UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LOUIS KERLINSKY,	)	
Plaintiff	)	
	)	
v.	)	**C.A. No. 09-cv-30136-MAP**
	)	
SANDOZ INC., ET AL.,	)	
Defendants	)	

MEMORANDUM AND ORDER REGARDING DEFENDANT SANDOZ'S MOTION FOR SUMMARY JUDGMENT, DEFENDANT SANDOZ'S MOTION TO STRIKE PLAINTIFF'S EXPERT DISCLOSURE, DEFENDANT USDVA'S MOTION TO STRIKE EXPERT DISCLOSURE, DEFENDANT USDVA'S MOTION FOR SUMMARY JUDGMENT, AND DEFENDANT SANDOZ'S MOTION FOR JUDGMENT ON THE PLEADINGS
(Dkt. Nos. 64, 67, 69, 71, and 73)

May 9, 2011

PONSOR, D.J.

I. INTRODUCTION

Plaintiff Louis Kerlinsky, acting pro se, brings this products liability suit against Defendants Sandoz, Inc. ("Sandoz") and the United States Department of Veteran's Affairs ("USDVA")[1] for personal injuries allegedly sustained

[1] **Although Plaintiff has named the United States Department of Veterans Affairs as a defendant, the United States of America is the only proper defendant in an action under the Federal Tort Claims Act. See 28 U.S.C. §§ 2671 et seq. Nonetheless, for the sake of clarity, the court will use the abbreviation "USDVA."**

after taking medication manufactured by Defendant Sandoz and prescribed by a hospital that Defendant USDVA operates.[2] The sole remaining counts in the twelve-count complaint are Counts 1 and 2 against Defendant Sandoz for, respectively, breach of warranty and negligent failure to warn, and Count 6 against Defendant USDVA for negligent failure to obtain informed consent.

Presently before this court are Defendant Sandoz's Motion for Summary Judgment as to Causation (Dkt. No. 64), Defendant Sandoz's Motion to Strike Plaintiff's Expert Disclosure (Dkt. No. 67), Defendant USDVA's Motion to Strike Expert Disclosure (Dkt. No. 69), Defendant USDVA's Motion for Summary Judgment (Dkt. No. 71), and Defendant Sandoz's Motion for Judgment on the Pleadings (Dkt. No. 73). For the reasons stated below, Defendants' motions to strike expert disclosure (Dkt. Nos. 67 & 69) and motions for summary judgment (Dkt. Nos. 64 & 71) will be allowed. Given these rulings, Defendant Sandoz's Motion for Judgment on the

[2] Plaintiff originally included Main Line Hospitals, Inc. d/b/a Lankenau Hospital as a defendant in this action, but the court dismissed this party from the case on March 26, 2010. (Dkt. No. 29.)

Pleadings (Dkt. No. 73) will be denied as moot.

II. FACTUAL BACKGROUND

The relevant facts, viewed in the light most favorable to Plaintiff, are as follows.

Intermittently throughout 2005, Plaintiff visited an outpatient clinic operated by Defendant USDVA in Springfield, Massachusetts. The clinic prescribed and furnished to Plaintiff several medications, including Terazosin HCL, Flovent, Felodipine, Allopurinel, Finasteride, Aricept, Loratadine, aspirin, Lactase, eardrops, multivitamins, suppositories, sertaline, nasal spray, and carbonide peroxide.[3] Of primary importance here is the prescription of Terazosin HCL, a medicine manufactured by Defendant Sandoz and prescribed to Plaintiff by Defendant USDVA to treat high blood pressure and an enlarged prostate gland.

On September 21, 2005, and again on October 21, 2005, Defendant USDVA provided to Plaintiff ten pages of medical

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[3] **Apart from Terazosin and Felodipine, the complaint is silent as to which of these medications Plaintiff had actually ingested in the days and hours prior to the event in question.**

literature, including the following description of Terazosin:

> It is used to treat high blood pressure (hypertension) . . . symptoms of prostate enlargement. Take the first dose at bedtime to minimize the changes of getting dizzy or fainting. PRECAUTIONS: To avoid dizziness or fainting get up slowly from a lying or seated position especially when you first start using this drug.

(Dkt. No. 1, Compl. ¶ 15.) The literature also warned that "lightheadedness or dizziness upon standing may occur, especially after the first dose." (Id. ¶ 22.) Plaintiff alleges that the only warning on the vials of Terazosin HCL prescribed to him was as follows: "May cause drowsiness." (Id. ¶ 17.)

On September 1, 2006, Plaintiff was visiting his sister-in-law in Philadelphia, Pennsylvania. At approximately 5:00 p.m., Plaintiff ingested for the first time one capsule of Terazosin HCL. At approximately 7:00 p.m., Plaintiff's heart stopped beating, and he stopped breathing. He was taken by ambulance to Lankenau Hospital in Wynnewood, Pennsylvania. Plaintiff was discharged from the hospital four days later, on September 5, with instructions to have a pacemaker surgically implanted in his

chest. He incurred over $41,000 in medical bills as a result of his hospital visit.

Between September 5 and September 8, Plaintiff was examined and tested at Baystate Medical Center ("Baystate") in Springfield, Massachusetts, to determine whether he was a good candidate for a pacemaker. On September 8, Baystate informed Plaintiff that he did not need a pacemaker.

Plaintiff alleges that the September 1, 2006, episode was caused by Terazosin HCL and that Defendants failed to adequately warn him of its possible side effects. Plaintiff demands $700,000 in damages.

III. PROCEDURAL BACKGROUND

On March 26, 2010, this court adopted in part Magistrate Judge Kenneth P. Neiman's Report and Recommendation concerning Defendants' motions to dismiss. (Dkt. No. 29.) The court dismissed all counts against Defendant Lankenau (eliminating Counts 9, 10, and 11 from the complaint) as well as Counts 3, 4, and 5 against Defendant Sandoz. The court denied Defendant Sandoz's motion as to Counts 1 (breach of warranty) and 2 (negligence) insofar as those counts relied on a failure-to-

warn theory. The court declined to adopt the Magistrate Judge's recommendation that Count 7 be dismissed sua sponte along with the portions of Count 12 offering class action allegations against Defendant USDVA. However, on November 4, 2010, the court adopted a second report and recommendation by Judge Neiman and allowed Defendant USDVA's motion to dismiss Counts 7, 8, and 12. The court noted, in its memorandum, that the quotations from case law relied upon by Plaintiff to oppose the motion did not, in fact, appear in the cases cited. (Dkt. No. 51.)

At a scheduling conference less than a week following the dismissal of Counts 7, 8, and 12, Judge Neiman pointed out to Plaintiff that he had failed to comply with Federal Rule 26 governing expert disclosure regarding the remaining counts. See Fed. R. Civ. P. 26(a)(2)(B). Plaintiff had submitted a letter purportedly written by his daughter, Dr. Susan Kerlinsky, who practiced family medicine.[4] (Dkt. No. 68, Ex. 1, Kerlinsky Statement at 1.) The letter consisted, in its entirety, of two sentences setting forth the author's

[4] As will be seen, at footnote six infra, it is far from clear that Dr. Kerlinsky actually wrote the letter attributed to her.

conclusion that Plaintiff's injuries resulted from his use of Terazosin. (Id.) At the conference, Judge Neiman explained in detail the requirements of Rule 26 and gave Plaintiff until December 31, 2010, to submit a revised expert report. (Dkt. No. 68, Ex. 3, Tr. 11/10/10, at 4-6.)

On December 13, 2010, Plaintiff submitted a supplemental statement, again purportedly written by Dr. Susan Kerlinsky. (Dkt. No. 68, Ex. 2, Kerlinsky Supp. Statement.) He submitted no other statements or reports by the December 31 deadline. Defendants then filed the motions currently pending in this case. On January 26, 2011, Judge Neiman allowed Defendants' Joint Motion to Stay Discovery Pending Disposition of Motions to Strike and Motions for Summary Judgment (Dkt. No. 66).

IV. DISCUSSION

A. Defendants' Motions to Strike Plaintiff's Expert Disclosure (Dkt. Nos. 67 & 69).

Defendants have filed separate motions seeking to strike the supplemental expert statement of Dr. Kerlinsky (Dkt. Nos. 67 & 69.), on the ground that it fails to comply with the requirements of Fed. R. Civ. P. 26(a)(2)(B). For

the reasons that follow, this court agrees.

Rule 26 requires that an expert report contain the following: (1) a complete statement of all opinions the witness will express and the basis and reasons for them; (2) the facts or data considered by the witness in forming each opinion; (3) any exhibits that will be used; (4) the witness's qualifications; (5) a list of all other cases in which the witness testified as an expert in the previous four years; and (6) a statement of the compensation to be paid for his or her testimony. See **Fed. R. Civ. P. 26(a)(2)(B)(i)-(vi).**

Here, Dr. Kerlinsky's supplemental statement represents only a slight improvement over her initial two-sentence statement and still falls far short of the requirements of Rule 26. The most recent statement comprises three brief, handwritten pages. Given that the first page contains only one sentence, which simply lists the requirements of Rule 26, the substance of the report is limited to two handwritten pages. This submission is deficient for several reasons.

First, it does not contain a complete statement of all

opinions the witness will express and the basis and reasons for them. See Fed. R. Civ. P. 26(a)(2)(B)(i). Dr. Kerlinsky's opinion is clear enough: "the 8 days of hospitalization in 9-1-06 to 9-8-06 were a result of the Terazosin [Plaintiff] took on 9-1-06 . . . ." (Dkt. No. 68, Ex. 2, Kerlinsky Supp. Statement at 2.) However, the basis and reasons for that opinion are not. The relevant portion of Dr. Kerlinsky's report reads:

> The basis and reasons for my above opinions are my education and experience including graduating from Harvard College and N.Y.U. medical school and my continuing education and studies including my readings pertaining to Terazosin. The basis for my opinion that the first dose of Terazosin manufactured by Sandoz and prescribed by the VA clinic in Spfld caused Louis Kerlinsky's syncope, loss of consciousness, heart stoppage and breathing stoppage is that it is well known and admitted by the VA in its literature on Terazosin that a first dose of Terazosin can cause loss of consciousness, heart stoppage and breathing stoppage. There is no other reasonable cause for the occurrence on 9-1-06 other than the first dose of Terazosin.

(Dkt. No. 68, Ex. 2, Kerlinsky Supp. Statement at 2-3.)

As Defendants correctly note, an expert opinion on medical causation must contain two elements -- general causation, i.e., that the drug can cause the injury, and

specific causation, i.e., that the drug did cause the injury in this case. See In re Neurontin Mktg., Sales Practices, and Prods. Liab. Lit., 612 F. Supp. 2d 116, 123 (D. Mass. 2009) ("In order to prevail in a pharmaceutical personal injury case, a plaintiff must establish two types of causation: general and specific. General causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a substance can cause a particular disease. . . . Specific, or individual, causation . . . is established by demonstrating that a given exposure is the cause of an individual's disease.") (internal quotation omitted).

As to general causation, Dr. Kerlinsky's report states that it is "well known" and "admitted by the VA in its literature on Terazosin" that a causal link exists, but the report does not identify any sources that the author relied on as the basis for these statements. Similarly, Dr. Kerlinsky refers to her "readings pertaining to Terazosin" without providing any specific references whatsoever.

As to specific causation, the report merely states that "there is no other reasonable cause" for Plaintiff's

syncope. This shorthand is tantamount to no explanation at all. Obviously, many other factors might account for a sudden loss of consciousness, including dehydration, intoxication, shock, extreme fright, blunt force trauma, or the various other medications Plaintiff alleges he was prescribed by Defendant USDVA. (See Dkt. No. 1, Compl. ¶ 13.) Dr. Kerlinsky's report simply fails to explain what led her to her ultimate conclusion in this case.

This deficiency extends to Dr. Kerlinsky's opinion regarding the issue of informed consent as well. Dr. Kerlinsky's report states that "[t]he VA clinic was required by good accepted medical practise [sic] to inform its patients of the possible affects [sic] of the medication it prescribed and to obtain its patients' informed consent" and concludes that such failure "constitutes substandard medical treatment." (Dkt. No. 68, Ex. 2, Kerlinsky Supp. Statement at 3.) Again, Dr. Kerlinsky offers only conclusory statements that fail to explain how she formed her opinions.

Second, and relatedly, Dr. Kerlinsky's report does not disclose the facts or data she considered in arriving at her conclusions. See Fed. R. Civ. P. 26(a)(2)(B)(ii).

Significantly, the report does not state that the author has reviewed the pharmaceutical information provided to Plaintiff by Defendants or even her father's medical records. Other than the excerpt quoted above, the only reference to facts or data underlying her opinion is the following statement: "the other information considered by me in forming my opinions is my general knowledge of medicine and the practise [sic] of medicine." (Dkt. No. 68, Ex. 2, Kerlinsky Supp. Statement at 3.) The report does not give any indication of what this "general knowledge" might include.

Third, the report does not adequately describe Dr. Kerlinsky's qualifications. See Fed. R. Civ. P. 26(a)(2)(B)(iv). The report states, "My qualifications are my education and experience. I am licensed to practise [sic] medicine in New York state." (Dkt. No. 68, Ex. 2, Kerlinsky Supp. Statement at 3.) The report does not explain whether Dr. Kerlinsky has treated patients with medical conditions like Plaintiff's, has studied fields of medicine related to this case (e.g., cardiology, pulmonology), has participated in any relevant training or

clinical work, or has any familiarity with the drug Terazosin. Plaintiff's short, vague statement is flatly insufficient to comply with Rule 26.[5] See Adams v. J. Meyers Builders, Inc., 671 F. Supp. 2d 262, 268 (D.N.H. 2009) (excluding expert where report "failed to give [the expert's] qualifications apart from the brief references to [the expert's] '38 years of experience' and his 'client list'").

In sum, even after being warned that his submissions were deficient, Plaintiff failed to provide adequate expert disclosure pursuant to Rule 26. For the reasons noted, Dr. Kerlinsky's supplemental statement does not provide with any reasonable degree of specificity the basis and reasons for her opinions, the facts or data underlying her opinions, or her qualifications. Under such circumstances, striking the expert report is the proper remedy. See Santiago-Diaz v. Laboratorio Clinico y de Referencia del Este, 456 F.3d 272,

[5] It is worth noting that Dr. Kerlinsky in fact appears entirely unqualified to offer an expert opinion in this case. She practices family medicine, and, as noted, Plaintiff has failed to point to any relevant experience that would qualify her to render an opinion as to medical causation in a pharmaceutical products liability action.

274 (1st Cir. 2006) (affirming the trial court's grant of summary judgment and noting that the plaintiff's expert's one-page statement, which consisted only of two "conclusory" paragraphs, "did not by any stretch of the most fertile imagination meet the criteria set by the Civil Rules for expert witness reports"); Flebotte v. Dow Jones & Co., Inc., No. 97-30117-FHF, 2001 WL 35988081, at *2 (D. Mass. Feb. 7, 2001) (striking an expert report where it failed to identify any diagnostic tools as the basis for the proposed medical causation opinion, and, instead, "merely indicate[d] that [the expert] formulated his opinion based on his conversations with [the plaintiff] during treatment sessions"). Consequently, the court will strike Dr. Kerlinsky's expert report and preclude her from testifying.[6]

[6] Defendants have raised one additional independent basis for excluding Dr. Kerlinsky's expert testimony. Defendants observe that Dr. Kerlinsky's entire supplemental statement, including her signature, appears to be in the same handwriting as all other documents authored and signed by her father, Plaintiff Louis Kerlinsky. (See Dkt. No. 68, Ex. 2, Kerlinsky Rep. at 2-5.) Given that the proposed expert may not have participated in the drafting of the expert report, Dr. Kerlinsky's report could be stricken on these grounds alone. See Fed. R. Civ. P. 26(a)(2)(B) (requiring that expert reports be "prepared and signed by the witness"); see also Flebotte v. Dow Jones & Co., Inc., No. 97-30117-FHF, 2000 WL 35539238, at *2 (D. Mass. Dec. 6,

B. Defendants' Motions for Summary Judgment (Dkt. Nos. 64 & 71).

Both Defendant Sandoz and Defendant USDVA have filed motions for summary judgment on the counts remaining in the complaint: Count 1 alleging breach of warranty against Defendant Sandoz, Count 2 alleging negligent failure to warn against Defendant Sandoz, and Count 6 alleging negligent failure to obtain informed consent against Defendant USDVA. (Dkt. Nos. 64 & 71). In these motions, Defendants argue that if the report of Plaintiff's sole expert, Dr. Kerlinsky, is stricken, the court should grant summary judgment for Defendants due to Plaintiff's inability to establish a key element of his case: causation.

Defendants correctly observe that the issue of medical causation requires expert analysis. See, e.g., Case of Canavan, 733 N.E.2d 1042, 1051 (Mass. 2000) ("Because understanding medical causation is beyond the . . .

2000) (noting that "it is generally accepted that [Rule 26(a)(2)(B)] requires the expert to substantially participate in the preparation of his report") (citation and quotation marks omitted). However, because several other grounds exist for excluding this testimony, the court need not anchor its holding on the disturbing possibility that the expert statement was fabricated.

knowledge of the ordinary layman . . . proof of it must rest upon expert medical testimony.") (citation and quotation marks omitted); Polaino v. Bayer Corp., 122 F. Supp. 2d 63, 71(D. Mass. 2000) (allowing defendants' motions to strike expert testimony and granting summary judgment for defendants on plaintiff's product liability claims because "without such testimony, plaintiff can prove neither a design defect nor causation"). This rule applies with equal force to cases involving informed consent. See Harnish v. Children's Hosp. Med. Ctr., 439 N.E.2d 240, 243 (Mass. 1982) ("What the physician should know [and should convey to the patient] involves professional expertise and can ordinarily be proved only through the testimony of experts.") (citing Haggerty v. McCarthy, 181 N.E.2d 562, 566 (Mass. 1962)).

In opposition to these motions, Plaintiff does not address the above case law but instead cites two cases that do not touch upon the issue presently before the court. See Wyeth v. Levine, 129 S. Ct. 1187, 1204 (2009) (holding that state law failure-to-warn claims against manufacturer of antihistamine were not preempted by federal law); Hayes v. Ariens Co., 462 N.E.2d 273, 277 (Mass. 1984) (holding that

jury's verdict for plaintiff on theory of negligence was inconsistent with its finding that manufacturer did not breach warranty of merchantability and noting that "the vendor is presumed to have been fully informed at the time of the sale of all risks").[7]

Given that Plaintiff's sole expert will not be allowed to testify, Plaintiff cannot prove causation with respect to any of the remaining counts.[8] Accordingly, the court will allow Defendants' motions for summary judgment (Dkt. Nos. 64 & 71).

C. Defendant Sandoz's Motion for Judgment on the Pleadings (Dkt. No. 73).

Given the above rulings, the court will deny as moot Defendant Sandoz's Motion for Judgment on the Pleadings

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[7] Hayes was later abrogated by Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 922-23 (Mass. 1998), which held that a manufacturer cannot be found liable for failure to warn about risks not reasonably foreseeable at time of sale.

[8] Plaintiff's complaint also refers to letters authored by two physicians allegedly linking Plaintiff's syncope to his use of Terazosin HCL. (See Dkt. No. 1, Compl. ¶¶ 25, 26.) However, Plaintiff did not produce these documents to the court in opposition to the pending motions. More importantly, Plaintiff has not presented expert reports on behalf of either of these individuals.

(Dkt. No. 73).

V. CONCLUSION

For the foregoing reasons, Defendant Sandoz's Motion to Strike Plaintiff's Expert Disclosure (Dkt. No. 67) and Defendant USDVA's Motion to Strike Expert Disclosure (Dkt. No. 69) are hereby ALLOWED. Defendant Sandoz's Motion for Summary Judgment as to Causation (Dkt. No. 64) and Defendant USDVA's Motion for Summary Judgment (Dkt. No. 71) are hereby ALLOWED. Defendant Sandoz's Motion for Judgment on the Pleadings (Dkt. No. 73) is hereby DENIED AS MOOT. The clerk will enter judgment for Defendants. The case may now be closed.

It is So Ordered.

/s/ Michael A. Ponsor
MICHAEL A. PONSOR
U. S. District Judge