UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MEDPACE, INC.,

Plaintiff,

vs.

BIOTHERA, INC., *et al*.,

Defendants.

Case No. 1:12-cv-179

Judge Timothy S. Black

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION TO SUBSTITUTE EXPERT WITNESS (Doc. 95)

This civil action is before the Court on Medpace's motion for leave to substitute a new expert witness (Doc. 95), and the parties' responsive memoranda (Docs. 105, 117).[1]

I. FACTUAL BACKGROUND

Medpace moves the Court for leave to substitute a new expert witness for its contract research organization expert, Dr. Bertram Spilker. On August 12, 2013, Medpace disclosed Dr. Spilker as its rebuttal liability expert to respond to Biothera's expert testimony that Medpace's performance on four clinical trials breached the standards in the Master Services Agreement and the contract research organization

[1] Biothera seeks costs and fees associated with opposing the motion, arguing that Medpace did not meet and confer as required by Local Rule 37.1. Specifically, Biothera argues that the motion and costs incurred in defending the motion were unnecessary since Biothera does not move to strike Dr. Spilker on the basis of any potential conflict of interest. (Doc. 105-1 at ¶ 2, Ex. A). Conversely, Medpace maintains that it met and conferred with Biothera on December 16, 2013 regarding the instant motion. (Doc. 117 at 7). The Court declines to award Biothera fees for defending the motion.

industry. Dr. Spilker generated a rebuttal report over ninety pages in length which cited hundreds of pages of additional documents. (Doc. 95, Ex. A at ¶ 8).[2]

Biothera's experts, its counsel, and select employees spent the next several weeks reviewing the voluminous opinions and documents produced by Dr. Spilker. (Doc. 105 at 3). On September 5, 2013, Biothera employee Michele Gargano identified Dr. Spilker as a consultant with whom she had previously worked. (*Id.* at 4). Although she did not immediately recall the details, Ms. Gargano generally remembered that Dr. Spilker consulted for Regulatory Affairs Associates ("RAA"), an organization that provides National Cancer Institute ("NCI") grant recipients with up to thirty hours of regulatory consultant services. Biothera had received an NCI grant and engaged RAA in 2011 to provide consulting services for clinical and regulatory aspects of its drug development program. (*Id*.)

Over the next several weeks, counsel for Biothera attempted to determine the scope of Dr. Spilker's consultancy for Biothera, as well as any confidentiality obligations he owed Biothera. (Doc. 105 at 4). Biothera located a number of documents that appeared to relate to Dr. Spilker's work for Biothrea including: (1) an unsigned confidentiality agreement between Biothera and RAA (Doc. 105-4 at ¶ 4, Ex. C); (2) a Biothera PowerPoint presentation to RAA that did not mention Dr. Spilker by name (*Id.* at ¶ 5, Ex. D); and (3) one email to a number of RAA consultants, including Dr. Spilker, regarding an April 11, 2011 presentation made by Biothera to RAA over Skype (*Id.* at

[2] For his services, Dr. Spilker billed Medpace for 548.7 hours at $655 per hour. (Doc. 95, Ex. C at ¶ 3). **Medpace has paid Dr. Spilker at least $359,738.15.** (*Id.* at ¶ 4).

¶ 6, Ex. E). Because the contract was not signed, and any direct link to Dr. Spilker was tenuous, counsel could not confirm the extent of any contractual relationship with RAA and the specific role Dr. Spilker played in that relationship, including the scope of any confidentiality or non-disclosure obligations. (Doc. 105 at 4).

Counsel for Biothera also reviewed Dr. Spilker's publications to determine his views on the propriety of serving as Medpace's expert witness, given his prior work for Biothera. (Doc. 105 at 5). Biothera learned that Dr. Spilker had opined that even when an actual conflict of interest exists, it may not necessarily influence the expert. (Doc. 105-4 at ¶ 7, Ex. F at 155). Dr. Spilker opined that even if a conflict is present, a conflict can be cured if the expert erects "satisfactory barriers" to prevent inappropriate influence. (*Id.* at 158). In light of the foregoing, Biothera assumed that Dr. Spilker had disclosed his prior work with Biothera to Medpace, but that Medpace and Dr. Spilker were comfortable with moving forward. (Doc. 105 at 5). Accordingly, Biothera prepared deposition questions to determine what barriers Dr. Spilker had erected to prevent any information he obtained as Biothera's consultant from influencing his opinions as Medpace's expert witness. (*Id*.)

On October 9, 2013, Dr. Spilker issued a supplemental rebuttal report, at which point Biothera's focus shifted to the newly referenced documents on the FTP server. (Doc. 101 at 5).

At his deposition, Dr. Spilker testified that he did not recall, but could not deny, having performed consulting work for Biothera in 2011. (Doc. 117-1 at 159). Dr. Spilker testified that he did not check his records prior to his engagement as an expert in

this litigation to determine whether he had performed any such work for Biothera and did not disclose any such conflict to Medpace. (Doc. 95 at 7). Dr. Spilker never disclosed a conflict of interest or any pre-existing confidentiality obligations to any party in this litigation. In fact, he represented orally and in writing that he did not have any conflicts. (Doc. 95, Ex. A at ¶¶ 6-7, Tabs 1-2).

During the deposition, Dr. Spilker maintained that he did not believe his consultancy with Biothera constituted a conflict of interest, but stated that even if there were a conflict, "it is not anything that has influenced me in any way whatsoever." (Doc. 117-1 at 162). Upon conclusion of his deposition, Dr. Spilker checked his records to determine what work he performed for Biothera and what, if any, confidentiality obligations covered that work. (Doc. 95, Ex. A at ¶ 8). Dr. Spilker provided counsel for Medpace with two invoices from February and April 2011. (*Id.* at ¶ 9, Tabs 5, 6). The invoices confirm that Dr. Spilker performed 7.4 hours of consulting work for Biothera in February and April 2011, including reviewing slides, preparing for a meeting, and attending a Skype conference call with Biothera executives. (*Id.*)

Medpace maintains that due to the restrictions imposed by confidentiality provisions (Doc. 95-1 at Tabs 1 and 8), Medpace can no longer work with or use Dr. Spilker as an expert. Accordingly, Medpace seeks: (1) to substitute its rebuttal expert; and (2) an award of fees and costs incurred in briefing this motion as a result of Biothera's "obstructionist behavior."

Biothera does not oppose Medpace's motion to substitute Dr. Spilker, but urges the Court to address the prejudicial impact of granting such a request. Specifically,

Biothera asks the Court to: (1) narrowly limit the substitute expert to Dr. Spilker's opinions; and (2) reimburse Biothera for all prospective fees and costs associated with the substitution.

II. STANDARD OF REVIEW

Courts generally apply a four factor test when deciding a motion to substitute an expert witness:

> (1) the surprise or prejudice to the blameless party;
> (2) any bad faith involved in not producing the evidence earlier;
> (3) the ability of the offending party to cure resulting prejudice; and,
> (4) the amount of disruption to the trial that would result from permitting the use of the evidence.

Assaf v. Cottrell, Inc., No. 10cv85, 2012 U.S. Dist. LEXIS 9243, at *8-9 (N.D. Ill. Jan. 26, 2012). Courts also "take into account the effect that denial of the motion would have on the disposition of the case." *Id*. at 9. Furthermore, courts consider the "good cause" standard under Rule 16 and the "substantial justification" standard under Rule 37. *See* Fed. R. Civ. P. 16(b)(4) (scheduling orders may be modified only for "good cause and with the judge's consent"); Rule 37(c)(1) (a party's failure to timely disclose information as required by Rule 26, including expert reports under Rule 26(a)(2)(B), may not be used at a hearing or trial "unless the failure was substantially justified or is harmless").

III. ANALYSIS

A. Good Cause and Substantial Justification

Dr. Spilker is available and willing to testify on Medpace's behalf,[3] and Biothera declines to strike him on the basis of his prior contractual relationship. Therefore, Biothera argues that Medpace cannot establish good cause to substitute Dr. Spilker.[4]

During early 2011, Dr. Spilker entered into two agreements with RAA. (Doc. 95, Tabs 6-7). Both agreements contain confidentiality provisions. (*Id.*)[5] Due to the restrictions imposed by the confidentiality provisions, and the "clear conflict of interest" created by Dr. Spilker's consulting work for Biothera involving the very drug and two of the clinical trials that are at issue in this litigation, Medpace maintains that it can no longer work with or use Dr. Spilker. (Doc. 95 at 8).[6]

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[3] In all of the cases cited by Plaintiff, the courts granted motions to substitute because the expert was expressly unavailable for trial due to the expert's own withdrawal or the opposing party's motion to exclude. *See, e.g., TIC-The Indus. Co. Wyo., Inc. v. Factory Mut. Ins. Co*., No. 4:10cv3153, 2012 U.S. Dist. LEXIS 17854, at *5 (D. Neb. July 10, 2012) (expert advised the party that "he could not be involved in the case" and accordingly withdrew); *Assaf*, 2012 U.S. Dist. LEXIS 9243 at 1 (defendant's motion to bar expert's testimony was granted); *Pierce v. Fremar*, No. 09-4066, 2010 U.S. Dist. LEXIS 132839, at *2 (D.S.D. Dec. 14, 2010) ("Lacey refused to be her expert witness"); *Payless Shoesource Worldwide, Inc. v. Target Corp*., No. 05-4023, 2007 U.S. Dist. LEXIS 87762, at *2 (D. Kan. Nov. 28, 2007) (expert "was withdrawing").

[4] *See, e.g., Crandall v. Hartford Cas. Ins. Co.*, No. 10-00127, 2012 U.S. Dist. LEXIS 173995, at *3 (D. Idaho Dec. 6, 2012) (if an expert "is unavailable to testify at trial because of death…that is a legitimate and appropriate reason for allowing a new expert to be named," but holding that if a "party's relationship with an expert becomes difficult, and leads to some regret that someone else had not been hired instead, that is a problem of the party's own making, and not a proper basis to further delay the case").

[5] RAA's website currently lists Dr. Spilker as an "FDA consultant." (*Id*., Tab 8).

[6] It appears that Dr. Spilker was introduced to Biothera through RAA. (Doc. 95, Tabs 1-4). Biothera compensated Dr. Spilker $740.00 for 7.4 hours of work. (*Id.*, Tabs 5-6).

Medpace argues that Biothera cannot unilaterally waive the conflict of interest on Medpace's behalf. Under ABA Model Rule of Professional Conduct 1.7, a lawyer "shall not represent a client if … there is a significant risk that the representation of one or more clients will be materially limited by the lawyer's responsibilities to … a former client." Model Rules of Prof'l Conduct R. 1.7(a)(2) (1983). To waive this conflict, an attorney needs "each affected client [to] give…informed consent." *Id.* at 1.7(b)(4). Medpace claims the same is true here. In order to waive Dr. Spilker's conflict, both Medpace and Biothera as the "clients" must waive the conflict. Medpace maintains that had it been aware of any prior relationship between Dr. Spilker and Biothera, Medpace would not have engaged Dr. Spilker as a rebuttal expert. Thus, Medpace declines to waive the conflict. Medpace claims that the only way to cure this prejudice is to allow it the opportunity to substitute a new expert witness. *TIC v. Factory Mut. Ins. Co.*, No. 4:10cv3153, 2012 U.S. Dist. LEXIS 94956 at 22 (D. Neb. July 10, 2012) (granting motion to substitute where plaintiff would "be substantially prejudiced i[f] it is not permitted to name a substitute [for its] sole liability expert.").

It appears that Dr. Spilker may have breached his contract with Medpace in failing to disclose his work with Biothera, but the Court is not overwhelmed by the alleged conflict of interest. Dr. Spilker clearly did not recall that he had performed seven hours of consulting work for Biothera in 2011. Moreover, the evidence supports a finding that Dr. Spilker was essentially provided to Biothera as a consultant through RAA. While this

Court will not require Medpace to proceed with Dr. Spilker, it is perplexed, especially given the extraordinary time and money already spent, why Medpace insists on substituting Dr. Spilker, whose "conflict" does not appear to have affected his opinions in any respect.[7]

In considering the good cause and substantial justification standards, together with the facts of this case, the Court finds sufficient evidence to permit Medpace to substitute for Dr. Spilker.

B. Prejudice

Courts considering motions to substitute expert testimony after the close of discovery have routinely denied them in two situations: (1) the moving party seeks to benefit from broader or different testimony than the original expert;[8] and/or (2) the non-moving party would be significantly prejudiced by a delay in the proceedings.[9]

Courts granting motions to substitute experts after the close of discovery have routinely required the new expert's testimony to be limited to the subject matter opinions espoused in the first expert's report. *See, e.g., Roberts v. Galen of Virgina, Inc*., 325 F.3d 776, 784 (6th Cir. 2003) (affirming district court's "sensible compromise," which

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[7] The fact that Dr. Spilker could not even recall the work he performed for Biothera further supports a finding that the "conflict" did not affect his reports.

[8] *See, e.g., Lopez v. I-Flow, Inc*., No. 08-1063, 2011 U.S. Dist. LEXIS 155826, at *2 (D. Ariz. May 12, 2011) ("Courts regularly deny a request to late-disclose an expert witness where it would result in significant expense to the opposing side and delay proceedings.").

[9] *See, e.g., Smith v. Reynolds Transport Co*., No. 3:11cv2728, 2012 U.S. Dist. LEXIS 147921, at *3 (D.S.C. Jan. 23, 2013) (denying motion to substitute because it would "entail significant prejudice both to Defendants and the administration of justice").

prevented the substitute expert from testifying "to matters outside of [the first expert's] report").[10] Absent a reasonable scope of limitations, Medpace could solicit a new expert to offer more favorable opinions than Dr. Spilker. In addition to prejudice that would likely ensue from permitting substitution at such a late juncture, "fairness does not require that a plaintiff … be afforded a second chance to marshal other expert opinions and shore up his case." *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 250 (6th Cir. 2001). If Medpace were permitted to introduce expert testimony that went beyond Dr. Spilker's testimony, Biothera would likely require additional sur-rebuttal testimony and thus incur significant additional costs.

Medpace argues that it cannot simply plug in a new expert to opine, as Dr. Spilker did, on complex contract research organization liability and performance issues. While Medpace obviously cannot guarantee that its new expert will adopt all of Dr. Spilker's opinions, or articulate opinions in the same manner, if Medpace insists on proceeding with a new expert, it is reasonable to limit that expert to findings that are "substantially similar" to those presented in Dr. Spilker's comprehensive reports. The parties have already engaged in two full rounds of expert reports, and Biothera has invested hundreds of attorney and staff hours and tens of thousands of dollars evaluating the two lengthy rebuttal reports.

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[10] *See also Whiteside v. State Farm Fire & Cas. Co.*, No. 11-10091, 2011 U.S. Dist. LEXIS 123978, at *2 (E.D. Mich. Oct. 26, 2011) (new expert's findings "will be substantially similar" to first expert's findings); *Cardiac Science, Inc. v. Koninklijke Philips Elecs. N.V.*, No. 03-1064, 2006 U.S. Dist. LEXIS 93833, at *4 (D. Minn. Dec. 22, 2006) (new expert could not testify "in any manner that is contrary to or inconsistent with" first expert and could not "enlarge" opinions in any manner).

Accordingly, the Court finds that Biothera would be unfairly prejudiced if forced to incur the significant costs required to evaluate and respond to an entirely new expert report.

C. Bad Faith/Sanctions

When courts allow expert substitution, they also regularly order that the costs and fees associated with the substitution be reimbursed to the non-moving party. *See, e.g., Assaf*, 2012 U.S. Dist. LEXIS 9243 at 5, n. 59 ("[T]o redress the prejudice caused where resources are wasted preparing for the disqualified expert, Rule 37 permits a court to award costs to the blameless party to offset the unnecessary discovery. Imposed cost-sharing is a standard method of alleviating prejudice.").[11] However, "[g]enerally, in cases in which courts have awarded costs and expenses associated with the substitution of an expert, there has been some evidence of bad faith, fault, or tactical maneuvering on the part of the party making the substitution." *Doctor's Assocs., Inc. v. QIP Holder LLC*, No. 3:06cv1710(VLB), 2009 U.S. Dist. LEXIS 119949, at *11-12 (D. Conn. Dec. 23, 2009) (declining to award costs and fees).

The Court acknowledges that Biothera has spent hundreds of hours and tens of thousands of dollars evaluating Dr. Spilker's reports. In an effort to mitigate additional costs, this Court has limited the substitute expert to "substantially similar" opinions. However, the Court declines to award Biothera costs and expenses associated with the substitution of the expert.

[11] *Pierce v. Fremar, LLC*, No. 09-4066, 2010 U.S. Dist. LEXIS 132839, at *3 (D.S.D. Dec. 14, 2010) ("The court, however, can rectify this prejudice by requiring Pierce to pay for any additional expert witness fees incurred by defendants in an award of sanctions.").

With respect to Medpace's request for fees and costs as a result of Biothera's "obstructionist behavior," the Court finds that there is absolutely no evidence that Biothera withheld information about Dr. Spilker's conflict of interest "to ambush Medpace during the deposition of Dr. Spilker." (Doc. 117 at 18). Medpace's finger-pointing is misdirected and should be redirected to their own expert who admitted that he failed to check his records for any conflicts. (Doc. 95 at 7).

IV. CONCLUSION

Accordingly, for these reasons, Plaintiff's motion for leave to substitute a new expert witness for Dr. Spilker (Doc. 95) is **GRANTED IN PART** and **DENIED IN PART**.[12]

IT IS SO ORDERED.

Date: 3/17/2014

s/ Timothy S. Black
Timothy S. Black
United States District Judge

[12] Pursuant to the Amended Calendar Order, Medpace must submit a new rebuttal expert report from its substitute expert on or before September 5, 2014. (Doc. 103).