UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING AND SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO:	CIVIL ACTION NO. 04-cv-10981-PBS
MARY DORSEY	
v.	
PFIZER, INC., et al. Case No. 05-cv-10639-PBS	

MEMORANDUM AND ORDER

August 10, 2010

Saris, U.S.D.J.

Plaintiff Mary Dorsey brings this case against Pfizer, Inc., alleging that she was injured by defendants' drug Neurontin, and that defendants failed to adequately warn of potential adverse effects connected to ingestion of the drug. She argues that her injury was connected to defendants' illegal off-label marketing of Neurontin. Defendants have moved for summary judgment on three grounds: (1) Plaintiff does not have a causation expert who will testify that Neurontin specifically caused her injuries; (2) plaintiff has conceded that the side effects from which she suffered were the subject of warnings on Neurontin's label; and (3) the plaintiff does not have any proximate cause evidence that

either she or her prescribing physicians would have done anything differently if additional warnings had been listed on the label.

After a review of the record and a hearing, Pfizer's motion for summary judgment [docket no. 2798] is **ALLOWED**.

I. BACKGROUND

When all reasonable inferences are drawn in favor of the non-moving party, the record contains the following relevant facts, which, unless noted, are undisputed.

Plaintiff Mary Dorsey has had a difficult and complex medical history, beginning in 1997 when she suffered from a stroke. Following her stroke in June 1997, she suffered from multiple medical ailments, and her physicians believed that she was experiencing non-epileptic seizures. (Dorsey Aff. ¶ 5.) Mrs. Dorsey was initially prescribed Neurontin, an anti-epileptic drug developed by Warner Lambert Company, by Dr. Jonathan Alpert in or about 1999. (Id. ¶ 2.)

Neurontin has been approved by the FDA for the adjunctive treatment of epilepsy. Plaintiff claims that she was prescribed Neurontin off-label, which defendants do not appear to dispute. However, the record is not clear which medical condition Neurontin was prescribed to treat. During 2002 and 2003, while still taking Neurontin, plaintiff began to experience more seizure-like symptoms. She was constantly lethargic and often experienced "black-outs." (Id. ¶ 8.) In September 2002,

plaintiff suffered a second stroke. (Id. ¶ 13.)

She continued to suffer from severe anxiety, depression and seizures, which plaintiff alleges were black-outs. (Id. ¶ 14.) In early 2003, plaintiff blacked-out while in her therapist's office and was taken to the hospital. (Id. ¶ 9.) She was admitted to the hospital due to her symptoms, which included fainting spells and increased difficulty finding words. (Id. ¶ 12.) Plaintiff's husband and family members recall that during 2002 and 2003, she was "like a zombie." (Id. ¶ 11.) At this point, plaintiff was on 16 medications. (Cheffo Decl., Ex. G.)

In May 2003, plaintiff consulted a neurologist, Dr. Jeremy D. Schmahmann, who told her she had not been experiencing seizures and that she was in fact "over-medicated." (Perry Aff., Ex. 4.) Dr. Schmahmann reduced plaintiff's medication regimen by taking her off both Neurontin and a drug called Klonopin. (Perry Aff., Ex. 6 at 7.) She experienced significant improvement and no longer suffered seizure-like symptoms or unresponsiveness. However, in April 2006, plaintiff was again hospitalized after increased communication difficulties, problems with walking, and frequent falls. (Cheffo Decl., Ex. G.)

During Dr. Schmahmann's first deposition in this case, he was asked "Had you concluded by February 11, 2004 that the panoply of drugs that included Neurontin [along with Klonopin and Lithium] had contributed to cause [plaintiff's] symptoms?" The doctor responded "Yes." (Perry Aff., Ex. 10 at 47.) In

plaintiff's affidavit, she states:

> Since this case began, I have learned that the symptoms I suffered from Neurontin use were known risks associated with the drug. As I was being prescribed Neurontin off-label, however, it never occurred to me at the time that I took Neurontin to heed any of the warnings issued on the labels of the drug. I relied upon the drug company's good faith, believing that they would not illegally market the drug.

(Dorsey Aff. ¶ 18.)

II. DISCUSSION

A. Legal Standard

Summary judgment is appropriate when "'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" Barbour v. Dynamics Research Corp., 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). To succeed on a motion for summary judgment, "the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir. 1990); see also Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986).

Once the moving party has made such a showing, the burden shifts to the non-moving party, who "'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial.'" Barbour, 63 F.3d at 37 (quoting Anderson v. Liberty Lobby, Inc.,

477 U.S. 242, 256 (1986)). The non-moving party must establish that there is "sufficient evidence favoring [its position] for a jury to return a verdict [in its favor]. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (internal citations omitted). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36 (citation omitted).

B. Causation

Defendants argue that summary judgment is appropriate because the plaintiff does not have an expert who will testify that Neurontin specifically caused her symptoms. Plaintiff responds that she has designated her prescribing and treating physicians as causation experts, and relies most heavily on Dr. Schmahmann's opinions.

Under Massachusetts law, a plaintiff seeking to establish causation in a case where an injury may be attributable to multiple causes must show that the defendant's conduct was a "substantial contributing factor" to the plaintiff's injury. See Matsuyama v. Birnbaum, 452 Mass. 1, 30-31 (2008) (approving the use of the "substantial contributing factor" test for causation "in cases in which damage has multiple causes") (citing O'Connor v. Raymark Indus., 401 Mass. 586, 587 (1988)).

In support of their argument on this point, defendants direct the Court to testimony given in Dr. Schmahmann's second deposition. In that deposition, Dr. Schmahmann's again stated that he "thought that the polypharmacy was producing lethargy and disorientation." (Cheffo Decl., Ex. F at 64 (Schmahmann Dep.).) According to Dr. Schmahmann, polypharmacy is "the use of multiple medications in the same patient." During that deposition, defendant's counsel engaged in the following line of questioning:

Defense Counsel:	So you're tapering her Neurontin because you don't believe that she has the seizure indication that would require her to take an anticonvulsant?
Dr. Schmahmann:	That's correct.
Defense Counsel:	You are not tapering her off Neurontin because you believe Neurontin had a direct causal impact on her condition at that time?
Dr. Schmahmann:	My understanding was that the records of Falmouth Hospital were fairly straightforward. When they stopped Clonazepam, she got better.

(Id. at 66.) When asked directly whether he believed Neurontin was a substantial contributing cause of the plaintiff's side effects, Dr. Schmahmann stated: "[W]hen she had her trouble at Falmouth Hospital with all that lethargy and Klonopin was discontinued and she improved, then I would have to think that, based on that evidence, that the medication that caused her the most trouble was Clonazepam." (Id. at 74.) Plaintiff's counsel pressed the doctor during the deposition about whether Neurontin was a substantial factor in the plaintiff's injury, and Dr. Schmahmann responded: "[Y]ou're putting me into a place I'm not

willing to go. If you're going to use my testimony to say that Neurontin did this, then I'm not going to let you make me do that." (Id. at 93.)

Because the witness upon whom plaintiff relies most heavily to prove specific causation has stated that he does not believe Neurontin was the source of plaintiff's symptoms, summary judgment is appropriate on this record.

C. Neurontin Label

Plaintiff's claims are based on an alleged failure to warn of risks associated with Neurontin. Defendants argue that these claims are governed by the learned intermediary rule, which provides that "a prescription drug manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer." Cottam v. CVS Pharmacy, 436 Mass. 316, 321 (2002) (citations omitted). Under Massachusetts law, once a plaintiff establishes that there is a triable issue of fact concerning defendant's failure to warn of a nonobvious risk, a rebuttable presumption arises that the physician would have heeded an adequate warning from the manufacturer. Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1st Cir. 1992). At that point, the burden of proof shifts to the defendant, who has the opportunity to rebut that presumption. "Where the manufacturer fails to provide the physician with an adequate warning, courts have held that the manufacturer may

still be shielded from liability if it can show that the prescribing physician would not have heeded an adequate warning." Id. at 80.

In this case, however, plaintiff concedes that many of her symptoms were listed in a warning on Neurontin's label during all relevant time periods. See Dorsey Aff. ¶ 18 ("Since this case began, I have learned that the symptoms I suffered from Neurontin use were known risks associated with the drug."); Pl.'s Opp. Mot. For Summ. J. at 3 ("Known side effects of Neurontin contained in the PDR include somnolence, sedation, depression and dizziness.").) Although Neurontin's label does mention central nervous system depression as a possible side effect, it does not specifically warn that Neurontin might cause "black-outs." However, plaintiff does not provide any general or specific causation testimony that Neurontin causes black-outs or fainting.

D. Proximate Causation

Defendants' final basis on which they seeks summary judgment is that plaintiff has not presented evidence of proximate causation because there is no evidence that her prescribing or treating physicians relied on any misrepresentation by Pfizer. Moreover, they argue that plaintiff's prescribing or treating physicians have testified that, if they had known defendant was engaged in an off-label marketing scheme, they would not have prescribed Neurontin to the plaintiff. (See, e.g., Cheffo Decl.,

Ex. D at 44 (Alpert Dep.) (stating that he believes his prescribing of Neurontin to the plaintiff was completely appropriate); id. at 52 (stating that he cannot recall meeting with any Pfizer representative to discuss Neurontin prior to prescribing it to the plaintiff).)

Doctors are permitted to prescribe drugs off-label. (See United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) ("Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA.") (citing Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001)). Accordingly, plaintiff must prove that the doctors prescribed the medication as a result of a failure to warn or a misrepresentation. On the record currently before the Court, plaintiff cannot meet that burden. Plaintiff has not presented any evidence of proximate causation and, accordingly, summary judgment is appropriate.

E. Plaintiff's Remaining Claims

Plaintiff's remaining claims[1] suffer from the same flaws as her failure-to-warn claims: there is no evidence in the record to

[1] In addition to products liability claims, plaintiff asserts claims for violation of the Massachusetts Consumer Protection Statute; breach of express warranty; breach of implied warranty; fraud, misrepresentation and deceit; negligence; unjust enrichment; intentional infliction of emotional distress; and loss of consortium. (Docket No. 1, Case No. 05-cv-10639.)

support her claim that Neurontin specifically caused her injuries, or that her doctors would not have prescribed Neurontin if they had known of the off-label marketing scheme.

III. ORDER

The motion for summary judgment is **ALLOWED**.

/s/ PATTI B. SARIS
PATTI B. SARIS
UNITED STATES DISTRICT JUDGE