United States Court of Appeals
For the Eighth Circuit

No. 17-1730

Jan Vallejo, Individually and As Personal Representative of Steve Vallejo, estate of, Steve Vallejo

Plaintiff - Appellant

v.

Amgen, Inc.; Wyeth, Inc.; Pfizer, Inc.

Defendants - Appellees

No. 17-2593

Jan Vallejo, Individually and As Personal Representative of Steve Vallejo, estate of, Steve Vallejo

Plaintiff - Appellant

v.

Amgen, Inc.; Wyeth, Inc.; Pfizer, Inc.

Defendants - Appellees

Appeals from United States District Court
for the District of Nebraska - Omaha

Submitted: May 15, 2018
Filed: September 10, 2018

Before SMITH, Chief Judge, BEAM and COLLOTON, Circuit Judges.

SMITH, Chief Judge.

In this consolidated products liability suit appeal, Jan Vallejo challenges the district court's[1] order limiting the scope of her general causation phase discovery. She also contests the court's sanctions order against her counsel. We find no abuse of discretion in either of the court's decisions and affirm.

I. *Background*

Steve Vallejo ("Steve"), Vallejo's husband, began using the biologic Enbrel[2] in 2004 to treat psoriasis, a skin condition. At some point between 2004 and 2011, Steve developed myelodysplastic syndrome (MDS).[3] He succumbed to MDS in 2011. Vallejo, individually and on behalf of Steve's estate, sued Amgen Inc., Wyeth, and

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[1]The Honorable John M. Gerrard, United States District Judge for the District of Nebraska.

[2]Enbrel is manufactured and marketed by Amgen Inc. Wyeth LLC ("Wyeth"), later acquired by Pfizer Inc. ("Pfizer"), promotes Enbrel. We omit Enbrel's registered trademark ® symbol in this opinion, including those in quotations.

[3]MDS is a blood "disorder characterized by the bone marrow's inability to produce a sufficient number of healthy erythrocytes (red blood cells), leukocytes (white blood cells including neutrophils, lymphocytes, monocytes, eosinophils, and basophils), and platelets." Order at 1, *Vallejo v. Amgen, Inc.*, No. 8:14-cv-00050-JMG-CRZ (D. Neb. Mar. 28, 2016), ECF. No. 83 ("Disc. Order"). MDS could lead to "anemia, leukemia, thrombocytopenia, pancytopenia, or severe [bone] marrow failure." *Id.* at 2.

Pfizer (collectively, "Amgen"), alleging that Enbrel caused Steve's MDS, resulting in his death.

A. *Discovery Disputes*

In May 2015, the magistrate judge[4] ordered phased discovery. The first phase addressed general medical causation to determine whether Enbrel can cause MDS. Vallejo complained that the magistrate judge's order was unclear, and the magistrate judge granted her leave to file a motion for clarification. Upon review, the magistrate judge granted Vallejo's motion and provided further instructions. After three planning conferences, the parties still disagreed on the scope of discovery, and the magistrate judge scheduled a hearing to resolve the issues. Although the magistrate judge ordered a joint filing outlining the disputed discovery issues, the parties could not agree on a single list and instead filed separate documents. The magistrate judge also ordered the parties to file briefs on Amgen's potential burden and the proportionality of the discovery requests.

At the hearing, Vallejo's expert, Dr. Linda Levesque, testified that she needed everything originally on Vallejo's request list, which amounted to "every document the defendants or any of its predecessors have or can access for any person who ingested Enbrel and reported a symptom or impact on that person's red blood cells, white blood cells, platelets, or any precursor cells for these blood cell lines." Disc. Order at 3–4. Dr. Levesque told the court that she "is normally provided with 'every single clinical trial that has been done with a drug, whether it's a drug related to particular disease or disorder or not[.]'" *Id.* at 3 n.1 (alteration in original). But Amgen's cross-examination revealed Dr. Levesque had "never testified before." *Id.* Further, Dr. Levesque would not personally review the discovery; rather, "[s]he would look at the synthesis of the information prepared by [Vallejo's] reviewing experts."

[4]The Honorable Cheryl R. Zwart, United States Magistrate Judge for the District of Nebraska.

Id. at 4 n.2. The magistrate judge found Vallejo's expert not credible and her demands unreasonable, concluding that the "testimony did not assist the court in determining whether [Vallejo's] need for the requested information was proportional to the burden imposed on the defendants in responding to [Vallejo's] discovery." *Id.* at 4.

Amgen objected to many of Vallejo's demands, claiming the request would cost millions. The company was willing to produce the Biologic License Application (BLA)[5] for Enbrel, MedWatch reports,[6] and the original Investigator's Brochure[7] for the agent. Amgen also was willing to produce information regarding Enbrel and an MDS diagnosis, but it objected to the much broader request for *all* information regarding Enbrel, an MDS diagnosis, *and* any reported symptom associated with the disorder. Associated symptoms for MDS include generic conditions such as shortness of breath, pallor, and fatigue.

Vallejo attempted to rebut Amgen's objection by demonstrating at the hearing "the ease of researching [the] discovery demands." *Id.* at 8. The demonstration backfired. Vallejo had requested 206 search terms of adverse event reports submitted to the FDA based on Enbrel. Vallejo's counsel ran 21 of the 206 terms before the court; the search yielded 4,193 adverse event reports. The magistrate judge noted that

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[5]Pharmaceutical companies are required to file a BLA with the U.S. Food and Drug Administration (FDA) for marketing approval of a biological product such as Enbrel. *See* 21 C.F.R. § 601 *et seq.*

[6]"A MedWatch report is a voluntary report to the FDA of an adverse event or undesirable effect associated with using a medical product, including pharmaceuticals and medical devices." *In re: Benicar (Olmesartan) Prods. Liab. Litig.*, No. 15-2606 (RBK/JS), 2016 WL 6652358, at *4 n.6 (D.N.J. Nov. 9, 2016).

[7]The Investigator's Brochure is part of a company's Investigational New Drug Application and includes "[a] description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs." 21 C.F.R. § 312.23(a)(5)(v).

"the courtroom search conducted retrieved *only reports provided to the FDA*, and *not to other entities*, and it included only the entry of a report—*not the underlying research and follow up documentation as to each report*." *Id.* (emphases added). The overbreadth of the discovery requests was obvious. The magistrate judge thus limited discovery to 15 search terms that provided the most specificity to MDS.

Vallejo also demanded information on other agents that work similarly to Enbrel.[8] Amgen objected to the relevance of the request and argued that the information was available in the public domain. The company also represented that it did not maintain a database on the other agents, and the search would impose an enormous burden. The search would entail examining the files of nearly 100,000 employees, as well as the files of its predecessor companies. The court, noting that it could have simply sustained Amgen's objection, nevertheless required Amgen "to answer or produce discovery regarding studies on the causal relationship, if any, between Enbrel and MDS and produce such studies or reports within [Amgen's] custody or control that are not available in the public domain" because "the case [was] languishing." *Id.* at 10.

Lastly, Amgen provided Vallejo with the name of one individual who has knowledge of Enbrel's safety—Dr. Janet Isles, Amgen's global safety officer in charge of Enbrel. Amgen also agreed to supplement individuals to the list as it became aware of them. Vallejo objected and demanded that Amgen provide

> the organizational charts of 1) the persons responsible for determining whether Enbrel causes and/or is capable of causing MDS, and those working at their direction; 2) the person in charge of compiling adverse

[8]Enbrel is a biological agent commonly known as a TNF blocker. Enbrel works by neutralizing, or blocking, tumor necrosis factor, a protein produced by the cells of the immune system. *See id.* at 1.

> events, and those working at their direction; and 3) the person in charge of maintaining source documents for MDS adverse events.

Id. at 11 (citation omitted). The magistrate judge concluded that Vallejo's request was unreasonable, given "Enbrel's extensive history going back to the early 1990s and the fact that there were at least four companies involved with Enbrel's development and production since that time." *Id.* at 11. She then permitted Vallejo to depose only Dr. Isles, with the understanding that should Isles be unable to provide Vallejo with necessary information, Amgen would "need to locate witnesses who can answer [Vallejo's] relevant inquiries." *Id.* at 12 (citation omitted).

In her discovery order, the magistrate judge noted that Amgen "ha[s] failed to submit affidavits or sworn information by employees or experts regarding the burden of searching for and providing information or providing any meaningful estimates for the time and cost required by the plaintiff's discovery." *Id.* at 6. Further, "the attorneys in this case put the onerous responsibility on the court to balance proportionality while failing to provide substantial and reasonable guidance on this key point: In its current state the court is being forced to 'wade through generalized and conflated arguments of need, burden, and relevance.'" *Id.* at 5 (citation omitted). And, the magistrate judge emphasized that should further discovery disagreements arise, "the parties must provide . . . a more thorough proportionality analysis with each side addressing and shouldering its burden: The party who served the discovery must show why the information is important to the issues and the party opposing . . . must quantifiably explain the burden of providing the requested information." *Id.* at 12.

Shortly after the discovery order, Vallejo filed a motion seeking clarification from the magistrate judge; she also promptly filed an objection to the discovery order, asking the district court to reverse the magistrate judge's order. Vallejo argued that the magistrate judge's order was contrary to the law because Amgen failed to provide sufficient evidence to support the magistrate judge's discovery determinations. While

those motions were pending, Vallejo served Amgen with a notice of deposition of Dr. Isles, prompting Amgen to move for a protective order seeking to limit the scope of the deposition to the magistrate judge's discovery order. The magistrate judge granted Amgen's motion and ordered Vallejo to delay the deposition until the district court ruled on Vallejo's objections.

The district court overruled Vallejo's discovery objection. It concluded that "[t]he parties and the [magistrate judge] have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." *Vallejo v. Amgen, Inc.*, No. 8:14CV50, 2016 WL 2986250, at *3 (D. Neb. May 20, 2016) (first alteration in original) (quoting Fed. R. Civ. P. 26 advisory committee's notes to 2015 amendment). It determined that Amgen's shortcomings in failing to "quantify [its] burden to the extent [the magistrate judge] would have liked did not obligate [the magistrate judge] as a matter of law to accept the [Vallejo's] expert witness's testimony in its entirety." *Id.* at *4. The district court then overruled Vallejo's objections and affirmed the magistrate judge's discovery order.

Vallejo deposed Dr. Isles in June 2016. About one hour into the deposition, the parties disputed the scope of Vallejo's questions to Dr. Isles and sought the magistrate judge's intervention. The magistrate judge suspended the deposition and reconvened it two months later in order to provide "direct judicial supervision." *Vallejo v. Amgen, Inc.*, No. 8:14CV50, 2017 WL 3037391, at *2 (D. Neb. May 30, 2017) ("Sanctions Order"). Prior to the rescheduled deposition of Dr. Isles, Vallejo complained that Amgen had not complied with the discovery order. The magistrate judge ordered a briefing schedule in anticipation of Vallejo's motion to compel.

The magistrate judge presided over the reconvened deposition and "field[ed] . . . numerous objections, arguments, and re-arguments over the court's past and present rulings." *Id.* Vallejo's "counsel argued with the [magistrate judge's] ruling on objections approximately 16 times, and on more than one occasion, counsel asked the

witness questions which were explicitly beyond the scope of discovery as ordered by the court." *Id.* at *5 (citations omitted). At the deposition, Vallejo informed the magistrate judge that she had a general causation expert.

The following day, the magistrate judge denied Vallejo's motion to compel, which requested leave to depose additional Amgen employees and to compel Amgen to produce additional documents. The magistrate judge noted the "highly confrontational" tenor of the case. *Vallejo v. Amgen, Inc.*, No. 8:14CV50, 2016 WL 4250285, at *1 (D. Neb. Aug. 11, 2016). She denied Vallejo's motion because despite claiming she lacked the necessary information, Vallejo's

> counsel was able to confront Dr. Isles with case reports, letters, and articles which he claims support a finding that Enbrel can cause MDS. In addition, [Vallejo's] counsel [was] able to, and has demonstrated his ability to independently search and obtain information from drug reporting databases in the public domain. Dr. Isles testified that Amgen posts all adverse events on FDA's site, which is then available to the public. Finally, [Vallejo's] counsel has full access to Steve Vallejo's medical records and history, and likely to his treating physicians.

Id. at *2. The magistrate judge then ordered Vallejo to disclose all retained and non-retained experts on the issue of "whether ingesting Enbrel can cause MDS." *Id.* The magistrate judge denied Vallejo's request to depose more Amgen employees, but she stated that "[f]urther depositions may later be permitted upon a showing that [Vallejo] can present scientifically reliable evidence and opinions supporting the allegation that Enbrel can cause MDS." *Id.* Vallejo filed an objection to the magistrate judge's order denying her motion to compel discovery. The district court overruled Vallejo's objection.

B. *Attorney Sanctions*

In its response to Vallejo's objection to the magistrate judge's order, Amgen requested sanctions against Vallejo's counsel. Vallejo then moved to strike Amgen's sanctions request. The district court denied the motion to strike. But, the district court ordered Amgen to file a separate motion for sanctions, to include requests for fees and supporting documentation.

In its sanctions motion, Amgen claimed Vallejo "made repeated attempts to circumvent the court's limitations on the first stage of discovery and abused the judicial process." Sanctions Order, 2017 WL 3037391, at *2 (citations omitted). Amgen sought an award of $141,257.21 for work performed responding to or filing: (1) the motion for clarification, (2) objections to the discovery order, (3) the motion for a protective order, (4) the motion to compel discovery, (5) objections to the denial of the motion to compel, (6) the motion to strike, (7) the request for sanctions, (8) expenses incurred for having to reschedule Dr. Isles's deposition, and (9) the motion for sanctions. The magistrate judge granted Amgen's motion for sanctions, citing the court's to sanction under Federal Rule of Civil Procedure 11, 28 U.S.C. § 1927, and the court's inherent power.

The magistrate judge found that Vallejo's counsel's sanctionable conduct included filing: (1) the motion for clarification, (2) the premature notice of deposition and refusing to withdraw the notice, (3) the motion to compel discovery, and (4) the motion to strike. The magistrate judge also awarded Amgen fees for part of Dr. Isles's travel and fees related to the motion for sanctions. The award totaled $25,665. The district court, after a de novo review, overruled Vallejo's objections to the magistrate judge's sanctions order.

II. *Discussion*

On appeal,[9] Vallejo claims that the district court erred in limiting her discovery and by imposing sanctions. "We review a district court's discovery rulings for abuse of discretion." *Jackson v. Allstate Ins.* Co., 785 F.3d 1193, 1202 (8th Cir. 2015) (quoting *Harvey v. Schoen*, 245 F.3d 718, 720–21 (8th Cir. 2001)). Our review is "both narrow and deferential," and "[r]elief will be granted on the basis of erroneous discovery rulings only where the errors amount to a gross abuse of discretion resulting in fundamental unfairness." *Roberts v. Shawnee Mission Ford, Inc.*, 352 F.3d 358, 360 (8th Cir. 2003) (cleaned up). Likewise, we review for abuse of discretion the district court's order for sanctions. *Willhite v. Collins*, 459 F.3d 866, 869 (8th Cir. 2006) (citing *United States v. Gonzalez-Lopez*, 403 F.3d 558, 564 (8th Cir. 2005)). "We give substantial deference to the district court's determination as to whether sanctions are warranted because of its familiarity with the case and counsel involved." *Id.* (citing *Lee v. First Lenders Ins. Servs., Inc.*, 236 F.3d 443, 445 (8th Cir. 2001)).

A. *Discovery Disputes*

Vallejo contends that the magistrate judge erred when she: (1) assessed the proportionality of Vallejo's discovery request without evidence of Amgen's alleged burden; (2) based her ruling on Amgen's factual misrepresentations; (3) denied Vallejo the opportunity to cross-examine Amgen's expert witness; and (4) denied Vallejo's requests for the same information the FDA considers when the agency determines medical causation. Vallejo asserts that the discovery ruling caused significant prejudice to her case.

> Unless otherwise limited by court order, . . . [p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the

[9]We deny Vallejo's motion to amend her reply brief, filed 12 days after the due date of the original reply brief, which had already received a 21-day extension.

> amount in controversy, the parties' relative access to relevant information, the parties' resources, the 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). "The parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." *Id.*, advisory committee's notes to 2015 amendment. Just as prior to the 2015 amendment to Rule 26,

> a court can—and must—limit proposed discovery that it determines is not proportional to the needs of the case, considering 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 importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit—and the court must do so even in the absence of a motion.

Carr v. State Farm Mut. Auto. Ins., Co., 312 F.R.D. 459, 468 (N.D. Tex. 2015); *see also id.* at 466 ("[T]he existing allocation of burdens to show undue burden or lack of proportionality have not fundamentally changed."); Fed. R. Civ. P. 26 advisory committee's notes to 2015 amendment ("The considerations that bear on proportionality are moved from present Rule 26(b)(2)(C)(iii), slightly rearranged and with one addition."). "A party claiming requests are unduly burdensome cannot make conclusory allegations, but must provide some evidence regarding the time or expense required." *Doe v. Nebraska*, 788 F. Supp. 2d 975, 981 (D. Neb. 2011) (citation omitted). Rule 26 requires "a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." *Gen. Dynamics Corp. v. Selb Mfg. Co.*, 481 F.2d 1204, 1212 (8th Cir. 1973) (citation omitted).

1. *Evidence of Proportionality*

Vallejo contends that the district court lacked a basis for weighing proportionality because Amgen failed to provide affidavits showing Vallejo's discovery requests were unduly burdensome. She argues that "particular and specific demonstration of fact" "mean[s] 'affidavits which explain[] why the requested information cannot be reasonably obtained.'" Appellant's Br. at 11 (second alteration in original) (quoting *Wal-Mart Stores, Inc. v. Vidalakis*, No. 5:07-MC-00039-RTD, 2007 WL 4591569, at *5 (W.D. Ark. Dec. 28, 2007)). Vallejo interprets *Vidalakis* to mean that affidavits or some form of sworn declarations or statements are the only acceptable form of evidentiary submission to the court.

Vallejo is mistaken. The party in *Vidalakis* failed to establish undue burden because "[t]he only thing[s] [it submitted to] the court [were] the conclusory statements . . . that the requested information is onerous." *Vidalakis*, 2007 WL 4591569, at *5. The *Vidalakis* court simply restated the well-settled rule that courts require the party seeking to limit discovery to "establish grounds for not providing the discovery that are specific and factual; the party cannot meet its burden by making conclusory allegations as to undue burden." *Hill v. Auto Owners Ins. Co.*, No. 5:14-CV-05037-KES, 2015 WL 1280016, at *7 (D.S.D. Mar. 20, 2015) (citing *Burns v. Imagine Films Entm't Inc.*, 164 F.R.D. 589, 593 (W.D.N.Y. 1996)).

Amgen concedes that it did not provide supporting affidavits to support its objections to Vallejo's Rule 26 requests, but it argues that it did not have to submit affidavits. Amgen argues that under Federal Rule of Civil Procedure 11(b)(3), by signing a brief, a party's counsel certifies to the court that "the factual contentions have evidentiary support." And, Amgen contends that it provided sufficiently detailed explanations to Vallejo's unduly burdensome discovery requests through its briefing to the court. As support, Amgen cites to persuasive authority where "[a] district court has . . . accepted [Amgen's] counsel's representations—in another suit brought by Vallejo's counsel regarding Enbrel—as an adequate demonstration of the burdens

associated with Vallejo's counsel's discovery requests." Appellees' Br. at 31 (citing *Small v. Amgen, Inc.*, No. 2:12-cv-476-FtM-29MRM, 2016 WL 7228863, at *6, *7 n.7, *9–10, *15 (M.D. Fla. Sept. 28, 2016)).

We reject Amgen's proposition that, as a general rule, attorney assertions in briefs to the court can adequately substitute for affidavits and other forms of evidence. By signing a brief, an attorney certifies that the factual assertions contained within the brief have evidentiary support. But certification that the facts have evidentiary support may not be helpful in the context of Rule 26(b)(1), where a party's burden must be quantified. Amgen insists that "[g]iven the nature and scope of the information requested, in addition to the multiple Defendants from whom discovery was sought, consolidated representations from Defendants' counsel properly conveyed the burdens posed by Vallejo's discovery requests." *Id.* at 32. But, the district court disagreed. The magistrate judge and the district court found that "the attorneys in this case put the onerous responsibility on the court to balance proportionality while failing to provide substantial and reasonable guidance on this key point: In its current state the court is being forced to 'wade through generalized and conflated arguments of need, burden, and relevance.'" Disc. Order at 5 (citation omitted). Thus, despite Amgen's assertion that it provided adequate information through its briefing, the district court disagreed, finding the information not "objectively quantified." *Id.* at 6.

We find no abuse of discretion in the district court's conclusion that Vallejo's discovery requests were "overbroad and unreasonable" despite the lack of affidavits or other sworn statements. Disc. Order at 12. Contrary to Vallejo's contention that the district court had no basis to weigh proportionality, the district court, "based on common sense and the search conducted by [Vallejo's] counsel during the [discovery] hearing," *id.*, had sufficient information to make an informed decision. *See Onwuka v. Fed. Express Corp.*, 178 F.R.D. 508, 516 (D. Minn. 1997) ("The[] [Rule 26] factors are not talismanic. Rather, they are to be applied in a common sense, and practical

manner." (citation omitted)); *In re Convergent Techs. Sec. Litig.*, 108 F.R.D. 328, 331 (N.D. Cal. 1985).

2. *Attorney Misrepresentations to the Court*

Vallejo claims that Amgen, in arguing lack of proportionality, misrepresented facts to the district court. For example, Vallejo claims that Amgen said Dr. Isles was "the only Amgen employee who can provide relevant information about Enbrel's safety" when in truth at least eight other Amgen employees possessed "relevant information about Enbrel's safety." Appellant's Br. at 19. Amgen disputes that it ever claimed Dr. Isles was the sole possessor of knowledge about Enbrel's safety. Indeed, the record does not support Vallejo's claim. At the discovery hearing, Amgen stated that Dr. Isles "would be the one to . . . talk to the causation point. That said, this is very early, and as our investigation continues, if there are additional people, we'll certainly supplement. But at this point in time, she's the only company witness who would speak to the safety of Enbrel." Tr. of Disc. H'rg at 25, *Vallejo v. Amgen*, No. 8:14-cv-00050-JMG-CRZ (D. Neb. Dec. 9, 2015), ECF. No. 79. The magistrate judge, too, interpreted Amgen's statement to mean that Vallejo should first depose Dr. Isles, because she was the Amgen global safety officer for Enbrel. However, the magistrate judge indicated that Amgen "may need to locate witnesses who can answer the plaintiff's relevant inquiries" in the event Dr. Isles cannot. Disc. Order at 12 (citation omitted). We find no misrepresentation by Amgen.

Vallejo also alleges that Amgen falsely represented to the court that it does not routinely track the studies involving other TNF blockers. According to Vallejo, Amgen participated in at least one study looking at TNF blockers, including Enbrel. Amgen does not dispute that it conducted the study, but asserts—and we agree—that conducting *one* study does not equate to *routinely* tracking other TNF blockers. In another instance, Vallejo says Amgen misrepresented when it asserted that "[m]any studies done on Enbrel are not designed to examine safety but instead look at other issues like medication utilization." Appellant's Br. at 18 (citation omitted). She cites

to an Amgen-sponsored study examining "whether Enbrel (and other TNF inhibitors) increase the risk of serious infection following a prior incident of serious infection." *Id.* (citation omitted). The record contains no statement by Amgen stating *no* study ever studied safety effects. Rather, Amgen stated that *many* studies do not.

A discussion of every accusation of misrepresentation that Vallejo raised against Amgen is unnecessary. Having thoroughly reviewed the record, we are satisfied that the district court did not rely on misrepresented facts by Amgen in issuing its discovery orders.

3. *Opportunity to Cross-Examine Amgen's Expert Witness*

Vallejo says the district court erroneously denied her the opportunity to cross-examine Dr. Peter Greenberg, Amgen's expert witness, at the discovery hearing. She alleges that the "error [was] particularly egregious considering Dr. Greenberg's scientific opinions were the singular foundation of [Amgen's] objections to Vallejo's discovery requests." Appellant's Br. at 22.

Vallejo's argument is without merit. Even if the court should have afforded Vallejo an opportunity to cross-examine Amgen's expert, any error was harmless. *See Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 381–82 (8th Cir. 1992) ("If a party can demonstrate a gross abuse of discretion by the trial court (bearing in mind that in the discovery arena the trial judge's discretion is particularly broad), then the complaining party must also demonstrate prejudice." (citations omitted)).

Amgen relied on Dr. Greenberg's opinion that an inquiry into whether Enbrel causes MDS "does not require an investigation into every symptom that could be associated with MDS as such an inquiry would not be probative of the causation question." Def. Mem. Regarding the Burden Associated with Pl.'s Disc. Reqs. at 6, *Vallejo v. Amgen*, No. 8:14-cv-00050-JMG-CRZ (D. Neb. Jan. 19, 2016), ECF. No. 80. Amgen also relied on Dr. Greenberg's opinion that the Enbrel BLA contains "the

relevant studies, if any, to determine whether Enbrel causes MDS." *Id.* at 10–11. Dr. Greenberg also opined that "the [Enbrel] BLA would include any information about pre-approval toxicology studies or in vitro studies, which are the studies that . . . may be relevant to the causation question." *Id.* at 17. Amgen provided the BLA to Vallejo, and the district court did not rely on Dr. Greenberg's opinion to reach its discovery decision. *See* Disc. Order at 12 ("[B]ased on common sense and the search conducted by [Vallejo's] counsel during the hearing, the court finds the burden of [Vallejo's] discovery demands is unreasonable."). Thus, even if the district court erred in failing to provide Vallejo an opportunity to cross-examine Dr. Greenberg, the error was harmless. *See Hofer*, 981 F.2d at 382.

4. *Same Information on Causation as the FDA Utilizes*

Next, Vallejo contends the district court should have ordered Amgen to provide her with the same information the FDA considers when it determines medical causation. In denying her request, Vallejo says the district court "ignored the relevancy of the pharmacovigilance materials with which the FDA determines general causation." Appellant's Br. at 28. Vallejo refers to the FDA's Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment. In the section "Interpreting Safety Signals: From Signal to Potential Safety Risk," the agency *recommends* that pharmaceutical companies submit to the agency "a synthesis of all available safety information and analyses performed, ranging from preclinical findings to current observations." J.A. at 821. The FDA then enumerated a list of materials to include in the submission when evaluating whether "a safety signal . . . may represent a potential safety risk." *Id.* But, throughout the entire document, the FDA placed as a header a description that the manual "*Contains Nonbinding Recommendations*." *Id.* at 804–24 (bold omitted).

Vallejo's argument fails. First, MDS has never been identified as a safety signal in connection with Enbrel. Second, notwithstanding that the FDA does not require the information Vallejo suggested it does, the agency "evaluates pharmaceutical drugs

using a different standard than the causation standard" courts apply. *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (per curiam). For instance, "[t]he FDA will remove drugs from the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability." *Id.* Third, Vallejo's contention that the district court ignored the relevancy of the pharmacovigilance materials used by the FDA is not supported by the agency's own statements—the FDA requests are optional and nonbinding. In other words, the requested materials may be helpful to assess safety but are not deemed essential.

The district court was under no obligation to order Amgen to provide Vallejo with materials the FDA requests—but does not require—from pharmaceutical companies when the agency evaluates safety risks. We find no abuse of discretion.

5. *Prejudice*

Lastly, Vallejo asserts that the district court's order limiting the scope of her discovery prejudiced her case. She argues that the discovery ruling directly and adversely impacted her case, leading to the court's grant of summary judgment to Amgen. We will not reverse the district court's discovery ruling "absent a 'gross abuse of discretion resulting in fundamental unfairness.'" *McGowan v. Gen. Dynamics Corp.*, 794 F.2d 361, 363 (8th Cir. 1986) (quoting *Voegeli v. Lewis*, 568 F.2d 89, 96 (8th Cir. 1977)).

Vallejo asserts that the magistrate judge misunderstood her counsel's statement at Dr. Isles's deposition. At the deposition, the magistrate judge asked Vallejo if she had a general causation expert. Vallejo's counsel replied, "I have an expert that is part of it and I'm going to have other experts." Appellant's Br. at 29 (citation omitted). Vallejo says the magistrate judge should not have interpreted the answer to mean that Vallejo "had an expert who was ready to testify as to general causation." *Id.* Vallejo claims that within the discovery she received, a Pfizer employee filed a Medwatch

report, stating, "Based on the information provided; drug profile, temporal association and positive dechallenge result, the events myelodysplastic syndrome and pancytopenia are considered related to the use of [Enbrel]." *Id.* at 29–30 (citation omitted). Vallejo says the employee's statement amounted to an admission of general causation and that the magistrate judge's denial of further depositions severely prejudiced her case. We disagree.

First, Vallejo indicated to the magistrate judge that she had a general causation expert. When the magistrate judge ordered Vallejo to disclose all retained and non-retained experts expected to testify at trial on the issue of general causation, Vallejo listed one expert, a "John Doe (Pfizer Employee)." Thus, although Vallejo informed the magistrate judge that she had an expert on causation, in actuality she did not. But even had the magistrate judge and the district court misunderstood Vallejo's counsel on whether she had an expert ready to testify on causation, Vallejo nevertheless failed to "specify the way in which the . . . discovery denials resulted in fundamental unfairness." *Moses.com Sec., Inc. v. Comprehensive Software Sys.*, 406 F.3d 1052, 1060 (8th Cir. 2005). Although "[n]o longer can the time-honored cry of 'fishing expedition' serve to preclude a party from inquiring into the facts underlying his opponent's case," *Edgar v. Finley*, 312 F.2d 533, 535 (8th Cir. 1963), "[t]he discovery rules are designed to assist a party to prove a claim it reasonably believes to be viable *without discovery*, not to find out if it has any basis for a claim."*Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990) (citations omitted). Here, Vallejo relied on an unidentified Pfizer employee's Medwatch report to say that Amgen had an admission on the issue of causation. She is wrong. Neither Amgen nor any of its employees admitted to causation. At best, the Medwatch report noted one incident of a temporal association between taking Enbrel and MDS. The law is clear "that association is not scientifically valid proof of causation." *Glastetter*, 252 F.3d at 990.

The district court ultimately granted summary judgment to Amgen because "[t]here is no dispute that Vallejo's allegations involve complex scientific matters, and yet inexplicably—throughout the 3-year life span of this litigation—she has failed to retain an expert." *Vallejo v. Amgen, Inc.*, 274 F. Supp. 3d 922, 927 (D. Neb. 2017). Allowing Vallejo to depose the unidentified Pfizer employee would not have supplied its missing general causation expert witness.

The district court properly exercised its broad discretion in rendering its discovery rulings.

B. *Sanctions*

Vallejo contends that the district court erred in imposing sanctions under Federal Rule of Civil Procedure 11, under 28 U.S.C. § 1927, and under its inherent power. "Part of the purpose of the sanctioning power . . . is to control litigation and to preserve the integrity of the judicial process." *Nick v. Morgan's Foods, Inc.*, 270 F.3d 590, 594 (8th Cir. 2001) (citing *Martin v. DaimlerChrysler Corp.*, 251 F.3d 691, 695 (8th Cir. 2001)). "A district court . . . abuse[s] its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence." *Adams v. USAA Cas. Ins. Co.*, 863 F.3d 1069, 1076 (8th Cir. 2017) (quoting *Plaintiffs' Baycol Steering Comm. v. Bayer Corp.*, 419 F.3d 794, 802 (8th Cir. 2005)).

1. *Rule 11*

"[T]he primary purpose of Rule 11 sanctions is to deter attorney and litigant misconduct, not to compensate the opposing party for all of its costs in defending." *Kirk Capital Corp. v. Bailey*, 16 F.3d 1485, 1490 (8th Cir. 1994) (citation omitted). In the context of Rule 11, "appellate courts have forcefully suggested that trial courts consider which sanction 'constitutes the least severe sanction that will adequately deter the undesirable conduct.'" *Id.* (quoting *Pope v. Fed. Express*, 974 F.2d 982, 984 (8th Cir. 1992)). The rule operates in part on the assumption

> that an attorney [will] conduct a reasonable inquiry of the factual and legal basis for a claim before filing. To constitute a reasonable inquiry, the prefiling investigation must uncover a factual basis for the plaintiff's allegations, as well as a legal basis. Whether the attorney's inquiry is reasonable may depend on factors such as whether counsel had to rely on a client for factual information, or whether the attorney depended on forwarding counsel or another member of the bar. The District Court must determine whether a reasonable and competent attorney would believe in the merit of an argument.

Coonts v. Potts, 316 F.3d 745, 753 (8th Cir. 2003) (cleaned up). "The [district] court has broad discretion in the choice of sanctions." *Id.* (citing *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 400 (1990)).

Vallejo denies her counsel "abused the judicial process in any manner." Appellant's Br. at 35. Rather, she insists that her counsel made good faith attempts to obtain information in the uphill battle against a "restrictive . . . discovery [process that] has frustrated all reasonable pursuits of discovery." *Id.* We disagree with Vallejo's characterization. Vallejo's counsel filed successive motions to relitigate issues previously denied by the court. Even *after* the district court overruled counsel's objection to the magistrate judge's discovery order, Vallejo filed a motion to compel discovery.

Vallejo argues she had cause to file the motion for clarification. Vallejo asserts that the discovery order was unclear on whether Vallejo was limited to a single deposition of Dr. Isles despite her allowance of ten under Federal Rule of Civil Procedure 30, or whether she was permitted to depose other individuals after seeking leave from the court. Vallejo offers as further justification for her motion the order's "clear[] contemplat[ion] that Dr. I[s]les would identify additional witnesses who would be deposed." *Id.* at 37. As to the motion to compel, Vallejo decries as "utterly false and offensive" the magistrate judge's characterization of the motion as an attempt to reconsider already litigated issues. *Id.* at 41. Instead, she avers that "[a]ll

of the discovery sought was carefully crafted to meet previous orders of the Court." *Id.* at 45.

The record belies Vallejo's contentions. The magistrate judge's discovery order clearly permitted Vallejo to depose *only* Dr. Isles as the initial deponent. *See* Disc. Order at 12 ("The plaintiff should instead depose Ms. Isles, and *if* she cannot provide the necessary information, [Amgen] may need to locate witnesses who can answer the plaintiff's relevant inquiries." (emphasis added) (citation omitted)). At the discovery hearing, the magistrate judge explained to Vallejo,

> If you're planning on doing a 30(b)(6) deposition, that's just another opening to do exactly what you've done today, which is bring in all of this stuff. *There's no point in going down that path at this point,* because you'll ask that witness to come up with everything that you've said you need today.

Tr. of Disc. Hr'g at 119 (emphasis added). The magistrate judge did open the prospect of Vallejo deposing additional Amgen witnesses. But, Vallejo would be permitted to do so *only* after first deposing Dr. Isles and if Dr. Isles failed to supply Vallejo with the necessary information. The magistrate judge's order was clear and required no clarification.

Vallejo's motion to compel also sought to relitigate issues previously decided by the district court. Again Vallejo argued the issue of whether the district court permitted deponents other than Dr. Isles. Vallejo sought to compel the *supplemental* BLA for psoriasis, but the magistrate judge already limited Amgen's production to the *original* BLA. Vallejo also sought production of the "Canadian Monograph," Enbrel's package insert for products sold in Canada. She argues that "[a]t the time of the motion to compel, [Amgen] had not provided any discovery on this topic" and that she thus "was acting within the Court's boundaries of discovery and substantially justified in seeking this information." Appellant's Br. at 44–45. But, the magistrate judge made

clear that she "re-craft[ed] [Vallejo's] discovery to match the case, and . . . order[ed] [Amgen] to answer or produce discovery . . . that [is] not available in the public domain." Disc. Order at 10. The Canadian Monograph is readily available in the public domain.[10] Vallejo defied the court's discovery order and sought to relitigate the issue in her motion to compel discovery.

The bulk, if not the entirety, of Vallejo's motion to compel represented relitigation of issues already decided by the court. The magistrate judge concluded that "absent any change in circumstances, filing additional motions raising the same arguments was harassing, caused unnecessary delay, and needlessly increased the cost of this litigation." Sanctions Order, 2017 WL 3037391, at *4. The district court did not abuse its discretion by imposing sanctions under Rule 11.

2. *Statutory Sanction*

Congress mandates that "[a]ny attorney . . . who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct." 28 U.S.C. § 1927. Sanctions under § 1927 may be imposed irrespective of "winners and losers, or between plaintiffs and defendants. The statute is indifferent to the equities of a dispute and to the values advanced by the substantive law. It is concerned only with limiting the abuse of court processes." *Roadway Express v. Piper*, 447 U.S. 752, 762 (1980). As previously discussed, *see supra* Part II.B.1, Vallejo's attempts to relitigate already decided issues in the form of a motion for clarification and a motion to compel discovery, as well as her motion to strike,[11]

[10]Enbrel's Canadian package insert, labeled "Product Monograph," is found at https://www.amgen.ca/products/~/media/5d0a40b2b8774fb5994190f97daf7fbd.ashx.

[11]Vallejo argues that Amgen's inclusion of requests for sanctions in its opposition to her motion to compel discovery was improper. While that may be the case, as the district court noted, "[o]pposition to a motion can be accomplished simply by opposing the motion. It is a waste of everyone's time when one motion

unreasonably and vexatiously multiplied the proceedings, "wast[ing] . . . everyone's time." Sanctions Order, 2017 WL 3037391, at *7 (citation omitted).

The district court's imposition of sanctions under § 1927 was not an abuse of discretion.[12]

3. *Inherent Power*

"[T]he district court possesses inherent power 'to manage [its] own affairs so as to achieve the orderly and expeditious disposition of cases.'" *Adams*, 863 F.3d at 1077 (second alteration in original) (quoting *Chambers v. NASCO, Inc.*, 501 U.S. 32, 43 (1991)). The court's powers include "the ability to supervise and 'discipline attorneys who appear before it' and discretion 'to fashion an appropriate sanction for conduct which abuses the judicial process,' including assessing attorney fees or dismissing the case." *Id.* (quoting *Wescott Agri-Prods., Inc. v. Sterling State Bank, Inc.*, 682 F.3d 1091, 1095 (8th Cir. 2012)).

Vallejo's counsel "disregarded or re-argued nearly all unfavorable court rulings." Sanctions Order, 2017 WL 3037391, at *5. Further, during the court's supervision of Dr. Isles's deposition, Vallejo's counsel argued with the magistrate judge's ruling approximately 16 times; counsel also repeatedly asked Dr. Isles questions "explicitly beyond the scope of discovery as ordered by the court." *Id.* Vallejo's counsel faults the district court for "ignor[ing] that the vast bulk of the

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metastasizes into two or three." Order at 1, *Vallejo v. Amgen*, No. 8:14-cv-00050-JMG-CRZ (D. Neb. Sept. 29, 2016), ECF. No. 127 (citation omitted).

[12]Vallejo argues in her reply brief about the procedural impropriety of the § 1927 sanction, because she did not get a fair notice and an opportunity to be heard. However, we consider the issue waived, as Vallejo did not raise the argument in her opening brief. *See United States v. Brown*, 108 F.3d 863, 867 (8th Cir. 1997) (holding that an argument first raised in the appellant's reply brief will not be considered without reason for failure to raise the issue earlier).

disputes were ruled upon in favor of Vallejo or for which Vallejo simply accepted the ruling." Appellant's Br. at 51.

This argument misses the point. The district court has the discretion to exercise its inherent power to achieve the orderly and expeditious resolution of cases. In reviewing sanctions under the district court's inherent power, we do not look at the frequency of counsel's success or compliance. Rather, courts assess whether and when an attorney's conduct became not just "merely the disruption of court proceedings. . . . [but] disobedience to the orders of the Judiciary, regardless of whether such disobedience interfered with the conduct of trial." *Chambers*, 501 U.S. at 44 (quoting *Young v. United States ex rel. Vuitton et Fils S.A.*, 481 U.S. 787, 798 (1987)). In addition to filing multiple motions as barely veiled attempts to relitigate decided issues, Vallejo's counsel also became unnecessarily argumentative with the magistrate judge.

Attorneys are entitled to advocate zealously for their clients, but they must do so in accordance with the law, the court rules, and the orders of the court. The district court properly exercised its inherent power to sanction Vallejo's counsel, and we find no abuse of discretion.

III. *Conclusion*

Accordingly, we affirm the district court.
