UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MEDPACE, INC.,	:	Case No. 1:12-cv-179
	:	
Plaintiff,	:	Judge Timothy S. Black
	:	
vs.	:	
	:	
BIOTHERA, INC., *et al*.,	:	
	:	
Defendants.	:	

ORDER DENYING DEFENDANT'S MOTION FOR INVOLUNTARY DISMISSAL (Doc. 138)

This civil action is before the Court on Defendant's motion for involuntary dismissal (Doc. 138), and the parties' responsive memoranda (Docs. 143, 148).

I. BACKGROUND[1]

This Court's November 6, 2012 Preliminary Injunction required Medpace to return Biothera's Trial Property "forthwith." (Doc. 36 at 18). When Medpace failed to timely return the Trial Property, this Court issued a December 14, 2012 Order, which required Medpace to return Biothera's Trial Property "by 12/21/12." (Doc. 42). These Orders were based on the Court's express finding that Biothera had presented "compelling evidence" of potential irreparable harm because "prospective acquirers will not proceed with a sale without the Trial Property." (Doc. 36 at 15). Throughout 2013, Biothera repeatedly sought and received Medpace's assurance that it had complied with the Court's Orders and had returned a full and complete set of Biothera's Trial Property.

[1] For a more detailed factual background, see the Court's Order denying Defendant's first motion for involuntary dismissal. (Doc. 101).

(Cockson Decl. ¶ 10, Ex. I at 3).

However, Medpace subsequently admitted that monitoring reports, site contacts, and protocol deviations were "not uploaded to the FTP site as a part of the Trial Master File" (and thereby produced to Biothera) until October 2013, nearly a year after this Court's Orders. (Cockson Decl. ¶ 11, Ex. J at 1-2; ¶ 12, Ex. K at 45, 55). Accordingly, Biothera moved this Court to involuntarily dismiss Medpace's complaint. (Doc. 80). The Court declined to dismiss the action, but warned Medpace that the Court would dismiss Medpace's claims if it engaged in further egregious misconduct. (Doc. 101 at 7 fn 1).

Recently, Biothera discovered that Medpace *still* had not produced all of the Trial Property. The additional documents were produced in May 2014. Now, Biothera reasserts its claim for involuntary dismissal, based on both the recently produced Trial Property and discovery that Biothera claims evidences Medpace's recklessness.

II. STANDARD OF REVIEW

Rule 41(b) authorizes the involuntary dismissal of an action "[i]f the plaintiff fails to prosecute or to comply with these [Federal Rules of Civil Procedure] or a court order[.]" Fed. R. Civ. P. 41(b); *Knoll v. AT&T*, 176 F.3d 359, 363 (6th Cir. 1999) ("[Rule 41(b) dismissal] is available to the district court as a tool to effect management of its docket and avoidance of unnecessary burdens on the tax-supported courts [and] opposing parties.").

In determining whether dismissal under Rule 41(b) or Rule 37(b) is appropriate, this Court must consider the following factors: "(1) whether the party's failure to cooperate is due to willfulness, bad faith, or fault; (2) whether the adversary was prejudiced by the dilatory conduct of the party; (3) whether the dismissed party was warned that failure to cooperate could lead to dismissal; and (4) whether less drastic sanctions were imposed or considered before dismissal was ordered." *Stough v. Mayville Cmty. Sch.*, 138 F.3d 612, 615 (6th Cir. 1998). "Although none of the factors is outcome dispositve, … a case is properly dismissed by the district court where there is a clear record of delay or contumacious conduct." *Schafer v. City of Defiance Police Dep't*, 529 F.3d 731, 737 (6th Cir. 2008) (quoting *Knoll*, 176 F.3d at 363).

Sanctions may include dismissal of a case when a party has "acted in bad faith" or when conduct was "tantamount to bad faith." *Laukus v. Rio Brands, Inc.*, 292 F.R.D. 485, 502-503 (N.D. Ohio 2013). "[T]he burden of showing that a failure to comply with court orders and discovery requests was due to inability, not willfulness or bad faith, rests with the individual against whom sanctions are sought." *Id.* at 509-510.

III. ANALYSIS

Biothera claims that Medpace acted recklessly when it certified its full compliance with the preliminary injunction on January 8, 2013, but returned additional Trial Property in October 2013 (Doc. 101), and then, after again certifying its compliance on December 13, 2013 (Doc. 126-1 at 5-7), returned additional Trial Property on May 7, 2014 (Doc. 126-1 at 5-7).

For a party's conduct to rise to the level of culpability that warrants dismissal, its conduct must display either an intent to thwart judicial proceedings or a reckless disregard for the effect of its conduct on those proceedings. *Mulbah v. Detroit Bd. of Educ*., 261 F.3d 586, 591 (6th Cir. 2001). Here, while the Court finds that Medpace's conduct was negligent, it does not rise to the level of either intentional or reckless. Moreover, when dismissing with prejudice, the Sixth Circuit generally urges restraint and frowns upon dismissing cases under Rule 41(b) for failure to comply with court orders. (*Id*.)

This Court declines to dismiss this civil action.[2] Medpace clearly erred when it certified on multiple occasions that it had returned all of the Trial Property when it had not. However, involuntary dismissal is still an extraordinary sanction. The Court urges counsel to refocus its efforts on litigating the substantive issues in this case.[3]

A. Standard Operating Procedures

Medpace argues that "Biothera itself created the situation it now complains about" because Biothera "would not let" Medpace follow a detailed quality control check and organize the trial data. (Doc. 143 at 2, 7). Medpace also argues that because this Court required Medpace to return the trial property "forthwith," Medpace was unable to follow

[2] The Court reiterates its warning that the Court will dismiss Medpace's claims if Medpace engages in egregious misconduct.

[3] The Court acknowledges that the underlying contract claim may be related to Medpace's failure to timely produce Trial Property. Specifically, as counsel for Medpace acknowledged on September 12, 2012: "if Biothera finds any defects in the trial data or any failures on Medpace's part to perform under the MSA, Task Orders or Consulting agreement, the parties can resolve what amount, if any, Biothera is entitled to recoup from the amounts paid to Medpace through this litigation." (Doc. 25-9 at 1).

its Standard Operating Procedures ("SOP's").[4] This rationale is stunningly disingenuous as Medpace never advised the Court that the timeline was impracticable given its quality control protocol, and, indeed, Medpace proposed the December 21, 2012 deadline.

Medpace does present evidence that it at least attempted, albeit apathetically, to comply with the Court's Orders. For example, Medpace points to: (1) a November 14, 2012 email advising Medpace employees that they "need[ed] to quickly compile … extraneous documents" (Doc. 143 at 15); and (2) an explanation from Medpace's Clinical Trial Manager that the documents that were missed in the original trial data production were the result of a miscommunication between the clinical team and IT (Richels Dep. at 42-44; Doc. 143, Ex. L at 498-500) (Doc. 143, Ex. G) ("I have a sinking feeling that we were supposed to download the monitoring reports from clintrack to the FTP site (I thought Gary was doing it). There are none in there. Can you start on that first thing tomorrow?").

Ultimately, Medpace was negligent in its production of the Trial Property. Period. Medpace is in the business of collecting and organizing clinical trial data and documents and has binding SOP's that govern how it maintains and transfers Trial Property. Yet Medpace argues that it does not have SOP's governing the production of trial data "in response to a court order." (Doc. 143 at 8). While this Court does not find that it was reasonable for Medpace to deviate from its SOP's in returning the Trial Property, the Court declines, in its discretion, to find that Medpace was reckless. This Court is

[4] N.B. By the time the Court entered the November 6, 2012 preliminary injunction, Biothera had already been wrongfully deprived of its Trial Property for more than eight months. (Doc. 148 at 3).

committed to deciding cases on the merits. *Foman v. Davis*, 371 U.S. 178 (1962). *See also* Rule 15(a).

B. Case Report Forms

Next Medpace suggests that Biothera was not harmed by receiving the Case Report Forms ("CRF's") in May 2014, because those documents were triplicates of forms that Biothera had or because Biothera's clinical trial manager was not aware that they were missing. (Doc. 143 at 20).

CRF's track the case history for each patient in a trial. (Cockson Decla. at ¶ 14, Ex. M at 11). They are kept in "triplicate" with the "original" being the top of three identical forms that trial monitors take when they visit the study sites. Medpace claims that Biothera "could easily access copies" of the CRF's at the sites. (Doc. 143 at 20). However, Biothera could not know if the originals withheld by Medpace matched the copies Biothera had, because sites could make changes to the remaining copies. (Smith Dep. at 289-291). Moreover, up to 30% of the CRF "copies" Biothera obtained are unreadable. (Cockson Decla. at ¶ 15, Ex. N, Dep. of Conners at 105). Furthermore, even if only a small number of documents were missing from the Trial Property, that could lead the FDA to doubt that a clinical trial was well-monitored and therefore withhold approval. (Supp. Decla. of Switzer at ¶¶ 5-6; Gargano Decla. at ¶¶ 2-4).

Medpace's argument, that Biothera was not harmed by receiving the Case Report Forms ("CRF's") in May 2014, fails. (Cockson Decla. at ¶ 16, Ex. O).

C. Medpace's Explanation for its October 2013 and December 2013 Productions

Medpace offers identical explanations for the October 2013 and December 2013 uploads – that there was a miscommunication between the clinical team and the IT department regarding who was responsible for returning the documents. (Doc. 143 at 15-17). Biothera argues that even if Medpace was not reckless in January 2013 when Medpace first missed documents due to a "miscommunication" between its clinical and IT teams, Medpace's conduct reflected the very definition of reckless when Medpace made the same mistake in October 2013. While the Court finds this argument persuasive, the Court declines, in its discretion, to find that the negligence warrants dismissal. (*See, e.g.*, Gaffney Dep. at 524 ("I feel that at the time any of those certifications were made, everyone truly believed that all documents had been provided and, as in any organization, we all have different responsibilities and we don't all follow up to double and triple check the detailed work of other people.")).

D. Medpace's May 2014 Production

Despite the fact that Medpace admits that it missed hundreds of pages of documents on three different occasions, Medpace fails to set forth evidence of any comprehensive review that it ever undertook. Indeed, even now, nearly two years since the Court ordered Medpace to return the Trial Property to Biothera, Medpace has not properly certified that it has fully complied with the Court's Orders. This is

unacceptable.[5]

Medpace's business model is based on its ability to properly return Trial Property to its customers, and there is no question that Medpace could have and should have complied with this Court's Orders. Accordingly, Medpace shall take all necessary steps to certify forthwith that it has fully complied with the Court's Orders of 11/6/12 (two years ago) and 12/14/12 (almost two years ago).[6]

IV. CONCLUSION

Upon careful review, and for these reasons stated here, Biothera's motion for involuntary dismissal is **DENIED**. (Doc. 138). Medpace shall certify forthwith that it has produced all Trial Property. Should this certification prove to be false, the Court may well dismiss Medpace's claims.

IT IS SO ORDERED.

Date: 11/5/14

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

[5] This Court is not satisfied with Medpace's June 27, 2014 representation that "Medpace is not aware of any Biothera trial master file documents in its possession that have not been provided to Biothera. As Medpace has done in the past, if it becomes aware of any unproduced trial master file documents, it will immediately produce them." (Cockson Decla. at ¶ 11, Ex. J).

[6] This Court clearly agreed that Biothera was prejudiced by Medpace's untimely production of the Trial Property in October 2013, as the Court awarded Biothera $931,399.01 in fees. (Doc. 101 at 8, Doc. 122 at 12). Medpace still has not paid the $931,399.01 sanction, despite the fact that the Sixth Circuit dismissed Medpace's appeal (Doc. 140) and denied its emergency motion for reconsideration (Doc. 146). Biothera estimates that it has incurred tens of thousands of dollars in fees and costs in pursuit of the sanctions order since it was entered, including moving to dismiss Medpace's appeal and moving this Court to hold Medpace in contempt. (Cockson Decla. at ¶ 18). Biothera has also incurred significant attorneys' fees and costs investigating the events surrounding Medpace's May 2014 production. These issues are addressed in Biothera's pending motion for contempt (Doc. 141) and Medpace's cross-motion for modification of the supersedeas bond (Doc. 149), which motions are not yet ripe for decision by the Court.