IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

ANGELO REYNOLDS,

Plaintiff,

v.

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

OPINION AND ORDER

19-cv-762-wmc

In 2014, plaintiff Angelo Reynolds was implanted with a Bard Eclipse Filter, a prescription medical device that is designed to catch blood clots before reaching the heart or lungs. After being implanted, one of the filter's struts fractured and embedded in the tissue near his spine. Although the main body of the filter was ultimately removed successfully in 2018, the broken strut remains in Reynolds' body. In late 2019, Reynolds brought suit against defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., arguing both should be held liable for the allegedly defective design and warnings of the Eclipse Filter on both strict liability and standard negligence grounds. Although plaintiff also originally asserted claim for breach of warranty, misrepresentation, wrongful manufacturing, and negligence *per se* (*see* Compl. (dkt. #1)), he no longer is pursuing those claims. (*See* Pl.'s Opp'n (dkt. #72) 11.)

This case was previously part of a multidistrict litigation ("MDL") proceeding, which was consolidated in the District of Arizona and consisted of plaintiffs who claimed to have been implanted with defective Bard IVC filters, causing them serious injury or even death. During the course of the MDL proceedings, six plaintiffs were selected for

bellwether trials. (Remand & Transfer Order (dkt. #3).) Three of those cases proceeded to trial. *See Booker v. C.R. Bard, Inc.*, No. CV-16-00474; *Jones v. C.R. Bard, Inc.*, No. CV-16-00782; *Hyde v. C.R. Bard, Inc.*, No. CV-16-00893. The court granted summary judgment in another case, concluding that those claims were barred by the applicable statute of limitations. *See Kruse v. C.R. Bard, Inc.*, No. CV-15-01634. As for the remaining two cases, one was removed from the bellwether trial schedule, and the other settled shortly before trial. *See Mulkey v. C.R. Bard, Inc.*, No. CV-16-00853; *Tinlin v. C.R. Bard, Inc.*, No. CV-16- 00263. In 2019, a number of cases from this MDL were remanded to this court, including the instant case and *Johnson v. C.R. Bard, Inc.*, 19-cv-760 (W.D. Wis.), which was tried to a jury in June of 2021.

Defendants now seek to exclude certain opinion testimony by plaintiff's experts (dkts. #44, 47, 49), and assuming they are successful, also move for summary judgment, contending that in the absence of any genuine dispute as to any of the material facts, they are entitled to judgment as a matter of law. (Dkt. #32.) However reluctantly, the court is inclined to agree on this record.

UNDISPUTED FACTS[1]

A. Background

The Bard Eclipse Filter is a medical device designed to catch blood clots before they reach the heart or lungs. Conical in shape and consisting of a main shaft to which twelve struts (six relatively shorter "arms" and six somewhat longer "legs") are attached, the tiny

[1] Unless otherwise noted, the court finds the following facts undisputed and material.

device is implanted in the inferior vena cava ("IVC") -- the largest vein in the human body -- where its arms and legs open, helping to anchor the filter in the walls of the IVC and directing any blood clots into spinning blades at the center of the device. Once implanted, this design is intended to prevent blood clots from traveling to the heart, lungs, or brain. IVC filters such as the Eclipse are often used in patients who have a history of deep venous thrombosis ("DVT") or blood clots to address a risk of potentially life-threatening pulmonary emboli ("PE"). The Eclipse in particular as designed to be a "retrievable" filter that could be implanted and then be percutaneously removed at a later time,[2] hopefully after the risk of blood clots have substantially subsided, although defendants also represented that the Eclipse was safe for permanent use.

Other retrievable IVC filters had already been in use prior to the Eclipse. The Recovery Filter was Bard's first-generation retrievable filter, followed by the G2, G2 Express, G2 X, and eventually, the Eclipse, making it Bard's fifth-generation, retrievable filter. A number of design changes were made between iterations of these filters, which differ somewhat in geometry, dimensions, composition, functions, and manufacture. Additionally, Bard also manufactures the Simon Nitinol Filter (sometimes referred to as "SNF"), which is a permanent-only filter, meaning it cannot be easily retrieved from the patient's body once implanted, and preceded all of Bard's retrievable designs.

[2] "In surgery, a percutaneous procedure is any medical procedure or method where access to inner organs or other tissue is done via needle-puncture of the skin [and in this case, the IVC], rather than by using an 'open' approach where inner organs or tissue are exposed (typically with the use of a scalpel)." *Percutaneous*, Wikipedia (last accessed April 19, 2021), https://en.wikipedia.org/wiki/Percutaneous.

Each iteration of the Bard implantable filters were cleared via the U.S. Food and Drug Administration's ("FDA") § 510(k) process for marketing to the public, based on the device's "substantial equivalence" to a predicate device. In particular, the Eclipse was predicated on the G2; the G2 was predicated on the Recovery; and the Recovery was predicated on the original Simon Nitinol Filter.[3]

B. Warnings

Plaintiff's expert, Dr. Darren Hurst, opines that:

> Bard failed to notify the operating physician and the implanted patients of the much higher complication rates of fracture, embolization of fractured components, penetration, migration, including the known risk of death associated with the Recovery, G2, G2X, and Eclipse filters in comparison to the original predicate device, the Simon Nitinol Filter, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality, and performance.

(Hurst Rep. (dkt. #45) 4(b)(i).)[4] Similarly, plaintiff's expert Dr. Derek Muehrcke opines that

> Bard failed to notify the operating physicians and the

[3] The court understands that the SNF, too, was predicated on another device, but that fact was not included in the parties' proposed findings of fact.

[4] Defendants additionally object to plaintiff's assertions related to complication rates, which they contend are all based on data from the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. According to defendants, "[s]cientific conclusions regarding comparative rates cannot be drawn from MAUDE data because of the many limitations and inherent inaccuracies in the data." (Defs.' Reply to Pl.'s Resp. to Defs.' PFOFs (dkt. #79) ¶ 15.) While these "limitations" and "inaccuracies" may affect the weight a trier of fact might assign this data, defendants have not provided a sufficient basis for the court to preclude consideration of the MAUDE data for the purposes of summary judgment. In addition, defendants object to plaintiff's use of this particular opinion from Dr. Hurst on the grounds that the MDL court excluded it in a prior order. That objection is addressed in the opinion below.

> implanted patients of the much higher complication rates associated with Recovery, G2, G2 Express, G2S, and Eclipse filters in comparison to the original predicate device, the Simon Nitinol Filter, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality and performance.

(Muehrcke Rep. (dkt. #46) 10.)[5]

The Instructions for Use ("IFU") that accompanied the Eclipse Filter included two section titled "**Warnings**," which advised physicians that:

> Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment using endovascular and/or surgical techniques. . . . Movement, migration or tilt of the filter is a known complication of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots, and/or dislodgement due to large clot burdens.

(Eclipse IFU (dkt. #33-3) 2). The "**Potential Complications**" section in the IFU similarly warned of the risk of "Filter Tilt"; "Filter malposition"; "Perforation or other acute or chronic damage of the IVC wall"; "Vessel injury" and "Organ injury." (*Id.* at 3.)

In addition, the IFU details in a bolded paragraph "**All of the above complications have been associated with serious adverse events such as medical intervention and/or death**." (*Id.*) The IFU also included a bolded section titled "**Eclipse Filter**

[5] Defendants also object to plaintiff's use of this particular opinion from Dr. Muehrcke on the grounds that the MDL court excluded it in a prior order. Again, that objection is addressed in the opinion that follows.

Removal" that warned physicians to "**NOTE: It is possible that complications such as those described in the 'Warnings', 'Precautions,' or 'Potential Complications' sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted**." (*Id.* at 2).

Finally, defendants emphasize that the risks associated with all IVC filters were noted in medical literature as early as 1996. In particular, defendants point to various articles and publications discussing the rate and types of complications associated with such filters.

C. Plaintiff's Implant

In 2014, while traveling on a motorcycle, plaintiff Angelo Reynolds was run off the road and into a ditch, sustaining various traumatic injuries, including significant knee and leg injuries, necessitating fourteen surgeries. A few days after his accident, on September 3, 2014, Reynolds experienced extreme swelling in his leg and was admitted to emergency surgery with DVT and a femoral bleed. Because his physicians were concerned that he would suffer a PE from the blood clots in his legs, Dr. Hee Soo Jung placed a Bard Eclipse Filter in Reynolds's IVC. Plaintiff's medical experts, Drs. Hurst and Muehrcke, both agree that Reynolds was an appropriate candidate to receive the Eclipse Filter.

Although Reynolds was advised by his physicians in November of 2014 to follow up in a "couple of months" to discuss removal of the Filter, he did not make a follow up appointment for removal until 2018. Unfortunately, imaging taken on March 27, 2018,

revealed that his filter had by then fractured and perforated Reynolds's IVC, with one strut embedded near his spine. On October 10, 2018, the majority of the Bard Eclipse Filter was successfully percutaneously removed by his physician, Dr. Courtney Morgan. However, a portion of one strut was unable to be removed and remains embedded in Reynolds's pre-spinal peritoneum (the tissue between his spinal cord and abdomen).

While Reynolds has never experienced any physical symptoms related to his filter or the fractured strut, he has experienced anxiety and nervousness related to the retained strut. Moreover, Dr. Hurst has opined that Reynolds has somewhere between "a greater than 0 but less than 100%" risk of experiencing certain potential, future complications if the strut in his retroperitoneum moves or migrates, including infection, irritation, chronic pain, or hemorrhage. In addition, if any of these events occur, Dr. Hurst opined that plaintiff could face an increased risk of morbidity, death or complex surgery to remove the retained strut. At the same time, Hurst is unable to say with a reasonable degree of medical certainty that it is more likely than not the retained strut will move, or if it does, Reynolds will suffer any adverse events. Similarly, Dr. Muehrcke opines that Reynolds will require lifelong CT scans for the retained strut, as well as surgical intervention if the strut causes problems with his abdominal organs, including bleeding, infection, and pain, although like Dr. Hurst, he cannot say with a reasonable degree of medical certainty whether these problems are more likely than not to occur. To date, there is also no evidence that the remaining strut has moved since it was first discovered in March of 2018.

OPINION

I. Expert Motions

Before turning to defendants' motion for summary judgment, the court must address defendants' motions related to plaintiff's proposed expert testimony.

A. Michael Freeman, M.D.

Defendants seek to exclude opinions from plaintiff's expert Michael Freeman, M.D. on two grounds. First, defendants contend plaintiff failed to identify timely the facts and data that Dr. Freeman considered in forming his opinions, nor did plaintiff produce the documents he actually relied on despite defendants' request to do so. Second, defendants argue that Dr. Freeman's report contains only general, rather than case-specific, opinions in violation of the MDL court's order requiring all fact and expert discovery be completed before remand. For the reasons that follow, the court agrees that Dr. Freeman's opinions must be excluded.

As noted above, this case was previously pending for some time in an MDL proceeding before Judge David G. Campbell in the District Court for the District of Arizona. The express purpose of the MDL was to "centralize all pretrial proceedings and complete all common fact and expert discovery concerning Bard IVC filters." (Suggestion of Remand & Transfer Order (dkt. #4) 9 (Campbell, J.).) General expert discovery closed on July 14, 2017, while the case was still in the MDL. (*Id.* at 13.) In a joint status report to this court after remand, the parties further agreed that "[a]ll common or 'general' fact and expert discovery in the above-styled case has been completed." (Joint Status Rep. (dkt.

#13) 2.) Thus, this court's scheduling order only contemplated discovery of case-specific experts and facts. (Scheduling Order (dkt. #20).)

Nevertheless, on September 25, 2020, plaintiff served Dr. Freeman's expert report and CV on defendants. In his report, Dr. Freeman opines that: (1) "relative to the non-Bard retrievable filters and non-Bard permanent filters, the Eclipse filter fails 3.8 and 2.9 times more often, respectively"; (2) there were early indicators available to Bard showing that the Eclipse was failing "at a significantly increased rate" relative to the SNF and other, non-Bard retrievable filters; and (3) had Reynolds received a non-Bard retrievable filter, rather than the Eclipse, there is a 73.7% chance that he would have avoided a filter-failure related adverse event. (Freeman Rep. (dkt. #50) 3, 8.) Dr. Freeman also noted that he reviewed Reynolds' "UW Hospital and Clinics" records and includes some citations to articles and books regarding methodologies for calculating adverse events. (*Id.* at 3-7.) However, other than general references to the MAUDE database, Freeman did not include a list of documents or data that he relied upon in preparing his report. (*See generally id.*)

Before Dr. Freeman's January 20, 2021, deposition, defendants asked plaintiff to produce a list of documents that Freeman had consulted to prepare his opinions and also asked that he bring to his deposition all materials and documents on which he relied. However, plaintiff's counsel neglected to provide any of this information until after Dr. Freeman's deposition, after defendants filed the instant motion, and almost four months after plaintiff's expert disclosure deadline. Finally, defendants maintain that plaintiff *still* has not produced "nearly one hundred documents, including adverse event data foundational to his opinions." (Defs.' Reply (dkt. #68) 1 (internal emphases omitted).)

Federal Rules of Civil Procedure 26(a) requires that an expert report to contain "the facts or data considered by the witness" in forming his or her opinions. Fed. R. Civ. P. 26(a)(2)(B)(ii). Moreover, if a party fails to disclose information as required by Rule 26(a) timely, that information must be excluded unless the failure was "substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Plaintiff's counsel does not appear to dispute that the information was not timely disclosed; instead, they argue that the violation was justified and harmless.

As for the late disclosure being justified, plaintiff vaguely asserts that the ongoing COVID-19 pandemic "created numerous challenges and unique work arrangements." (Pl.'s Opp'n (dkt. #59) 8.) This excuse falls flat. Indeed, at the beginning of the pandemic, the parties requested and the court largely granted a three month extension of practically all deadlines due to disruptions caused by COVID-19. (Dkts. #25-26.) To the extent that this was insufficient, plaintiff was obligated to bring it to the court's attention in advance and seek an appropriate extension. Regardless, as defendants point out, Dr. Freeman testified at his deposition that *had he merely been asked*, he could have provided a list of documents reviewed and relied on in forming his opinions at the time he authored his report. (Freeman Dep. (dkt. #49-2) 27:11-17.)

Plaintiff's argument as to harmlessness is perhaps closer. Although Dr. Freeman's report did not contain a formal list of documents he relied upon, the sources of that data appears to be disclosed and discussed in the report itself. Moreover, plaintiff did eventually produce at least some of the requested evidence and offered to make Dr. Freeman available for another deposition well in advance of the November 2021 trial date. *See Rudersdorf v.*

First Choice Logistics, Inc, No. 16-CV-336-JPS, 2017 WL 237626, at *2 (E.D. Wis. Jan. 19, 2017) (concluding that late-disclosed expert report was harmless because defendants had been on notice of the subject of the report from the outset and because the report was disclosed approximately five months before trial).

Ultimately, the court need not resolve whether the report should be excluded under Rule 37 because Dr. Freeman's opinions also violate Judge Campbell's and this court's order regarding expert discovery. Having reviewed Dr. Freeman's report, the court agrees that the opinions expressed go only to the risks of Bard IVC filters *generally*. Indeed, the vast majority of Dr. Freeman's report analyzes the relative risks of adverse events related to the Eclipse filter compared to other IVC filters on the market. Although he then purports to opine as to the probability that *Reynolds* could have avoided a adverse health event due to a filter failure, it is apparent from the report that Dr. Freeman arrived at this estimate based only on his general analysis, *not* from any individualized assessment of Reynolds. In particular, he opines generally that the Eclipse filter fails 3.8 times more often than non-Bard retrievable filters, or in other words, that the Eclipse is 73.7% more likely to fail than a non-Bard retrievable filter.[6] Thus, his opinion that there is a 73.7% chance that Reynolds would have avoided serious adverse events had he been implanted with a non-Bard retrievable filter reflects *no* individualized adjustment for Reynolds' specific data. Indeed, in his deposition, Dr. Freeman specifically confirmed that his analysis would apply to *any* plaintiff who had a Bard Eclipse filter implanted during the same time period. (Freeman Dep. (dkt. #49-2) 81:13-16, 45:17-46:19.)

[6] 1 – (1 ÷ 3.8 or 26.3%) = .737 or 73.7%

Of note, plaintiff had the opportunity to use expert testimony from the MDL that addressed some of the same material discussed by Dr. Freeman. In the MDL, Rebecca Betensky, Ph.D., was retained as a general expert to offer opinions regarding risks of adverse events associated with Bard's retrievable Recovery, G2, G2X, Eclipse, Meridian, and Denali filters compared to the permanent Simon Nitinol Filter in various categories and time-periods, albeit perhaps not looking at the performance of retrievable filters offered by other manufacturers. Like Dr. Freeman, Dr. Betensky specifically calculated and broke down the reporting risk ratios for the Eclipse Filter in her MDL report. (*See* Freeman Rep (dkt. #50) 5-11; Betensky Rep (dkt. #51) 3.) Plaintiff even acknowledges that Dr. Freeman analyzed the same data and arrived at similar conclusions as Dr. Betensky. (Pl.'s Opp'n (dkt. #65) 7.) For reasons unknown to the court, however, plaintiff chose *not* to disclose Dr. Betensky as an expert and instead retained Dr. Freeman. (Pl.'s Expert Witness Disclosures (dkt. #31).) For this reason, the court must grant defendants' motion to strike Dr. Freeman's report as containing only general, rather than case-specific opinions in violation the MDL and this courts' orders regarding discovery. Because the court is excluding Dr. Freeman's report in its entirety on this ground, the court will deny as moot defendants' motion to exclude the opinion as untimely under Rule 37.

The court recognizes that complete exclusion of one of plaintiff's three expert witnesses is ordinarily a harsh result, but Dr. Freeman's report cannot be squared with the clear mandate from the MDL court that general expert discovery be conducted in the MDL, which was finalized long before this case was remanded back to this court. The very purpose of the MDL was to consolidate and complete as efficiently as reasonable all shared

pretrial matters, including especially general discovery. *See* 17 Moore's Federal Practice - Civil § 112.07 (2021) ("The transferee court has the power to manage discovery. The key purpose of the multidistrict litigation statute is to provide the transferee judge with the discretion to develop an effective and efficient pretrial program."); *Id.* § 112.02 ("The purpose of [the MDL] transfer procedure is to conserve judicial resources and to avoid the delays that would inevitably result if all aspects of each action, such as discovery, were conducted separately."). To permit plaintiff to inject a new general expert opinion into this case would undermine this very purpose.

B. Drs. Hurst and Muehrcke

Defendants next seek to exclude certain opinions rendered by Darren Hurst, M.D., and Derek D. Muehrcke, M.D., both of whom were retained as generic experts in the MDL proceedings. In particular, defendants seek to exclude Dr. Hurst's opinions that:

1) Bard filters had higher complication rates than other manufacturers' filters. (Hurst Rep. (dkt. #45) 9-11 (Opinion 4(b)(i), (vi)(3), and (viii)).)

2) Bard ignored safety signals with its filters, and elected not to perform additional studies to evaluate durability, safety, and efficacy, all while falsely representing superior safety, quality, and performance. (*Id.* at 9-12 (Opinion 4(b)(i), (iii), (v), (vii)).)

Defendants additionally seek to exclude the opinions of Dr. Muehrcke that:

1) Opinions regarding design or engineering characteristics of IVC filters. (Muehrcke Rep. (dkt. #46) 8-10.)

2) Opinions regarding Bard filter failure rates (in particular about the failure rates of Eclipse filters). (*Id.* at 10-12.)

3) Opinions regarding an "unacceptable risk" of caudal migration posed by Bard filters. (*Id.* at 9-10.)

4) Opinions regarding Bard's knowledge, intent, or ethics. (*Id.* at 9, 11.)

According to defendants, these opinions were already excluded by the MDL court, and this court must abide by those rulings. Under the "law of the case" doctrine, a court will not revisit prior decisions "of its own or of a coordinate court" except in extraordinary circumstances. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988). Plaintiff does not contend that this court should overturn Judge Campbell's rulings; instead, he argues that the challenged opinions were *not* excluded during the MDL proceedings and defendants are improperly seeking to extend the MDL court's actual ruling.

Turning then to the MDL court's rulings on the disputed opinions themselves, Judge Campbell found that the admissibility of Dr. Hurst's testimony as to the allegedly higher complication rates of Bard filters "will depend on the manner in which it is given." *In re Bard IVC Filters Prod. Liability Litigation*, No. MDL 15-02641-PHS DGC, 2018 WL 495189, *3 (D. Ariz. Jan. 22, 2018). More specifically, Judge Campbell concluded that

> Dr. Hurst can testify that if Bard IVC filters had higher complication rates and unacceptable risks of caudal migration, then, in his opinion as a practicing interventional radiologist, those facts should have been disclosed by Defendants. But he cannot present an expert opinion that Bard IVC filters did in fact have higher complication rates and unacceptable risks of caudal migration without satisfying the reliability requirements of Rule 702. He has not done so in his report or deposition testimony.

Id. at *4. Similarly, as to Dr. Hurst's second disputed opinion, Judge Campbell ruled, "Dr. Hurst can testify about what a physician would expect to receive from Bard. But he cannot

state opinions about what was known within Bard or what was or was not done within Bard." *Id.* at *4

As to Dr. Muehrcke's opinions, Judge Campbell noted that Dr. Muehrcke did not have a background in engineering, and thus, could not testify "as a design or engineering expert on characteristics of IVC filters." *In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495188, at *2 (D. Ariz. Jan. 22, 2018). However, Dr. Muehrcke was given leave to "opine on factors that caused a filter's failure -- in this case, an inability to resist migration in the IVC." *Id.* at *3. Judge Campbell also prohibited Dr. Muehrcke from opining on Bard filter failure rates or that Bard filters present an "unacceptable risk." *Id.* at *5. Still, Dr. Muehrcke was permitted to "opine, as a treating physician who must make decisions about IVC filter use, that Bard should have disclosed any risks it found in its products that would be unacceptable to doctors and patients." *Id*. Finally, Judge Campbell concluded that while Dr. Muehrcke could "opine that Bard should have provided warnings to physicians and patients if it knew of excess risks," he was not permitted "to opine about Bard's knowledge, intent, or ethics." *Id.* at *6.

Overall then, Judge Campbell did partially exclude, or at least limit, some of the identified opinions by Drs. Hurst and Muehrcke, but he did not *fully* exclude these opinions, and defendants' requests for exclusions go too far. Accordingly, the court will grant in part and deny in part defendants' motion, and simply reaffirm the rulings issued by Judge Campbell in the MDL, limiting both experts' testimony at trial to those portions of their reports not expressly excluded by the MDL court as set forth above.

II. Motion for Summary Judgment

Summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material facts and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The court must view all facts and draw all inferences in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Although the initial burden rests on the moving party, once that party has "made a properly-supported motion for summary judgment, the nonmoving party may not simply rest upon the pleadings but must instead submit evidentiary materials that 'set forth specific facts showing that there is a genuine issue for trial.'" *Siegel v. Shell Oil Co.*, 612 F.3d 932, 937 (7th Cir. 2010) (quoting Fed. R. Civ. P. 56(e)). Thus, "[a] party will be successful in opposing summary judgment only when they present definite, competent evidence to rebut the motion." *Burton v. Kohn L. Firm, S.C.*, 934 F.3d 572, 579 (7th Cir. 2019) (quoting *EEOC v. Sears, Roebuck & Co.*, 233 F.3d 432, 437 (7th Cir. 2000)).

In this case, plaintiff argues that the Bard Eclipse Filter implanted in Reynolds was defective in design and had defective warnings, making defendants liable under both strict liability and negligence theories. A common element of all four claims is proof of a product defect. Wis. Stat. § 895.047; *Burton v. E.I. du Pont de Nemours & Co., Inc.*, 994 F.3d 791, 819 (7th Cir. 2021). Defendants advance a number of arguments against plaintiff's claims; however, because the court concludes that plaintiff has failed to proffer sufficient evidence for a reasonably jury to find that the Eclipse was defective in design or warnings, the court will begin and end with its discussion of those issues.

A. Design Defect

Under Wisconsin law, "[a] product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). Defendants contend that plaintiff has failed to produce sufficient evidence for a jury to conclude that a reasonable alternative design for the Eclipse existed at the time Reynolds received his implant, and therefore, has failed to establish that the Eclipse was defective in design.

Although expert testimony may not be required to prove a reasonable alternative design where the feasibility of such a design is obvious and understandable to laypersons, *Restatement (Third) of Torts: Prod. Liab.* § 2 cmt. f (1998), expert testimony *is* required in cases involving complex medical and scientific issues as to design that are beyond the layperson's common knowledge, *Johnson v. Mylan, Inc.*, 107 F. Supp. 3d 967, 974-75 (E.D. Wis. 2015); *see also Smoot v. Mazda Motors of Am., Inc.*, 469 F.3d 675, 682 (7th Cir. 2006) (requiring expert testimony in product liability case to prove that airbag control unit was defective). There can be little doubt that expert testimony is required in this case to prove that a reasonable alternative design existed to the Eclipse. In particular, the safety and effectiveness of the Eclipse and other IVC filters is not readily apparent to a layperson just by considering the devices themselves. Likewise, the data regarding the relative effectiveness of, as well as rates of risk applicable to, the various IVC filters on the market is complex and is not reasonably susceptible to interpretation by a lay jury without the assistance of an expert.

Only three experts were disclosed by plaintiff. (Pl.'s Expert Witness Disclosures (dkt. #31).) As explained in detail above, Dr. Freeman's expert testimony must be excluded entirely.[7] That leaves only the testimony from Drs. Hurst and Muehrcke. However, none of their opinions provide support for plaintiff's claim that there exists a reasonable alternative design to the Eclipse. As plaintiff points out, both doctors opined that Bard failed to notify the operating physicians of the "much higher complication rates" associated with the Bard retrievable filters, including the Eclipse, in comparison to the SNF and competitor filters. (Hurst Rep. (dkt. #45) 9(b)(i); (Muehrcke Rep. (dkt. #46) 10.) As just explained, Judge Campbell specifically *prohibited* both Drs. Hurst and Muehrcke from testifying as to the relative complication rates of IVC filters because their testimony on that subject lacked reliability under Federal Rule of Civil Procedure 702. *In re Bard IVC Filters Prod. Liability Litigation*, 2018 WL 495189, *3; *In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 495188, at *2.

In his opposition brief to defendants' motion for summary judgment, plaintiff relies heavily on Judge Campbell's Rule 50 opinion in *Hyde v. C.R. Bard, Inc.*, No. CV-16-00893-PHX-DGC, 2018 WL 4742976 (D. Ariz. Oct. 2, 2018), which was both one of the MDL bellwether cases and decided under Wisconsin law. In that opinion, Judge Campbell rejected defendants' argument that plaintiffs' design defect claim failed as a matter of law because plaintiffs had failed to identify a reasonable alternative design, reasoning that

[7] Even if the court had not excluded Dr. Freeman's testimony, the court notes that plaintiff failed entirely to cite to that report in his summary judgment submissions. *See* Fed. R. Civ. P. 56(c)(3) (although a court may consider materials not cited by the parties, it is only required to consider those materials cited).

plaintiffs had presented sufficient evidence for a reasonable jury to find the SNF was a safer and reasonable alternative. *Id.* at *3. Plaintiff fails to acknowledge, however, that the *Hyde* plaintiffs offered expert testimony from Robert McMeeking, Ph.D., who as a Professor of Structural Materials and Distinguished Professor of Mechanical Engineering used his knowledge of design and analysis of engineering components to analyze and assess the various models of IVC filters. Although Dr. McMeeking produced a general expert report in the MDL that could have been offered, plaintiff for whatever reason chose not to disclose him as an expert in this case.

Accordingly, unlike in *Hyde*, plaintiff here has not offered the kind of expert testimony that Judge Campbell found would support a design defect claim. Moreover, given the nature of the highly technical design at issue, plaintiff was required to produce relevant and admissible expert testimony that could lead a reasonable jury to find there existed a reasonable alternative to the Eclipse filter's design, even with respect to Bards' own, permanent SNF filter.[8] Because plaintiff has failed to do so, summary judgment must be entered in favor of defendants as to plaintiff's design-based claims.

B. Defective Failure to Warn

Wisconsin law provides that "[a] product is defective because of inadequate

[8] In order to succeed under a failure to warn theory, plaintiff must show that there was something particularly dangerous about the Eclipse filter that necessitated further instructions in order to make the product safe. Wis. Stat. § 895.047(1)(a). However, plaintiff is again unable to provide any admissible expert testimony showing that the Eclipse filter was especially dangerous. Indeed, plaintiff simply cites conclusions reached by Drs. Hurst, Muehrcke, and Freeman, which have been excluded as contrary to the restrictions on that expert's testimony established by the MDL. (Pl.'s Opp. (dkt #72) 9.)

instructions or warnings only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). As a threshold matter, the court finds that the learned intermediary doctrine applies here, meaning that defendants' duty to warn ran to Reynolds's physicians, not Reynolds himself. *See In re Zimmer, NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 751 (7th Cir. 2018); *Johnson v. C.R. Bard, Inc.*, 19-cv-760, 2021 WL 1784661, at *7 (W.D. Wis. May 5, 2021). Plaintiff disputes this characterization, but the bulk of applicable law, as well as this court's previous decisions, weigh in favor of application of the learned intermediary doctrine. (Pl.'s Opp. (dkt. #72) 8.) Thus, the relevant question is whether Reynolds' implanting doctor, Dr. Jung, would have changed his treatment decisions. Since plaintiff has offered *no* evidence from Dr. Jung by affidavit or deposition testimony regarding his treatment decisions, the remaining question is whether defendants' warnings were adequate on their face as a matter of law.

Again, plaintiff relies on Dr. Hurst's and Dr. Muehrcke's opinions that Bard should have, but failed to, notify physicians of the "much higher complication rates" associated with Bard's retrievable IVC filters as compared to the SNF and other competitor filters. However, plaintiff's position once more runs into Judge Campbell's rulings as to the limitations of both their experts' testimony. In particular, Drs. Hurst and Maehrke were only permitted to opine that *if* Bard retrievable filters have high relative complication rates, *then* defendants should have warned of those rates. As noted above, however, both experts were specifically prohibited from opining as to the underlying complication rates, nor has

plaintiff produced any other admissible expert testimony or evidence to support those complication rates.[9] Since a jury could not reasonably find in favor of plaintiff without this underlying evidence to support Drs. Hurst's and Muehrcke's conditional opinions regarding adequate warnings, Wis JI-Civil 260 (stating that expert opinions should "be based on the facts in the case"), the court must also grant summary judgment in favor of defendants as to plaintiff's design-based claims.

Given that at least some of plaintiff's errors could potentially have been corrected by employment of existing MDL expert reports (or offering other documentary evidence from Bards' own records) this result is admittedly unsatisfying. Nevertheless, as the Seventh Circuit has repeatedly admonished, "[s]ummary judgment is not a dress rehearsal or practice run; it is the put up or shut up moment in a lawsuit, when a party must show what evidence it has that would convince a trier of fact to accept its version of the events." *Hammel v. Eau Galle Cheese Factory*, 407 F.3d 852, 859 (7th Cir. 2005) (internal quotations omitted). Given the long-past expert disclosure deadlines and impending trial date, the court sees no fair way to correct plaintiff's glaring omissions. Accordingly, the court will grant defendant's summary judgment motion.

ORDER

IT IS ORDERED that:

1) Defendants' motion to strike opinions and testimony from Michael Freeman, M.D., as generic and non-case specific (dkt. #49) is GRANTED. Defendants'

[9] Even the MAUDE data that certain of plaintiff's experts rely upon for their excluded opinions require interpretation, which he neither presents nor even cites in opposition to defendants' proposed findings of fact.

motion to exclude opinions and testimony of Michael Freeman, M.D., as untimely (dkt. #47) is DENIED AS MOOT

2) Defendants' motion to exclude opinions and testimony of Darren Hurst, M.D. and Derek D. Muehrcke, M.D. (dkt. #44) is GRANTED IN PART AND DENIED IN PART, consistent with the opinion above.

3) Defendants' motion for summary judgment (dkt. #32) is GRANTED.

4) The clerk of court is directed to enter judgment in defendants' favor and close this case.

Entered this 15th day of September, 2021.

BY THE COURT:

/s/

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WILLIAM M. CONLEY
District Judge