UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING AND SALES PRACTICES LITIGATION	MDL NO. 1629
THIS DOCUMENT RELATES TO:	CIVIL ACTION NO. 04-cv-10981-PBS
ALL SALES & MARKETING ACTIONS	

MEMORANDUM AND ORDER

May 17, 2011

Saris, U.S.D.J.

In this proposed nationwide class action, plaintiffs, consumers and third party payors ("TPPs") who paid for a prescription for the drug Neurontin, allege that defendants Warner-Lambert and Pfizer, the manufacturers of Neurontin, systematically and knowingly engaged in a fraudulent campaign to market and sell Neurontin for treatment of "off-label" indications – conditions for which the Food and Drug Administration ("FDA") had not approved Neurontin – even though defendants knew Neurontin was not effective for those conditions. The Court denied plaintiffs' renewed motion for class certification on May 13, 2009. In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 257 F.R.D. 315 (D. Mass. 2009). Plaintiffs moved for reconsideration of that decision, only as to the TPP bipolar and mood disorder subclass (Docket No. 1796). (See also Hr'g Tr. 5, May 4, 2011.)

As a threshold issue, defendants argue that plaintiffs' motion for reconsideration of the Court's denial of class certification is now moot, as the Court recently issued an opinion allowing defendants' motion for summary judgment as to all class TPP plaintiffs. See In re Neurontin Mktg. & Sales Practices Litig., __ F. Supp. 2d __, 2010 WL 5037005 (D. Mass. Dec. 10, 2010). As there are no adequate class representatives remaining, defendants contend that the Court need not decide plaintiffs' motion for reconsideration. See Cowen v. Bank United of Texas, FSB, 70 F.3d 937, 941-42 (7th Cir. 1995) (holding that the effect of dismissing the class representatives' case is to moot the question whether to certify the suit as a class action unless the lawyers for the class manage to find another representative). Plaintiffs concede that in order to prevail on their motion for reconsideration of the Court's denial of class certification, the Court must also reconsider its December 2010 decision on defendants' motion for summary judgment.

After a review of the voluminous record and multiple hearings in this multi-district litigation, the Court **DENIES** plaintiffs' motion.

I. DISCUSSION

In the Court's May 2009 denial of class certification, I wrote, "TPPs exhibit a great degree of heterogeneity" in terms of their placement of Neurontin on drug formularies. In re

Neurontin, 257 F.R.D. at 332. In support of defendants' opposition to the motion for class certification, their expert, Dr. Gregory K. Bell, submitted a report to the Court that focused heavily on the differences among TPP formularies, describing their varying use of preferred and nonpreferred tiers, prior authorization, step therapy and other tools to control the use of pharmaceutical products by beneficiaries. Id. (citing Bell Decl. ¶¶ 53-54). Relying on Dr. Bell's report, the Court concluded

> Given this background information, formularies, and hence the decision making of the P & T Committees that created the formularies, become central to plaintiffs' claims. To prevail, plaintiffs must prove that defendants' fraudulent omissions or representations caused these committees to approve the use and reimbursement of Neurontin for off-label indications in a manner that was different from what would have occurred absent the alleged fraudulent marketing.

Id. at 333.

Submissions related to this motion for reconsideration, along with plaintiffs' submissions opposing defendants' motion for summary judgment (Docket No. 1689) and the evidence produced in the recent Kaiser trial, which is part of this multi-district litigation, have presented a more expansive record and have provided the Court with a more nuanced understanding of the placement of Neurontin on drug formularies by TPPs. It is now undisputed that virtually every TPP initially placed Neurontin on its drug formulary with few restrictions in the mid-1990s in order to facilitate access to the drug for patients with epilepsy, which was Neurontin's sole on-label indication after it

received FDA approval in 1993. See Kaiser Foundation Health Plan, Inc. v. Pfizer, Inc., 748 F. Supp. 2d 34, 40 (D. Mass. 2010). The Court discussed the need for access to epilepsy drugs in its recent opinion on defendants' motion for summary judgment:

> 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.

In re Neurontin Mktg. & Sales Practices Litig., 677 F. Supp. 2d 479, 488 n.4 (D. Mass. 2010). Contrary to my earlier understanding from the not-so-clear-as-a Bell report, the TPPs exhibited homogeneity in their initial decisions to place Neurontin on the formulary in the mid-1990s.

During the recent trial, Kaiser Foundation Health Plan presented evidence that it adopted a hands-on approach to managing the prescribing of Neurontin after it was placed on the drug formulary. Kaiser regularly reviews drugs on its formulary and produces drug monographs for off-label indications for which a drug might be used. Kaiser relied directly on misrepresentations made by Pfizer in its formulations of these drug monographs. In this case, Kaiser also engaged in a successful information campaign to reduce off-label prescribing of Neurontin to its members once it learned of defendants'

fraudulent marketing scheme. See Kaiser, 748 F. Supp. 2d at 39-40, 66-67. Both the Court and the jury found that, with respect to the Kaiser case, defendants had engaged in fraudulent marketing of Neurontin for certain off-label indications. Compelling evidence of fraudulent marketing was with respect to bipolar disorder. Id.

The question, then, is whether Kaiser was an outlier or if it was typical of other TPPs. The plaintiffs argue that the typical TPP takes a hands-off approach, stating, "When prescribed by a licensed physician, virtually every TPP in the country reimburses for [Neurontin], and always has, never even knowing the condition for which it was prescribed." (Pl.'s Mot. for Reconsideration at 16 (citing Expert Report of Kimberly P. McDonough).) For example, Aetna, a large TPP, chose not to "manage," or monitor, prescribing of Neurontin at all once it was placed on the drug formulary. See In re Neurontin, 677 F. Supp. 2d at 487-88. Aetna produced no evidence that it relied on any misrepresentations when it made reimbursements regarding the use of Neurontin for the treatment of bipolar disorder. Many other TPPs, such as the Guardian Life Insurance Company of America and Blue Cross Blue Shield of Louisiana, relied on a pharmacy benefit manager ("PBM") to manage their drug formularies. Similarly, there is no evidence in the record that PBMs typically took a proactive approach to managing off-label prescriptions of Neurontin, or relied on any misrepresentations made by Pfizer.

Defendants' expert, Dr. Gregory Bell, initially claimed that "there was variation in how TPPs chose to restrict - or encourage (even after this litigation was filed) - the prescribing of Neurontin for specific off-label uses." (Bell Decl. ¶ 8 (Docket No. 1175, Ex. 35).) He relied in large part on generalities in the prescription drug market as opposed to specifics about the anticonvulsant class of drugs. (See, e.g., id. ¶ 31 ("The insurance companies have a variety of tools at their disposal to manage prescription benefits and there exists considerable variability in the net reimbursement cost of prescriptions for specific products, such as Neurontin, across TPPs and over time."); id. ¶ 45 ("There is substantial diversity . . . regarding how TPPs use formularies to influence physicians' prescribing behavior and how that may have affected the prescribing of Neurontin.") (emphasis added); id. ¶ 48 ("It is thus apparent that formulary design varies among TPPs and their clients. As a result, Neurontin's position on those formularies can be expected to be different.") (emphasis added).) Significantly, the examples that Dr. Bell uses of restrictions placed on Neurontin by TPPs are largely outside the class period. (See id. ¶ 59.) Moreover, he has never dealt with the specific evidence in this case.

Accordingly, based on the broader record, the Court finds, for purposes of class certification, that the greater weight of

the evidence is that the typical TPP put Neurontin on its formulary without restrictions due to its use as an anti-convulsant drug, and subsequently did not actively manage Neurontin during the class period, or directly rely on any Pfizer misrepresentations in making formulary or drug management decisions. See In re Initial Public Offering Secs. Litig., 471 F.3d 24, 41 (2d Cir. 2006) (holding that a district judge may certify a class only after resolving factual disputes to make determinations as to whether each of the Rule 23 requirements has been met). Thus, with respect to liability, the Court finds that the common issues predominate over individual TPP issues. Kaiser represents the atypical situation.

Nonetheless, the question remains whether plaintiffs can satisfy Rule 23(b)(3)'s predominance requirement with respect to damages, and whether a nationwide class of TPPs is a superior way of managing the litigation. Fed. R. Civ. P. 23(b)(3) ("A class action may be maintained if Rule 23(a) is satisfied and if . . . the court finds . . . that a class action is superior to other methods of adjudication for fairness and efficiency."); see also UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 131-32 (2d Cir. 2010) (noting that, "[i]n order to pursue their claims as a class rather than as individual plaintiffs," a TPP class must be able to prove the damages suffered by "generalized proof"); cf. Hemi Group, LLC v. City of New York, 130 S. Ct. 983, 990 (2010)

(rejecting causation where the theory of liability relied on the independent actions of third parties).

Plaintiffs have wisely narrowed the requested class to the bipolar indication, their strongest case. There was no reliable scientific evidence to support the use of Neurontin to treat bipolar disorder and attenuated reasons for Pfizer to detail psychiatrists to sell Neurontin. See Kaiser, 748 F. Supp. 2d at 73-74. In the case of the TPP subclass here, because the TPP plaintiffs agree that they did not rely directly on Pfizer misrepresentations, they would need to show that the prescribing physicians relied on fraudulent communications or suppression of evidence by Pfizer regarding the negative clinical trials showing Neurontin to be ineffective in treating bipolar disorder. Class plaintiffs must also show how much damage was caused by such reliance.

Aggregate proof has generally been held not to be sufficient to prove causation. See Eli Lilly, 620 F.3d at 133-36. In Lilly, TPP plaintiffs argued that defendant's misrepresentations caused doctors to prescribe drug more often for off-label indications, which in turn caused the TPPs to pay for more units of that drug. The Second Circuit wrote

> The nature of prescriptions, however, means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof. Plaintiffs argue that "the ultimate source for the information on which doctors based their prescribing decisions was Lilly and its consistent,

> pervasive marketing plan." Lilly was not, however, the only source of information on which doctors based prescribing decisions. An individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by Lilly.
>
> Furthermore, additional variables interfere further with plaintiffs' theory of causation. As the district court noted, the evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations, and thus would not have written "excess" prescriptions as identified by the plaintiffs. This makes general proof of but-for causation impossible.

Id. at 135.

In attempting to meet their burden, plaintiffs rely heavily on Dr. Meredith Rosenthal's analysis, which 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. She concluded that 99.4% of bipolar prescriptions resulted from Pfizer's off-label promotion. At the instruction of plaintiffs' attorneys, Dr. Rosenthal assumed that all off-label promotion was fraudulent. Her testimony demonstrates the likelihood of injury to TPPs from fraudulent promotion of the use of Neurontin to treat bipolar disorder. But, it does not suffice to demonstrate the extent of harm caused by the fraud, as opposed to run-of-the-mill off-label detailing.

The record shows that treating physicians varied widely in their reasons for prescribing Neurontin. Doctors who were

deposed during the MDL litigation testified repeatedly that they relied on their own clinical experience or the clinical experience of trusted colleagues, rather than Pfizer's misleading advertising, skewing of information in medical journals, suppression of negative results of clinical trials, or Dear Doctor letters distributed by the defendants during details. While some of this testimony is not entirely credible, particularly from heavily detailed doctors, it is significant in light of the Court's previous rulings in this case. In the Court's December 2010 summary judgment opinion, the Court differentiated between off-label promotion and fraudulent promotion, finding in cases where the TPPs did not directly rely on misrepresentations, "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." 2010 WL 51037005, at *9. There, the Court found that evidence that a doctor was detailed by a Pfizer sales representative was not sufficient to survive summary judgment, even when the doctor's Neurontin prescriptions increased after the detailing visit. The two consumer plaintiffs who survived summary judgment were prescribed Neurontin by physicians who received "Dear Doctor" letters that included half-truths and misrepresentations about off-label uses of Neurontin. In re Neurontin, 2010 WL 5037005, at *9.

Thus, in order to differentiate those prescriptions that

were caused by fraud from those that were attributable to non-fraudulent off-label marketing or other independent factors, a factfinder would have to perform a granular doctor-by-doctor analysis. This would be unmanageable. See Fed. R. Civ. P. 23(b)(3)(D) (stating that a district court must consider "the likely difficulties in managing a class action" in making a certification decision); see also Eli Lilly, 620 F.3d at 135 (rejecting causation theory of the putative class because "[a]n individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa are all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by Lilly"); McLaughlin v. Am. Tobacco Co., 522 F.3d 215, 223 (2d Cir. 2008) (in a putative class action by smokers of "light" cigarettes against tobacco company, the court held that because each individual consumer might have purchased light cigarettes for any number of reasons other than the purported health claim, individualized proof was necessary to prove causation).

The question posed by plaintiffs' motion, however, is very difficult, both because Pfizer did engage in a nationwide fraudulent marketing campaign and because there is no reliable scientific evidence to support the use of Neurontin to treat

bipolar disorder.[1] Plaintiffs have proved that it is more likely than not likely that they were harmed by Pfizer's conduct because many doctors would not have prescribed Neurontin for bipolar disorder if they had known there was no reliable scientific evidence supporting its use.

Still, complex issues related to calculating damages make the class unmanageable. The TPP subclass, even for bipolar and mood disorders, cannot satisfy Rule 23(b)(3)'s "superiority" requirement, and the Court will not reconsider its denial of class certification to the TPP bipolar and mood disorder subclass.

II. ORDER

Having found that plaintiffs cannot satisfy the Rule 23(b)(3) superiority requirement, and in light of the fact that there are no remaining named class representatives with viable claims, the Court **DENIES** the motion for reconsideration (Docket No. 1796). The parties shall propose a form of judgment within two weeks.

---

[1] In post-judgment motions in the Kaiser case, defendants emphasize a 1999 study by Dr. Atul Pande, which suggested that Neurontin was an effective treatment for social phobia (a condition that is distinct from, but often co-morbid with, bipolar disorder), in support of their argument that Pfizer had non-fraudulent reasons for detailing psychiatrists. (See Docket No. 3365 at 15.) However, there is no evidence that a significant number of the prescriptions written by psychiatrists were for "social phobia."

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