

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
CEDAR RAPIDS DIVISION**

RICHARD WESSELS,

Plaintiff,

vs.

BIOMET ORTHOPEDICS, LLC;
BIOMET, INC.; and BIOMET US
RECONSTRUCTION, LLC;¹

Defendants.

No. 18-CV-97-KEM

**MEMORANDUM OPINION
AND ORDER**

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This product-liability action, previously part of a multidistrict litigation (MDL), involves allegations of a defective metal-on-metal hip implant designed and manufactured by Defendants Biomet Inc. and related entities (collectively, Biomet). Biomet now moves

¹ After the summary-judgment hearing, Plaintiff confirmed that Defendant “Biomet LLC” should not be listed on the docket in this case and has been dismissed as a defendant. *See* Doc. 285.

to exclude Plaintiff Richard Wessels’s claim-specific expert witness’s causation opinion and for summary judgment. Docs. 253, 256. Wessels resists. Docs. 268, 269. I **grant in part and deny in part** the motion to exclude (Doc. 256) and **grant in part and deny in part** the motion for summary judgment (Doc. 253).

I. BACKGROUND

In December 2001, Wessels sought treatment from Jeffrey Nassif, MD, for hip pain that started after Wessels slipped and fell on ice. Def. SOF ¶¶ 1-2; Pl. Resp. SOF ¶¶ 1-2.² X-rays at that time showed severe osteoarthritis in the right hip and the beginnings of arthritis in the left hip. Def. SOF ¶¶ 7-8; Pl. Resp. SOF ¶¶ 7-8. In June 2002, when Wessels was 47 years old, Dr. Nassif performed right hip replacement surgery on Wessels using the Biomet M2a-Taper, a metal-on-metal hip replacement made of cobalt and chromium, among other things. Def. SOF ¶ 17-19, 121, 129-31; Pl. Resp. SOF ¶¶ 17-19, 121, 129-31. A few months later, in November 2002, Dr. Nassif performed the same hip replacement surgery on Wessels’s left hip. Def. SOF ¶¶ 25, 28; Pl. Resp. ¶¶ 25, 28.

Initially, Wessels did well post-operatively. Def. SOF ¶ 34; Pl. Resp. ¶ 34. In June 2011, more than eight years after his hip replacement surgeries, Wessels presented to the emergency room complaining of hip pain. Def. SOF ¶¶ 35-36; Pl. Resp. SOF ¶¶ 35-36. Laboratory results showed numerous markers for infection. Def. SOF ¶ 39; Pl. Resp. SOF ¶ 39. On June 29, 2011, Dr. Nassif operated, performing irrigation and debridement procedures to remove fluid and necrotic muscle tissue from both of Wessels’s hips (more from the left than the right). Def. SOF ¶¶ 41-48; Pl. Resp. SOF ¶¶ 41-48; Def. App. 318-19. Pathology of the removed tissue revealed it contained metal

² “Def. SOF” refers to Biomet’s Statement of Facts, filed at Doc. 265. “Pl. Resp. SOF” refers to Wessels’s Response to Biomet’s Statement of Facts, filed at Doc. 269-2. “Def. App.” refers to Biomet’s Appendix, filed at Docs. 253-2 to 253-9. “Pl. App.” refers to Wessels’s Appendix, filed at Doc. 269-1.

fragments, and Dr. Nassif's treatment notes reflect that he was unsure whether the fluid collection and muscle loss was due to the metal debris or infection. *Id.* On follow-up on July 21, 2011, Dr. Nassif debrided some additional muscle tissue from Wessels's left hip. Def. SOF ¶¶ 53-54; Pl. Resp. SOF ¶¶ 53-54; Def. App. 311.

Wessels ultimately had multiple revision surgeries to remove the metal-on-metal hip replacements and replace them with a different kind of implant. On August 8, 2012, Dr. Nassif performed the first part of a revision surgery on Wessels's right hip, and on October 31, 2012, he completed the revision surgery and implanted a new metal-on-polyethylene implant in Wessels's right hip. Def. SOF ¶¶ 61-70; Pl. Resp. SOF ¶¶ 61-70; Def. App. 314-15; Pl. App. 130. Dr. Nassif performed a revision surgery on Wessels's left hip and replaced Wessels's implant with a metal-on-polyethylene implant on February 6, 2013. Def. SOF ¶ 71; Pl. Resp. SOF ¶ 71; Def. App. 82, 312-13. Wessels underwent a second revision surgery on his left hip on January 29, 2018, this time performed by Nicholas Noiseux, MD. Def. SOF ¶ 83; Pl. SOF Resp. ¶ 83.

Wessels brought design-defect claims sounding in products liability and negligence against Biomet, alleging that Biomet's design of the metal-on-metal M2a-Taper hip implant was defective. Wessels also based his products-liability and negligence claims on Biomet's failure to warn of the dangers of the hip implant.³ To support his claims, Wessels relies on expert George Kantor, MD, who submitted a general expert opinion on Biomet metal-on-metal hip implants in the multidistrict litigation, as well as a case-specific expert opinion from Dr. Noiseux. *See* Def. App. 78-88; Pl. App. 1-135.

Biomet moves to exclude Dr. Noiseux's expert opinions on causation under Federal Rule of Evidence 702 and *Daubert v. Merrell Lynch Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Doc. 256. Biomet also moves for summary judgment on all Wessels's

³ Wessels also brought claims of manufacturing defect and breach of implied warranty, but the parties previously stipulated to the dismissal of these claims. Doc. 252. The stipulation also notes Wessels will not seek punitive damages or damages based on lost wages or loss of earning capacity. *Id.*

remaining claims. Doc. 253. Wessels resists. Docs. 268, 269. Biomet filed replies. Docs. 276, 277. The parties consented to the exercise of jurisdiction by a United States magistrate judge, and the case was referred to me for final disposition. Doc. 226. I held a telephonic hearing on the motions on May 14, 2020. Doc. 284.

II. MOTION TO EXCLUDE EXPERT OPINION

Biomet argues that Dr. Noiseux's expert report failed to disclose "the basis and reasons for" his opinions and that therefore, his opinion must be excluded under Federal Rule of Civil Procedure 26(a)(2)(B). Biomet further argues that Dr. Noiseux withdrew the opinions in his expert report related to Wessels's right hip implant at his deposition. Biomet also challenges the reliability of Dr. Noiseux's causation opinion with regards to Wessels's left hip.

A. Inadequacy of the Rule 26(a)(2) Disclosure

Under Federal Rule of Civil Procedure 26(a)(2)(B), expert witnesses must provide a written report containing, among other things, "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them." Wessels provided Biomet with Dr. Noiseux's expert report in March 2019, in accordance with the deadline set by the scheduling order in this case. *See* Doc. 226. Biomet now argues that this report was deficient under Rule 26, warranting exclusion of Dr. Noiseux's opinion.

Dr. Noiseux's report consisted of a series of yes or no questions (formulated by Plaintiff's counsel after a telephone conversation with Dr. Noiseux) with space for Dr. Noiseux to add comments, if any. Def. App. 78-88.⁴ It indicated Dr. Noiseux believed that Wessels experienced an adverse local tissue reaction (ALTR), particularly in his left hip; that Wessels's Biomet implant caused both ALTR and osteolysis (bone loss) in his

⁴ To avoid having to cite to the same material at two different places, I cite to the summary-judgment record, rather than the motion-to-exclude record.

left hip; that Wessels's Biomet implant caused either an ALTR or osteolysis in his right hip; and that Wessels continued to experience ALTR and osteolysis in his left hip through January 2018, when Dr. Noiseux conducted surgery. Def. App. 80-85. The report indicated that each of these opinions was based on a particular surgical note from Dr. Nassif or, in the case of the last opinion, based on Dr. Noiseux's findings during surgery on Wessels. *Id.* For a few of the opinions, Dr. Noiseux included comments pointing to specific references in Dr. Nassif's notes supporting his conclusion, but for others, Dr. Noiseux did not elaborate. *Id.*

The purpose of the expert report is to eliminate "unfair surprise to the opposing party" and to conserve resources by eliminating the need for lengthy expert depositions. *Sylla-Sawdon v. Uniroyal Goodrich Tire Co.*, 47 F.3d 277, 284 (8th Cir. 1995) (citing Fed. R. Civ. P. 26(a)(2)(B) advisory committee's note to 1993 amendment). In accordance with this purpose, expert reports should be "detailed and complete," not "sketchy and vague." *Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635, 642 (7th Cir. 2008) (citing Fed. R. Civ. P. 26(a)(2)(B) advisory committee's note to 1993 amendment); see also *Sylla-Sawdon*, 47 F.3d at 284. They "must include 'how' and 'why' the expert reached a particular result, not merely the expert's conclusory opinions." *Cooper v. Wullweber*, No. C10-1032, 2012 WL 1904806, at *5 (N.D. Iowa May 25, 2012) (quoting *Salgado v. Gen. Motors Corp.*, 150 F.3d 735, 742 n.6 (7th Cir. 1998)); see also Fed. R. Civ. P. 26(a)(2)(B)(i). An expert report need not "replicate every word that the expert might say on the stand," but it should "convey the substance of the expert's opinion" so that "'opposing parties have a reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses.'" *Walsh v. Chez*, 583 F.3d 990, 993-94 (7th Cir. 2009) (quoting Fed. R. Civ. P. 26(a)(2)(B) advisory committee's note to 1993 amendment); see also *Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051, 1060 (D. Minn. 2012) ("The requirement to provide a report containing all bases for an expert's opinion is intended to permit opposing counsel to effectively prepare to depose the expert in advance of trial."). In sum, Rule 26

contemplates that the report will provide notice to opposing counsel of the expert's opinions, but "that the expert will supplement, elaborate upon, explain and subject himself to cross-examination upon his report." *Thompson v. Doane Pet Care Co.*, 470 F.3d 1201, 1203 (6th Cir. 2006).

If a report fails to comply with Rule 26, the "court has wide discretion to fashion a remedy or sanction as appropriate for the particular circumstances of the case." *Wegener v. Johnson*, 527 F.3d 687, 692 (8th Cir. 2008). "The district court may exclude the information or testimony as a self-executing sanction unless the party's failure to comply is substantially justified or harmless." *Id.* "When fashioning a remedy, the district court should consider, *inter alia*, the reason for noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony." *Id.* The Eighth Circuit has cautioned against the "harsh penalty" of exclusion "where exclusion of evidence [i]s tantamount to dismissal of claims" (as it would be here), noting that a finding of willfulness, bad faith, or fault may be required. *Id.*

Although Dr. Noiseux's report could have elaborated further on the bases for his opinions, I do not find that exclusion of his expert opinion is warranted as a sanction for a discovery violation. First, I note that if Biomet believed it needed more information about the bases for Dr. Noiseux's expert opinion, it could have raised this issue in the eight months between the disclosure of Dr. Noiseux's expert report in early March 2019 and his deposition in late October 2019. It did not do so. I further note that it appears Biomet had adequate information to prepare for Dr. Noiseux's deposition, as the deposition transcript reflects Biomet's counsel had a good enough understanding of Dr. Noiseux's opinions to effectively cross-examine him about them. Even if Dr. Noiseux's report failed to comply with Rule 26, Biomet has not been prejudiced, and the harsh sanction of exclusion (which the parties agree would result in dismissal of this action) is not warranted here.

The cases cited by Biomet are all distinguishable. In *Wegener*, the plaintiff disclosed a new supplemental expert opinion two-and-a-half weeks before trial, and the Eighth Circuit affirmed the district court’s finding that this non-case-dispositive opinion was not admissible as impeachment or rebuttal evidence and that exclusion was an appropriate remedy. 527 F.3d at 690, 692-94. In *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1363, 1366 (Fed. Cir. 2011), the court affirmed exclusion of a non-case-dispositive expert opinion submitted for the first time in support of a summary-judgment resistance. In both of these cases, there was cognizable prejudice to the opposing party, as the timing of the disclosure did not allow for the opposing party to depose the expert prior to summary judgment, unlike here.

Biomet also relies on the Seventh Circuit case *Ciomber*. In that case, the plaintiff’s expert report contained only “eight terse statements,” opining that a “buildup of [LP] gas from [a] failed . . . pipe connection in the basement area” caused the explosion in plaintiff’s house. 527 F.3d at 638 (first alteration in original). The expert report indicated this conclusion was based on “inspection” and “analysis.” *Id.* The expert report also indicated that the expert had reviewed documents prior to forming his conclusions but provided only “vague references” to those documents. *Id.* Dr. Noiseux’s expert report here contained more information regarding the basis for his opinions than the expert report in *Ciomber*—Dr. Noiseux pointed to some specific observations from the treatment records supporting his opinions (in contrast to the *Ciomber* expert who just noted “inspection” and “analysis” as the basis for his opinions), and it was clear from Dr. Noiseux’s expert report that he relied upon a review of the treatment records, as well as two specific articles (unlike in *Ciomber* where it was unclear what documents the expert relied upon). Moreover, in *Ciomber*, the plaintiffs recognized the expert report was incomplete and requested additional time to supplement the expert report upon its disclosure, but they never provided additional information, even though their request for more time was granted. *Id.* at 638-39. Thus, the plaintiffs in *Ciomber*

were seemingly on notice of the deficient expert report—unlike here, where the issue was not raised until summary judgment.

Finally, Biomet cites *Cooper*, a decision from this district. In that case, the court recognized that the expert report’s failure to include the “basis and reasons” for the expert’s opinions would not necessitate exclusion if the violation of the disclosure rule was “substantially justified or harmless.” *Id.* at *6 (quoting *Wegener*, 572 F.3d at 692). The court noted that if the expert “had provided the ‘basis and reasons’ for his opinions” at his deposition, “then it could be argued that [the] failure to include that information in the written report was harmless.” *Id.* Because the expert testified that “he could not recall the events” at issue “at the time of his deposition,” he was “necessarily . . . unable to testify regarding” the “‘how’ and ‘why’” of his opinion. *Id.* at *7. Here, Dr. Noiseux further fleshed out the basis for his opinions at his deposition, and it does not appear that Biomet was prejudiced by any inadequacy in the expert report.

I find that Dr. Noiseux’s expert report sufficiently provided Biomet “notice of the theory against which [it] had to defend,” and it “alerted [Biomet] to the kind of rebuttal and cross-examination [it] would need to undertake.” *Walsh*, 583 F.3d at 994. I further find that any noncompliance with the expert-disclosure rule was harmless, as Biomet was able to effectively cross-examine Dr. Noiseux at his deposition. *See Nicholson v. Biomet, Inc.*, No. 18-CV-3057-CJW-KEM, Doc. 321 at 20-21 (N.D.I.A. March 6, 2020).

B. The Reliability of Dr. Noiseux’s Opinions

Under Federal Rule of Evidence 702, an expert opinion is admissible if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert*, the Supreme Court held that Rule 702 requires trial courts to “serve as ‘gatekeepers to “insure that proffered expert testimony is both relevant and reliable.”” *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006) (quoting *Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003)). The Supreme Court identified in *Daubert* several factors for the court to consider when assessing reliability: “(1) whether the theory ‘can be (and has been) tested,’ (2) whether the theory ‘has been subject to peer review and publication,’ (3) ‘the known or potential rate of error,’ and (4) whether the theory enjoys general acceptance in the relevant scientific community.” *Id.* (quoting *Daubert*, 509 U.S. at 593-94). The Eighth Circuit has identified additional factors to consider, including “whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.” *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 687 (8th Cir. 2001). The party offering the expert testimony bears the burden of proving reliability. *Wagner*, 450 F.3d at 758. District courts have “broad discretion” in determining the admissibility of expert testimony. *Id.*

Biomet challenges the reliability of Dr. Noiseux’s opinions related to causation. As Dr. Noiseux’s deposition testimony about Wessels’s right hip implant differs from his testimony about Wessels’s left hip implant, I will address the reliability of Dr. Noiseux’s opinions about Wessels’s right and left hip implants separately.

1. Right Hip Implant

Biomet argues that at his deposition, Dr. Noiseux withdrew his opinions regarding Wessels’s right hip implant or otherwise demonstrated that those opinions are not reliable. In his expert report, Dr. Noiseux opined that Wessels suffered either ALTR or osteolysis in his right hip caused by his Biomet implant (in numbered paragraph 12). Def. App.

80. The report indicated this opinion was based on Dr. Nassif's surgical note from August 2012, and Dr. Noiseux specifically commented: "in addition to failed [total hip arthroplasty] due to chronic infection concomitant with osteolysis, likely secondary to metal-on-metal ALTR." *Id.*; *see also* Def. App. 316-17 (Dr. Nassif's surgical note indicated a diagnosis of "[c]hronically infected right metal-on-metal total hip arthroplasty"; noted Wessels "developed an infection with what appeared to be metal-on-metal debris over a year ago; and reflected "[t]here was significant osteolysis laterally with minimal to no bone at the lateral aspect of the femur"). Dr. Noiseux also opined in his report that if Wessels's right hip implant in 2002 had been metal-on-polyethylene (instead of metal-on-metal), it would "have reduced the risk of . . . Wessels experiencing the infections in his hip in 2011" and "the risk of . . . Wessels needing to have a two-stage [right] hip revision surgery in 2012." Def. App. 84-85. The report acknowledged that the opinion regarding the reduced risk of infections was "more speculative," but noted "there is evidence that deep infections occur more frequently in metal-on-metal hips." Def. App. 84.

Biomet's theory is that Wessels's need for revision surgeries was caused by infections, which arose independently of his metal-on-metal hip implants. At his deposition, Dr. Noiseux explained that there was no way to know whether Wessels's infections were caused by his hip implants or by some other source. Pl. App. 73-74. He explained that the two studies he relied upon in his expert report demonstrated an increased likelihood of infection when a patient suffers an adverse reaction to a metal-on-metal hip implant, but neither study concluded that the implant or ALTR causes the infection; rather, they simply note the association between the two. *See* Def. App. 73. Dr. Noiseux also recognized that infections can impact the function of a hip implant. Pl. App. 74. When asked whether Wessels's infection impacted the functioning of his right hip, Dr. Noiseux responded that it could have had an impact, noting that Wessels needed a two-stage revision surgery for his right hip (with surgeries in August and October 2012) and that "typically[,]. . . having . . . the infection in there for a certain period of time

and then having it treated with two surgeries [as opposed to one] is going to ultimately lead to a lower functional result.” Pl. App. 74-75. When asked again whether the infection “independently impact[ed] the functioning” of Wessels’s right hip implant, Dr. Noiseux noted that because he never operated on Wessels’s right hip, it was hard for him to know the answer, but based on his experience with other patients, “the function of [Wessels’s] right hip would be . . . impacted negatively by the infection that he had and the surgeries that he had.” Pl. App. 75. After Dr. Noiseux testified that there was no way to know whether Wessels’s right hip developed ALTR, he stated, “I’m going to try to focus [on] . . . his left hip, just since I’ve never operated on his right hip, if that’s okay.” Pl. App. 77-79. The following exchange then occurred between defense counsel and Dr. Noiseux:

Counsel: [In your expert report, in response to question twelve asking “whether Wessels experienced either an [ALTR] or osteolysis that was caused by his right metal-on-metal hip implant,” y]ou said yes . . . , but I thought you just said --

Dr. Noiseux: Right.

Counsel: -- with regard to ALTR you could not do that.

Dr. Noiseux: Yeah. I -- That’s correct. I, again, would only have surmised . . . in accordance with . . . pretty much the only two papers that . . . specify that, that it was perhaps likely that there was [ALTR] as well as infection. But you’re right, I cannot . . . agree with myself with having said yes that both were necessarily there just based on Dr. Nassif’s description of the surgery.

Counsel: And osteolysis can be caused by infection too, correct?

Dr. Noiseux: Correct.

Counsel: So you can’t say that the metal-on-metal --

Dr. Noiseux: Well, I don’t know that we -- I think that’s maybe -- semantically I don’t know that that’s the correct term. I think we would . . . call the damage osteomyelitis if it was infection that caused the bone or septic damage. . . . We try to shy away from the name osteolysis just because of the actual meaning of osteolysis when it was described was a -- again, a tribological term, so some sort of bony reaction to debris of artificial components, so whether those are metal ions or polyethylene particles, but not to body’s own reaction to bacteria. So I . . . -- Again, we’re using a lot of terms generally because we probably don’t have a better

term for them, but I would say osteolysis is not a term we typically associate with infection.

Counsel: Would it be fair that, as we sit here today, that you want to sort of withdraw any opinions associated with the right hip and the impact of the metal-on-metal implant; is that fair?

Dr. Noiseux: That's fair. And I would say probably when I was asked to do all these things I was somewhat reluctant to specifically talk about his right hip since I'm not asked to be an expert but more describing my experience with treating his left hip and so that would be my preference.

Pl. App. 79-81. Later, when plaintiff's counsel questioned defense counsel's statement that Dr. Noiseux was only offering opinions related to the left hip, defense counsel elicited the following testimony:

Counsel: [Y]our opinions are only going to focus on the left hip, correct, for the purpose of this lawsuit?

Dr. Noiseux: Again, I would say you've asked me questions and opinions about the right hip. I feel like I'm not in a good place to offer you opinions since I've never operated on that hip and I only ever saw it, both in x-ray and how he functioned clinically, after everything was revised to nonmetal-on-metal containing hip. So everything is real sort of extrapolation and opinion. The left hip I feel much more qualified to call myself a treating physician for having seen inside of --

Counsel: So any opinion or discussions or answers you've done for the right hip are not to a reasonable degree of medical certainty?

Dr. Noiseux: Right.

Pl. App. 92.

On cross-examination, plaintiff's counsel attempted to rehabilitate Dr. Noiseux's opinions about Wessels's right hip. Plaintiff's counsel asked whether Dr. Noiseux needed "to know the entire clinical picture of what's happened in both hips" to properly treat Wessels's left hip. Pl. App. 117. Dr. Noiseux responded that he had "certainly made opinions of what happened on [Wessels's] right hip by reading the story, it's just that they're opinions rather than . . . part of [his] treating [Wessels's] . . . problems with surgery and such." *Id.* Plaintiff's counsel reminded Dr. Noiseux that "[d]octors get to give opinions" and that Dr. Noiseux routinely reviews other doctors' treatment records to inform himself of a patient's history. Pl. App. 117-18. Plaintiff's counsel asked Dr.

Noiseux to review the pathology report from June 2011, after Dr. Nassif had operated on both Wessels's hips to remove fluid and decayed muscle. Pl. App. 119; *see* Def. App. 318-19 (Dr. Nassif's June 2011 operative report reflects that upon opening the right hip, "a copious amount of purulence was obtained"; that this fluid would be sent to "pathology to . . . look for metal fragments"; and that Dr. Nassif removed "devitalized tissue" from the right hip); Def. App. 347 (June 2011 pathology report notes a diagnosis of "metallosis (detritic synovitis)" based on the right hip tissue). The following exchange then occurred:

Counsel: Based on the pathology findings . . . under diagnosis, do you believe that in addition to the infection, [Wessels's] tissue showed that he was having -- whether you want to call it an [ALTR] or adverse reaction to metal debris -- that that was going on in both hips at that time?

Dr. Noiseux: Based on this pathological diagnosis I would agree.

Counsel: It says, metallosis in the soft tissue of the left and metallosis in the soft tissue of the right hip as well?

Dr. Noiseux: Correct.

Counsel: So we know he had an infection, but the pathology and Dr. Nassif's surgery report indicates that he also had a metal-metal reaction going on at the same time --

Dr. Noiseux: Correct. . . .

Counsel: [The treatment note from June 2011 indicates Dr. Nassif] removed all devitalized tissue from the right hip. That suggests that there was, in addition to the infection, at least some metal-metal reaction going on in the right hip at that time as well, right?

Dr. Noiseux: It does suggest it. I -- it -- oh, it does not near -- wait a second. [Dr. Nassif noted he] will send fluid to pathology again to look for metal fragments. So this one didn't have the kind of resultant pathology described there, so I would say --

Counsel: But we know from the pathology report . . . that the right tissue was -- . . . The pathologist diagnosed it as metallosis?

Dr. Noiseux: Right. So -- so --

Counsel: What was the pathologist's diagnosis of the right tissue hip in the pathology report from the June 29th, 2011 [surgery?]

Dr. Noiseux: Right hip -- Soft tissue of right hip joint excision. Metallosis and that's all. That's B --

Counsel: Okay.

Dr. Noiseux: -- from the pathology.

Pl. App. 119-122. That was the last Plaintiff's counsel and Dr. Noiseux discussed Wessels's right hip specifically until the very end of the deposition, when plaintiff's counsel asked whether Dr. Noiseux believed that "the reaction to metal wear and debris was a substantial factor in causing [Wessels's] need to have revision surgery" in his right hip. Pl. App. 131-32. Dr. Noiseux responded that he was "formulating an opinion without having" treated Wessels's right hip and without having looked at x-rays and MRIs "or any other aspect of the right hip other than the final x-ray and the prior [treatment] notes," but indicated he "would still say yes based on our understanding of how these things evolve and proceed and the pathology and the operative note from Dr. Nassif." Pl. App. 132. Dr. Noiseux also responded yes to plaintiff's counsel's question asking generally whether he had "answered all the questions . . . today on the basis of reasonable medical probability." Pl. App. 131.

I agree with Biomet that Dr. Noiseux's causation opinions related to Wessels's right hip are unreliable. Dr. Noiseux agreed with defense counsel that he wanted to "withdraw" his causation opinions related to the right hip and that any such opinions were not to a reasonable degree of medical certainty. Although he testified generally on cross-examination that all his opinions during the deposition were based on "reasonable medical probability," he did not specifically state that this applied to his right-hip causation opinions. Wessels argues that once Dr. Noiseux understood during cross-examination that he was allowed to offer opinions on the hip he did not treat, he became more comfortable discussing the right hip. Although Dr. Noiseux recognized on cross-examination that Wessels suffered "metallosis" in the right hip in June 2011, he had earlier explained that metallosis could mean simply that the tissue or bone was stained gray or black from the metal debris, as opposed to ALTR, in which the muscle tissue is "light brownish, grayish yellow" because it is necrotic. Pl. App. 54, 119-23. Most importantly to the reliability determination, Dr. Noiseux could not eliminate infection as the cause of Wessels's right hip issues, recognizing that infection likely impacted Wessels's right-hip functioning and the need for his two-stage revision surgery in 2012.

Although Dr. Noiseux recognized that Wessels suffered osteolysis in the right hip, which is not often caused by infection, he did not testify that this osteolysis, as opposed to infection, caused the need for Wessels's right-hip revision surgeries. I find that Dr. Noiseux's causation opinions related to Wessels's right hip are unreliable and should be excluded.

I briefly address Biomet's arguments that Dr. Noiseux contradicted his expert report at his deposition, since Biomet suggests these contradictions are relevant to the reliability of Dr. Noiseux's left-hip opinions. First, Biomet argues that because Dr. Noiseux testified that he could not say Wessels suffered ALTR in his right hip, he contradicted his expert report. But Dr. Noiseux opined in his expert report that Wessels suffered "either ALTR or osteolysis" in the right hip, and the evidence supports that Wessels suffered osteolysis. To the extent that Dr. Noiseux agreed with Biomet's counsel at the deposition that he disagreed with his prior opinion, it appears based on a misunderstanding of what he said in his expert report. Biomet also argues that the following opinions conflict: that Wessels's risk of infection would have been reduced with a non-metal-on-metal hip (in Dr. Noiseux's expert report) and that Wessels could have suffered an infection even if his original implant had been a non-metal-on-metal hip (at Dr. Noiseux's deposition). Dr. Noiseux explained that studies showed an increased association between infection and metal-on-metal hips, but he acknowledged that there is still a risk of infection when a person receives a metal-on-polyethylene hip, albeit a smaller risk (a 1.3% chance as compared to a 5.6% chance). Pl. App. 61. These opinions do not conflict.

2. Left Hip Implant

In his expert report, Dr. Noiseux opined that based on his review of Dr. Nassif's operative reports from Wessels's June 2011 and February 2013 surgeries, Wessels suffered from ALTR and osteolysis in his left hip. Def. App. 80-82; *see also* Def. App. 318-19 (Dr. Nassif's June 2011 surgical note indicates Wessels's left hip contained fluid;

“a very large pocket extending distally in his vastus muscle”; “near complete loss of the greater trochanter” bone such that “[i]t was bare prosthesis on the lateral aspect of the femur”; and “devitalized vastus muscle that was . . . black in nature” and that pathology showed had “metal fragments” and a “histiocytic response”—Dr. Nassif noted a “concern about an allergic hypersensitivity to the metal debris,” but noted he was “unsure if this was the case due to” the evidence of infection); Def. App. 312-13 (Dr. Nassif’s February 2013 surgical note indicates Wessels’s “develop[ed] . . . tissue response consistent with metallosis”; that “there was a silver-gray tissue” with “evidence of metallosis”; that there was fluid and “grayish-silver debris throughout the hip”; that “[a]t this point, it was felt that everything was metallosis and not infection”; that “[t]here was significant osteolysis of the proximal femur” and “partial absence of the greater trochanter”; and that upon removing part of the metal-on-metal implant, Dr. Nassif discovered “significant osteolytic debris” and “significant metallic debris”). Dr. Noiseux also opined that based upon his findings during surgery on Wessels’s left hip in January 2018, Wessels continued to experience ALTR and osteolysis caused by the metal debris from the original Biomet metal-on-metal implant (removed by Dr. Noiseux in February 2013). Def. App. 82-83.

Biomet argues that Dr. Noiseux did not adequately rule out alternative causes for Wessels’s need for left hip revision surgery—specifically, infection and patient factors such as Wessels’s weight and activity level. The Eighth Circuit has held that “a medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*.” *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000).

A differential diagnosis begins with an expert’s “ruling in” plausible causes of an injury. Then the expert “rules out” less likely causes until the most likely cause remains. While differential diagnoses are generally admissible, they should be excluded if they are scientifically invalid.

Junk v. Terminix Int’l Co., 628 F.3d 439, 449 (8th Cir. 2010) (citations omitted). “[A]n expert need not rule out all possible causes of an injury,” but “an expert . . . should

‘adequately account[] for obvious alternative explanations.’” *Redd v. DePuy Orthopaedics, Inc.*, 700 F. App’x 551, 554 (8th Cir. 2017) (per curiam) (alteration in original) (quoting **Fed. R. Evid. 702 advisory committee note to 2000 amendment** (comparing “*Claar v. Burlington N.R.R.*, 29 F.3d 499 (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiff’s condition),” with “*Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996) (the possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert)”)).

Contrary to Biomet’s argument otherwise, Dr. Noiseux adequately considered and rejected infection as the cause of Wessels’s need for revision surgeries in his left hip. As Biomet notes, Dr. Noiseux recognized that the June 2011 surgery confirmed infection in Wessels’s left hip. Pl. App. 58. Dr. Noiseux also admitted that he did not know what caused the infection, that infection can cause osteolysis, and that infection can impact the function of an implant. Pl. App. 73-74, 80. He denied, however, that infection can cause ALTR, explaining that bacteria from an infection would not make the body react differently to the same amount of cobalt or chromium from a metal-on-metal hip implant. Pl. App. 93-94. As Biomet notes, Dr. Noiseux suggested that the extent of the osteolysis in Wessels’s case supports that it was caused by ALTR, not infection. Pl. App. 83-84, 88-89. Biomet argues that Dr. Noiseux identified no support for that opinion, but Dr. Noiseux explained that “infection does not cause . . . complete destruction of local tissues” like ALTR does and as seen in Wessels’s case. Pl. App. 89. Biomet did not question Dr. Noiseux further about the basis for this statement, but it seems within Dr. Noiseux’s general knowledge based on his experience as an orthopedic surgeon specializing in hip-implant revision surgeries, who in addition, has written several book chapters and publications, completed a research fellowship at the Mayo Clinic that included training in epidemiology, and has served in leadership positions on the Mid-America Orthopaedic Association. Def. App. 78-79; Pl. App. 41-47; *see also* **Fed. R. Evid. 702 advisory committee note to 2002 amendment** (“Nothing in this amendment

is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.” (citation omitted) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) (stating that “no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience”))). Furthermore, Biomet does not acknowledge Dr. Noiseux’s main reasoning ruling out infection: Dr. Noiseux opined that the infection did not impact Wessels’s left hip functioning in this case because the infection was cured by Dr. Nassif’s June 2011 surgery, but Wessels still required revision surgery in February 2013, the results of which showed worsening ALTR and osteolysis since June 2011, despite the lack of infection. Pl. App. 84-86.

Biomet also argues that Dr. Noiseux did not adequately consider whether patient factors like activity level or weight impacted Wessels’s need for revision surgery. At his deposition, Dr. Noiseux responded as follows to Biomet’s questioning:

Counsel: As Mr. Wessels’[s] treating physician, do you believe that his weight status has impacted either the need for an original revision or the subsequent revisions of his left hip?

Dr. Noiseux: Based on our understanding of the evolution of osteoarthritis and other needs for revision, I would say yes for his primary hip and no for his revisions.

Counsel: Why not for his revisions?

Dr. Noiseux: I don’t think the diagnoses for his revision are related to weight, infection, ALTR or cup loosening.

The Court Reporter: I’m sorry, what was the last one?

Dr. Noiseux: Cup loosening.

The Court Reporter: Thank you.

Dr. Noiseux: That was his diagnosis for which I did a revision.

Def. App. 108. I agree with Biomet that this response is somewhat confusing, as Dr. Noiseux said that the “diagnosis for his revision” surgeries was not related to cup loosening, but then said that cup loosening was the diagnosis for the 2018 revision

surgery; and because Dr. Noiseux's testimony on the whole supports that ALTR was also a reason for the revision surgeries. Nevertheless, Dr. Noiseux's answer supports that he considered and rejected Wessels's weight as a cause of the need for revision surgery. Although Biomet argues that Dr. Noiseux's response was too "dismissive," considered in the context of his testimony as a whole, his response can fairly be read as relying on his reading of the treatment notes (including the "diagnosis" section) as supporting that ALTR and osteolysis caused the need for the revision surgeries, which in turn were caused by the metal-on-metal hip implant, and not Wessels's weight. Overall, I find that Dr. Noiseux adequately considered and rejected alternative explanations for Wessels's need for revision surgeries on his left hip.

The cases cited by Biomet are distinguishable. In both *Bland v. Verizon Wireless (VAW) L.L.C.*, 538 F.3d 893 (8th Cir. 2008); and *Turner*, 229 F.3d at 1205-06, 1208; the Eighth Circuit affirmed the exclusion of the plaintiffs' treating doctors' expert opinions when the doctors relied on the temporal proximity between an accident and the plaintiff's symptoms in determining causation and did not rule out other possible causes. Here, by contrast, Dr. Noiseux relied on medical findings (not temporal proximity) to support his causation opinion, and he explained why those findings demonstrated the metal-on-metal hip implant caused Wessels's injuries, not infection. In *Redd*, 700 F. App'x at, 553, the plaintiff's expert witness was a metal expert who did not study the effects of metal in humans. In concluding that a manufacturing defect in the metal of plaintiff's hip implant caused it to fracture, the expert did not consider "biomechanical factors" that come from implanting metal in a human body, even though the plaintiff's treating doctors had determined such factors caused the fracture (specifically, that the hip implant did not grow into the bone as it should have). *Id.* at 554-55. Here, unlike in *Redd*, Dr. Noiseux has "adequately account[ed] for obvious alternative explanations." *Id.* at 554.

Biomet also argues that some of Dr. Noiseux's conclusions are mere speculation. Biomet relies on *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), in which the Supreme Court held:

Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* [(unproven statement)] of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

In that case, the Court held that the district court did not abuse its discretion in excluding expert testimony opining that plaintiff's lung cancer was caused by his exposure to PCB, a hazardous chemical. *Id.* at 146-47. In forming his opinion, the expert relied on the following studies: (1) a study showing that mice developed cancer when injected with PCB (the mice developed a different kind of cancer than plaintiff, and their exposure was much different, as they were directly injected with PCB at a higher concentration than plaintiff's exposure); (2) a study demonstrating a higher incidence of lung cancer deaths in workers exposed to PCB, but in which the authors declined to conclude that the PCB exposure caused the cancer; (3) a study in which the authors concluded the higher incidence of lung cancer deaths in those exposed to PCB was not statistically significant; and (4) studies that examined exposure to chemicals other than PCB. *Id.* at 144-46. The Court affirmed the district court's conclusion that there was too great a gap between the studies and the expert's causation opinion and that the expert's opinion was therefore mere speculation. *Id.* at 143, 146.

Biomet argues that several of Dr. Noiseux's opinions lack support and amount to speculation. Biomet points to Dr. Noiseux's opinion in his expert report that if Wessels had been implanted with a metal-on-polyethylene implant in 2002, rather than a metal-on-metal implant, that would "have reduced the risk of . . . Wessels experiencing the infections in his hip in 2011." Def. App. 84. Dr. Noiseux commented in his report that this opinion was "more speculative," but he noted "there is evidence that deep infections

occur more frequently in metal-on-metal hips.” *Id.* At his deposition, Dr. Noiseux acknowledged that he could not say that Wessels’s metal-on-metal hip implant caused his infection or that Wessels would not have gotten an infection if he had a metal-on-polyethylene implant (and this appears to be what Dr. Noiseux meant by saying the opinion was “more speculative”—that he opined only as to a higher risk, but not to definitive causation). Dr. Noiseux explained that he simply noted in his expert report that based on a study he performed and another study by the Mayo Clinic, there was a higher chance of infection when a person developed ALTR as a result of a metal-on-metal hip implant—5.6% as compared to 1.3%. Pl. App. 59-61, 73, 78. This study supports Dr. Noiseux’s opinion in his expert report that Wessels faced a greater risk of infection due to his metal-on-metal hip implant. Unlike the expert in *General Electric*, the studies Dr. Noiseux relied upon involved similar circumstances to Wessels, and Dr. Noiseux did not extrapolate from these studies a conclusion that the authors themselves declined to make. Dr. Noiseux simply noted the conclusion of the studies: that there is a higher chance of infection when a person suffers ALTR from a metal-on-metal hip implant. There is not “too big a gap” between the studies and this opinion such that it amounts to speculation.⁵

Dr. Noiseux also opined in his expert report that based on his findings from the second revision surgery on Wessels’s left hip in January 2018, Wessels continued to

⁵ *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039 (8th Cir. 2000), does not support Biomet’s argument otherwise. In that case, the Eighth Circuit held the district court abused its discretion in an antitrust case in admitting plaintiff’s expert’s testimony on the market effects of defendants’ anticompetitive behavior when the expert used a model “to construct a hypothetical market . . . not grounded in the economic reality of the” market at issue, “ignor[ing] inconvenient evidence” and failing to account for market events that both sides agreed were not related to defendant’s anticompetitive conduct. *Id.* at 1056-57. The Eighth Circuit held that “[b]ecause of the deficiencies in the foundation of the opinion, the expert’s resulting conclusions were ‘mere speculation.’” *Id.* at 1057. Similarly, in *Junk*, 628 F.3d at 444, 448; the Eighth Circuit affirmed the district court’s exclusion of plaintiff’s expert’s testimony when the expert did not have sufficient data to use his normal methodology so instead, compared the facts of plaintiff’s case to published studies, without considering factual differences between the studies and plaintiff’s case (including where and how insecticide was applied and the size of the homes involved).

experience ALTR and osteolysis in his left hip caused by the Biomet metal-on-metal implant, even after its removal in February 2013. Def. App. 83-84. Dr. Noiseux opined that implanting Wessels with a metal-on-polyethylene left hip implant in 2002, rather than the Biomet metal-on-metal implant, would have “reduced the risk of . . . Wessels needing” a second left hip revision surgery in 2018. Def. App. 85. At his deposition, when asked if “there was a continuation of ALTR after the 2013 left hip revision,” Dr. Noiseux responded as follows:

Again, difficult question to answer. I call it echoes of the former metal-on-metal hip. The tissue in the hip that has all the cobalt and chromium embedded in it, I think most of us would assume and think we understand that that can continue to cause local damage. There was also another problem in the left hip -- and I'm sure we're getting to that -- which I don't know that anyone could say specifically happened because of metal-on-metal or not, which is the lack of ingrowth or loosening of the second cup. So I don't know that anyone has the answer of whether that had a higher likelihood of happening because he had ALTR there before.

The reason I would overall answer yes that I think there was continuation of the [ALTR] is there was further destruction of the greater trochanter and the femoral bone past the revision on successive x-rays which -- and, again, assuming we're going to get to it -- in reviewing my notes was called or presumed to be osteolysis from ceramic-on-polyethylene of his revision, but that had only been in there one year. And, again, our understanding of osteolysis, particularly with newer polyethylenes and ceramic heads, is that it maybe starts to be seen at 15 to 20 years. Would not at all expected to see -- expect to see it at one year.

Pl. App. 95-96.

Biomet argues that Dr. Noiseux's “convoluted” answer fails to demonstrate a “reliable” reason for his opinion. I disagree. First, to the extent that Biomet argues Dr. Noiseux testified that he doesn't “know that anyone could say specifically” that what happened was “because of metal-on-metal,” that statement related only to the problem of cup loosening (not the problems of osteolysis and ALTR, which Dr. Noiseux testified were the result of the metal-on-metal implant). Although Dr. Noiseux prefaced his response by indicating it was a “difficult question to answer,” he explained that even

after the removal of the metal-on-metal hip implant, Wessels's muscle tissue continued to have metal embedded in it, which can cause damage. Dr. Noiseux further pointed to Wessels's x-rays showing continued bone loss (osteolysis) even after the removal of the metal-on-metal hip implant. And he noted that given the medical community's understanding of ceramic-on-polyethylene hip implants, that damage would not have been caused within a year by Wessels's replacement hip implant, citing studies in follow-up as support. Pl. App. 97-98. Biomet argues that Dr. Noiseux's own treatment notes from 2014 presumed osteolysis was related to the ceramic-on-polyethylene the previous year, but Dr. Noiseux could come to a different opinion years later based on additional evidence and studies. Dr. Noiseux's opinions are supported by his extensive experience as an orthopedic surgeon and the medical evidence and studies he cited.

Ultimately, I find that Dr. Noiseux's causation opinions related to Wessels's left hip are reliable and should not be excluded. Biomet's arguments go to the weight the jury should give Dr. Noiseux's opinions, not their admissibility.

III. MOTION FOR SUMMARY JUDGMENT

Under Federal Rule of Civil Procedure 56(a), “[t]he court shall grant [a motion for] summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” For the plaintiff to avoid summary judgment, sufficient evidence must exist “on which the jury could reasonably find for the plaintiff.” *Olmsted v. Saint Paul Pub. Sch.*, 830 F.3d 824, 828 (8th Cir. 2016) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)). The court “view[s] the record in the light most favorable to the nonmoving party and draw[s] all reasonable inferences in that party's favor.” *Soo Line R.R. Co. v. WernerEnters.*, 825 F.3d 413, 418 (8th Cir. 2016) (quoting *Bishop v. Glazier*, 723 F.3d 957, 960-61 (8th Cir. 2013)).

Biomet moves for summary judgment on all Wessels’s remaining claims—products-liability and negligence claims based on the defective design of the Biomet metal-on-metal implant and based on Biomet’s failure to warn Wessels of the risks of the implant. Biomet argues that all Wessels’s claims fail for lack of sufficient causation evidence. Biomet also offers additional reasons why summary judgment is appropriate on Wessels’s failure-to-warn claims.

As an initial matter, I note that the Iowa Supreme Court does not distinguish between strict-liability and negligence theories for claims based on defective design, “prefer[ring] to label a claim based on a defective product design as a design defect claim without reference to strict liability or negligence.” *Wright v. Brooke Grp. Ltd.*, 652 N.W.2d 159, 169 (Iowa 2002). Neither does Iowa law recognize strict-liability failure-to-warn claims distinct from ones sounding in negligence; “[f]ailure to warn claims cannot be brought under a theory of strict liability.” *Scott v. Dutton-Lainson Co.*, 774 N.W.2d 501, 504 (Iowa 2009). At the hearing, the parties agreed that Wessels has two remaining claims (rather than four): a defective-design claim and a failure-to-warn claim.

A. Causation

Both of Wessels’s claims require proof of causation. *See Specht v. Kubota Tractor Corp.*, No. 16-CV-1012-LRR, 2017 WL 2454319, at *7 (N.D. Iowa June 6, 2017) (design defect); *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 624 (Iowa 2000) (failure to warn); *see also Iowa Civil Model Jury Instructions 1000.2, 1000.3*. “[U]nder Iowa law, ‘[d]ue to its complex and scientific nature, medical causation almost always requires expert testimony.’” *Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 707 (8th Cir. 2018) (second alteration in original) (quoting *Anderson v. Bristol, Inc.*, 936 F. Supp. 2d 1039, 1067 (S.D. Iowa 2013)).

Biomet argues that if Dr. Noiseux’s case-specific causation testimony is excluded, then it is entitled to summary judgment. Wessels does not disagree, instead arguing that Dr. Noiseux’s testimony should not be excluded. I have already determined that Dr.

Noiseux's testimony related to Wessels's right hip implant should be excluded, but not his testimony related to Wessels's left hip implant. Therefore, I find that Biomet is entitled to partial summary judgment on Wessels's design-defect and failure-to-warn claims relating to Wessels's right hip implant.

I have found that Dr. Noiseux's causation opinions on Wessels's left hip implant are admissible. Biomet argues that Dr. Noiseux's testimony fails to establish that a design defect in the Biomet metal-on-metal hip implant caused Wessels's injuries and need for revision surgeries. Biomet reiterates many of the same arguments I have already rejected in ruling on the *Daubert* motion. As I discussed earlier, a jury could find based on Dr. Noiseux's testimony that the Biomet metal-on-metal left hip implant caused Wessels to suffer osteolysis and ALTR and ultimately led to his need for revision surgeries in 2013 and 2018. Although Dr. Noiseux did not know whether the metal-on-metal hip implant caused Wessels's infection (or whether ALTR caused by the implant caused the infection), he adequately explained why Wessels's left-hip damage stemmed from ALTR and osteolysis caused by the metal-on-metal hip implant, not infection.

Biomet argues that because Dr. Noiseux could affirmatively opine only that Wessels's metal-on-metal hip implant caused the need for revision surgeries in his left hip, but not his right hip, any causal connection between the metal-on-metal hip implants and Wessels's need for revision surgeries in the left hip is destroyed. I disagree. First, contrary to Biomet's argument, Dr. Noiseux did not testify that infection definitively caused Wessels's need for revision surgeries in his right hip or that the metal-on-metal implant did not cause the need for his revision surgeries in his right hip. His testimony suggests that both the metal-on-metal implant and the infection likely contributed to Wessels's need for revision surgeries in his right hip. He explained why the evidence (and therefore his opinion) differed between Wessels's left hip implant and right hip implant. His opinions on Wessels's left hip implant are reliable and sufficient to create a genuine dispute of material fact on the issue of causation.

Biomet relies on a case in which the Iowa Court of Appeals affirmed the trial court's grant of summary judgment on plaintiff's medical-malpractice claim for lack of causation evidence. In that case, the plaintiff's decedent twice sought treatment at an urgent care for a bump on her nail, and the providers failed to diagnose her with nailbed cancer, which eventually led to her death. *Waddell v. Univ. of Iowa Cmty. Med. Servs., Inc.*, No. 17-0716, 2018 WL 4638311, at *1 (Iowa Ct. App. 2018). The only expert testimony offered by the plaintiff were from the doctors who later treated plaintiff's decedent's cancer, who testified "to the actions and decisions they made in the course of treating" plaintiff's decedent and did not refer "to the earlier [urgent care] clinic visits at all" in their depositions. *Id.* at *4. The plaintiff argued, however, that based on their general statements that "the earlier [plaintiff's decedent] began treatment, the better," a genuine issue of material fact existed whether the urgent care providers' failure to diagnose plaintiff's decedent's cancer caused her cancer to spread undetected and ultimately, her death. *Id.* at * 5. Unlike the treating doctors in *Waddell*, Dr. Noiseux specifically opined to the causation issues here and offered support for those opinions. *Waddell* is readily distinguishable.

Biomet also suggests that Dr. Noiseux's testimony fails to establish causation because he opined only that the Biomet metal-on-metal implant caused Wessels's injuries, rather than that a specific defect in the device caused his injuries. Wessels responds that he does not rely solely on Dr. Noiseux's opinion to establish causation; rather, he relies on the expert testimony obtained in the MDL proceedings on the issue of design defect in combination with Dr. Noiseux's case-specific expert testimony. In the MDL, Dr. Kantor submitted an expert report outlining the history of metal-on-metal hip implants and opining that the risks of using a metal-on-metal hip implant—particularly, "the generation and production of metal particulate wear debris"—outweigh the benefits, given the existence of safer options of hip implants (such as metal-on-polyethylene and ceramic-on-polyethylene). Pl. App. 5-7, 9-11. Dr. Kantor opined that metal debris from metal-on-metal hip implants "can destroy the soft tissues . . . , as well as the bony foundation

to the hip joint in implanted patients[,] which leads to pain, poor performance of the [metal-on-metal] hip implant, the need for revision surgeries, and the chance that the patient will have less than optimal results from future hip implant surgeries due to bone and tissue damage caused by the [metal-on-metal] device.” Pl. App. 12. Dr. Kantor also noted that metal-on-metal implants can result in “metal ion particulate debris” in the body, the risks of which are “not well understood,” but include “bone and tissue damage.” Pl. App. 12-13. The district judge presiding over the MDL denied Biomet’s motion to exclude Dr. Kantor’s opinion that “metal-on-metal devices generally . . . are defectively designed and their risks outweigh their benefits.” Doc. 186 at 34-39.

I agree with Wessels that Dr. Kantor’s expert report, in combination with Dr. Noiseux’s testimony, establishes causation. Biomet cites no caselaw supporting that causation must be established by only one expert who testifies that the design defect caused the plaintiff’s injuries. Here, the evidence from Dr. Kantor supports that metal-on-metal hip implants (such as the one manufactured by Biomet and implanted in Wessels) are defectively designed because they cause bone and tissue damage. Dr. Noiseux testified that Wessels’s Biomet hip implant caused bone damage (osteolysis) and tissue damage (ALTR) in his left hip. A jury could reasonably find, based on these opinions in combination, that the defective design of the Biomet hip implant caused Wessel’s bone and tissue damage and need for revision surgeries in his left hip. A genuine issue of material fact exists on the issue of causation, and Biomet is not entitled to summary judgment on this basis.

B. Failure to Warn

Biomet raises two additional reasons why it is entitled to summary judgment on Wessels’s failure-to-warn claim: that its warnings to Dr. Nassif, Wessels’s orthopedic surgeon, adequately conveyed the risks associated with the Biomet metal-on-metal hip implant; and that no evidence establishes Dr. Nassif would have chosen a different hip implant for Wessels in 2002 with additional warnings. As I find that the second of these

arguments disposes of Wessels's failure-to-warn claim, I decline to address the adequacy of the warnings.

A manufacturer of a product has a duty to warn of “reasonably foresee[able] danger of injury or damage.” *Lovick v. Wil-Rich*, 588 N.W.2d 688, 693 (Iowa 1999).

In testing the defendant's liability for negligence in failing to warn, the defendant should be held to the standard of care of an expert in its field. The relevant inquiry therefore is whether the reasonable manufacturer knew or should have known of the danger, in light of the generally recognized and prevailing best scientific knowledge, yet failed to provide adequate warning to users or consumers.

Olson v. Prosoco, Inc., 522 N.W.2d 284, 289-90 (Iowa 1994). A manufacturer must “exercise reasonable care to inform [consumers] of [the product's] dangerous condition or of the facts which make it likely to be dangerous.” *Lamb v. Manitowoc Co.*, 570 N.W.2d 65, 68 (Iowa 1997) (quoting **Restatement (Second) of Torts § 388** (1965)).

The parties agree that the “learned intermediary” doctrine is applicable in this case. Under that rule, Biomet need only have adequately warned Dr. Nassif about the risks of the hip implant, not Wessels himself. *See Nicholson*, No. 18-cv-3057-CJW-KEM, Doc. 321 at 31-32; *Gilliland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 960, 969 (S.D. Iowa 2014); *Madsen v. Am. Home Prod. Corp.*, 477 F. Supp. 2d 1025, 1033-35 (E.D. Mo. 2007) (applying Iowa law). Biomet argues that it adequately warned Dr. Nassif of the risks of the hip implant by its warnings in the “Instructions for Use” package insert for the Biomet hip implant. Wessels disputes the adequacy of these warnings, arguing that the Instructions for Use should have included additional warnings of the effects of metal wear debris.

Wessels offers insufficient evidence that additional warnings in the Instructions for Use would have avoided his injury. A failure-to-warn claim requires proof of two types of causation: that the product caused the plaintiff's injuries (as discussed earlier) and that “the lack of adequate warning . . . was the proximate cause of [the plaintiff's] injury.” *Brazzell v. United States*, 880 F.2d 84, 87 (8th Cir. 1989) (applying Iowa law) (quoting

Moore v. Vanderloo, 386 N.W.2d 108, 117 (Iowa 1986)). To establish this second type of causation, the plaintiff “must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product.” *Madsen*, 477 F. Supp. 2d at 1035 (quoting *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 821 (E.D. Tex. 2002)); accord *Doe v. Baxter Healthcare Corp.*, No. 4-96-CV-10738, 2003 WL 27384538, at *4 (S.D. Iowa June 3, 2003), *aff’d*, 380 F.3d 399 (8th Cir. 2004).

Biomet argues that no evidence establishes that additional warnings in the Instructions for Use would have caused Dr. Nassif to use a different hip implant for Wessels. Biomet points to Dr. Nassif’s treatment notes indicating that he warned Wessels he would likely need another hip implant in the future given his relatively young age. Def. App. 336; *see also* Def. SOF ¶¶ 11, 13, 15-16; Pl. Resp. SOF ¶¶ 11, 13, 15-16. Dr. Nassif testified at his deposition that he chose the Biomet metal-on-metal hip implant for Wessels because Wessels was young and overweight, and at the time, he believed a metal-on-metal hip implant would last the longest without other complications; he was concerned about the high risk of breakage in a ceramic-on-ceramic hip implant for a young, heavy, active person like Wessels. Def. SOF ¶ 121; Pl. Resp. SOF ¶ 121; Def. App. 30. Dr. Nassif testified that he did not read the Biomet “Instructions for Use” prior to implanting the Biomet hip implant, stating at his deposition that was the first time he had seen the package insert. Def. SOF ¶ 33; Pl. Resp. SOF ¶ 33; Def. App. 30. Dr. Nassif testified that he instead stayed current on data and research about the safety of hip implant devices by reading articles and attending conferences, and he indicated that he stopped using metal-on-metal hip implants shortly after Wessels’s surgeries in 2002. Def. App. 30.

In his resistance, Wessels did not respond to Biomet’s failure-to-warn causation argument. At the hearing, when asked what evidence established that additional warnings in the Instructions for Use would have caused Dr. Nassif to choose a different implant, given that he did not read the Instructions for Use, Wessels argued that an objective

(rather than subjective) standard of causation should apply, suggesting that the evidence establishes no reasonable physician would have chosen a metal-on-metal hip implant with additional warnings. In support, Wessels cited *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Product Liability Litigation*, 888 F.3d 753 (5th Cir. 2018). In that case, the Fifth Circuit noted that under Texas law, causation for a failure-to-warn claim “entails *two distinct factual predicates*: first, that the doctor would have read or encountered the adequate warning; and second that the adequate warning would have altered his treatment decision for . . . the patient.” *Id.* at 775 (footnotes omitted). The court recognized that “objective evidence” may be “relevant” to the second part of this test, but not the first. *Id.* at 774-75 & n.30. Furthermore, the court noted it had previously rejected at summary judgment a “failure-to-warn claim where [the] treating physician ‘did not recall ever reading the package insert’ and plaintiff offered no more than ‘speculat[ion] about other ways an adequate warning might have reached [the treating physician] and altered her decision.’” *Id.* at 775 n.27 (second and third alterations in original) (quoting *Pustejovsky v. Pliva Inc.*, 623 F.3d 271, 277 (5th Cir. 2010)). Ultimately, the Fifth Circuit struck down the jury’s failure-to-warn verdict for two of the plaintiffs, holding that the claims failed because the plaintiffs’ treating doctors “did not testify, and plaintiffs offer[ed] no record evidence suggesting the two [doctors] actually read or encountered defendants’ inadequate warnings.” *Id.* at 775. On the other hand, the court upheld the failure-to-warn claims for plaintiffs whose doctors testified that they chose the defendant’s metal-on-metal hip implants based on statements made by defendant’s representatives and in defendant’s brochures, noting “the subjective testimony itself—which included evidence of both deception and reliance—likely permitted an inference of causation” (even though the doctors did not read the Instructions for Use). *Id.* at 776-77.

Here, no evidence establishes how additional warnings “might have reached [Dr. Nassif] and altered [his] decision.” *Id.* at 775 n.27 (quoting *Pustejovsky*, 623 F.3d at 277). *In re Depuy* does not support that Wessels can rely on “objective evidence” alone to establish that Dr. Nassif would have seen or otherwise learned of additional warnings.

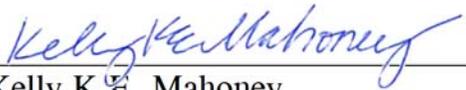
I agree with Biomet that because Dr. Nassif testified he did not read the Instructions for Use, and no evidence establishes that Dr. Nassif would have otherwise encountered additional warnings, Wessels cannot prove that additional warnings in the Instructions for Use would have prevented his injury. *See Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659, 661 (9th Cir. 2004) (applying California law) (“Because the doctor testified that he did not read the warning label that accompanied [the prescription medication] or rely on information provided by [representatives of the defendant manufacturer] before prescribing the drug to [plaintiff], . . . [plaintiff] failed to establish that stronger warnings would have changed her husband’s medical treatment or averted [his injury].”); *In re Wright Med. Tech. Inc., Conserve Hip Implant Prods. Liab. Litig.*, 127 F. Supp. 3d 1306, 1360 (N.D. Ga. 2015) (applying Utah law) (holding that when “the undisputed evidence is that [the doctor] did not and would not have read the insert warnings that were provided with the” hip implant, the evidence did “not support a failure to warn claim based on the warning provided for the implant at issue . . . , even if the warning was defective”); *cf. also Rowson v. Kawasaki Heavy Indus., Ltd.*, 866 F. Supp. 1221, 1232-40 & n.19 (N.D. Iowa 1994) (applying Iowa law) (collecting cases from other jurisdictions and concluding that Iowa would adopt the general rule that a plaintiff’s failure to read a warning does not bar a failure-to-warn claim challenging the adequacy of the presentation and location of the warnings, but does bar a failure-to-warn claim based only on the inadequacy of the content of the warning; and suggesting that this rule may not apply and a failure-to-warn claim fails when “a professional fails to read warnings supplied with the tools of his trade”). Accordingly, I find that Biomet is entitled to summary judgment on Wessels’s failure-to-warn claim.

IV. CONCLUSION

The motion to exclude (Doc. 256) is **granted in part and denied in part**. Dr. Noiseux will not be permitted to testify to the cause of Wessels's revision surgeries in his right hip, but he may offer causation opinions on Wessels's left hip.

The motion for summary judgment (Doc. 253) is **granted in part and denied in part**. Biomet is entitled to summary judgment on Wessels's design-defect claim related to his right hip implant and on Wessels's failure-to-warn claim. Only Wessels's design-defect claim related to his left hip implant remains.

IT IS SO ORDERED this 22nd day of June, 2020.



Kelly K.E. Mahoney
Chief United States Magistrate Judge
Northern District of Iowa