IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

ROSEANNE SANCHEZ, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-05762

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Plaintiffs' Motion for Reconsideration)

Pending before the court is the Plaintiffs' Motion for Reconsideration [Docket 149]. The defendant has responded. [Docket 150]. As discussed below, the motion is **DENIED**.

I. Background

On September 29, 2014, I entered a memorandum opinion and order resolving the parties' motions to exclude or limit expert testimony.[1] The plaintiffs ask that I reconsider or clarify three of those rulings. I address each of the rulings below.

II. Legal Standard

Rule 54(b) of the Federal Rules of Civil Procedure governs reconsideration here. *See Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1469–70 (4th Cir. 1991)

1 By this Order, I amend my Memorandum Opinion and Order entered on September 29, 2014 [Docket 148], at page 29 to replace the words "the plaintiffs" with "BSC" and the appropriate verb agreement in the following sentences: (1) "The plaintiffs argue that Dr. Mays's opinions are not reliable because they are litigation driven, not scientific, and not fair and balanced."; (2) "Next, the plaintiffs contend that Dr. Mays 'selectively cite[s] several articles' and 'fails[s] to include contrary statements or literature in [his] report."; (3) "If the plaintiffs take issue with Dr. Mays's failure to review or cite particular documents, this goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination."; and (4) "Finally, the plaintiffs argue that Dr. Mays's opinions are a poor fit and would not be helpful to a jury because Dr. Mays was not able to correlate degradation to any clinical symptoms in an individual patient."

(finding that the district court properly reconsidered an interlocutory order under Rule 54(b)); *In re Digitek Prods. Liab. Litig.*, MDL No. 1968, 2010 WL 5396377, at *1 n.2 (S.D. W. Va. Oct. 20, 2010); *Bragg v. Robertson*, 183 F.R.D. 494, 495–96 (S.D. W. Va. 1998) (stating that "the Court retains power to amend interlocutory orders to achieve complete justice"). Rule 54(b) states:

> [A]ny order or other decision, however, designated, that adjudicates fewer than all of the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Fed. R. Civ. P. 54(b). "Notwithstanding that precept, it is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through—rightly or wrongly." *Mt. Hawley Ins. Co. v. Felman Prod., Inc.*, No. 3:09-cv-00481, 2010 WL 1404107, at *2 (S.D. W. Va. Mar. 30, 2010).

Additionally, although a "motion for reconsideration under Rule 54(b) is not subject to the strictures of a Rule 60(b) motion," this district has been "guided by the general principles of Rule 59(e) and 60(b) in determining whether a Rule 54(b) motion should be granted. *Shrewsbury v. Cyprus Kanawha Corp.*, 183 F.R.D. 492, 493 (S.D. W. Va. 1998). In that regard, the Fourth Circuit has recognized three grounds for amending a judgment: "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998). Such motions "may not be used, however, to raise arguments which could have been raised prior to the issuance of the judgment, nor may they be used to argue a case under a novel legal theory that the party had the ability to address in the first instance." *Id.*

III. Analysis

The plaintiffs ask that I reconsider three *Daubert* rulings in this case, wherein I granted Boston Scientific Corporation's ("BSC") motion to exclude the expert testimony of Dr. Thomas Barker, Dr. Michael Thomas Margolis, and Dr. Mark Slack. *See Sanchez et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *5–19, *30–32 (S.D. W. Va. Sept. 29, 2014).

1. Dr. Michael Margolis

Dr. Margolis is a pelvic floor surgeon and urogynecologist who seeks to opine as to general and specific causation. In my *Daubert* ruling, I excluded several of his opinions because I found his method to be unreliable. *See Sanchez*, 2014 WL 4851989, at *10-19. The plaintiffs request reconsideration of the following decisions.

A. Dr. Margolis's Rejection of the Ulmsten and Nilsson Studies[2]

In my *Daubert* ruling, I excluded Dr. Margolis's opinion that polypropylene slings are not safe and effective because his method was unreliable. *See id.* at *12. In particular, Dr. Margolis failed to provide a scientific basis for discounting the *Nilsson* follow-up study, which supports the conclusion that polypropylene slings are safe and effective. In their original response to BSC's *Daubert* motion, the plaintiffs contended that Dr. Margolis could not explain his rejection of the *Nilsson* study because he was "bound by the confidentiality order entered by this Court in Ethicon" and because of the "work product privilege related to his role in the Ethicon litigation." (Pls.' Resp. re: Margolis [Docket 73], at 9). In their original response, the plaintiffs wrote:

[2] The plaintiffs' Motion for Reconsideration refers to "the *Ulmsten* and *Nilsson* series of studies." (Pls.' Mot. for Recons. [Docket 149], at 3). However, the plaintiffs' original response to BSC's *Daubert* motion only notes the *Nilsson* study. (*See* Pls.' Resp. & Mem. of Law in Opp'n to Mot. to Exclude Michael Thomas Margolis, M.D. ("Pls.' Resp. re: Margolis") [Docket 73], at 9-10). Dr. Margolis's deposition testimony sheds light on the relationship between these two studies, where he refers to them as "Ulmsten's original work and then Nilsson's followup." (Margolis Dep. [Docket 132-2], at 193:19-20). Distinguishing between these two studies is immaterial to my *Daubert* ruling on Dr. Margolis and my ruling on the plaintiffs' Motion for Reconsideration, but I point it out for clarification.

> Dr. Margolis strongly disagrees with the reliability of findings in the [*Nilsson*] study, citing potential bias in data collection. He was not in a position at his deposition to offer a detailed analysis supporting his rationale for disagreement with the conclusions in the *Nilsson* study. Dr. Margolis holds a very sound basis for his treatment of the findings in the *Nilsson* study. His understanding of the potential bias in findings arises from his knowledge obtained in his role as an expert witness in the Ethicon mesh cases. During deposition, Dr. Margolis testified that he did not want to directly or indirectly violate confidentiality orders and work-product privilege in the Ethicon case. These documents may be produced *in camera* or under seal, and the parties continue to meet and confer on this issue.

(*Id.* at 9-10 (internal citations omitted)). However, the plaintiffs never provided the court with documentation explaining Dr. Margolis's rejection of the study. The plaintiffs even admit this in their Motion for Reconsideration, stating "Plaintiffs' counsel offered to produce the documents *in camera*, but failed to do so with the result that the Court did not have the information it needed to make a determination as to the reliability of Dr. Margolis's methodology." (Pls.' Mot. for Recons. [Docket 149], at 3).

The plaintiffs filed their original response to BSC's *Daubert* motion on January 27, 2014, yet did not provide the court with this information until their Motion for Reconsideration 8 months later and after I had entered my ruling. The plaintiffs' untimeliness is an insufficient ground for reconsideration. *See Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998) ("[T]here are three grounds for amending an earlier judgment: (1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice."). The plaintiffs do not get a second chance to argue their case.

B. Failure to Consider Contrary Data

In my *Daubert* ruling, I excluded several other of Dr. Margolis's opinions because his method was unreliable. *See Sanchez*, 2014 WL 4851989, at *11-18. I found that Dr. Margolis failed to provide a scientific basis for rejecting studies contrary to his opinions and failed to provide any scientific support for his other opinions. In their Motion for Reconsideration, the plaintiffs argue that Dr. Margolis considered contrary literature. (*See* Pls.' Motion for Recons. [Docket 149], at 5). This argument was made in the plaintiffs' original response. (*See* Pls.' Resp. re: Margolis [Docket 73], at 8). In my *Daubert* ruling, I did not doubt that Dr. Margolis looked at contrary studies. I found his method to be unreliable because he failed to provide a scientific basis for rejecting those studies. Thus, this argument is unavailing.

The plaintiffs additionally argue that, in fact, "Dr. Margolis has scientific bases for giving many of pro-mesh articles less credibility, including (1) his personal knowledge of payment for results . . . ; (2) peer-reviewed literature demonstrating that industry sponsored literature is inherently biased for positive results . . . ; (3) his clinical practice and experience that complication rates are underreported . . . ; and (4) peer reviewed literature demonstrating patients lost the follow up at alarming rates . . ." (Pls.' Mot. for Recons. [Docket 149], at 6 (citations omitted)). In support, the plaintiffs cite and attach an October 2, 2014 affidavit from Dr. Margolis, where he attempts to better explain his reasoning and deposition testimony that I found so damaging to his reliability. (*See* Margolis Oct. 2, 2014 Aff. [Docket 149-2]).

Motions for reconsideration "may not be used . . . to raise arguments which could have been raised prior to the issuance of the judgment . . ." *See Poole v. Ethicon, Inc.*, No. 2:12-cv-01978, 2013 WL 6164078, at *2 (S.D. W. Va. Nov. 25, 2013) (internal quotations

omitted) (citation omitted). The plaintiffs already had their chance to raise these arguments in their original response to BSC's *Daubert* motion. *See id.* at *3 (rejecting motion for reconsideration, in part, because "the plaintiffs appear to raise arguments that could have been raised prior to the denial of their motion to remand").

Therefore, the plaintiff's Motion for Reconsideration as to Dr. Margolis is **DENIED**.

2. **Dr. Mark Slack**

The plaintiffs seek clarification or reconsideration of the court's Order as to Dr. Slack's opinions only as it pertains to product development and testing. (Pls.' Motion for Recons. [Docket 149], at 6). In my order, I found that Dr. Slack failed to provide a scientific basis for his opinions because no regulation or authority requires the particular testing Dr. Slack advocates. *See Sanchez*, 2014 WL 4851989, at *31. In their Motion for Reconsideration, the plaintiffs argue that Dr. Slack employed a reliable methodology by applying "a published and peer-reviewed set of standards for pre-market testing to determine whether BSC properly tested and systematically developed the design of the Pinnacle prior to launch." (Pls.' Motion for Recons. [Docket 149], at 6). The plaintiffs restate the same five standards from a protocol Dr. Slack helped develop as part of the International Urogynecological Association ("IUGA") that they cite in their original briefing – standards which Dr. Slack failed to include in his expert report.[3] The reliability of the IUGA protocol does not dictate my present decision.

[3] Dr. Slack cites the IUGA article at the beginning of his expert report in the description of his background but does not attach the text. (*See* Slack Report [Docket 116-1], at 3). When discussing his opinion on product testing and design, Dr. Slack never mentions the article or the five standards it describes. At the end of his section on clinical trials, Dr. Slack lists a variety of things BSC should have done prior to product launch, three of which conform to the standards from his article. However, without aid from the plaintiffs' brief, I have no way of knowing that Dr. Slack is relying on the IUGA article in coming to these conclusions.

Moreover, the plaintiffs have ignored the more significant portion of my order stating that "[m]uch of Dr. Slack's export report is a narrative review of corporate documents and his opinions are riddled with improper testimony regarding BSC's state of mind and legal conclusions." *Sanchez*, 2014 WL 4851989, at *31. My decision stands based solely on this analysis. Because "Dr. Slack's impermissible state of mind opinions permeate his entire expert report," I need not delve any further into the issue of whether Dr. Slack relied on scientific standards in coming to his conclusions regarding product testing and design. *Id.* Accordingly, the plaintiffs' motion is **DENIED**.

3. Dr. Thomas Barker

Dr. Barker is a biomedical engineer, seeking to offer expert testimony regarding the effects of polypropylene mesh inside of the human body. In my *Daubert* ruling, I excluded several of his opinions because I found his method to be unreliable. *See Sanchez, et al., v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *5-10 (S.D. W. Va. Sept. 29, 2014). The plaintiffs request reconsideration of the following decisions.

A. Mechanical Testing

Dr. Barker based his opinions on a series of mechanical tests that he performed on the Obtryx and Pinnacle mesh. I found his testing method to be unreliable because he (1) failed to follow published protocols; (2) used an insufficient sample size; (3) failed to meet peer reviewed standards; and (4) failed to replicate an in vivo environment. *See id.* at *6.

I found that Dr. Barker failed to follow the published protocols because he did not use a saline bath in his testing, which was meant to help replicate the physiological environment of the

human body. *See id.* at *7. I found this flaw to be especially important, since he seeks to opine about the behavior of the mesh in vivo. *See id.*

In their original response to BSC's *Daubert* motion, the plaintiffs did not refute BSC's allegation that Dr. Barker failed to use a saline bath. (Pls.' Opp'n to Def. Boston Scientific's Mot. & Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Thomas H. Barker, Ph.D. ("Pls.' Resp. re: Barker") [Docket 89], at 11-13). In fact, the plaintiffs appear to acknowledge this fact. For example, they stated, "While *it is true that Dr. Barker did not use a saline bath in his mechanical testing*, this in no way proves that Dr. Barker's methodology was flawed." (*Id.* at 12 (emphasis added)). The plaintiffs also wrote that "no flaws in methodology can be associated with *Dr. Barker's failure to use a saline bath* in his mechanical testing." (*Id.* (emphasis added)).

However, now, in their Motion for Reconsideration, the plaintiffs change their argument entirely, stating that, in actuality, "Dr. Barker's testing subjected BSC's meshes to an identical saline bath" as the published protocols require. (Pls.' Mot. for Recons. [Docket 149], at 10). The plaintiffs attach an October 4, 2014 affidavit from Dr. Barker, where he explains that he did, in fact, soak the meshes in saline. (*See* Barker Oct. 4, 2014 Aff. [Docket 149-15], at 1-2). They also cite to a sentence in Dr. Barker's expert report where he states, "[a] phosphate buffered saline solution was used to hydrate each of the Boston Scientific products before testing." (Barker Report [Docket 149-16], at 22).

It is unclear to me why the plaintiffs did not raise this argument in their original response. It is also strange that Dr. Barker himself provided the following deposition testimony:

> Q: It goes on to say that, The mesh was allowed to sit in the 37-degree Celsius saline bath for 10 minutes prior to testing. Correct?
>
> A: Correct.

Q: Obviously, in your test the mesh did not sit in any 37-degree Celsius saline bath prior to testing, is that right?

A: That's correct.

(Barker Dep. [Docket 71-4], at 197:25-198:8). Under oath, Dr. Barker plainly admits that his *mesh* did not sit in a saline bath. Whether this is a misunderstanding on the part of Dr. Barker or on the part of the plaintiffs, I need not reconcile these inconsistencies. The plaintiffs cannot simply change their stance by way of a motion for reconsideration. *See Pac. Ins. Co.*, 148 F.3d at 403.

More importantly, even if Dr. Barker did, in fact, soak the mesh in saline, my *Daubert* ruling as to Dr. Barker would not change. I still find his method to be unreliable. The use of a saline bath would not change the fact that his testing also failed to replicate the multi-directional forces of the female pelvic floor. In their Motion for Reconsideration, the plaintiffs argue that "testing does not have to replicate the multi-directional forces in the female pelvic floor to arrive at in vivo conclusions." (Pls.' Mot. for Recons. [Docket 149], at 13). In support, the plaintiffs cite to Dr. Barker's deposition testimony and new affidavit where he claims that his testing is reflective of the performance of the mesh in vivo. (*See* Barker Oct. 4, 2014 Aff. [Docket 149:15], at 4-5; Barker Dep. [Docket 149-17], at 328:18-330:6). Even so, "it is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through—rightly or wrongly." *Mt. Hawley Ins. Co.*, 2010 WL 1404107, at *2. I found ex vivo mechanical stress tests to be an unreliable basis in forming opinions about the behavior of mesh inside of the human body. Regardless of the new arguments that the plaintiffs make as to Dr.

Barker's testing, including those regarding the saline bath or sample size,[4] my ultimate conclusion to exclude Dr. Barker's testimony is unaffected.

B. Mechanical Mismatch Opinions

In *Sanchez*, I found Dr. Barker's opinions as to the mechanical mismatch between the mesh and the human body to be unreliable, in part, because he based his elastic modulus calculations of the mesh on his methodologically flawed and unreliable testing. *See Sanchez*, 2014 WL 4851989, at *9. In their Motion for Reconsideration, the plaintiffs now argue that the calculations reached by Dr. Barker are also available from other sources and are, thus, reliable. The plaintiffs cannot re-argue their case here. If other sources confirm Dr. Barker's calculations, the plaintiffs should have demonstrated that in their original response to BSC's *Daubert* motion. *See Pac. Ins. Co.*, 148 F.3d at 403 (stating that motions to amend a judgment "may not be used . . . to raise arguments which could have been raised prior to the issuance of the judgment . . .").

Therefore, the Plaintiffs' Motion for Reconsideration as to Dr. Barker is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 17, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

[4] In their Motion for Reconsideration, the plaintiffs make an additional argument about Dr. Barker's sample size. (*See* Pls.' Motion for Recons. [Docket 149], at 12-13). I need not address this argument because of my finding that his ex vivo testing provided an unreliable basis for his opinions regarding the mesh's behavior in vivo.