

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

STEPHANIE IDEUS,

Plaintiff,

vs.

TEVA PHARMACEUTICALS USA,
INC., and TEVA WOMEN'S HEALTH,
INC.,

Defendants.

4:16CV3086

MEMORANDUM AND ORDER

Plaintiff's motion to compel, ([Filing No. 69](#)), is pending and fully submitted. For the reasons discussed below, the motion will be granted in part, and denied in part.

STATEMENT OF FACTS

Plaintiff Stephanie Ideus ("Plaintiff") filed a lawsuit against Defendants Teva Pharmaceuticals USA, Inc. and Teva Women's Health, Inc. ("Defendants"), alleging she experienced complications during and after removal of ParaGard T-380 ("ParaGuard"), an intrauterine copper contraceptive device manufactured by Defendants. As Plaintiff's physician removed the device in 2014, a piece broke off and became embedded in the myometrium of her uterine wall, necessitating a surgical extraction procedure. At present, Plaintiff's sole remaining claim alleges Defendants failed to warn of the possible breakage and embedment risks associated with the removal of Paragard.

Defendants have raised a federal preemption defense to Plaintiff's failure to warn claim. Defendants argue—and this the court previously agreed—that

federal regulations restrict a drug manufacturer's ability to change the drug labelling approved by the Food and Drug Administration ("FDA"). ([Filing No. 56](#)) (granting Defendants' motion for judgment on the pleadings on the basis of federal preemption but allowing Plaintiff a chance to amend her complaint). Thus, Defendants claim any state law warning and labelling requirements—as here proffered by Plaintiff—are preempted by federal law. ([Filing No. 61](#)).

Plaintiff, in turn, argues that the FDA's "changes being effected" regulation allows for labelling changes when a drug manufacturer comes into possession of "newly acquired information" subsequent to a label's FDA approval. ([Filing Nos. 64 and 69](#)). And when evaluating Defendants' renewed motion for judgment on the pleadings, this court agreed, ([Filing No. 66](#)), finding Plaintiff had pleaded the existence of newly acquired information so as to overcome Defendants' preemption defense at the pleading stage (emphasis added).

Therefore, as this litigation enters the discovery phase, a central dispute is the existence, sufficiency and character of "newly acquired information" that Defendants may possess. Plaintiff's motion to compel requests an order compelling a response to Request No. 36, which seeks "all documents that concern any Complaint Investigation Process regarding Paragard T-380 A Copper IUD."¹ ([Filing No. 69 at CM/ECF p. 1](#)). Despite the broad wording, Plaintiff concedes that Request No. 36 seeks only documents concerning "breakage and embedment" of ParaGard. ([Id. at CM/ECF p. 2](#)).

¹ Plaintiff's Request for Production No. 36 was the subject of a previous motion to compel before the undersigned magistrate judge, ([Filing No. 40](#)). However, the undersigned determined that the motion was premature—citing the then pending motion for judgment on the pleadings. ([Filing No. 54](#)). The undersigned gave Plaintiff leave to re-file her motion to compel after a ruling was issued on the dispositive motion—as she has done.

To date, in response to Request No. 36, Defendants have produced only documents specifically related to the manufacturing “lot” in which Plaintiff’s ParaGard device was produced. ([ld](#)). Plaintiff contends Defendants should be required to produce breakage and embedment information for all manufacturing lots of ParaGard spanning November 9, 2005 to present—not just for the lot specific to Plaintiff’s device. ([ld](#)).

For the following reasons, Plaintiff’s motion to compel will be granted in part, and denied in part.

ANALYSIS

Generally speaking, the Federal Rules of Civil Procedure allow for discovery of “any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.” [Fed. R. Civ. P. 26\(b\)\(1\)](#). Thus, the proper scope of discovery embraces information that is not only relevant but also proportionate to the litigants’ needs.

Relevancy², for the purposes of discovery, includes “any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.” [Oppenheimer Fund, Inc. v. Sanders](#), 437 U.S. 340, 351 (1978). The proportionality analysis then requires the court to weigh “the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the

² The undersigned magistrate judge previously indicated on the record that the information sought in Plaintiff’s Request No. 36 was relevant to Plaintiff’s claims as originally pleaded. ([Filing No. 39](#)). However, in the intervening months, Plaintiff has abandoned her design and manufacturing defect claims. Therefore, the court will conduct the relevancy determination anew in light of Plaintiff’s sole remaining claim—failure to warn.

importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.” [Fed. R. Civ. P. 26\(b\)\(1\)](#).

Defendants argue against production, claiming the requested documents are not “newly acquired information” and are thereby irrelevant, unduly burdensome, and disproportionate to the needs of the case.

I. Relevancy

Whether Defendants possessed “newly acquired information,” as defined by federal regulation, is an integral substantive issue in this case. The parties have conflicting views as to whether “documents that concern any Complaint Investigation Process,” as targeted by Request No. 36, meet that regulatory definition. However, the court need not here resolve this substantive dispute to determine this information’s relevancy.

“Information within [the] scope of discovery need not be admissible in evidence to be discoverable.” [Fed. R. Civ. P. 26\(b\)\(1\)](#). Discovery is sufficiently relevant if it “appears reasonably calculated to lead to the discovery of admissible evidence.” [WWP, Inc. v. Wounded Warriors Family Support, Inc.](#), 628 F.3d 1032, 1039 (8th Cir. 2011) (internal citation omitted). By narrowly focusing on whether these documents satisfy a federal regulatory definition, the parties employ too narrow a view of relevancy under Rule 26.

The correct inquiry is not whether the information sought is alone sufficient to substantiate Plaintiff’s claim. The correct inquiry is whether the requests are reasonably calculated to lead to information that could bear on an issue in the

case. Put differently, the documents sought in Request No. 36 do not have to themselves be “newly acquired information” if the request is reasonably calculated to lead to documents that are. By narrowly focusing on whether these documents satisfy a federal regulatory definition, both parties take a view unsupported by the broad scope of Rule 26—which does not limit relevancy “to the precise issues set out in the pleadings” and generally allows discovery “unless it is clear the information sought can have no possible bearing on the case.” [Ingram v. Covenant Care Midwest, Inc.](#), No. 8:09CV110, 2010 WL 1994866, at *3 (D. Neb. May 18, 2010).

Defendants indicate that the files sought by Request No. 36 are “created in the process of investigating product complaints” and “[t]here may be circumstances where information found in complaint investigation files might support a change in the manufacturing process.” ([Filing No. 70 at CM/ECF p. 4](#)). The court finds this description instructive. Regardless of the manufacturing lot number of Plaintiff’s ParaGuard or whether the complaint investigation files are themselves “newly acquired information,” such files could lead to information or other admissible facts regarding whether Defendants received information warranting changing or expanding ParaGuard’s product labelling.

Labelling provides information which Plaintiff may review when deciding whether to use ParaGuard as a contraceptive, with Defendants required to maintain and update that labeling with new safety information as it becomes available. ([Filing No. 66](#), at CM/ECF p. 2). Thus, the information known by Defendants as of January 11, 2010, when Plaintiff decided to have the ParaGuard device inserted, may be relevant in deciding what the label should have stated at that time. ([Filing No. 57, at CM/ECF p. 3](#), ¶ 10). I am not, however, convinced that complaint investigation files received after that date are relevant.

Defendants' knowledge and conduct are not evaluated from the perspective of hindsight. Information received by Defendants after January 11, 2010—when Plaintiff made her decision to have ParaGuard inserted—cannot provide a basis for imposing labelling modification requirements on or before January 11, 2010.

Based on the foregoing, the court determines that for the period of November 9, 2005 through January 11, 2010, as to all lot numbers, Request No. 36 meets the relevancy threshold required by the federal rules.³ As to documents received after January 11, 2010, the documents requested in Request No. 36 are not relevant.

II. Proportionality

The party resisting discovery may defeat a motion to compel information—even information that is demonstrably relevant—if that party establishes that production would constitute an undue burden or an unreasonable hardship, and are thus disproportionate to the needs of the case. The parties' obligations are not satisfied by overly generalized or conclusory arguments. Instead, the parties must state—with some particularity—the bases for their assertions. [Doe v. Nebraska](#), 788 F. Supp. 2d 975, 981 (D. Neb. 2011).

“The parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes.” [Fed. R. Civ. P. 26 advisory committee's notes \(2015\)](#). Here, Defendants argue that production of documents regarding the Complaint Review Process, in

³ The court notes that it the burden of the party seeking discovery to provide some basis for the information's importance to the case. [Hofer v. Mack Trucks, Inc.](#), 981 F.2d 377, 380 (8th Cir.1992). The court agrees with Plaintiff's stated basis for the necessity of this discovery, and she has thus carried her burden, regardless of the court's broader view of relevancy.

compliance with Request No. 36, would cause a substantial burden to and hardship on Defendants, offering evidence and supporting declarations indicating production of all the requested documents would require approximately 85 hours to locate and review. ([Filing No. 70 at CM/ECF pp. 10-11](#)). Defendants indicate that the documents requested are housed in a tripartite system that will require search and review of documents across the three separate platforms. In addition, Defendants contend that production would unfairly burden already busy employees of the defendant companies and would saddle Defendants with unnecessary, additional legal expenses. ([id.](#)).

The court is sympathetic to the time and expense production of these documents may require. But “[t]he fact that production of documents would be burdensome and expensive and would hamper a party’s business operation is not a reason for refusing to order production of relevant documents.” [Wagner v. Dryvit Systems, Inc., 208 F.R.D. 606, 610 \(D. Neb. 2001\)](#) (internal citation omitted). The standard is whether the burden or expense is “undue” and whether the “hardship is unreasonable in the light of the benefits to be secured from the discovery.” [id.](#)

In terms of access to the information, and the importance to the case, Plaintiff’s arguments are availing. Defendants have exclusive access to these documents. Moreover, these documents are reasonably calculated to lead to information that could preclude Defendants’ federal preemption defense, an issue of paramount importance to the substance of this dispute. In carefully weighing the information regarding Defendants’ anticipated burden and expense, and the other factors of proportionality, the court finds the hardships are not undue or unreasonable and the requested information is not disproportionate to the needs of the case.

As a result, the undersigned will allow discovery of responsive documents for a four-year period preceding Plaintiff's procedure to insert her ParaGard device. Thus, Defendants will be compelled to produce documents responsive to Request No. 36, specifically regarding breakage and embedment of ParaGard, from November 9, 2005 through January 11, 2010.

Accordingly,

IT IS ORDERED that Defendant's Motion to Compel, ([Filing No. 69](#)), is granted in part and denied in part as set forth in this order. Defendants shall produce documents responsive to Plaintiff's Request for Production No. 36, as required herein, on or before June 4, 2018.

Dated this 6th day of May, 2018.

BY THE COURT:

s/ Cheryl R. Zwart
United States Magistrate Judge