Sprafka v. DePuy Orthopaedics, Inc. Doc. 148

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Julie Sprafka,

Plaintiff,

v.

Medical Device Business Services, Inc., *an Indiana Corporation formerly known as DePuy Orthopaedics, Inc.*, and DePuy Orthopaedics, Inc.,

Defendants.

Civil No. 22-331 (DWF/TNL)

MEMORANDUM OPINION AND ORDER

INTRODUCTION

This matter is before the Court on Defendants DePuy Orthopaedics, Inc. and Medical Device Business Services, Inc.'s (collectively, "MDBS") motion to exclude expert testimony (Doc. No. 91) and motion for summary judgment (Doc. No. 123). Plaintiff Julie Sprafka opposes the motions. (Doc. Nos. 112, 137.) For the reasons set forth below, the Court grants both motions.

BACKGROUND

Plaintiff Julie Sprafka suffered from osteoarthritis in her right knee. (Doc. No. 127-2 ("Saterbak Dep.") at 26-27.) Sprafka initially tried treating the pain with conservative treatments such as anti-inflammatory drugs and cortisone injections. (*Id.* at 33.) When those treatments failed, Sprafka's doctor, Dr. Andrea Saterbak, discussed knee replacement surgery. (*Id.* at 34-35.) On August 18, 2016, Sprafka underwent a

Dockets.Justia.com

right total knee replacement, which was performed by Dr. Saterbak. (*Id.* at 81.) Dr. Saterbak implanted an Attune device. (*Id.*) Attune devices consist of a metallic femoral component, a metallic tibial baseplate, a tibial polyethylene insert, and a dome patella. (Doc. No. 94-3 ("Truman Report") at 25-26.) At issue in this case is the tibial baseplate, which was cemented to the tibia bone. (*Id.* at 26.) Sprafka received an Attune with a fixed bearing tibial baseplate. (*Id.* at 3.)

Following the surgery, Sprafka continued to experience pain in her right knee. (Saterbak Dep. at 95-101.) Sprafka returned to see Dr. Saterbak in October 2018, reporting constant pain and swelling in her right knee. (*Id.* at 109-11.) Dr. Saterbak tested Sprafka's range of motion and did a bone scan and x-ray. (*Id.* at 112.) Dr. Saterbak saw no evidence of loosening and concluded that Sprafka's range of motion indicated moderate PCL laxity and swelling. (*Id.* at 113-17, 121-22.) She discussed with Sprafka that laxity could eventually require revision surgery. (*Id.* at 117-18.) She told Sprafka to return for a follow-up visit in six-months. (*Id.*)

Over a year and a half later, in June 2020, Sprafka saw a new orthopedic surgeon, Dr. Kristoffer Breien. (Doc. No. 127-3 ("Breien Dep.") at 102.) Sprafka told Dr. Breien that she had been experiencing knee pain. (*Id.* at 104.) Dr. Breien was not provided with Sprafka's prior medical records and instead conducted an independent examination of Sprafka. (*Id.* at 88-89, 93, 214.) Dr. Breien took x-rays of the knee and, after review, concluded that Sprafka's pain was caused by loosening. (*Id.* at 88-89.) Dr. Breien did a revision surgery of Sprafka's knee in September 2020. (*Id.* at 162.) During the revision surgery, Dr. Breien put a mallet underneath the tibial baseplate and after one tap, the

baseplate came loose. (*Id.* at 175-77.) Based on the little effort that it took to remove the tibial baseplate, Dr. Breien concluded that the baseplate had debonded and had caused the device to come loose. (*Id.* at 128-29.) The tibial baseplate also contained little visible cement debris and the cement mantle remained intact. (Truman Report at 22-23.)

Sprafka then sued MDBS, asserting four claims: (1) strict liability, (2) negligent products liability; (3) breach of implied warranties; and (4) breach of express warranty.[1] To support these claims, Sprafka relies on expert testimony from Mari Truman. MDBS now moves to exclude this expert testimony and moves for summary judgment.

DISCUSSION

I. Daubert Motion

MDBS moves to exclude the testimony of Sprafka's expert, Mari Truman. Before accepting the testimony of an expert witness, the trial court is charged with the "gatekeeper" function of determining whether an opinion is both relevant and reliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589-90 (1993).

A duly qualified expert may testify "if the proponent demonstrates to the court that it is more likely than not that": (1) "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"; (2) "the testimony is based on sufficient facts or data"; (3) "the testimony is the product of reliable principles and methods"; and (4) "the expert's opinion reflects a

[1] Sprafka's Complaint was filed under a separate case number: 21-cv-1785. On December 5, 2022, the Court consolidated Sprafka's case with another similar case and ordered all future filing to be filed under the current case number: 22-cv-331. (Doc. No. 40.)

reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702. The language of this rule changed in December 2023, but the substantive law did not. The change was intended to clarify that preponderance of the evidence standard applies to expert opinions under this rule. *See id.* advisory committee's note to 2023 amendment ("But many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).").

In determining whether the proposed expert testimony is reliable, the Court considers the following: (1) whether the theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known rate of potential error; and (4) whether the theory has been generally accepted. *Daubert*, 509 U.S. at 593-94. The purpose of these requirements "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). "[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Id.*

The Court also notes that "Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony," and it favors admissibility over exclusion. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations and

citation omitted). When examining an expert opinion, a court applies a general rule that "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chicago Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995)). "[I]f the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury," then it must be excluded. *Id*. at 929-30.

There is no dispute that Truman is a qualified expert. She is a biomedical engineer with over forty years of experience in the fields of biomechanics and orthopedics. (Truman Report at 4.) Nor is there dispute that expert testimony about the Attune implant would help the jury in this case. In fact, Minnesota law requires expert testimony "to get a product-liability claim past summary judgment when the product at issue and any of its relevant inner workings are beyond the ken of a lay jury." *Markel v. Douglas Techs. Grp., Inc.*, 968 F.3d 888, 890 (8th Cir. 2020). The parties solely dispute whether Truman's testimony is reliable.

Truman offers three main opinions related to the Attune device: (1) the Attune was defectively designed; (2) a safer alternative existed at the time Attune was developed; and (3) MDBS's testing of the Attune was inadequate. MDBS argues that each opinion is unreliable and thus Truman's testimony should be excluded in its entirety. The Court addresses each of Truman's opinions in turn below.

A. Design

Truman asserts that the Attune total knee replacement device was defectively designed because the tibial baseplate had shallow pockets and a smooth surface, which increased the prevalence of debonding. Debonding is a type of aseptic loosening. (Doc. No. 114-1 ("Wright Dep.") at 13.) Aseptic loosening is the loosening of the device from the bone in the absence of infection. This case specifically focuses on debonding, or separation, at the cement-implant interface. But loosening can also occur between the tibia bone and cement mantle.

MDBS asserts that Truman's opinions are speculative because Truman has no data demonstrating what pocket depth or surface roughness would have decreased debonding, and she admitted during her deposition that she would need to do testing in order to determine the exact specifications that would have prevented debonding. Moreover, MDBS argues that Truman admitted that the clinical performance of the Attune appears to be the same or better than other devices on the market and acknowledged that people with Attune devices seem to be happier overall than those with other competitor devices. In sum, MDBS contends that Truman has a hypothesis based on anecdotal evidence "that has not been tested, has not been subjected to peer review and publication, has no known or potential rate of error and has not been accepted by or otherwise acknowledged by the scientific community." (Doc. No. 93 at 18.)

In response, Sprafka argues that MDBS's challenges to Truman's testimony goes to weight and not admissibility. Sprafka asserts that Truman is allowed to rely on her expertise and knowledge as a biomedical engineer when forming her opinions. In

addition, Sprafka contends that Truman identified data that showed that the Attune's successor, the Attune S+, significantly improved fixation using features that were feasible when the Attune was developed. Lastly, Sprafka asserts that Truman was not required to test her opinions for them to be admissible.

To begin, "courts have discounted the reliability of experts who formed their opinions only within the context of litigation." *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 967 (W.D. Mo. 2000). Truman's testimony is not based on independent research, and she developed these opinions expressly for the purpose of litigation. The Court considers the fact that Truman's opinions "have [not] been subjected to normal scientific scrutiny through peer review and publication." *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 9 F.4th 768, 783 (8th Cir. 2021).

The Court also considers the literature that Truman based her opinions on. Truman relied heavily on anecdotal evidence to support her opinion that Attune is more susceptible to debonding than Attune's predecessor (the Sigma) and the Attune's successor (the Attune S+). Specifically, Truman relied on two published case studies, Manufacturer and User Facility Device Experience ("MAUDE") data, and Dr. Breien's testimony as the foundation for her opinion.[2] (Truman Dep. at 180.) The first case study focused on fifteen patients with an Attune device from three different hospital databases

[2] Truman also cites the Hazelwood article to support her assertion that the Attune tibial component "has been implicated in early aseptic loosening" (Truman Report at 53), but that article concerned the Sigma device, not the Attune. *See* Hazelwood, *et al.*, *Case Series Report: Early Cement-Implant Interface Fixation Failure in Total Knee Replacement*, 22 The Knee 424-28 (2015) ("Hazelwood article").

that experienced debonding of the tibial implant-cement interface. Bonutti, *et al.*, *Unusually High Rate of Early Failure of Tibial Component in Attune Total Knee Arthroplasty System at Implant-Cement Interface*, 30 J. Knee Surg. 435-39 (2017) ("Bonutti Article"). Dr. Bonutti concluded that these three hospitals experienced "an unusually high rate of early aseptic failures as a result of failure of implant-cement interface." *Id.* Dr. Bonutti's article has received criticism because he failed to establish any "rate," as the report does not indicate the size of the case series. *See* Cerquiglini, *et al.*, *Analysis of the Attune Tibial Tray Backside: A Comparative Retrieval Study*, 8 Bone Joint Res. 136-145 (2019). In other words, Dr. Bonutti has a numerator (the number of Attune revisions due to debonding) but no denominator (the total number of Attunes implanted). Truman also admitted during her deposition that, given the limited information in the article, she could not consider other factors, such as the cement type, surgeon experience, surgical technique, post-operative care, or surgeon case load. (Truman Dep. at 236-37.) As Truman explained in her report, these factors have also been linked to debonding. (Truman Report at 54.)

The second case study that Truman relied on looked at three patients with Attune devices who experienced debonding of the tibial implant-cement interface. Murphy, *et al.*, *Early Aseptic Failure of the Tibial Component-Cement Interface in Attune Total Knee Arthroplasty: A Report of Three Cases*, 13 Cureus (2021). The article similarly concluded that the Attune design "has led to an unusually high rate of early aseptic failures" again without providing the size of the case series. *Id.* In addition, Truman relied on Dr. Breien's testimony. He testified that he and his partners observed an

unacceptably high rate of Attune revisions. (Breien Dep. at 41.) Here too, Dr. Breien acknowledged that he did not actually know the rate of debonding; rather, he and his partners felt that it was higher than it should be. (*Id*. at 41, 280.) Lastly, Truman relied on MAUDE data and noted that there were at least eleven incidents of loosening that occurred at the Attune tibial implant-cement interface between 2013 and 2014. (Truman Report at 64.) Truman recognized that the MAUDE data, like the other case studies, cannot be used to establish rates of events. (Truman Dep. at 192.)

In total, Truman relied on around thirty reports of debonding to support her conclusion that the Attune device is unusually susceptible to debonding and is therefore defective. In her deposition, Truman recognized that the anecdotal evidence that she relied on was at the bottom of the pyramid of reliability but asserted that she was "left with what [she] ha[d]." (*Id.* at 220.) While these reports establish that debonding occurs with the Attune, they do not establish the cause of the debonding or the rate at which debonding occurs. *See McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) ("Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation."). Even Dr. Bonutti cautioned that "[l]arger retrospective studies with longer follow-up" were warranted to further investigate the Attune device. *See* Bonutti Article.

In a recent case involving a different device, a court allowed expert testimony that relied on case reports when the expert "compared the number of medical device reports among different manufacturers and noted 'the data suggests that the liner dissociation problem affects the DePuy AltrX at a significantly higher rate than other products.'"

Jennings-Moline v. DePuy Orthopaedics, Inc., No. 23-cv-31, 2023 WL 7190739, at * 2 (D. Idaho Nov. 1, 2023). In that case, liner dissociation was "rarely seen in other products" and the failure appeared to be "specific to the [AltrX liner]" and the MAUDE data was used to demonstrate the outsized complaints the product received when compared to other products on the market. *Id.* at *5.

This case is distinguishable because debonding is not unique to the Attune. (*See* Truman Dep. at 186.) Truman cited studies that have documented debonding in the Sigma (*See* Truman Report at 53 (citing the Hazelwood article)) and other devices (*id.* at 58 (citing Sadauskas, *et al.*, *Implant Interface Debonding After Total Knee Arthroplasty: A New Cause for Concern?* 6 Arthroplasty Today 972-75 (2020))). Aseptic loosening is an issue for all devices and the fact that a device comes loose does not automatically mean that the device is defective. (Truman Dep. at 235.) Without more, the fact that there has been reports of debonding with the Attune device does not explain how this debonding compares with other devices on the market or what caused the debonding.

Evidence from registries seem to contradict Truman's opinion. Truman acknowledged during her deposition that registry data shows that the Attune performs the same or better than the Sigma device and other similar devices on the market. (*Id.* at 245-50.) In her report, Truman further noted that the Australian Orthopaedic Association National Joint Replacement Registry, using data from 1999 to 2017, "showed no difference in survivorship for the PFC Sigma CR [] and Attune CR." (Truman Report at 63.) Truman discounted this data in her report because the data "is

not specific enough to differentiate the reason for tibial loosening." (*Id.* at 65.) Despite the lack of specificity in the registry data, Truman fails to explain why the Attune's revision rates would not be higher given the increased rate of debonding that she alleges should be occurring. Her only explanation for why the registry data may not reflect the outsized incidence of debonding is because many people may experience "pain and function loss without agreeing to revision." (*Id.* at 64.) Those who decline to get a revision would not be represented in the registry data. But Truman does not explain why it would not be true for every device that certain people would decline to undergo a revision surgery and thus registry data for all devices would be missing a certain subset of people. Moreover, Truman admitted that based on the registry data, the Attune device is "staying in longer and making patients happier in the aggregate than competing knees." (Truman Dep. at 250; *see also id.* at 203-04.)

Along with the case reports, Truman also included several articles that have found that the Attune device experiences a higher rate of radiolucent lines than the Sigma device. (Truman Report at 31.) Truman stated that the "analysis of radiolucent lines represents an established modality for the prediction of component loosening." (*Id.*) During her deposition, she clarified this statement, noting that the presence of radiolucent lines alone does not necessarily mean that the device is loose or will become loose. (Truman Dep. at 331-32.) Radiolucent lines instead need to be "evaluated by the surgeon in context with everything else." (*Id.* at 333.) She further noted that radiolucent lines are only an issue when they progressively widen. (*Id.* at 332.) Some radiolucent lines are small and stagnant, which would not be a predictor of loosening. (*Id.*)

One article that Truman cited noted that the incidence of radiolucent lines was significantly higher in the Attune, but it also concluded that the "system achieves excellent results regarding the revision rate at very short-term follow-up." Staats, *et al.*, *Modern Cemented Total Knee Arthroplasty Design Shows a Higher Incidence of Radiolucent Lines Compared to its Predecessor*, 27 Sports Traumatology, Arthroscopy 1148-1155 (2019). And other articles found no difference in radiolucent lines between the Attune and the Sigma. *See* Willburger & Oberberg, *Early and Mid-Term Results with the Attune Total Knee Replacement System Compared to PFC Sigma: A Prospective Comparative Study*, 17 J. Orthop. Surg. Res. 509 (2022); Ranawat, *et al.*, *Clinical and Radiographic Results of Attune and PFC Sigma Knee Designs at 2-Year Follow-Up: A Prospective Matched-Pair Analysis*, 32 J. Arthroplasty 431-36 (2017). As Truman noted in her report, "[t]he clinical results from case reports are conflicting." (Truman Report at 53.)

Truman also relied on pullout strength data. Pullout testing involves implanting a tibial baseplate into an artificial bone, pulling off the implant axially, and measuring the amount of force required to separate the implant from the bone. (Doc. No. 139-1 ("Rowley Dep.") at 102-03.) Truman stated that one article, which tested the pullout strength of the Sigma, the Attune, and the Attune S+, concluded that certain design features, such as the tapered keel and smooth undersurface "may have predisposed [the Attune] baseplate to early failure." (Truman Report at 51; Doc. No. 114-6.) This statement, however, was made during the introductory paragraph of the article. The authors hypothesized that because the Attune has a smooth undersurface, the Sigma

"would have a significantly higher axial pullout strength when compared to the [Attune] with the smooth surface." (Doc. No. 114-6 at 7.) They further hypothesized that the Sigma "would perform comparably to the [Attune S+]." (*Id.*) After testing, however, they discovered that they were wrong. The pullout strengths of the Attune and the Sigma "were not statistically different from each other." (*Id.* at 11.) And the pullout strength of the Attune S+ was "significantly greater" than both the Sigma and the Attune, leading the authors to deduce that the design features of the Attune S+ improved fixation. (*Id.*) Contrary to Truman's report, however, the authors could not conclude that the Attune was "predisposed" to early failure, as the results of their testing showed that the Attune and the Sigma performed similarly. Sprafka also mischaracterizes this article in her briefing. (*See* Doc. No. 112 at 23.) Truman cited other evidence in her report that similarly shows no difference in pullout strength between the Sigma, the Attune, and other devices on the market. (Truman Report at 49.)

Lastly, Truman could not opine on the exact specifications of the tibial baseplate that would have prevented debonding. (Truman Dep. at 83-84, 356-57.) While at one point Truman mentioned that the cement pockets on the backside of the tibial baseplate should have been 1 to 1.5 millimeters in depth (*id.* at 361), she also states that she would need to do testing to figure out the exact measurements (*id.* at 83-84). Truman admitted that the Sigma was a clinically successful knee device, yet her report indicates that the Sigma devices had pockets less than one millimeter. (*Id.* at 256-57; Truman Report at 55.) As for surface roughness, Truman asserted that the surface of the Attune's tibial baseplate needed to be rougher but stated that she could not identify a specific roughness

without further testing. (Truman Dep. at 356-57.) And again, Truman admitted that the Sigma was clinically successful, yet prior versions of the Sigma were smoother than the Attune. (*See* Truman Report at 55.)

Overall, there are several red flags with Truman's methodology. She cannot show that the Attune debonds at a higher rate than the Sigma or the Attune S+, she relies on anecdotal case reports, she discounts the registry data—which overwhelmingly shows that the Attune has the same or better revision rates than other devices on the market, she cannot show that her opinions have an acceptable rate of error or are generally accepted, she admits that the Sigma was clinically successful yet argues that the Attune's design features needed to go beyond the features in the Sigma, and she is unable, without additional testing, to state what design features would have prevented debonding. While Sprafka argues that challenges to Truman's testimony should go to weight and not admissibility, the Court should exclude expert testimony when it is "so fundamentally unsupported that it can offer no assistance to the jury." *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 614 (8th Cir. 2011) (internal quotations and citation omitted). And while some guesswork is necessary for expert testimony, "too much is fatal to admission." *Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051, 1063 (D. Minn. 2012) (quoting *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003)).

Truman essentially concludes based on her knowledge, experience, and certain anecdotal reports that the Attune *should* debond at a higher rate than the Sigma and the Attune S+ based on certain features of the Attune tibial baseplate. (*See* Truman Dep.

at 163.) While this may be a sound hypothesis, it has not been tested or supported by reliable data. "[T]he function of expert testimony is to explain how something happened, not to speculate as to how something could possibly have happened." *Werth*, 856 F. Supp. 2d at 1062 (internal quotations and citation omitted). Truman's opinions merely establish that changes to the tibial baseplate could have possibly reduced instances of debonding. And she cannot specify exactly what changes should have been made. Courts often exclude expert testimony like this when there is too great an analytical gap between the data and the opinion proffered. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that expert testimony may be excluded when "there is simply too great an analytical gap between the data and the opinion proffered"); *Nelson*, 92 F. Supp. 2d at 969 (excluding expert testimony when the expert relied on case reports that were "mere compilations of reported occurrences" but did not "demonstrate a causal link sufficient for admission"); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1050 (D. Minn. 2007) ("*Daubert* decisions warn against leaping from an accepted scientific premise to an unsupported one.") (internal quotations and citation omitted).

Because Sprafka has not shown by a preponderance of the evidence the reliability of Truman's opinion that the Attune device is defective, the Court excludes this testimony.

B. Safer Alternative

Similar issues arise with Truman's opinion that a safer alternative existed. Truman testified that MDBS could have made the following changes to the Attune tibial baseplate to prevent debonding: (1) deepened the cement pockets; (2) increased the

cement pocket surface area; (3) provided undercuts or dovetails to the cement pockets; and (4) increased the surface texture. (Truman Report at 33-34.) As noted above, however, Truman cannot say what depth of pockets or level of roughness would have prevented debonding. She also testified that the Attune S+ is the only device on the market that she knew of that contains undercuts. (Truman Dep. at 82, 354.) Truman asserted that deeper pockets and higher roughness is better, but she acknowledged that a surface can be "too rough" and that the depth of the pockets can impact the integrity of the baseplate. (Truman Dep. at 326-27, 382-83.) Ultimately, she testified that she would need to do further testing to determine the exact specifications that she would recommend. (*Id.* at 325-27, 357, 363, 380-81.)

In addition, Truman noted that one of the goals of MDBS when designing the Attune was to limit bone loss during revision surgeries. (Truman Report at 32.) No matter how effectively designed a knee device may be, some devices will inevitably need to be replaced. (Wright Dep. at 74-75; Truman Dep. at 234.) Truman's report does not consider at all whether the Attune has resulted in less bone loss during revision surgeries. Such analysis is necessary to properly weigh the costs and benefits of making Truman's suggested changes to the design of the Attune tibial baseplate.

Truman testified that she "didn't really have to" consider the tradeoffs of making certain changes to the Attune, because the Attune S+ incorporated her suggested changes. (Truman Dep. at 326.) Truman relies heavily on the Attune S+ to show that certain design features were feasible and would have improved fixation. Notably, the Attune S+ did not exist at the time Sprafka received her knee replacement. Even setting that aside,

Truman provides little data or research about the Attune S+ in her report. She admitted that she does not actually know if the Attune S+ debonds at a lower rate than the original Attune. (Truman Dep. at 163.) Truman's report states that the Attune S+ has resulted in greater pullout strength, but Truman concedes that greater pullout strength does not necessarily translate to greater clinical results. (Truman Report at 51; Truman Dep. at 125.) In fact, Truman criticizes MDBS for relying on pullout testing when designing the Attune. (Truman Report at 41 (noting that the "simplistic axial pull-off" test has "low clinical relevance").) Truman has provided no research or data that suggests that the Attune performs worse than the Attune S+. And one article that Truman cited in her report suggests that the revision rates for the Attune and Attune S+ are similar. *See* Torino, *et al.*, *Tibial Baseplate-Cement Interface Debonding in the Attune Total Knee Arthroplasty System*, 17 Arthroplasty Today 165-71 (2022) ("Torino article").[3]

In sum, Truman asserts that the Attune S+ "should perform better than" the Attune (Truman Dep. at 163), but she does not have any testing, data, or peer-reviewed articles to support this proposition. Without more, Truman's opinion that a safer alternative existed is too speculative to be admissible. While in theory certain modifications to the tibial baseplate should improve fixation, Truman does not know if these modifications would lead to clinical results, nor is it generally accepted that devices need to have the specific features that Truman proposes to be clinically successful. It is also not clear that

[3] The authors, however, hypothesized that the Attune S+ improved tibial fixation but noted that their "series was not able to demonstrate [a] statistically significant difference in performance between [the] tibial components, likely due to a small sample size." *See* Torino article.

Truman has accounted for the costs and benefits of making such modifications. And as noted previously, the Attune S+ was not on the market at the time of Sprafka's surgery, and it does not appear that any knee device existed at that time with all the features that Truman asserts was necessary. The Court thus excludes Truman's opinion on this issue.

C. Testing

Lastly, Truman opined that MDBS should have conducted additional testing of the Attune. She asserted that, in addition to the pullout testing, MDBS should have conducted a test "under reasonably foreseeable operative room and in vivo physiologic loading conditions." (Truman Report at 76.) Truman, however, could not specify the parameters of such test. She also could not name any other manufacturer who has conducted similar testing or a peer-reviewed article that outlines the need for such testing. (*Id.* at 84-87, 111-12, 124, 139.) She did not conduct the test herself or explain the costs and benefits of such a test. Without more information, Truman's opinion is too speculative to be admissible.

The Court stresses that its decision today does not discount Truman's knowledge and experience as a biomedical engineer. The issue is not that Truman's opinions are wrong but that Truman simply does not have the information she needs to make reliable conclusions on whether certain design features of the Attune created an increased prevalence of debonding, what specific design features would have prevented debonding, and what, if any, additional testing should have been done. At best, Truman has an educated guess. Ultimately, "[t]he courtroom is not [the] place of scientific guesswork, even of the most inspired sort. Law lags science; it does not lead it." *Nelson*, 92 F. Supp.

2d at 970 (internal quotations and citation omitted). For the above reasons, the Court excludes Truman's opinion in its entirety.

II. Summary Judgment

The Court next considers MDBS's motion for summary judgment. Summary judgment is appropriate 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." Fed. R. Civ. P. 56(a). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A party opposing a motion for summary judgment "may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." *Id.* at 256. "Conclusory arguments, without evidence, are insufficient as a matter of law to establish a material question of fact." *Sieden v. Chipotle Mexican Grill, Inc.*, 846 F.3d 1013, 1019 (8th Cir. 2017). The Court views the evidence and all reasonable inferences in the light most favorable to the nonmoving party. *Weitz Co., LLC v. Lloyd's of London*, 574 F.3d 885, 892 (8th Cir. 2009).

Sprafka alleges four causes of action, including strict liability, negligent products liability, breach of implied warranty, and breach of express warranty. In her briefing, Sprafka withdrew her claims for breach of implied and express warranties (*see* Doc. No. 137 at 4) and thus only Sprafka's strict liability and negligent products liability claims remain. "Where design defect cases are involved, Minnesota merges the theories of strict liability and negligence." *Piotrowski v. Southworth Prods. Corp.*, 15 F.3d 748,

751 (8th Cir. 1994). Sprafka asserts two bases for her products liability claim. First, she argues that the Attune was defectively designed. Second, she asserts that MDBS failed to provide adequate warnings or instructions to warn about the risks of debonding.

Expert testimony is required under Minnesota law in products liability cases involving medical devices because they involve "complex medical issues with which a jury is unlikely to have experience." *Rye v. Matrixx Initiatives, Inc.*, No. 06-cv-3288, 2007 WL 2475960, at *4 (D. Minn. Aug. 24, 2007) (internal quotations and citation omitted); *see also In re Baycol Prods. Litig.*, 321 F. Supp. 2d 1118, 1126 (D. Minn. 2004) ("[T]his Court joins with those courts that have held personal injury cases involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person."). The Attune is a medical device and claims about its design and alleged failures are highly technical and complicated such that a jury is unlikely to understand without expert testimony. Sprafka relies on the expert testimony of Truman to establish that the Attune device was defective and that certain design features of the Attune caused Sprafka's Attune device to debond. Without this testimony, Sprafka is unable to prove her products liability claim. *See Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1009 (8th Cir. 1998) (concluding that summary judgment was appropriate when the only evidence the plaintiff offered of a product's defective condition was expert testimony that was excluded). The Court therefore grants summary judgment.

CONCLUSION

For the reasons outlined above, the Court grants MDBS's motion to exclude testimony and motion for summary judgment.

ORDER

Based upon the foregoing, and the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' motion to exclude expert testimony of Mari Truman (Doc. No. [91]) is **GRANTED.**

2. Defendants' motion for summary judgment (Doc. No. [123]) is **GRANTED**. Plaintiff's claims against Defendants are **DISMISSED WITH PREJUDICE.**

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 26, 2024

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge