UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

NICOLE BAKER,

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS INC.,

Defendant.

Case No. 13-cv-00490-TEH (KAW)

ORDER REGARDING JOINT DISCOVERY LETTER

Re: Dkt. No. 58

I. INTRODUCTION

Plaintiff commenced this products liability suit after experiencing complications from her use of Mirena, an intrauterine device. (2d Am. Compl. ("SAC"), Dkt. No. 21.) In her complaint, she alleges that Defendant failed to adequately warn of Mirena's risks, including perforation, embedment, infections, cysts, ectopic pregnancy, intrauterine pregnancy, adhesions, fetal injury, and fetal death. (Id. ¶ 19.)

Plaintiff now seeks databases[1] containing sales call notes from conversations between Defendant's sales representatives and healthcare providers without any geographical or time limitations. (Joint Ltr., Dkt. No. 58.) Defendant contends that only the call notes concerning Plaintiff's treating physician are relevant. (Id.) Alternatively, Defendant asserts that producing all sales call notes would be unduly burdensome and disproportionate to the needs of this case. (Id.) For the reasons set forth below, the Court finds that the sales call notes Plaintiff seeks are relevant, and Defendant shall produce them, subject to the limitations discussed below.

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[1] According to Plaintiff, Defendant maintains three databases for its sales call notes, and "[e]ach database contains basically the same information." Joint Ltr. at 4.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 26(b)(1) permits "discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." The information sought "need not be admissible at the trial" so long as it "appears reasonably calculated to lead to the discovery of admissible evidence." Id. Moreover, "[a]ll discovery is subject to the limitations imposed by Rule 26(b)(2)(C)," which requires the court to limit discovery upon a finding (1) that the discovery sought is unreasonably cumulative or duplicative, or can be obtained from other source that is more convenient, less burdensome, or less expensive; (2) that the party seeking discovery has had ample opportunity to obtain the information sought, or (3) that the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues. Fed. R. Civ. P. 26(b)(1), (b)(2)(C).

III. DISCUSSION

A. Relevance

Plaintiff asserts that her request for databases containing sales call notes falls within the scope of Request for Production No. 8, which reads: Produce ALL DOCUMENTS RELATING TO marketing plans, brand strategies and other such DOCUMENTS detailing the strategies and tactics BAYER employed to influence physicians and other health care providers to increase the number of MIRENA prescriptions."[2] (Joint Ltr. at 1, Ex. A, RFP No. 8 (capitalization in original).)

She asserts that all sales call notes, not just those relating to the physician who prescribed Mirena or inserted it, are relevant to whether the overpromotion of the pharmaceutical potentially affected any physician's decision to prescribe it. (Joint Ltr. at 1.) She asserts that the information should not be limited to the prescribing physician because "overpromotion by the manufacturer

[2] Defendant briefly disputes whether Plaintiff's request for sales call notes falls within the scope of Request for Production No. 8, which makes no reference to those specific materials. The sales call notes filed in connection with the joint letter reveal Defendant's marketing strategies and promotion tactics, bringing the materials within the ambit of the Request for Production No. 8. See, e.g., Joint Ltr., Ex. 6 at 1 ("Talked about Mirena. Talked about the pat that had an issue with the insertion . . . .").

and its sales force can result in the dilution or nullification of any warnings, thereby rendering them inadequate." (Id.) The sales call notes, she argues, "are evidence of a vigorous sales campaign to induce the entire medical profession in general to fail to heed any written warnings." (Id. at 5.)

In California, a drug manufacturer's duty to warn runs to physicians, not patients. Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996). Under this framework, so long as adequate warning of the "potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to ensure that the warning reaches the doctor's patient for whom the drug is prescribed." Stevens v. Parke, Davies & Co., 9 Cal. 3d 51, 65 (1983) (internal quotations and citation omitted). "An overpromotion theory is one way that a plaintiff in a failure-to-warn case can overcome the manufacturer's argument either (1) that it provided adequate warnings or (2) that the doctor's decision to prescribe a drug despite his awareness of its dangers was an intervening cause sufficient to vitiate the manufacturer's liability." Motus v. Pfizer, 196 F. Supp. 2d 984, 998 (C.D. Cal. 2001). "An adequate warning to the profession may be eroded or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given." Stevens, 9 Cal. 3d at 65. "The logic of an overpromotion theory is that the manufacturer's aggressive marketing caused a physician to discount a known risk when prescribing a drug to a patient." Id.

Here, Plaintiff alleges that Defendant failed to adequately warn of the dangers associated with Mirena. (SAC ¶ 19.) Overpromotion is one way warnings may be rendered inadequate. Stevens, 9 Cal. 3d at 65. Thus, to the extent Plaintiff wishes to advance that theory in this case, she is entitled to sales call notes that document Defendant's marketing strategies and promotion tactics. See id. The information sought, then, may lend support to Plaintiff's claim that Defendant's "promotional activities . . . diluted or minimized the warnings given with the product," rendering them inadequate. See, e.g., Stevens, 9 Cal. 3d at 68 (jury could infer that prescribing physician was induced by the manufacturer's promotional tactics to prescribe a toxic antibiotic); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1230 (1979) (noting that promoting a drug through personal contact via a sales force provided an effective means of communicating the associated

risks); Whitley v. Cubberly, 210 S.E.2d 289, 292 (1974) (drug manufacturer could be liable for negligence if "over-promotion through a vigorous sales campaign should induce the medical profession in general, and in this case, [the prescribing doctor] in particular, to fail to adequately heed the warnings given").

Accordingly, the Court finds that the sales call notes Plaintiff seeks, as opposed to only those concerning Plaintiff's healthcare provider, are relevant.[3] While the Court agrees that the sales call notes reflecting communications between sales representatives and Plaintiff's treating physician would presumably reflect the overpromotion Plaintiff suspects, other sales call notes could also lead a jury to infer that Defendant's Mirena campaign was so pervasive that any doctor, including Plaintiff's, would fail to heed any warning about the product. See Stevens, 9 Cal. 3d at 68.

B. Undue burden and proportionality

Defendant asserts that producing all sales call notes, which would include sales call notes for tens of thousands of healthcare providers, is unduly burdensome and disproportionate to the needs of this single-plaintiff case. (Joint Ltr. at 6.) Considering the sheer volume of material at issue here—Defendant represents that there are 1,588,507 calls from 2011 alone—the Court agrees.

The Food and Drug Administrative approved Defendant's New Drug Application for Mirena in December 2000. (SAC ¶ 14.) Absent any time restriction, which Plaintiff has not proposed, Defendant would have to search through 14 years of sales call notes. According to Defendant, this would require work from two separate teams of outside counsel, company counsel, and IT personnel. (Id.) The databases containing the sales call notes, including two legacy systems that present accessibility issues, would then be reviewed for potentially responsive documents. (Id.) That material, in turn, would be reviewed by counsel, compared with information related to a specific plaintiff, reviewed for accuracy, and redacted for any protected

[3] This conclusion is not at odds with Judge Seibel's decision to limit the content of a plaintiff fact sheet to a plaintiff's prescribing physician. That ruling arose in the context of a different discussion, which the parties have not engaged in here. See Joint Ltr., Ex. A at 41, Dkt. No. 60.

information. (Id. at 6-7.)

While engaging in this process for a thoughtfully defined subset of sales call notes may not constitute an undue burden, requiring Defendant to do so for each and every existing sales call note does. That Plaintiff concedes "[e]ach database contains basically the same information," lends support to that conclusion. To strike a balance between Plaintiff's entitlement to information relevant to her claims and the need to ease Defendant's burden of production, the Court finds it appropriate to order production of the sales call notes that have already been produced in the related multidistrict litigation ("MDL") discussed at length by the parties in their joint letter. Defendant states that the production of sales call notes in that case was limited to the plaintiffs' specific prescribing physicians. (Id. at 9.) As there are over 1,500 plaintiffs involved in that litigation, the material that has already been produced, and redacted, will reduce Defendant's burden to produce the same materials in this case, even if the materials must be redacted once more to conceal additional protected information. The volume that production will yield will certainly give Plaintiff a substantial cross-section of sales call notes, without burdening Defendant with the production of sales call notes for every physician in every market in which Mirena was promoted.

IT IS SO ORDERED.

Dated: 10/31/2014

KANDIS A. WESTMORE
United States Magistrate Judge

United States District Court
Northern District of California