have compensated for that, so that would at this point be speculative." (Id. at 218.)

Defendants now argue that the Court's instruction to the jury constituted error. As background, the defendants did not request a jury instruction regarding the effect of premium payments on an injury or damages analysis (see Docket No. 2492), nor did they raise this as a legal issue in their trial brief (Docket No. 2502). Likewise, defendants did not argue in any of their five motions for judgment as a matter of law that Kaiser could not prove its injury due to increased premium payments for its members. (See Docket Nos. 2668, 2670, 2672, 2674, 2676.)

In Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481 (1968), the Supreme Court disallowed a defense by antitrust defendants who claimed that plaintiff was not entitled to damages for costs passed on to its customers. Id. at 488-94. There were several important policy concerns buttressing the Hanover Shoe conclusion. First, the Court noted that "[n]ormally the impact of a single change in the relevant conditions cannot be measured after the fact," and that "[e]qually difficult to determine . . . is what effect a change in a company's price will have on its total sales." Id. at 492-93. The Court also foresaw significant trial management difficulties if every

treble-damage action required complex "pass-on" proof. Id. at 493. Finally, the Court expressed its concern that the "pass-on" theory would require those who are indirectly damaged to bring suit themselves.

> These ultimate consumers, in today's case the buyers of single pairs of shoes, would have only a tiny stake in a lawsuit and little interest in attempting a class action. In consequence, those who violate the antitrust laws by price fixing or monopolizing would retain the fruits of their illegality because no one was available who would bring suit against them.

Id. at 494.

The Seventh Circuit has held that the Hanover Shoe "approach prevails throughout the law," including in the context of a RICO claim. Carter v. Berger, 777 F.2d 1173, 1175 (7th Cir. 1985). The Second Circuit has also recognized the extension to RICO claims of the principle that the directly injured party is the proper party to seek redress from a wrongdoer. Rand v. Anaconda-Ericsson, Inc., 794 F.2d 843, 849 (2d Cir. 1986). The Eastern District of New York has provided a useful analysis of the "passing on" defense in the context of a RICO claim brought by an insurance company. See Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris, Inc., 138 F. Supp. 2d 357 (E.D.N.Y. 2001). In Philip Morris, the defendants argued that the plaintiffs had not suffered an injury because increased costs are passed on to subscribers through premiums. The court, however, held that under Hanover Shoe and its progeny, the "pass on" defense was unavailable to defendants. 138 F. Supp. 2d at 361-65.

In support of their argument, defendants rely on Ironworkers Local Union 68 v. AstraZeneca Pharms., LP, 634 F.3d 1352, (11th Cir. 2011), issued after the Kaiser trial, in which the district court had previously dismissed a RICO class action involving off-label Seroquel prescriptions. See Ironworkers Local Union No. 68 v. AstraZeneca Pharms. LP, 585 F. Supp. 2d 1339 (M.D. Fla. 2008). On appeal, the Eleventh Circuit affirmed[3], stating:

> The insurers, under the terms of their insurance policies, consciously exposed themselves to pay for all prescriptions of Seroquel, including those that were medically unnecessary or inappropriate—even if such prescriptions were birthed by fraud. In light of such broad exposure, conventionally a rational insurer would have charged its enrollees higher premiums than it would have if its policies offered more limited prescription drug coverage. These higher premiums, in turn, would compensate the insurer for its increased number of prescription payments, including payments for prescriptions that were medically unnecessary or inappropriate. Moreover, to the extent the insurer's payments for medically unnecessary or inappropriate prescriptions exceeded the premiums charged, only actuarial errors would be to blame. Here, the insurers plead no facts to suggest that they somehow established premiums in a manner distinct from this conventional understanding; consequently, the district court had to dismiss their claims because they failed to allege plausibly that AstraZeneca's false representations caused them to suffer economic injury.

634 F.3d at 1360. The court also noted that plaintiffs had asserted no cognizable fraud-by-omission claim against AstraZeneca. Id. at 1368 n.33. The Eleventh Circuit's discussion of the "pass on" theory in Ironworkers did not cite to

[3] The Eleventh Circuit's opinion was issued on March 11, 2011, several months after this Court issued its Findings of Fact and Conclusions of law.

Hanover Shoe, or to any other authority for its conclusion that the insurance company had not sufficiently pled any injury.

The instant case is distinguishable from the Ironworkers case, as this Court did find that Kaiser had a viable fraud-by-omission claim. The theory was presented to the jury at trial, and the jury found for Kaiser on the RICO claims involving mail and wire fraud. At the summary judgment stage, this Court wrote:

> The Coordinated Plaintiffs [including Kaiser] have presented evidence that Defendants communicated half truths that are actionable under the RICO statute. 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. 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.

In re Neurontin Mktg. & Sales Practices Litig., 677 F. Supp. 2d 479, 492 (D. Mass. 2010).

Accordingly, this Court will take a pass on defendants' Hail Mary pass-on theory regarding increased premiums because there was a viable fraud-by-omission claim, this theory was poorly developed legally and factually by defendants, and the Eleventh

Circuit in Ironworkers did not consider the important policies underpinning Hanover Shoe.

II. ORDER

The Court **DENIES** defendants' Motion for New Trial and to Re-Open Evidence or, Alternatively, to Alter or Amend Judgment (Docket No. 3362).

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