IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 14-cv-02667-REB-NYW

ALFONSO A. ALARID

Plaintiff,

v.

BIOMET, INC.;
BIOMET ORTHOPEDICS, LLC; and
BIOMET MANUFACTURING, LLC.,

Defendants.

ORDER ON PLAINTIFF'S MOTION TO STRIKE DEFENDANTS' EXPERT BRYCE ISCH FOR FAILURE TO COMPLY WITH FED. R. CIV. P. 26(a)(2)

Magistrate Judge Nina Y. Wang

This civil action is before the court on Plaintiff Alfonso A. Alarid's ("Plaintiff") Motion to Strike Defendants' Expert Bryce Isch for Failure to Comply with Fed. R. Civ. P. 26(a)(2), filed on August 10, 2015 [#50] (the "Motion to Strike" or "Motion").[1] Pursuant to the Order Referring Case dated October 3, 2014 [#22], the February 10, 2015 Reassignment [#35], and the August 10, 2015 Order Referring Motion [#51], the Motion to Strike is before this Magistrate Judge. The court has reviewed the papers and exhibits submitted by the Parties, considered the applicable case law, is sufficiently advised of the premises, and finds that oral argument would not materially assist the court's disposition of the Motion to Strike. For the reasons stated below, IT IS ORDERED that the Motion to Strike is GRANTED IN PART and DENIED IN PART.

[1] This Order refers to the ECF docket number for documents, and the page number as assigned by the court's ECF system for consistency and ease of reference.

RELVANT BACKGROUND AND PROCEDURAL HISTORY

On September 26, 2014, Defendants Biomet, Inc., Biomet Orthopedics, LLC, and Biomet Manufacturing, LLC (collectively, "Defendants" or "Biomet") removed this action from Denver District Court. [#1]. Plaintiff Alfonso Alarid's operative Amended Complaint [#5] alleges that Biomet made and sold a prosthetic device called the Comprehensive Reverse Shoulder System, a device implanted in reverse shoulder replacement surgery. [*Id.* at ¶ 10]. According to the Amended Complaint, in 2007 and 2008, Biomet applied for and received regulatory approval from the Food and Drug Administration ("FDA") through the FDA's 510(k) process to market the Comprehensive Reverse Shoulder System as a Class II device. [*Id.* at ¶¶ 12-13]. Plaintiff alleges that he received a Comprehensive Reverse Shoulder System implant in his left shoulder on September 24, 2009, and an additional such implant in his right shoulder on July 22, 2010. [*Id.* at ¶ 18]. Plaintiff further alleges that "[b]oth devices failed at the joint between the trunnion and the baseplate, causing pain and loss of function." [*Id.*].

Plaintiff also alleges that, in September of 2010, Biomet received multiple adverse reports with respect to the Comprehensive Reverse Shoulder System then on market, leading to a product recall. [*Id.* at ¶¶ 14-15]. Plaintiff alleges Biomet acknowledged that the recall was instituted as a result of complaints that the device was susceptible to fracture at the joint between the trunnion and the baseplate. [*Id.* at ¶ 16]. Based on these and other allegations, Plaintiff asserts eight claims for relief against Biomet, sounding in products liability (both strict liability and negligence) and breach of warranty (express and implied) for each shoulder. [*Id.* at ¶¶ 46-105]. As noted above, the case was removed to this court by Defendants on September 26, 2014. [#1].

The Scheduling Order entered in this action on January 22, 2015 originally provided that the Parties were to provide the expert disclosures, and any required reports, contemplated by Fed. R. Civ. P. 26(a)(2) on issues as to which a Party would bear the burden of proof at trial ("opening expert disclosures") by no later than July 10, 2015 . [#30 at 8]. The deadline for service of rebuttal expert disclosures pursuant to Fed. R. Civ. P. 26(a)(2) was set for August 21, 2015. [*Id.*]. Subsequently, upon stipulated motion of the Parties, the court granted an extension allowing the Parties up to August 7, 2015 to serve opening expert disclosures on non-engineering related topics, and up to August 28, 2015 to serve rebuttal expert disclosures . [#48].

On July 10, 2015, Defendants served the expert disclosure of Bryce Isch, which is the subject of this instant Motion to Strike (the "Isch Disclosure"). [#50-1 at 1-4]. Mr. Isch is a Biomet Development Engineer. [*Id.* at 1]. According to the Isch Disclosure, Mr. Isch is "expected to testify" to the relevant risks and benefits of the Comprehensive Reverse Shoulder System, including with respect to the present state of the art and knowledge in the industry. [*Id.* at 2]. The Isch Disclosure states that these opinions will be based not only on Mr. Isch's personal involvement in the design and development of the Comprehensive Reverse Shoulder System, but also numerous categories of documentation Defendants assert were previously produced to Plaintiff, including the relevant product design file history and 510k filings. [*Id.* at 2]. The Isch Disclosure provides similar summaries (including general references to categories of documents providing the foundation for Mr. Isch's opinions) with respect to Mr. Isch's opinions as to the Comprehensive Reverse Shoulder System manufacturing process, the adequacy of Biomet's design, manufacturing, and distribution of the Comprehensive Reverse Shoulder System, the sufficiency of any warnings about the device, and as to Biomet's

compliance with applicable regulatory standards with respect to the device. [*Id.* at 3-4].

On August 10, 2015, Plaintiff filed the instant Motion to Strike challenging the sufficiency of the Isch Disclosure. [#50]. Plaintiff's Motion to Strike first argues that, even if Mr. Isch, a Biomet employee, is not an expert "retained or specially employed to provide expert testimony" (which would obviate Fed. R. Civ. P. 26(a)(2)(B)(i)'s requirement that an expert report be provided), the Isch Disclosure fails to adequately set forth "a summary of the facts and opinions to which" Mr. Isch is "expected to testify" as required by Fed. R. Civ. P. 26(a)(2)(C)(ii) of non-retained experts who are not specially employed to provide expert testimony. [*Id.* at 4-6]. Plaintiff contends that the Isch Disclosure is deficient under this standard because it references categories of documents spanning at least several thousand pages as providing the bases for Mr. Isch's opinions, rather than providing a summary of the pertinent facts. [*Id.*]. Plaintiff also argues that Biomet was required to tender a complete expert report pursuant to Fed. R. Civ. P. 26(a)(2)(A), because the substance of Mr. Isch's opinions—including as to Biomet's regulatory compliance and the adequacy of Biomet's design, manufacturing, and distribution of the Comprehensive Reverse Shoulder System—would appear to extend to opinions prepared and developed in anticipation of and/or in the course of this litigation, rather than opinions derived from Mr. Isch's experience as a design engineer for Biomet. [*Id.* at 7-8].

In Response, Biomet argues that the relevant plain text of Rule 26 as construed by the Tenth Circuit imposes no requirement on a party to tender an expert report for an employee "whose duties as the party's employee" do not "regularly involve giving expert testimony," so long as the employee is neither retained nor specially employed to provide the expert testimony at issue. [#56 at 2-4]. Biomet asserts that Mr. Isch is not "retained or specially employed to

provide expert testimony in this case, and his duties do not regularly involve giving expert testimony" [*id.* at 2], and Plaintiff does not argue to the contrary on Reply. [#60]. Biomet also argues that the Isch Disclosure complies with the requirements of Rule 26(a)(2)(C)(ii), based on Biomet's contention that the Isch Disclosure "describes the specific facts" in the categories of documents cited in the Isch Disclosure that Mr. Isch "relies upon." [#*Id.* at 5-6]. Biomet argues in the alternative that if the court finds the Isch Disclosure deficient, Biomet should be granted leave to prepare and serve an appropriately comprehensive supplemental disclosure. [*Id.* at 6-7]. Indeed, Biomet contends that it "offered to spend its efforts on providing a full report for Mr. Isch, rather than responding to Plaintiff's motion, if Plaintiff would agree to withdraw his motion," but Plaintiff refused. [*Id.* at 2]. In Reply, Plaintiff acknowledges that Biomet made an offer to provide a report, but "Plaintiff would prefer that the court enter an order on this dispute." [#60 at 2].

ANALYSIS

I. Standard of Review

Rule 26(a)(2) of the Federal Rules of Civil Procedure provides that a party must disclose to all other parties the identity of any person who may be used at trial to present evidence under Rule 702, 703, or 705 of the Federal Rules of Evidence. Fed. R. Civ. P. 26(a)(2)(A). A retained or specially employed expert must provide a report that contains "(1) a complete statement of all opinions the witness will express and the basis and reasons for them; (2) the facts or data considered by the witness in forming them (3) any exhibits that will be used to summarize or support them; (4) the witness's qualifications, including a list of all publications authored in the

previous 10 years; and (5) a statement of the compensation to be paid for the study and testimony in the case." Fed. R. Civ. P. 26(a)(2)(B).

Pursuant to Fed. R. Civ. P. 26(a)(2)(C), expert witnesses not required to provide a written report by Fed. R. Civ. P. 26(a)(2)(a) must, absent contrary stipulation or court order, provide a disclosure stating the "subject matter on which the witness is expected to present evidence under Federal Rule of Evidence 702, 703, or 705" and "a summary of the facts and opinions to which the witness is expected to testify." Fed. R. Civ. P. 26(a)(2)(C)(i-ii).

A violation of Rule 26(a)(2) is addressed by the court pursuant to Rule 37(c) of the Federal Rules of Procedure. Rule 37(c)(1) of the Federal Rules of Civil Procedure provides:

> If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at hearing, or at a trial, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the court, on motion and after giving an opportunity to be heard:
>
> (A) may order payment of the reasonable expenses, including attorney's fees, caused by the failure;
> (B) may inform the jury of the party's failure; and
> (C) may impose other appropriate sanctions, including any of the orders listed in Rule 37(b)(2)(A)(i)-(iv).

Fed. R. Civ. P. 37(c)(1). The determination as to whether a Rule 26(a) violation is justified or harmless is entrusted to the broad discretion of the court. *Woodworker's Supply, Inc. v. Primcipal Mt. Life Ins. Co.*, 170 F.3d 985, 993 (10th Cir. 1999). In exercising its discretion, the court consideration is guided by the following four factors: (1) the prejudice or surprise to the impacted party; (2) the ability to cure the prejudice; (3) the potential for trial disruption; and (4) the erring party's bad faith or willfulness. *Id.*

II. Application to Motion to Strike

As discussed above, Rule 26(a)(2) of the Federal Rules of Civil Procedure govern whether an individual anticipated to give expert testimony at trial is required to propound a written expert report under Rule 26(a)(2)(B) or may provide an alternative disclosure under Rule 26(a)(2)(C). This court has traditionally employed a burden-shifting procedure for determining whether the requirements of Rule 26(a)(2) have been met. *See Carbaugh v. Home Depot U.S.A., Inc.*, Civil Action No. 13-cv-02848-REB-MEH, 2014 WL 3543714, *2 (July 16, 2014). The party seeking to strike the witness bears the initial burden of showing that the disclosing party failed to comply with Rule 26(a)(2)(B). *Id.* Then the burden shifts to the disclosing party to demonstrate that the witness was not required to provide a report as contemplated by Rule 26(a)(2)(B). *Id.* The substance of the testimony, rather than the status, of the expert will dictate whether a report under Rule 26(a)(2)(B) is required. *Id.* at *3.

There appears no dispute in the Parties' briefing that Mr. Isch is employed by Biomet as a Development Engineer. *Compare* [#50 at 2] *with* [#56 at 1]. However, Plaintiff contends that the contemplated scope of Mr. Isch's testimony "exceed[s] his job duties with Zimmer Biomet as a Development Engineer. The all encompassing scope of Mr. Isch's testimony required Biomet to comply with the requirements of providing a signed written report pursuant to Fed. R. Civ. P. 26(a)(2)(B)." [#50 at 4]. When an individual is testifying as to his percipient knowledge and opinions formed during his participation in the relevant events of the case, *i.e.*, what he personally saw and did in the course of his employment, no report under Rule 26(a)(2)(B) is necessary. *See Carbaugh*, 2014 WL 354714, at *3; *Guarantee Trust Life Ins. Co. v. American Medical and Life Ins. Co.*, 291 F.R.D. 234, 237 (N.D. Ill. 2013). But when an individual exceeds

the scope of his own personal knowledge and observation, that expert should propound a report pursuant to Rule 26(a)(2)(B). *See Carbaugh*, 2014 WL 354714 at *4 (holding that when a treating physician relies even in part upon information provided outside of the course of treatment, such opinions must be disclosed pursuant to Rule 26(a)(2)(B)).

In this case, Biomet has indicated that Mr. Isch is expected to testify at trial that in "designing, engineering, and manufacturing the Comprehensive® Reverse Shoulder Device, Biomet complied with applicable laws and regulations relevant to the device." [#50-1 at 3]. Biomet also expects that Mr. Isch will testify regarding the design and engineering of the Biomet Comprehensive® Reverse Shoulder device, including how this device was designed with the state of the art technology. [*Id.*] Biomet has also indicated that Mr. Isch is expected to testify at trial that the "Comprehensive® Reverse Shoulder devices at issue in the case were not defective in design, manufacture, were not insufficient in their warnings, or otherwise, and were not in a defective condition at the time they left Biomet's control." [*Id.* at 3]. In each case, the disclosure indicates that Mr. Isch will testify based on his personal involvement in the design and development of the Comprehensive Reverse Shoulder device; the regulatory approval process; and the quality control process. *See, e.g.* [#50-1 at 2-3].

While it is unclear whether Mr. Isch is qualified to testify or will be permitted to testify as as to the ultimate questions of whether Biomet complied with all applicable laws and regulations relevant to the device, or that the device was not defective in design, manufacturing, were not insufficient in their warnings or otherwise, and were not in a defective condition at the time they

left Biomet's control, this is not the appropriate motion for consideration of those issues.[2] On the record before the court, appears that Biomet may intend to offer Mr. Isch to testify about facts, data and opinions developed outside of his personal observations and knowledge as a Development Engineer. To the extent that is true, Mr. Isch was required to propound an expert report consistent with Rule 26(a)(2)(B) for such opinions. For example, design history files and 510k regulatory submissions to the FDA routinely span various topics and hundreds of pages. To the extent that Mr. Isch intends to testify on a portion of those files of which he does not have personal knowledge, he must comply with Rule 26(a)(2)(B).

With respect to the personal knowledge and opinions he developed during the course of his routine employment as a Design Engineer for Biomet, Mr. Isch's disclosure still does not comply with Rule 26(a)(2)(C). Rule 26(a)(2)(C) requires a summary of facts and opinions to which the expert will testify. Fed. R. Civ. P. 26(a)(2)(C). "A summary is defined as a brief account that states the main points of a larger body of information." *Nicastle v. Adams County Sheriff's Office*, Civil Action No. 10-cv-00816, 2011 WL 1674954 at *1. Biomet cannot satisfy its obligations under Rule 26(a)(2)(C) by merely pointing to large swaths of information, like general references to otherwise unidentified "testimony and documentation regarding the Food and Drug Administration's 510k clearance process, as well as information provided to Plaintiff in the Comprehensive® Reverse Shoulder design history file and 510k filings that were produced in Biomet's initial disclosure, including but not limited to, project analysis documentation, design and development planning procedures and documentation, verification

[2] The Honorable Robert E. Blackburn as the presiding judge in this matter set a deadline for the filing of motions pursuant to Rule 702, 703, and 704 of the Federal Rules of Evidence for September 21, 2015. [#31 at 2].

and validation testing and documentation, and indications for use documentation." [#50-1 at 3]. "Designation of such a prodigious volume of material does not constitute a summary of the facts to which the witness[] will testify within the meaning and requirements of Rule 26(a)(2)(C)." *See Nicastle*, 2011 WL 1674954, at *1.

Despite finding that Defendants' disclosure of Mr. Isch is insufficient under either Rule 26(a)(2)(B) or Rule 26(a)(2)(C), I also conclude that any prejudice suffered by Plaintiff should not be entirely borne by Defendants and is not irreparable. In doing so, this court specifically notes that as of August 27, 2015, Biomet offered to provide an expert report for Mr. Isch. [#60-1 at 5]. While Plaintiff notes concern that he had "no assurance that Biomet will comply with the intent and purpose of the disclosure rules under Fed. R. Civ. P. 26(a)(2)," [#60 at 2], Plaintiff's unwillingness to compromise has contributed to any prejudice from delay he may perceive. In addition, the court notes that discovery has not yet closed, and trial is not scheduled to commence until February 29, 2016.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED:**

(1) Plaintiff's Motion to Strike [#50] is **GRANTED IN PART and DENIED IN PART**;

(2) Defendants shall serve supplemental expert disclosures as to Mr. Isch, consistent with the direction in this Order, no later than **October 14, 2015**;

(3) Mr. Isch be made available for an additional one half day (3 1/2 hours) of deposition no later than **October 21, 2015**, as to the opinions set forth in the court-ordered supplemental disclosure;

(4) The Parties are required to meet and confer in good faith about the scheduling of Mr. Isch's deposition;

(5) Each party bear its own costs and fees for this Motion; and

(6) Nothing in this Order may be construed as altering the deadline of September 21, 2015 for the filing of motions pursuant to Fed. R. Evid. 702, 703, or 704.

DATED: October 7, 2015

BY THE COURT:

s/ Nina Y. Wang
United States Magistrate Judge