UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
VICTORIA DIVISION

CALVIN TIMBERLAKE and KAREN TIMBERLAKE,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. V-08-4**
SYNTHES SPINE COMPANY, L.P., *et al.*	§	
Defendants.	§	

ORDER

Pending before the Court are Defendant Synthes Spine Company, L.P.'s Motion for Protective Order and Objections to Plaintiffs' Third-Party Subpoenas (Dkt. # 22) and Defendant Spine Solutions, Inc.'s Motion for Protective Order and Objections to Plaintiffs' Third-Party Subpoenas (Dkt. # 25). After considering the motions, responses and applicable law, the Court is of the opinion that the motions should be GRANTED in part and DENIED in part.

The motions seek to preclude the production of documents requested pursuant to ten subpoenas issued by Plaintiffs to third-party physicians ("Physicians") and clinics in California, New York, Pennsylvania, Tennessee, and Texas. The Physicians are not parties to this action and were not involved in the treatment of Plaintiff; however, they were the clinical investigators in the Food and Drug Administration ("FDA") clinical trial of ProDisc prior to its pre-market approval. Plaintiff was not a participant in the clinical trial and was not implanted with ProDisc until after its pre-market approval by the FDA. Defendants object to the subpoenas and the documents requested on the following grounds: (1) overly broad and unduly burdensome; (2) irrelevant and not reasonably calculated to lead to the discovery of admissible evidence; (3) seek Synthes' confidential proprietary and trade secret information; and (4) violate the privacy regulations issued under the

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and Texas state law.[1] Spine Solutions joins in the motion, asserting the same arguments as Synthes.

Plaintiffs brought this products liability action against Defendants for negligence, strict liability and breach of warranty arising out of the implantation of the allegedly defective ProDisc artificial disc device distributed by and manufactured on behalf of Synthes. Plaintiffs' First Amended Original Complaint also presents causes of action for fraud/misrepresentation and conspiracy based on the allegation that many of the physicians performing the clinical trial of ProDisc were investors in the venture who, to protect their financial stake in the outcome of the trial, deliberately omitted unfavorable outcomes from the reported results. They contend that all the information related to the clinical trial, as well as the Physicians financial stake is relevant and discoverable to claims alleged in this action. In order to gain information related to this action, Plaintiffs issued subpoenas requesting the following documents[2] from the Physicians:

1) All documents relating to your investment, or potential investment, in any company affiliated with ProDisc.

2) All financial documents relating to your investment in, purchase or sale of your ownership interest in any company affiliated with ProDisc.

3) All documents relating to any agreements with any company affiliated with ProDisc to perform clinical trials or other trials relating to the ProDisc.

4) All financial documents pertaining to your agreement with any company affiliated with ProDisc to perform clinical trials or other trials on the ProDisc.

5) All documents relating to your relationship with Synthes, Inc. or any company affiliated with ProDisc.

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[1] Defendants also argue the subpoenas were issued prematurely, before the discovery period began. However, the Court held the Rule 26(f) conference on April 21, 2008 and discovery has commenced, making this argument moot.

[2] *See* Dkt. # 22, Ex. B (paraphrasing the documents requested).

6) All documents you filed with or provided to the FDA that discuss, mention, or in any way relate to the ProDisc.

7) All documents filed with or provided to the FDA that disclose, discuss or deny your ownership or any financial interest in any company affiliated with ProDisc.

8) All correspondence between you and the FDA that relate in any way to ProDisc.

9) All correspondence that relates to ProDisc between you and any company affiliated with ProDisc.

Discussion

The court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. FED. R. CIV. P. 26(c)(1). Good cause must be shown to support the issuance of a protective order, providing that "the burden is upon the movant to show the necessity of its issuance, which contemplates a particular and specific demonstration of fact as distinguished from stereotyped and conclusory statements." *In re Terra Int'l, Inc*., 134 F.3d 302, 306 (5th Cir. 1998). Under Federal Rule of Civil Procedure 45(c)(3), the court shall quash or modify a subpoena if it "requires disclosure of privileged or other protected matter and no exception or waiver applies" or subjects a person to undue burden. "When a subpoena is issued as a discovery device, relevance for purposes of the undue burden test is measured according to the standard of Rule 26(b)(1)." *Williams v. City of Dallas*, 178 F.R.D. 103, 109 (N.D. Tex. 1998) (citing *Linder v. Dep't of Def.*, 133 F.3d 17, 24 (D.C. Cir. 1998)). Rule 26(b)(1) limits the scope of discovery to "any matter, not privileged, that is relevant to the claim or defense of any party. . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." FED. R. CIV. P. 26(b)(1). The court must balance the need for discovery by the requesting party and the relevance of the discovery to the case against the harm, prejudice or burden to the other party. *Truswal Sys. Corp. v. Hydro-Air*

Eng'g, Inc., 813 F.2d 1207, 1210 (Fed. Cir. 1987). Modification of a subpoena is preferable to quashing it outright. *Wiwa v. Royal Dutch Petroleum Co.*, 392 F.3d 812, 818 (5th Cir. 2004). In deciding whether to grant a motion for a protective order, the court has significant discretion. *Harris v. Amoco Prod. Co.*, 768 F.2d 669, 684 (5th Cir. 1985).

I. Irrelevant/Overly Broad

Defendants argue that the information sought from the Physicians is irrelevant to Plaintiffs' claims and not likely to lead to the discovery of admissible evidence. Specifically, Defendants contend the information sought is irrelevant because Plaintiff was never treated by the Physicians, was never a participant in the clinical trial and was not implanted with ProDisc until after pre-market approval by the FDA. Many of the documents requested deal exclusively with the participants in the clinical trial, and thus, the information is not relevant to the surgery and treatment of Plaintiff. Further, requests for the financial information regarding the relationships of the Physicians to the manufacturer of the ProDisc invades the province of the FDA to monitor any conflicts of interest of the clinical investigators.[3]

The Court disagrees that the information requested by Plaintiffs is irrelevant. Although Plaintiff was not a participant in the clinical trial, the underlying data related to ProDisc is likely to lead to evidence relating to the design, manufacture and implantation of this device that will be relevant to Plaintiffs' allegation that the ProDisc is defective. Further, the clinical trial data will shed light on the accuracy of the reports disseminated by Defendants and the Physicians prior to FDA approval and will enable Plaintiffs to compare the data with that reported to the FDA. Other

[3] Defendants also submit to the Court that many of Plaintiffs' claims are preempted by the Safe Medical Devices Act of 1990. However, because this issue is not before the Court, it will not prematurely address any preemption arguments and use such arguments at this stage to preclude discovery.

courts have likewise found underlying clinical trial data prior to the product's approval to be relevant in a products liability action. *See In re Prempro Prods. Liab. Litig.*, 2006 WL 751299, at *2 (E.D. Ark. March 20, 2006) (compelling disclosure of the "meeting minutes and reports of any . . . committees . . . that relate to the WHI clinical trials"); *In re Zyprexa Prods. Liab. Litig.*, 2005 WL 2237793, at *1 (E.D.N.Y. April 7, 2005); *Grundberg v. Upjohn Co.*, 137 F.R.D. 365, 367 (D. Utah 1991) (overruling objections to the production of the raw data of drug protocol reports used to record the reaction of persons given the medication used in a clinical trial).

The Physicians' financial information is also relevant to Plaintiffs' allegations. Plaintiffs allege Spine Solutions' owners used investors (i.e the Physicians) as clinical investigators during the clinical trial of ProDisc. Mr. Timberlake read and relied on reports published prior to ProDisc's approval that allegedly misrepresented the performance capabilities of the device and failed to disclose the financial interests of the clinical investigators. The financial relationship between the Physicians and companies affiliated with ProDisc is thus relevant to Plaintiffs' fraud/misrepresentation and conspiracy claims to prove the necessary elements for these causes of action and to determine if the full extent of this relationship was disclosed to the FDA. Additionally, this evidence is not available through other means.

Defendants' arguments that the production requests are overly broad and unduly burdensome are likewise without merit. Defendants maintain the requests are oppressive and burdensome to the Physicians because Plaintiffs have failed to tailor their requests to the pending litigation or to a specific time period. Plaintiffs argue the subpoenas are not limited to treatment of Plaintiff because their primary purpose is to learn about the device and clinical trial before Mr. Timberlake's operation in order to show the defective nature of the device and to compare the actual data with that reported to the FDA. The information related to the clinical trial cannot be overly broad as it is

limited to the duration of the clinical trial of ProDisc, which is approximately a five year period from May 2001 to August 2006.

Further, the financial documents requested from the Physicians are not overly broad or burdensome as the request only seeks a limited segment of those financial documents involving any company affiliated with the ProDisc. There is a distinction between an unlimited request for personal financial information related to the Physicians' entire investment portfolio and information related to investments in ProDisc companies. The time period is also so limited as it begins with the Physicians' involvement with ProDisc and ends with the FDA approval. Thus, the clinical trial data and the Physicians' financial documents related to the companies affiliated with ProDisc are relevant to this litigation and the scope of the requests are not overly broad or unduly burdensome.

II. Proprietary Information

Defendants also argue that the documents sought in the subpoena will cause them major competitive harm because trade secrets and proprietary information are contained in the information related to ProDisc and the clinical trial. Specifically, Defendants contend the subpoenas require the Physicians to reveal its proprietary clinical trial design, protocol, and implementation documents. No absolute privilege for confidential information or trade secrets exists. *Exxon Chem. Patents, Inc. v. Lubrizol Corp*., 131 F.R.D. 668, 671 (S.D. Tex. 1990). Rule 45 provides that a court may place conditions upon the production of documents where the request requires disclosure of a trade secret or other confidential commercial information, and the party seeking discovery shows a substantial need for the material that cannot otherwise be met without undue hardship. FED. R. CIV. P. 45(c)(3)(B). The moving party has the burden to establish that the information sought is a trade secret and that its disclosure might be harmful. *Exxon Chem. Patents, Inc*., 131 F.R.D. at 671. The court then balances the need for the trade secrets against the claim of injury resulting from

disclosure. *Id.*

Assuming that proprietary information is contained in the clinical trial data, the Court finds that the information sought here is relevant to Plaintiffs' allegations, as discussed previously, and cannot be obtained by any other means. Presumably, Plaintiffs could make the same requests of Defendants instead of the Physicians, but as that would only insert a less efficient intermediary step, the Court finds no reason to delay discovery and make the Plaintiffs request the documents from Defendants. *See Cmedia, L.L.C. v. Lifekey Healthcare, L.L.C.*, 216 F.R.D. 387, 391 (N.D. Tex. 2003). The Physicians, as the persons supervising the clinical trials, are in the best position to disclose the information. However, the Court will require that the parties sign a mutually agreeable confidentiality order to ensure that no proprietary information is disclosed publicly or outside this litigation.

III. Privacy Laws

Defendants finally assert that Plaintiffs' requests necessarily seek protected healthcare information of the individual patients involved in the clinical trial. They contend redaction is insufficient to overcome the Texas physician-patient privilege. Generally, confidential communications between a physician and patient are privileged and may not be disclosed. Under HIPAA, a health care provider is permitted to disclose nonparty patient records during a lawsuit, subject to an appropriate protective order, without giving notice to the nonparty patients. 45 C.F.R. § 164.512(e). In Texas, however, the Texas Occupations Code and the Texas Rules of Evidence provide that records of the identity, diagnosis, evaluation or treatment of a patient are confidential and privileged and may not be disclosed. TEX. OCC. CODE § 159.002(b); TEX. R. EVID. 509(c)(2). The Texas Supreme Court explained that the basis for the physician-patient privilege is to "encourage the full communication necessary for effective treatment" and "to prevent unnecessary

disclosure of highly personal information." *R.K., M.D. v. Ramirez*, 887 S.W.2d 836, 840 (Tex. 1994).

The majority of Plaintiffs' document requests relate to the financial relationship between the Physicians and ProDisc companies. None of the requests specifically seek patients' medical records, but to the extent that any documents requested happen to include a patient's identity, diagnosis, treatment or evaluation unrelated to the ProDisc clinical trial, that information should be redacted and any remaining portions subject to a protective order. In other words, any information related to the implantation and outcome of the ProDisc clinical trial on the patient participants should be disclosed with all other information redacted. *See id.* at 843 ("patient records should only be revealed to the extent necessary to provide relevant evidence relating to the condition alleged"). The combination of redaction and protective order is consistent with the purposes of the privilege to allow for open communications without fear of disclosure, so that the physician can effectively treat the patient. *See In re Rezulin Prods. Liab. Litig.*, 178 F. Supp. 2d 412, 415 (S.D.N.Y. 2001) (interpreting Texas law and determining "[o]nce information cannot be connected with patient, the risk of embarrassment that might lead a patient to withhold information from a physician and thus interfere with proper treatment, as well as the risk of any invasion of personal privacy, is eliminated"); *see also In re Columbia Valley Reg'l Med. Ctr.*, 41 S.W.3d 797, 804 (Tex. App.–Corpus Christi 2001, orig. proceeding) (Dorsey, J. dissenting) (interpreting exceptions in § 159.003(a)(12) of the Texas Occupation Code which would allow redaction if the trial court determined that the confidentiality concerns of the patient are adequately protected). It also "achieves the appropriate balance between Plaintiffs' legitimate discovery needs and the protection of third party medical records." *Riley v. Walgreen Co.*, 233 F.R.D. 496, 501 (S.D. Tex. 2005).

Conclusion

For the foregoing reasons, Defendants' motions (Dkt. #s 22, 25) are GRANTED in part and DENIED in part. The Physicians shall produce all documents requested; however, the subpoenas are modified to the extent privileged patient information is contained in the documents. Such information should be redacted except that information relating to the implantation and the outcome of the clinical trial of the ProDisc. All proprietary information and patient information should also be protected by a confidentiality agreement, which the parties should mutually negotiate and submit to the Court for entry. Under HIPAA, the protective order should include a prohibition from the parties using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested and a requirement that the protected health care information (including all copies made) be returned to the health care provider or destroyed at the end of this litigation.

It is so ORDERED.

SIGNED this 4th day of June, 2008.

John D. Rainey

JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE