IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
WESTERN DIVISION

STEPHANIE S. KNOTH **PLAINTIFF**

v. **CIVIL ACTION NO. 5:18-cv-49-DCB-MTP**

APOLLO ENDOSURGERY US, INC **DEFENDANT**

ORDER

THIS MATTER is before the Court on Plaintiff's Motion to Reopen Discovery [224]. Having considered the parties' submissions, the record, and the applicable law, the Court finds that the Motion [224] should be denied.

BACKGROUND

This is a products liability dispute arising from the implant of an ORBERA gastric balloon manufactured by Defendant Apollo Endosurgery US, Inc. ("Apollo"). On May 4, 2018, Plaintiff, proceeding *pro se*, filed this action against Apollo.[1] Thereafter, Plaintiff retained counsel and on January 9, 2019, amended her Complaint to plead state-law claims that "parallel" federal law.

This amendment was precipitated by the Medical Device Amendments Act ("MDA"), which contains an express provision preempting state-law claims that impose requirements which differ from federal requirements. *See* 21 U.S.C. § 360k(a). A two-pronged test determines whether the MDA preempts a state-law claim: (1) whether the federal government has established requirements applicable to the medical device, and (2) if so, whether the state law

[1] Plaintiff also asserted claims against Dr. Stephen Keith, Southwest Mississippi Regional Medical Center, and Gastroenterology Associates, but Plaintiff's claims against these Defendants are no longer pending in this action.

claim would impose requirements that are "different from or in addition to" the federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). The parallel claims doctrine allows plaintiffs to employ state tort law as a "mechanism for enforcing federal requirements." *See Raab v. Smith & Nephew, Inc.*, 150 F.Supp.3d 671, 686 (S.D. W.Va. 2015). Thus, the claim must "parallel" the federal regulations.

The Food and Drug Administration ("FDA") regulates medical devices, and devices such as the gastric balloon at issue are considered Class III devices and are subject to a strenuous pre-market approval process. In her Amended Complaint [30], Plaintiff alleges that Apollo received pre-market approval for the subject gastric balloon. Plaintiff asserted several state-law claims in her Amended Complaint [30], but only two parallel state-law claims remain: manufacturing defect and breach of express warranty. *See* Pretrial Order [190].

On April 22, 2019, the Court entered a Case Management Order [45], which set a discovery deadline of December 16, 2019. On August 21, 2019, the Court stayed discovery pending a ruling on Apollo's Motion to Dismiss [46]. *See* Order [66]. On November 8, 2019, the Court granted in part and denied in part the Motion to Dismiss [46], leaving only Plaintiff's manufacturing defect and breach of express warranty claims. *See* Order [67].[2] On November 13, 2019, the Court lifted the stay, set a discovery deadline of August 7, 2020, and set the trial for February 1, 2021. *See* Order [68]. Discovery closed on August 7, 2020, and on August 28, 2020, Apollo filed a Motion for Summary Judgment [126]. On December 9, 2020, the Court denied the Motion for Summary Judgment [126]. *See* Order [149]. Thereafter, the Court conducted a pretrial conference, entered a Pretrial Order [190], and set the trial for June 7, 2021.

[2] The Court dismissed the following claims: negligence, failure to warn, implied warranty, unjust enrichment, lack of informed consent, negligent training and proctoring and negligent certification, violation of the Mississippi Deceptive Trade Practice Act.

On March 2, 2021, the Court continued the trial to August 30, 2021, at the behest of the parties. *See* Order [193]. On August 17, 2021, the Court continued the trial indefinitely due to the increase in COVID-19 cases in Mississippi. *See* Order [221].

On September 20, 2021, Plaintiff filed the instant Motion [224], requesting that the Court reopen discovery for a period of ninety days. According to Plaintiff, additional discovery is needed to obtain information concerning whether the subject gastric balloon had FDA approval and to allow Plaintiff an opportunity to produce additional medical records. Apollo opposes the Motion [224]. *See* Response [232].

ANALYSIS

Federal Rule of Civil Procedure 16(b) governs scheduling orders and provides that "[a] schedule may be modified only for good cause and with the judge's consent." *See* Fed. R. Civ. P. 16(b)(4). "The good cause standard requires a showing by the movant that the deadlines cannot reasonably be met despite the diligence of the party needing the extension." *Olivarez v. T-Mobile USA, Inc.*, 997 F.3d 595, 602 (5th Cir. 2021). In determining whether Rule 16(b)(4)'s good cause standard has been met, courts consider four factors: (1) the explanation for the failure to meet the deadline; (2) the importance of the requested relief; (3) the potential prejudice in granting the relief sought; and (4) the availability of a continuance to cure such prejudice. *Batiste v. Lewis*, 976 F.3d 493, 500 (5th Cir. 2020).

As previously mentioned, Plaintiff requests that the Court reopen discovery to allow the parties to obtain information concerning whether the subject gastric balloon had FDA approval and to allow Plaintiff an opportunity to produce additional medical records. Beginning with medical records, Plaintiff argues that discovery should be reopened because on October 20, 2020, she received a diagnosis from a neuropsychologist, Dr. Susan Andrews, following

diagnostic testing and treatment for brain hypoxia and damage.[3] Additionally, Plaintiff argues that discovery should be reopened because she was hospitalized from June 1, 2021, to June 5, 2021, for a gastric leak.

The Court will first address Plaintiff's explanation for her failure to comply with the scheduling order. "Courts within the Fifth Circuit have described the explanation for needing more time as the most important factor." *Ryan v. U.S. Dep't of Commerce*, 2021 WL 3134909, at *2 (S.D. Miss. July 23, 2021). Plaintiff points out that the developments in her medical condition occurred after the discovery deadline of August 7, 2020. While that is true, it is also true that Plaintiff was aware of these developments long before she filed the instant Motion [224]. Plaintiff received a diagnosis from a neuropsychologist on October 20, 2020, but waited nearly a year—until September 20, 2021—to request the reopening of discovery. Likewise, Plaintiff completed her hospitalization for a gastric leak on June 5, 2021, but waited more than 100 days to request the reopening of discovery.

Plaintiff asserts that she did not move for the reopening of discovery following the diagnosis from a neuropsychologist because she hoped to keep the February 1, 2021, trial date. That is not a reasonable justification for the delay, especially considering the fact that on January 5, 2021, the Court continued the trial to May 17, 2021. "[T]he good-cause standard will not be satisfied if the court concludes that the party seeking relief (or that party's attorney) has not acted diligently in compliance with the schedule." Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice & Procedure § 1522.2 at 322 (3d ed. 2010); *see also Smith v. Transocean Offshore USA, Inc.*, 2021 WL 1534503, at *10 (E.D. La. Apr. 19, 2021) (finding that a plaintiff

[3] Plaintiff does not provide details about Dr. Andrews's diagnosis.

failed to offer a reasonable explanation for his failure to seek a continuance once he became aware of a potential neck injury).

Turning to the factor of importance, the Court finds that additional discovery on Plaintiff's injuries is not critical to Plaintiff's case. The Court notes that in her Amended Compliant [30], Plaintiff alleges that she underwent extensive medical treatment and was on a ventilator for over a year—from December 9, 2016, to December 17, 2017. *See* Amended Complaint [30].

The Court also finds that, given the extensive briefing on dispositive and evidentiary motions and the current status of the case, Apollo would be prejudiced if the Court were to reopen discovery. *See Ryan*, 2021 WL 3134909, at *3. While a continuance might cure some prejudice, Defendant would be forced to devote additional time and resources to a case that has been ready for trial since February 10, 2021. *See* Pretrial Order [190]. This case has been pending for nearly three and a half years and will be tried as soon as reasonably possible. Having considered the appropriate factors, the Court finds that the Motion [224] should be denied to the extent Plaintiff seeks to have discovery reopened to allow the parties to obtain information concerning developments in her medical condition.

Plaintiff also requests that the Court reopen discovery to allow the parties to obtain information concerning whether the subject gastric balloon had FDA approval. As an explanation for her failure to comply with the scheduling order, Plaintiff asserts that on June 2, 2021, Apollo produced documents which call into question whether the subject gastric balloon had FDA approval and thus call into question the law that should govern this action. Again, the Court notes that these documents were produced on June 2, 2021, but Plaintiff waited until September 20, 2021 to file the instant Motion [224].

Moreover, the record reveals that any questions concerning FDA approval should have been raised and explored before the discovery deadline and long before Plaintiff filed her Motion [224]. In support of her Motion [224], Plaintiff submitted an affidavit from its retained expert witness, Dr. Joshua Sharlin. *See* [229] at 1-12. Most of the information discussed by Dr. Sharlin, however, is derived from documents which were produced on *February 21, 2020*, not the documents produced on June 2, 2021.

Dr. Sharlin explains that two models of the Orbera gastric balloon (B-50000 and B-40800) are sold outside the United States, and one model (B-4800) is sold in the United States with FDA approval. *See* [229] at 5-6. On December 30, 2015, 500 units of B-40800 model gastric balloons (included the subject gastric balloon) were shipped to the Netherlands. *Id*. at 6.[4] The gastric balloons were repackaged and shipped out as B-4800 model gastric balloons. *Id*.

The subject balloon was shipped to Southwest Regional Medical Center. *Id*. There are discrepancies with the subject gastric balloon's serial number and "Unique Device Identification" number. The subject gastric balloon's serial number is 20126127, but the serial number listed on the "Manufacturer and User Facility Device Experience" report was 20135589. *Id*. at 6-7. Additionally, in the box containing the subject gastric balloon, an Apollo representative recorded a Unique Device Identification number that differed from the number on Plaintiff's product card. *Id*. 9-10.

Plaintiff argues that the Court should reopen discovery because the issues surrounding the differing models, identifying numbers, and repackaging of the gastric balloons call into question whether the subject gastric balloon had FDA approval. *See* [225] at 6. However, the documents which raise questions concerning these issues were produced to Plaintiff on February 21, 2020.

[4] This shipment of gastric balloons was identified as Lot RWAP10299. *See* [229] at 76-83.

Plaintiff did not act with reasonable diligence by waiting nineteen months to seek additional discovery concerning these issues. *See Millennium Partners, L.P. v. Colmar Storage, LLC*, 494 F.3d 1293, 1298-99 (11th Cir. 2007) (defendant failed to demonstrate good cause for seeking to raise a defense after the district court's scheduling order deadline when the evidence showed that the defendant, "with some investigation," could have discovered the defense).

Turning to the documents produced by Apollo on June 2, 2021, Plaintiff explains that they purport to be documents from the manufacturing site.[5] Plaintiff argues that these documents contradict other documents produced by Apollo concerning the location of the manufacturing site of the subject gastric balloon. According to Plaintiff, the FDA approved only the Costa Rica location for manufacturing the gastric balloons, but these documents show that the subject gastric balloon may have been manufactured in the United Kingdom. *See* [225] at 2. Plaintiff argues that if the subject gastric balloon was manufactured in the United Kingdom, and not Costa Rica, the balloon may not have FDA approval.

Plaintiff argues that the issue of whether the subject gastric balloon had FDA approval is a "core issue for the entire litigation." Of course, the issue of whether a medical device has FDA approval and thus is covered by the MDA's preemption provision is important in product liability cases. The Court, however, is not confined to simply considering the importance of FDA approval of a medical device in a theoretical sense, but may consider the specific facts of this case. *See Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2017 WL 119366, at *6 (E.D. Tex. Jan. 12, 2017) ("What is called for in assessing the importance of the amendment is not just

[5] In their Response [233], Apollo explains that it came across these manufacturing documents in preparing for trial. *See* [233] at 8.

the theoretical effect of success on the claims being asserted, but a pragmatic judgment as to the likelihood that the newly asserted claims or defenses will succeed.").

Having considered the documents produced on June 2, 2021, the Court finds that the issue of FDA approval is no more important today than it was when Apollo produced documents on February 21, 2020. The documents produced on June 2, 2021, do not, in any consequential way, undermine the assertion that the subject gastric balloon had FDA approval.

Plaintiff points out that these documents list the "[United Kingdom] product label as the manufacturing site." *See* [225] at 2. Plaintiff is referring to the following address listed in the documents:

> Allergan
> Marlow International
> The Parkway, Marlow
> Bucks, SL7 1YL, United Kingdom

See [229] at 25. The documents list this address but do not state, or otherwise indicate, that it is the address of the manufacturing site. According to Apollo, this is the address for the manufacturer's headquarters in the United Kingdom, not the manufacturing site. Apollo also points out that the documents are in Spanish because the documents are from the manufacturing site in Costa Rica. The Court finds that the documents produced on June 2, 2021, do not provide a sufficient justification for reopening discovery.

Plaintiff has failed to show that additional discovery concerning FDA approval is critically important. Moreover, to the extent that additional discovery is important, the importance "cannot singularly override the enforcement of local rules and scheduling orders." *Geiserman v. MacDonald*, 893 F.2d 787, 792 (5th Cir. 1990). As previously discussed, Apollo would be prejudiced and the case could be further delayed if the Court were to reopen discovery. Another continuance is not warranted to address issues that were or could have been addressed in

the lengthy discovery period afforded the parties in the prior scheduling orders. *See Smith*, 2021 WL 1534503, at *10 (finding that a continuance would not cure the prejudice to defendants who would be forced to conduct additional discovery to address new issues raised two years after the accident underlying the case). Having considered the appropriate factors, the Court finds that the Motion [224] should be denied.

IT IS, THEREFORE, ORDERED that Plaintiff's Motion to Reopen Discovery [224] is DENIED.

SO ORDERED this the 2nd day of November, 2021.

s/Michael T. Parker
UNITED STATES MAGISTRATE JUDGE