

Karambelas v Pfizer, Inc.
2018 NY Slip Op 30738(U)
April 25, 2018
Supreme Court, New York County
Docket Number: 150334/16
Judge: Kathryn E. Freed
Cases posted with a "30000" identifier, i.e., 2013 NY Slip Op <u>30001</u> (U), are republished from various New York State and local government sources, including the New York State Unified Court System's eCourts Service.
This opinion is uncorrected and not selected for official publication.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: IAS PART 2

-----X
EVELYN KARAMBELAS,

Plaintiff,

-against-

PFIZER, INC.,

Defendant.
-----X

DECISION AND ORDER

Index No.: 150334/16

Mot. Seq. 002

HON. KATHRYN E. FREED, J.:

RECITATION, AS REQUIRED BY CPLR 2219 (a), OF THE PAPERS CONSIDERED IN THE REVIEW OF THIS MOTION:

PAPERS

NUMBERED

NOTICE OF MOTION AND AFFIDAVIT ANNEXED.....	1-2(Exs. A-F)
PLAINTIFF'S ANSWERING (OPPOSITION) AFFIDAVITS (2).....	3(Exs.A-C)
PFIZER REPLY AFFIDAVIT	4(Exs. G-J)
PFIZER MEMORANDUM OF LAW (moving and reply).....	5-6

UPON THE FOREGOING CITED PAPERS, THIS DECISION/ORDER ON THE MOTION IS AS FOLLOWS:

In this action seeking damages for negligence, breach of contract, and strict products liability, plaintiff Evelyn Karambelas seeks to recover for injuries she allegedly suffered due to her ingestion of the drug Lyrica in 2015. Defendant Pfizer, Inc., the manufacturer of the drug, now moves, pursuant to CPLR 3212, for summary judgment dismissing the complaint. After oral argument, and after a review of the parties' motion papers and the relevant statutes and case law, the motion is **denied**.

Factual Background:

There is no dispute that, in 2015, plaintiff was prescribed the medication Lyrica for neuropathic pain which resulted from previous cancer treatment. Plaintiff took Lyrica for about a month. In an interrogatory answer, plaintiff stated that she suffered the following ailments and conditions as a result of her ingestion of Lyrica: (1) exacerbation of a pre-existing thyroid condition; (2) eye tearing; (3) long term puffiness of the eyes; (4) acute conjunctivitis; (5) nuclear sclerosis; (6) dry eye syndrome; and (7) blurred vision resulting in multiple changes of eyeglass prescriptions. Plaintiff also asserted that she suffered a gastric ulcer, which was revealed through endoscopy in July 2015, as well as multiple gastric polyps and anemia. Plaintiff further asserted that she underwent a second endoscopy, on September 24, 2015, which revealed erthematous mucosa in the antrum, multiple gastric polyps, and bleeding from the stomach.¹

At her deposition, plaintiff testified that she took Aleve for pain she believed was caused by taking Lyrica. She also believed that Aleve caused her pre-existing ulcers to bleed. It is undisputed that plaintiff was treated for cancer and neuropathy by Dr. Chau Dang, who was deposed in this action and who prescribed Lyrica for plaintiff.

Legal Conclusions:

“The proponent of a summary judgment motion must make a prima facie showing of entitlement to judgment as a matter of law, tendering sufficient evidence to eliminate any material issues of fact from the case. Failure to make such showing requires denial of the motion, regardless

¹ A review of the documents filed with NYSCEF reflects that no bill of particulars was served in this case. The parties rely upon plaintiff’s interrogatory response as the source of her complaints about the injuries which she alleges were caused by her treatment with Lyrica.

of the sufficiency of the opposing papers” (*Santiago v Filstein*, 35 AD3d 184, 185–86 [1st Dept 2006] [internal quotation marks and citation omitted]). The burden then shifts to the opponent to “present evidentiary facts in admissible form sufficient to raise a genuine, triable issue of fact” (*Mazurek v Metropolitan Museum of Art*, 27 AD3d 227, 228 [1st Dept 2006]). If there is any doubt as to the existence of a triable fact, the motion must be denied (*see Rotuba Extruders v Ceppos*, 46 NY2d 223, 231 [1978]).

Plaintiff raises threshold issues, including the argument that the summary judgment motion is untimely because the 60-day deadline for making the motion fell on Saturday, and defendant did not make the motion until the following Monday. While defendant could have moved earlier, it was not obligated to do so (*see* 248 Siegel's Prac Rev 1 [discussing Judiciary Law § 282 and General Construction Law § 25]; *see Tafsiou v Arms Acres*, 95 AD3d 995, 996 [2d Dept 2012]).

Plaintiff also argues that the motion may not be heard because defendant did not include the answer with its moving papers. In addressing such a circumstance, the Appellate Division, First Department has stated that:

“Although CPLR 3212 (b) requires that a motion for summary judgment be supported by copies of the pleadings, the court has discretion to overlook the procedural defect of missing pleadings when the record is sufficiently complete. The record is sufficiently complete when, although the movant has not attached all of the pleadings to the motion, a complete set of the papers is available from the materials submitted”

(*Washington Realty Owners, LLC v 260 Wash. St., LLC*, 105 AD3d 675, 675 [1st Dept 2013] [internal quotation marks and citation omitted]). Since the answer has been electronically filed with the court (NYSCEF document No. 3), and was provided submitted in reply, this Court may consider the motion (*see id.*). To the extent that plaintiff argues that to permit defendant to provide the

answer in reply offends due process, she ignores that she was served with the answer and, thereby, apprised of its content, and also has access to this Court's e-filing system.

Plaintiff also submits an affidavit in which she objects to having her deposition testimony considered because, she avers, defendant did not provide a copy of plaintiff's transcript to her, and the transcripts are not signed.

"CPLR 3116 (a) provides that a deposition shall be submitted to the witness who can make changes. The witness must then sign the deposition under oath. If the witness fails to sign and return the deposition within 60 days, it may be used as fully as though signed. A failure to comply with CPLR 3116 (a) results in a party being unable to use the transcript pursuant to CPLR 3117. It is the burden of the party proffering the deposition transcript to establish compliance with CPLR 3116 (a)"

(*Ramirez v Willow Ridge Country Club, Inc.*, 84 AD3d 452, 453 [1st Dept 2011] [internal citations omitted]). Defendant has submitted a letter which indicates that a CD with a copy of plaintiff's transcript testimony was forwarded to plaintiff's counsel well over 60 days before plaintiff filed the note of issue, certifying that discovery was complete (*Rosenblatt v St. George Health & Racquetball Assoc., LLC*, 119 AD3d 45, 51-52 [2d Dept 2014] [reply evidence of compliance with CPLR 3116 (a) was in direct response to opposition allegations and motion should have been resolved on the merits]). Furthermore, plaintiff does not challenge the accuracy of her transcript (*see Franco v Rolling Frito-Lay Sales, Ltd.*, 103 AD3d 543, 543 [1st Dept 2013] [plaintiff did not challenge accuracy of certified transcript]). Plaintiff ignores that she has also submitted portions of Dr. Dang's transcript. Furthermore, both plaintiff and Dr. Dang's respective transcripts reflect that the witnesses were sworn (*see Rosenblatt*, 119 AD3d at 54), and thus the transcripts will be considered here.

With respect to the merits of the case, both sides agree that the issue is the sufficiency of the warning that defendant provided to plaintiff's prescribing physician, Dr. Dang, about Lyrica. No

matter the theory of liability asserted, such as strict liability or negligence, ultimately, “[t]o succeed on [her] failure-to-warn claim, [a] plaintiff [is] required to prove that the product did not contain adequate warnings and that the inadequacy of those warnings was the proximate cause of the injuries” (*Mulhall v Hannafin*, 45 AD3d 55, 58 [1st Dept 2007]). “Although a prescription drug is by its nature an inherently unsafe product and would in the usual case impute strict liability to its manufacturer, a defense is provided against such liability when the drug is ‘properly prepared, and accompanied by proper directions and warnings’” (*Martin v Hacker*, 83 NY2d 1, 8 [1993], quoting *Wolfgruber v Upjohn Co.*, 72 AD2d 59, 61 [4th Dept 1979], *affd* 52 NY2d 768 [1980] [quoting Restatement (Second) of Torts § 402A, comment k, remaining citations omitted]). “Therefore, even though its side effects may cause injury, a prescribed drug, accompanied by adequate warnings, is ‘not defective, nor is it unreasonably dangerous’” (*Martin*, 83 NY2d at 8, quoting *Wolfgruber*, 72 AD2d at 61).

A pharmaceutical manufacturer’s duty to warn of the known risks of a prescription drug runs to the prescribing medical professional, not to the patient (*Martin*, 83 NY2d at 9 [“duty to caution against a drug’s side effects is fulfilled by giving adequate warning through the prescribing physician”]; *Mulhall*, 45 AD3d at 58 [same]). “The manufacturer’s duty is to warn of *all* potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist (*Martin*, 83 NY2d at 8 [emphasis added]; *Glucksman v Halsey Drug Co., Inc.*, 160 AD2d 305, 307 [1st Dept 1990] [same]).

Although usually a fact question, the adequacy of the warning provided may be determined as a matter of law (*Martin*, 83 NY2d at 10). In determining whether a warning is adequate, a court must consider “whether the warning is accurate, clear, consistent on its face, and whether it portrays

with sufficient intensity the risk involved in taking the drug” (*id.* at 10-11). A warning is adequate, as a matter of law, “if it provides specific detailed information on the risks of the drug,” and is “correct, fully descriptive and complete” and “direct, unequivocal and sufficiently forceful to convey the risk” (*id.*).

On summary judgment, if the defendant demonstrates that it adequately warned the prescribing physician of all of the known risks associated with the medicine, the burden then shifts to plaintiff to raise a fact issue about the warning’s adequacy (*see Mulhall*, 45 AD3d at 59 [“once [defendant] met its threshold burden of showing it adequately warned prescribing physicians of all the known risks from using [the allegedly defective surgical product] the burden shifted to plaintiffs to create a material issue of fact by showing the warnings were deficient”]).

Defendant relies on section 5.10 of the Lyrica package insert (Section 5.10), contained in the “WARNINGS AND PRECAUTIONS” section, which provides:²

“5.10 Ophthalmological Effects

In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. Less than 1% of patients discontinued LYRICA treatment due to vision related events (primarily blurred vision).

Prospectively planned ophthalmologic testing, including visual acuity testing, formal visual field testing and dilated funduscopy examination, was performed in over 3600 patients. In these patients, visual acuity was reduced in 7% of patients treated with LYRICA, and 5% of placebo treated patients. Visual field changes were detected in 13% of LYRICA-treated, and 12% of placebo-treated patients. Funduscopy changes were observed in 2% of LYRICA-treated and 2% of placebo-treated patients.

² “A ‘warning’ usually relates to circumstances under which a drug may bring about a dangerous condition or side effect. A physician will consider the warning in weighing the risks and benefits of a drug for a particular patient” (*Baker v St. Agnes Hosp.*, 70 AD2d 400, 402 [2d Dept 1979]).

Although the clinical significance of the ophthalmologic findings is unknown, inform patients to notify their physician if changes in vision occur. If visual disturbance persists, consider further assessment. Consider more frequent assessment for patients who are already routinely monitored for ocular conditions [see Patient Counseling Information (17.8)].”

(NYSCEF document No. 26). In addition, under the “ADVERSE REACTIONS” section in the drug highlights portion of the Lyrica package insert, blurred vision is listed as one of the most common adverse reactions reported.

Plaintiff argues that defendant has not established its prima facie entitlement to summary judgment because it did not provide an affidavit from a witness with knowledge, pursuant to CPLR 3212 (b), since defendant’s counsel submits the package insert without a supporting affidavit from Pfizer.³ In reply, defendant requests that this Court take judicial notice of the package insert, from the relevant time period, available on the website of the United States Food and Drug Administration. Material derived from official government websites may be the subject of judicial notice (*LaSonde v Seabrook*, 89 AD3d 132, 137 n 8 [1st Dept 2011]).⁴

Plaintiff argues that, while Dr. Dang acknowledged that she was familiar with the warnings regarding common side effects, she did not reasonably believe that they were adequate and did not know that Lyrica might cause blurred vision. However, Dr. Dang testified that she had read Section

³ Defendant’s counsel affirmed that the 2013 Lyrica package insert was a true and correct copy.

⁴ In addition, Dr. Dang testified that the Lyrica package insert she was shown at her deposition stated that it was “Revised December 2013,” which is the date of the package insert submitted by defendant here. Plaintiff’s counsel questioned Dr. Dang about the same insert (*see* Dr. Dang tr at 118), and submits that testimony here. The package insert is not being submitted for the truth of whether or not Lyrica causes eye problems, but merely to demonstrate the warning contained therein (*see Rosario v New York City Health and Hosps. Corp.*, 87 AD2d 211, 214 [1st Dept 1982]).

5.10 and believed that the warning was sufficient. Dr. Dang also admitted that she knew what Pfizer meant by blurred vision in the package insert (*id.* at 118).

Plaintiff argues that, since Dr. Dang did not consider the warning about visual side effects as adequately demonstrating that the side effects were common, she did not warn plaintiff (*id.*). Indeed, Dr. Dang testified that she did not believe that blurred vision was a common side effect, which is why she did not advise plaintiff of this risk (*id.* at 118). Dr. Dang also testified that she read Section 5.10, and knew of the risk of blurred vision, but believed that the benefit of Lyrica for plaintiff outweighed its potential risks (*id.* at 105, 109). In response, defendant argues that whether plaintiff was warned is of no moment, as the relevant issue is whether Pfizer adequately warned Dr. Dang.⁵

However, another way to interpret plaintiff's argument is that Dr. Dang did not consider visual side effects to be a *common* side effect of Lyrica because the package insert did not adequately advise as to the frequency with which that side effect occurred. A reading of the ADVERSE REACTIONS section of the package insert reveals that it is clear in listing blurred vision as one of the most common side effects of Lyrica, and Section 5.10 also provides information as to the incidence of blurred vision in studies, as compared to a placebo. Dr. Dang's testimony (Dr. Dang tr at 118-119) may simply indicate that, based on the information contained in Section 5.10, the package insert, or otherwise, she disagreed with, or questioned, the definition of "common" relative to the other, more common, side effects of Lyrica.

⁵ Although plaintiff argues that Dr. Dang did not understand what other terms meant in the context of what plaintiff describes as the "alleged" packaging label, and that Dr. Dang did not understand the meaning of certain medical conditions, she points to nothing in the evidence which demonstrates this.

Section 5.10 warns of the risk of blurred vision and of the possibly of certain visual disturbances or changes, as compared to a placebo, and cautions physicians to inform patients to report any such disturbances. However, plaintiff's affidavit demonstrates that she is alleging permanent vision impairment and, thus, in plaintiff's case, this side effect may not be characterized as minor. The Lyrica warning appears to concern blurred vision which resolves with continued treatment, and also addresses that there is a low discontinuance rate among patients, in certain studies, due to visual side effects. However, it cannot be determined, as a matter of law, that the warning is sufficient in forcefully addressing the risk of permanent blurred vision or permanent visual impairment after a patient discontinues Lyrica treatment. Additionally, Section 5.10 does not discuss whether, outside of defendant's studies, there are reported cases of permanent vision impairment after treatment with Lyrica. It may be that data about this does not exist, or that permanent visual impairment or blurred vision after Lyrica treatment had not been reported at the time when plaintiff was treated with Lyrica, but defendant has not definitively demonstrated these things here (*Forte v Weiner*, 200 AD2d 421, 422 [1st Dept 1994]; compare *Mulhall*, 45 AD3d at 58 [medical device manufacturer demonstrated that package insert demonstrated "the most current knowledge available concerning potential risks associated with the product, which is all that the law requires" including that it had in the last two years received six reports (out of 10,000 to 20,000 devices sold each year) of transient adverse events, and not the protracted event alleged by plaintiff]).

Further, not all of plaintiff's eye complaints concerned her vision. She also complains of dry eye syndrome, nuclear sclerosis, and conjunctivitis as among her eye ailments. Defendant does not address whether, or how, the package insert demonstrates adequate warnings about these conditions or plaintiff's claim of aggravated thyroid problems. Defendant also fails to demonstrate that Lyrica

does not cause those side effects. Consequently, defendant has failed to establish the adequacy of the warnings as a matter of law.

Concerning plaintiff's alleged gastroenterological (GI) injuries, defendant challenges plaintiff's allegations of proximate causation. In support, defendant submits the affidavit of Dr. Shihab Ahmed, a medical doctor who is a board-certified anesthesiologist and pain specialist employed by Massachusetts General Hospital in Boston. Dr. Ahmed avers that he is a faculty member of Harvard University, has training and years of experience in the field of pain management, has prescribed Lyrica for over 10 years, and conducts pain research. Defendant submits this affidavit to demonstrate that Lyrica did not proximately cause plaintiff's GI injuries.

After reviewing plaintiff's medical records and deposition testimony, as well as Dr. Dang's deposition testimony, Dr. Ahmed opines, to a reasonable degree of medical certainty, that it is not "more likely than not" that, absent plaintiff's ingestion of Lyrica, she would not have experienced muscle pain and related symptoms. He also opines that Lyrica was not a substantial factor in causing plaintiff's muscle pain. In Dr. Ahmed's opinion, since plaintiff's medical records reveal that she had muscle and joint pain prior to her ingestion of Lyrica, the muscle pain was caused by her other conditions.

Dr. Ahmed also states that generalized muscle and joint pain from Lyrica is not a common side effect, and that he has not seen it at all in his patients in his decade plus experience with prescribing the medicine. He notes that plaintiff was exposed to Lyrica for a relatively short period of time and was prescribed what is considered to be a very low dose of the drug. Further, Dr. Ahmed points to other possible causes of muscle pain, such as plaintiff's cancer treatment and her previous and current medications. According to Dr. Ahmed, it is not possible, within a reasonable degree of

medical certainty, to rule out the other pre-existing conditions and risk factors that he discusses, including plaintiff's use of several other medications which, he states, produce muscle and joint pain.

Defendant argues that plaintiff's claims for GI injuries fail, as plaintiff cannot establish "warning causation," or offer evidence supporting medical causation. Defendant also argues that plaintiff has testified that her GI injuries were caused by Aleve which, defendant states, plaintiff testified that she took to treat muscle pain caused by Lyrica. Defendant argues that in pharmaceutical products liability cases, a plaintiff must submit admissible expert testimony to establish medical causation, that is, to establish that the plaintiff's injuries would not have occurred except for her ingestion of the medication. Defendant contends that it has established its prima facie entitlement to summary judgment by offering Dr. Ahmed's affidavit stating that it is not sufficiently likely that plaintiff's ingestion of Lyrica was a substantial factor in causing the muscle pain that plaintiff claims led to GI symptoms, and that it was not possible to rule out plaintiff's other pre-existing risk factors and conditions, and her other medications, as causes of her muscle pain.

In opposition, plaintiff challenges Dr. Ahmed's affirmation, arguing that he "allegedly reviewed some unidentified records and the transcripts of" plaintiff and Dr. Dang (Weinstein Aff. In Opp. at 6-7). Plaintiff argues that it is impossible for this Court to determine what Dr. Ahmed reviewed because he has not submitted the documents he relied upon. In reply, defendant does not challenge this argument.

An expert's opinion "must be based on facts in the record or personally known to the witness, and . . . an expert cannot reach a conclusion by assuming material facts not supported by record evidence" (*Dent v New York Downtown Hosp.*, 30 Misc 3d 1228 (A), 2011 NY Slip Op 50242 [u], *6 [Sup Ct, NY County 2011], quoting *Roques v Nobel*, 73 AD3d 204, 206 [1st Dept 2010]; see

Hambusch v New York City Tr. Auth., 63 NY2d 723, 725 [1984] [although objection was not preserved for review, the Court stated that it was error to permit plaintiff's physician to testify about his reading of plaintiff's x-ray without introducing the x-ray into evidence]). However, "an expert may rely on out-of-court material if it is of a kind accepted in the profession as reliable in forming a professional opinion or if it comes from a witness subject to full cross-examination on the trial" (*Hambusch*, 63 NY2d at 726 [internal quotation marks and citation omitted]). However, "[i]n order to qualify for the 'professional reliability' exception, there must be evidence establishing the reliability of the out-of-court material. Plaintiff presented no such evidence in the instant case and therefore the physician's opinion was inadmissible" (*id.* [internal citations omitted]).

Here, Dr. Ahmed did not discuss the reliability of any medical records he reviewed and defendant did not submit those records in support of the motion. This Court finds the absence of these records from the motion quite telling, since a physician's expert opinion as to causation would presumably be grounded in such medical proof. Although Dr. Ahmed represents that he has not had patients who complained of muscle pain as a result of taking Lyrica this, in and of itself, does not establish defendant's entitlement to summary judgment.

While plaintiff testified as to "pain," as opposed to muscle pain, that caused her to take Aleve, which she believed caused bleeding, the submitted transcript excerpt demonstrates that the questions plaintiff was being asked concerned GI problems in July, and not necessarily the later, September GI problems, about which she also complained. Dr. Ahmed's affidavit also does not sufficiently address all of plaintiff's alleged injuries, such as aggravation of preexisting thyroid disease or her alleged eye injuries (*Roques*, 73 AD3d at 206 ["medical expert affidavits or affirmations, submitted by a defendant, which fail to address the essential factual allegations in the

plaintiff's complaint or bill of particulars fail to establish prima facie entitlement to summary judgment as a matter of law").

Defendant notes that, as of the time it filed this motion, plaintiff had not disclosed that she has an expert who opines that her GI injuries are attributable to Lyrica. Defendant argues that this demonstrates that plaintiff lacks competent evidence concerning medical causation. Further, defendant contends that plaintiff's failure to proffer evidence that can establish inadequate warning of dangers of which Pfizer did or should have known, or that the alleged inadequacy of the warnings proximately caused plaintiff's injuries, is fatal to her claim. As to the adequacy of the warnings, as discussed above, defendant did not meet its moving burden (*see Mulhall*, 45 AD3d at 59 [addressing moving burden]). As to both the warnings and causation, defendant may not meet its burden by pointing to gaps in plaintiff's proof (*Hairston v Liberty Behavioral Mgt. Corp.*, 157 AD3d 404, 406 [1st Dept 2018]).⁶ That plaintiff may ultimately be unable to prevail at trial is not what is to be determined on summary judgment.

With respect to proximate cause, defendant argues that plaintiff cannot meet her burden of showing that an alleged deficiency in the Lyrica labeling warnings proximately caused any of her injuries. Defendant asserts that this is the case because plaintiff cannot show that, had a different warning been given, Dr. Dang would not have prescribed Lyrica to plaintiff, but, instead, would have departed from her normal practice and used another medication. "[A] physician's affirmative statement that he would have prescribed the drug even if adequately informed" may break the causal

⁶ To the extent that defendant relies on federal case law concerning plaintiff's lack of a showing of expert testimony, federal courts permit defendants to obtain summary judgment by pointing to the plaintiff's lack of evidence about an element, while, generally, New York State courts do not (*see Siegel & Connor*, NY Prac ¶ 281 at 535 [6th ed 2018]; *Hairston*, 157 AD3d at 406).

nexus, as this demonstrates that the physician did not make his or her prescribing decision based upon a lack of information about a potential risk of the medication (*Krasnopolsky v Warner-Lambert Co.*, 799 F Supp 1342, 1347 [ED NY 1992]).

To meet its burden of demonstrating that Dr. Dang would have prescribed Lyrica even had the package insert warning been different, defendant points to Dr. Dang's testimony that, when she prescribed Lyrica, she believed that it would be an effective treatment for plaintiff's neuropathy, and that the benefit that Lyrica could provide outweighed the potential risks. However, this testimony addressed Dr. Dang's knowledge at the time that she prescribed Lyrica, before plaintiff suffered what she claims are side effects of the drug. Consequently, an inference may not be drawn against plaintiff that Dr. Dang indicated that, had the Lyrica package insert warned Dr. Dang of all of the conditions of which plaintiff complains here, she still would have prescribed the drug (*Garcia v J.C. Duggan, Inc.*, 180 AD2d 579, 580 [1st Dept 1992] [on summary judgment, court must view evidence in a light favorable to the nonmoving party and grant that party the benefit of reasonable favorable inferences]).

Defendant notes that Dr. Dang testified that she was aware of all of the conditions that plaintiff now claims were caused by Lyrica, including her ophthalmological and gastrointestinal complaints, and that, with that knowledge, Dr. Dang also testified that she still believed that Lyrica was an appropriate treatment, "given everything [she knew] about [plaintiff's] condition and based on [her] medical judgment at the time" and Dr. Dang continues to believe that Lyrica was an appropriate treatment for plaintiff's unresolved neuropathy (defendant's moving memorandum of

law at 3, 8, citing to Dr. Dang tr at 75:7-15, 105:6-22, 110:2-24).⁷ Defendant argues that this testimony precludes plaintiff from establishing causation of any of her alleged injuries based upon the failure to warn Dr. Dang, because if Dr. Dang currently believes the prescription was appropriate, knowing of plaintiff's alleged injuries, then a different warning would not have made a difference in Dr. Dang's prescribing choice. Citing to *Mulhall* (45 AD3d at 61), defendant further contends that Dr. Dang testified that she was aware of the risk of side-effects, and still prescribed Lyrica, which demonstrates that a different warning would not have led Dr. Dang to depart "from her normal practice and use[] another" medication (*id.*).

First, Dr. Dang's testimony does not demonstrate that she had a normal practice of prescribing Lyrica, as she testified that she had not done so often (Dr. Dang tr at 78). Second, Dr. Dang was asked "[d]o you still believe Lyrica was an appropriate treatment for [plaintiff], given everything you *knew* about her condition and based on your medical judgment *at the time*" (Dr. Dang tr at 110: 2-7 [emphasis added] [compare defendant moving memorandum of law at 3, 8; reply memorandum of law at 1]).⁸ This does not demonstrate that Dr. Dang knew of plaintiff's current complaints, but, nonetheless, still would have prescribed Lyrica.⁹ Defendant also argues that "[Dr.] Dang continues to believe that Lyrica was an appropriate treatment for the neuropathy that [plaintiff] 'continued to have' while on other medications," citing to page 75 of Dr. Dang's deposition

⁷ Defendant also points to the FDA-approved patient medication guide (defendant's moving memorandum of law at 3), but does not demonstrate that plaintiff received a copy of the guide, or that Dr. Dang read this portion of the package insert, which is intended for patients.

⁸ Defendant correctly quoted the transcript only in its reply memorandum of law (at 5).

⁹ Defendant does not demonstrate that Dr. Dang, an oncologist, is an expert about a medication that she states that she did not use often, or that she read the entire package insert. In any event, this would not bear on the issue of whether or not the warning was adequate.

transcript for support (defendant's moving memorandum of law at 8). However, page 75 of Dr. Dang's testimony reflects that she was being asked about her thinking concerning Lyrica at the time that she prescribed it, not later, at the time that the deposition was conducted, when Dr. Dang was aware of plaintiff's injuries.

Dr. Dang testified that, based upon what she now knows, she still believed that her prescription of Lyrica was appropriate for plaintiff (Dr. Dang tr at 110; 20-24). However, the submitted excerpts do not demonstrate that Dr. Dang was, apart from her reading of the package insert, aware of Lyrica's side effects, but still decided to treat plaintiff with the medicine anyway (*compare Glucksman*, 160 AD2d at 307). It appears evident that Dr. Dang's testimony was based on the content of the 2013 package insert that she was shown at her deposition. The pages of Dr. Dang's transcript which defendant submits do not demonstrate that Dr. Dang was asked about warnings other than those in the 2013 package insert. Consequently, this Court cannot draw an inference in favor of defendant that, had Dr. Dang been provided with additional or more forceful warnings concerning the permanent loss of visual acuity and the other conditions about which plaintiff complains, she still would have deemed Lyrica appropriate for plaintiff. (*Garcia*, 180 AD2d at 580 [nonmoving party must be afforded benefit of all reasonable inferences]). Defendant has failed to demonstrate that Dr. Dang was sufficiently informed of all of the potential risks of Lyrica, but decided to use it anyway.

Alston v Caraco Pharm., Inc. (670 F Supp 2d 279, 285 [SD NY 2009]), upon which defendant relies, involved a situation where proximate cause could be determined as a matter of law. In that case, the court determined that the package insert adequately warned of the addiction and withdrawal problems that plaintiff alleged. The court also indicated that the records in that case

demonstrated that the prescribing physician knew of the plaintiff's pre-existing addiction and, therefore, with adequate warning from the manufacturer about the subject drug's risks, still made the choice to use what plaintiff claimed was an addictive medication, and then to withdraw that medication. Here, unlike *Alston*, defendant does not demonstrate that Dr. Dang was adequately warned concerning all of the injuries plaintiff sustained which allegedly resulted from taking Lyrica.

In *Krasnopolsky* (799 F Supp at 1347–48), also cited by defendant, the prescribing physician testified that he was fully aware of the possibility of a medication's renal side effect. Nevertheless, the doctor in that case prescribed the drug and the plaintiff sustained the renal side effect warned of to occur. The plaintiff in *Kransnopolsky* did not contest these facts, and the court determined that the alleged insufficiency of the warning was not a proximate cause of the plaintiff's injuries as a matter of law. Unlike *Krasnopolsky*, Dr. Dang did not testify that she was fully aware of the possibility of the risks of all of the side effects which plaintiff alleges here, and defendant has not demonstrated that the Lyrica package insert adequately warned Dr. Dang of all such effects, that Lyrica does not cause them, or that they were not known to defendant.

Therefore, in light of the foregoing, it is hereby:

ORDERED that the motion by defendant Pfizer, Inc. for summary judgment dismissing the complaint is denied; and it is further

ORDERED that this constitutes the decision and order of the court.

Dated: April 25, 2018

ENTER:



HON. KATHRYN E. FREED, J.S.C.