UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
NEW ALBANY DIVISION

DEBORAH DEAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:19-cv-00204-JMS-DML
	)	
PFIZER, INC.,	)	
	)	
Defendant.	)	

Order on Plaintiff's Motion to Compel (Dkt. 71)

Plaintiff Deborah Dean moves the court to require defendant Pfizer, Inc. to conduct a "thorough" search of its database for Lyrica-related adverse event reports, produce the reports tagged through that search, and produce a "limited number" of underlying source files. Pfizer opposes the motion on the ground that the requested discovery is unduly burdensome and not proportional to the needs of this case. For the following reasons, the court GRANTS IN PART and DENIES IN PART Ms. Dean's motion.

The court first describes the nature of this case and the requested discovery, then sets forth guiding discovery principles, and finally rules on the discovery dispute.

Synopsis of Claims

This is a product liability case. Ms. Dean was prescribed the drug Lyrica, manufactured by Pfizer. She contends that she suffered serious adverse skin reactions to the drug—toxic epidermal necrolysis ("TEN") and Stevens-Johnson

syndrome ("SJS")—that have resulted in severe and permanent injuries. Stevens-Johnson syndrome is a rare condition of the skin in which a painful rash occurs and spreads, and the top layer of skin blisters, dies, and sheds. If the condition occurs over a relatively large portion of a person's skin surface, it is called toxic epidermal necrolysis and carries a high risk of death. Although these adverse skin reactions are rare, they are among the most serious and scrutinized adverse drug reactions because of their high risk of mortality. Ms. Dean alleges that Pfizer knew about the risks of these serious skin reactions caused by Lyrica but did not warn consumers or doctors in the United States about them even though it included more robust warnings about skin reactions in its marketing of the drug in other countries. Ms. Dean says that Pfizer was far more concerned about increasing the drug's profitability than in telling the truth about the drug's risks, alleging that Pfizer focused its efforts on massive marketing campaigns to consumers and doctors and deliberately misled United States consumers and doctors about risks and ignored or downplayed burgeoning information about the drug's adverse risks.

Ms. Dean had been treated for fibromyalgia, diabetes Type 2, arthritis, and hypertension since at least 2015, and she took medications that had not caused any adverse reactions. In late September 2017, when she complained to her doctor about joint pain and fibromyalgia, the doctor prescribed Lyrica and gave Ms. Dean a 30-day supply of Lyrica samples. Within a week, Ms. Dean developed a rash, and after being seen at an urgent care center, she went to a hospital emergency room, was diagnosed as having suffered an allergic reaction, was told to stop taking

Lyrica, and was then discharged. She returned to the hospital the next day; her lips and tongue had swollen, the rash had grown and affected her arms, legs, trunk, and back, and blisters had developed on her feet. Ms. Dean was transferred to a burn unit at a larger hospital and was diagnosed as having SJS/TEN secondary to Lyrica. Ms. Dean asserts that her skin reaction was nearly fatal, and every doctor who treated the blistering and the sloughing of skin and various mucosal surfaces on and in her body (including burn surgeons, a dermatologist, ophthalmologist, and OB-GYN) concluded that Lyrica had caused the SJS and TEN.

Adverse Event Reports, Source Files, and the Parties' Disputes

A drug manufacturer whose drug has been approved by the FDA, such as Pfizer, has "an obligation to investigate and report any adverse events associated with the drug . . . and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug." *See Wyeth v. Levine,* 555 U.S. 555, 608 (2009) (citing 21 C.F.R. §§ 314.80 and 355(k)).

Pfizer has produced, or has agreed to produce, adverse event reports that were coded as either an SJS or TEN (or their long-form names) adverse event, but the parties disagree about whether Pfizer should (1) search the "N/EAR" field in the report database for references to SJS or TEN[1] and (2) produce source files for all

[1] The parties settled their dispute about whether Pfizer must use the "Broad Scope" Standardized MedDRA ["Medical Dictionary for Regulatory Activities"] Query (SMQ) for Severe Cutaneous Adverse Reaction (SCAR) search terms as opposed to the "Narrow Scope" SMQ. Pfizer agreed to use the Broad Scope SMQ.

SJS/TEN adverse events. Pfizer also asserts that Ms. Dean did not confer in good faith to impasse about these disputes before filing her motion to compel. Based on the nature of the disputes and the parties' lengthy attempts to work through their discovery disputes in general, the court finds that it would be inefficient to require additional conferences. The court will rule on the merits of the disputes.

Discovery Principles

The discovery sought by Ms. Dean is relevant to her claims and is designed to assist an expert evaluation about (possibly) causation and/or whether Pfizer provided adequate warnings. The issue before the court therefore is whether the discovery is proportional to the needs of the case, *see* Rule 26(b)(1), and the court has broad discretion in making that determination. *See Thermal Design, Inc. v. American Soc'y of Heating, Refrigerating and Air-Conditioning Engrs., Inc.,* 755 F.3d 832, 839 (7th Cir. 2014) (citation and quotation omitted).

Analysis

Pfizer insists that the additional search requested by Ms. Dean of its database (querying the N/EAR field too) and the production of source files for all SJS/TEN adverse event reports is not proportional discovery and is overly burdensome and expensive. The court rejects its contentions with respect to searching the N/EAR field and producing the adverse event reports triggered by that search. But, as explained below, the court will require additional proportionality analysis—after the parties know how many adverse event reports exist—with respect to the production of source files.

I. Pfizer must search the N/EAR field.

The N/EAR field—which stands for "narrative/event as reported"—is a field that captures the adverse event reporter's (usually a medical professional who treated a patient) description of the adverse event. When Pfizer receives an adverse event report, it reviews the narrative and then, using its coding rules informed by internal processes and the Medical Dictionary for Regulatory Activities, codes the adverse medical event—such as describing it as SJS or TEN. Pfizer states that requiring it to search the N/EAR field is burdensome because its coding system is sufficiently trustworthy to retrieve SJS/TEN events and using SJS/TEN terms to search the N/EAR field could retrieve irrelevant documents because for example, the reporter referenced the number ten or stated that SJS or TEN was ruled out and thus the record would not relate to an adverse SJS/TEN event. The plaintiff asserts, however, that "soft coding" occurs, meaning that even though a reporter used the terms SJS or TEN (or their long forms) in the narrative, Pfizer may not have coded the event as SJS or TEN, and thus a relevant SJS/TEN adverse event would be missed. In addition, the fact that Pfizer may produce some irrelevant adverse event reports does not itself make the production burdensome—indeed, some over-inclusiveness is expected in electronic searching. The court determines that because the N/EAR field is searchable electronically (just as the MedDRA coded-event is searchable electronically) and Pfizer has not shown there is any difficulty in writing code that searches the N/EAR field and the MedDRA coded

field, it is proportional discovery for Pfizer to search the N/EAR field as the plaintiff requested and to also produce the adverse event reports from that search.

II. More information is required to determine the proportionality of producing all source files.

With respect to source files, the court does not yet have sufficient information to determine whether the production of *all* source files is proportional discovery because the parties do not yet know (and have not informed the court) about how many SJS/TEN adverse event reports exist. If many hundreds (or perhaps thousands) of event reports exist, the court will require the parties to confer about whether only a sampling of source files must be provided or whether the number of event reports is relatively small in number such that gathering, redacting, and producing all source files is appropriate discovery. While Pfizer did not quantify, in terms of client and attorney time and expense, the exact burden in producing the source files, it provided a list of tasks that would be required to produce the files. Those tasks—retrieving, reviewing, and redacting records—obviously require time and expense and at some level that expense reasonably may be considered burdensome, and perhaps unduly burdensome depending on the strength of a showing by the plaintiff of the materiality of her review of all source files to a fair prosecution of her claims. The court may also consider—to the extent that the plaintiff rejects sampling even if the number of event reports is very high—whether the plaintiff must bear some of the costs of that discovery, which would depend on the persuasiveness of the parties' proportionality analyses based on all of the Rule 26(b) considerations.

When the parties know how many non-duplicative adverse events exist, they promptly must confer in good faith to attempt to agree on the production of source files, including whether a sampling method and/or cost sharing is appropriate. If they cannot agree, one or the other may file an appropriate discovery motion.

Conclusion

For the foregoing reasons, the plaintiff's motion to compel adverse event search terms and source files is GRANTED IN PART and DENIED IN PART as provided in this order.

So ORDERED.

Dated: December 14, 2020

Debra McVicker Lynch
United States Magistrate Judge
Southern District of Indiana

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