IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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AMY MARIE STEVENS,

OPINION AND ORDER

Plaintiff,

12-cv-63-bbc

v.

STRYKER CORPORATION and
STRYKER SALES CORPORATION,

Defendants.

- -

Plaintiff Amy Marie Stevens is suing defendants Stryker Corporation and Stryker Sales Corporation for negligence, alleging that a pain pump defendant manufactured caused her to suffer from a condition called chondrolysis, which involves "severe cartilage loss." In an order dated May 9, 2013, I granted defendants' motion for summary judgment with respect to plaintiff's request for punitive damages, but I denied the motion in all other respects. Trial is scheduled for October 7, 2013.

On June 14, 2013, defendants filed nine lengthy motions in limine (nearly three months before the deadline for doing so), all of which challenge the admissibility of testimony by various experts named by plaintiff. Each motion includes as many as a dozen different arguments for excluding the testimony of a particular expert. Because of the large number of issues, it will be necessary to address the motions without extended discussion. Although I conclude that most of the objections defendants raise are more appropriately

addressed through cross examination rather than by excluding the expert's testimony, I am granting their motions as to the testimony of Yadin David, as well as certain opinions of Peter Kurzweil, Martin Wells, Stephen Trippel, James Gracey and Paul Randle, as discussed below. I am denying the motions in all other respects.

OPINION

A. Causation Experts

Under Wisconsin negligence law, a plaintiff must show that the defendant's conduct was a "substantial factor" in producing the plaintiff's injury. Morgan v. Pennsylvania General Insurance Co., 87 Wis. 2d 723, 275 N.W.2d 660 (1979). Plaintiff has named four experts to help prove this element of her claim: (1) Brian Fukushima, who will testify that defendant's pain pump caused her chondrolysis (what the parties refer to as "specific causation"); (2) Peter Kurzweil, who will testify that pain pumps can cause chondrolysis as a general matter ("general causation"); (3) Sander Greenland, an epidemiologist, who plaintiff says will "help the jury understand the significance of the mounting evidence of general causation"; and (4) Martin Wells, who will provide a statistical analysis in an attempt to show a causal relationship between pain pumps and chondrolysis. Defendants have filed motions to exclude all the testimony of each of plaintiff's causation experts. Although defendants raise numerous objections to the testimony, I conclude that only a few require discussion.

First, defendants argue that all of the experts should be precluded from testifying

because they do not address the particular type of pain pump at issue in this case, which involved a relatively low dose of anesthetic (120 mL of bupivicaine, dispensed at a rate of approximately 2 mL an hour) and no epinephrine. However, I am not persuaded that such specific testimony is required. In concluding that defendants' pain pump caused plaintiff's injury, Fukushima used a process called "differential etiology," in which "the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." Myers v. Illinois Central Rail Co., 629 F.3d 639, 644-45 (7th Cir. 2010). The court of appeals has "recognized this method of . . . differential etiology as a generally accepted means for evaluating the cause of a plaintiff's injury." Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426, 433-34 (7th Cir. 2013). Because this method of determining causation isolates defendant's particular pain pump by eliminating other potential causes, I see no reason to require plaintiff to adduce other evidence that a pain pump with the same characteristics as defendant's can cause chondrolysis.

Although it is true that an expert must first "rule in" a particular cause before "ruling out" other causes, I conclude that the testimony of the other experts about the link between pain pumps and chondrolysis generally is sufficient for that purpose. Defendants make much of the fact that Fukushima does not develop his own opinion about general causation, but they fail to explain why it is necessary for the same expert to provide opinions about both specific and general causation. Further, defendants cite no authority for the view that plaintiff must "rule in" a cause with evidence showing that an identical pain pump has

caused chondrolysis before. Finally, defendants say that Fukushima failed to explain why he considered things such as pre-existing shoulder trauma, arthritis and infections as potential causes of chondrolysis before ruling them out, but defendants do not dispute plaintiff's argument that *defendants'* experts identify the same potential causes, so it is not clear why defendants are objecting. Cf. Gil v. Reed, 381 F.3d 649, 660 (7th Cir. 2004) (party may rely on other side's expert testimony to prove her case).

With respect to the opinions of Kurzweil, Wells and Greenland, defendants attack many of the studies and articles discussed in their opinions. First, they say that the experts' opinions are inherently unreliable because they rely in part on case reports, but the only support defendants cite for the view that case reports are unreliable sources are quotations from district court opinions taken out of context. Defendants have not shown that case reports are categorically inadmissible; many courts have held the opposite. E.g., Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1202 (11th Cir. 2002) (noting that district court identified types of evidence that would have been considered reliable, including "a very large number of case reports"); Burks v. Abbott Laboratories, 917 F. Supp. 2d 902, 923 (D. Minn. 2013) (allowing expert to rely on case reports, even though "case reports and cross-sectional analysis may not be as reliable or persuasive as other methods of assessing risk"); In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation, 890 F. Supp. 2d 552, 562 (E.D. Pa. 2012) (allowing expert opinion that relied on case reports); Davids v. Novartis Pharmaceuticals Corp., 857 F. Supp. 2d 267, 278 (E.D.N.Y. 2012) (same); Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 660 (E.D. Pa.

2012) (same); Deutsch v. Novartis Pharmaceuticals Corp., 768 F. Supp. 2d 420 (E.D.N.Y.2011) (same).

Defendants criticize one article on the ground that it was prepared in anticipation of litigation. Brett P. Wiater et al., "Risk Factors for Chondrolysis of the Glenohumeral Joint," Journal of Bone & Joint Surgery 615-25 (2011). However, defendants do not develop an argument showing that the actual methods used in the study are unsound. Of course, defendants are free to cross examine plaintiff's experts about potential bias in this study, but they have not shown that the study should be excluded.

Finally, defendants argue that some of the studies do not control for confounding factors and the experts did not discuss other studies that may have undermined their conclusions, but it is well established that an opinion may be admissible even if it does not establish a single cause with certainty and even if there is contrary authority. Schultz, 721 F.3d at 432-33 ("Rule 702 did not require, or even permit, the district court to choose between . . . two studies at the gatekeeping stage."); Cyrus v. Town of Mukwonago, 624 F.3d 856, 864 (7th Cir. 2010) ("[A]n expert's inability to isolate one specific factor when multiple factors cause an injury implicates the weight of the expert's testimony, not its admissibility."); Gayton v. McCoy, 593 F.3d 610, 618-19 (7th Cir. 2010) ("[A]n expert need not testify with complete certainty about the cause of an injury; rather he may testify that one factor could have been a contributing factor to a given outcome.").

An objection common to two of the experts (Kurzweil and Wells) is that each of them relies on studies of animals without providing a basis for concluding that the studies'

conclusions may be applied to humans. In response, plaintiff cites various articles in support of a view that animal cartilage is similar to human cartilage, but she does not cite any passages from the experts' reports in which they explain why it is reasonable to rely on the animal studies for the purpose of determining causation in humans. Lawyer argument cannot fill gaps left by the experts. Accordingly, I am granting defendants' motion to exclude testimony on animal studies.

B. Stephen Trippel

Plaintiff says that Trippel will testify about the state of scientific knowledge as of the time of plaintiff's surgery in 2004. Defendants argue that Trippel should be precluded from offering opinions about the following issues: (1) safety testing that defendants should have performed; (2) the lack of information available in 2004 about the safety of defendants' products; and (3) medical literature available in 2004 that would have put defendants on notice that their product was dangerous. Plaintiff does not oppose the motion as it applies to safety testing, so I will grant the motion as to that issue.

With respect to the other two issues, defendants' motion represents a request to reconsider this court's summary judgment decision, though defendants do not acknowledge this. In the summary judgment decision, I rejected defendants' argument that Trippel's opinion was insufficient to show that defendants should have known that their pain pump was dangerous. Plaintiff did not file a motion for reconsideration of that decision and I decline to revisit the issue now.

C. Standard of Care Experts

Plaintiff has named two experts to testify about the standard of care: Peggy Spence and Yadin David. Again, defendants argue that both experts should be precluded from testifying for various reasons.

Defendants argue that Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), "preempts" the experts' opinions because those opinions are about compliance with regulations by the Food and Drug Administration. Defendants interpret Buckman as prohibiting any witness from giving an opinion about those regulations, but that goes well beyond the holding in that case, in which the Supreme Court concluded that federal law preempted a claim under state law that was premised on a fraud against the FDA. Defendants point to no court that has adopted their expansive interpretation of Buckman. In fact, one of the main cases defendants cite states that Buckman does not prohibit parties from relying on FDA regulations to help establish a duty of care in a state law negligence case. Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 588 (6th Cir. 2013) ("Unless federal law bears on the state duty of care, evidence of such law is inadmissible. If such evidence is relevant, however, Buckman is no bar to its admission.").

That being said, the question in this case is not whether defendants violated federal regulations, but whether they were negligent under Wisconsin law. Thus, the testimony of a standard of care expert for either side should address what a reasonable manufacturer would do. That determination may be informed in part by federal regulations, but the focus should be on the underlying safety reasons for recommending a particular course of action,

not on the regulations. Allowing the experts to debate obscure terms of complex regulations would serve no purpose but to confuse the jury and waste time on issues that are not central to the case. Accordingly, I decline to strike the experts' testimony simply because they discuss FDA regulations, but I will not hesitate to limit testimony if it devolves into a discussion of regulatory interpretation.

Defendants raise several other objections to Spence's testimony but they are not persuasive. However, defendants raise a separate objection to David, which is that he is not qualified to give an opinion about FDA regulations, the only subject of his report. In my view, David's report consists of nothing but a list of regulations and conclusions that defendants violated them, along with a narrative of historical facts that does not require an expert to interpret. I agree with defendants that nothing in David's report suggests that he is a regulatory expert (he is a biomedical engineer), but even if he were, plaintiff has not shown how his testimony would be helpful to the jury.

Plaintiff says in her response that David has "evaluated the biomedical engineering risks of some 20,000 medical devices." Dkt. #150 at 6. However, plaintiff fails to point to any aspect of David's report that draws on this experience in reaching any of his conclusions. Instead, the only support he cites are regulations about which he has no apparent expertise and which have only a peripheral relationship to plaintiff's claims. Accordingly, I am granting defendants' motion to exclude David's testimony.

D. Damages Experts

James Gracey and Paul Randle are damages experts. Defendant challenges Gracey's opinions that (1) plaintiff is a "disabled worker" with a reduced earning capacity; (2) she will have to retire at age 50; and (3) she will require household assistance. I agree that Gracey has failed to support any of these opinions. To begin with, it is undisputed that Gracey gave his opinions before plaintiff had shoulder replacement surgery and he has not supplemented his opinion to account for that or considered any possible improvements that the surgery might bring. That fact alone undermines many of Gracey's opinions. Even setting that fact aside, however, Gracey's opinion that plaintiff is a "disabled worker" is contradicted by the fact that plaintiff is working now and has not reduced her hours or responsibilities. Plaintiff says that she endures pain while she works, but that is beside the point for the purpose of Gracey's testimony. Plaintiff is free to seek damages for pain and suffering, but she cannot be compensated for lost wages if she is working the same job and the same hours she was working before her injury.

With respect to Gracey's opinions that plaintiff will have a diminished earning capacity, Gracey points to plaintiff's concern that her condition will affect her ability to get promoted, but plaintiff points to no specific evidence to support that concern. In particular, plaintiff points to no evidence that her job performance has suffered, that her employer has questioned her ability to do her job or that she has any plans to limit her work in the future.

With respect to Gracey's opinion that plaintiff may have to retire when she is fifty years old, Gracey relies on various publications for the general proposition that many

"disabled workers" retire early. However, he fails to consider any facts about plaintiff's situation in particular that would require early retirement, let alone that would support a conclusion that she would have to retire at a particular age.

Finally, Gracey provides no support in his report for his opinion that plaintiff will require household assistance. In her brief, plaintiff acknowledges that she does not require assistance now, but she says that does not mean that she will not require assistance at some time in the future. That is true, but not helpful. Gracey cannot provide an expert opinion that is supported by nothing but a theoretical possibility.

With respect to Randle, defendants seek to exclude his opinions about plaintiff's lost earnings and expenses for household assistance. Because the parties agree that Randle relied on Gracey's report to generate these opinions and I have concluded that Gracey's testimony as to those issues must be excluded, I am granting this motion as well.

ORDER

IT IS ORDERED that

1. The motion in limine filed by defendants Stryker Corportation and Stryker Sales Corporation to exclude the testimony of Yadin David, dkt. #117, is GRANTED.

2. Defendants' motion to exclude the testimony of Brian Fukushima, dkt. #119, is DENIED.

3. Defendants' motion to exclude the testimony of Sander Greenland, dkt. #121, is DENIED.

4. Defendants' motion to limit the testimony of James Gracey, dkt. #123, is GRANTED. Gracey may not give testimony about any of the following opinions: (1) plaintiff is a "disabled worker" with a reduced earning capacity; (2) plaintiff will have to retire at age 50; and (3) plaintiff will require household assistance.

5. Defendants' motion to exclude the testimony of Stephen Trippel, dkt. #124, is GRANTED with respect to any opinion about safety testing that defendants should have performed. The motion is DENIED in all other respects.

6. Defendants' motion to exclude the testimony of Martin Wells, dkt. #126, is, GRANTED with respect to Wells's reliance on animal studies. The motion is DENIED in all other respects.

7. Defendants' motion to limit the testimony of Paul Randle, dkt. #128, is GRANTED. Randle may not offer opinions about plaintiff's lost earnings or expenses for household assistance.

8. Defendants' motion to exclude the testimony of Peggy Pence, dkt. #129, is DENIED. However, Pence's testimony must focus on the underlying safety reasons for the standard of care, not on questions about whether defendants violated particular federal regulations.

9. Defendants' motion to exclude the testimony of Peter Kurzweil, dkt. #131, is

GRANTED with respect to Kurzweil's reliance on animal studies. The motion is DENIED in all other respects.

Entered this 4th day of September, 2013.

BY THE COURT:
/s/
BARBARA B. CRABB
District Judge