



This is a failure-to-warn case involving the prescription drug Baycol, a cholesterol-reducing medication. The case comes to us after the district court<sup>1</sup> granted Bayer's motion for summary judgment on Flesner's claims for strict liability, negligence, express and implied warranty, and unjust enrichment. On appeal, our decision focuses on whether the district court abused its discretion in finding that Flesner failed to present competent expert testimony on medical causation, requiring entry of summary judgment. We also address whether the district court abused its discretion in striking, as untimely, Flesner's supplemental expert report. For the following reasons, we affirm the judgment of the district court on both issues.

## I.

Cerivastatin, marketed under the brand name Baycol, is a prescription cholesterol-reducing medication manufactured by Appellees Bayer AG and its subsidiary Bayer Corporation and marketed by Appellees Bayer and GlaxoSmithKline. Baycol is a member of a class of drugs called statins. Doctors routinely prescribe statins to lower the lipid levels of patients diagnosed with high cholesterol, with the goal of decreasing the risk of heart disease and stroke. In August 2001, Bayer withdrew Baycol from the market after a number of deaths were linked to Baycol use and reports suggested a link between Baycol and myopathy.<sup>2</sup>

After Bayer withdrew Baycol from the market, plaintiffs throughout the country commenced lawsuits asserting various claims, including strict liability, negligence,

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<sup>1</sup>The Honorable Michael J. Davis, Chief Judge, United States District Court for the District of Minnesota.

<sup>2</sup>Myopathy entails a broad range of muscle damage, which can be grouped into three categories, with increasing levels of severity: myalgia, myositis, and, the most severe, rhabdomyolysis. See Stedman's Medical Dictionary (24th ed. 1982). Because any distinction is immaterial to our decision here, we refer broadly to Flesner's alleged condition as "myopathy."

breach of express and implied warranty, medical monitoring, and unjust enrichment. Due to the number of lawsuits initiated, the Judicial Panel on Multidistrict Litigation consolidated plaintiffs' cases in the District of Minnesota under 28 U.S.C. § 1407. See In re Baycol Prods. Liab. Litig., 180 F. Supp. 2d 1378, 1380 (J.P.M.L. 2001). Among those plaintiffs is Appellant, David Flesner.

Flesner, a sixty-seven-year-old California resident, has been treated by his primary-care physician, Dr. Milan Brandon, since 1969. Flesner first sought treatment for back and neck pain when Dr. Brandon treated him for an on-the-job injury in 1988. Dr. Brandon prescribed a variety of medications to treat this pain. Flesner also received chiropractic treatment from Dr. Robert McPherson, beginning in August 2000, when Flesner suffered an injury from being hit by a tree branch and began to suffer neck and back pain. Dr. Gary Miller later took over chiropractic treatment for Flesner's back and neck pain.

Flesner's experience with statins began in November 1999 when Dr. Brandon prescribed Zocor, and later Provachol, after diagnosing Flesner with high cholesterol. In February 2001, after weighing the risks and benefits associated with the medication, Dr. Brandon prescribed Baycol to Flesner. On March 15, 2001, Flesner complained to Dr. Miller about "general body fatigue and pain, with specific complaints of severe pain in his lower back, hips, and legs." During the same month, Flesner requested that Dr. Brandon renew his Baycol prescription. Dr. Brandon complied.

Flesner continued to express concern about muscle pain to Dr. Miller through May 2001. In late May 2001, Flesner complained in a note to Dr. Brandon about pain in his lower back and groin and dark red blood in his urine. Dr. Brandon informed Flesner that a kidney stone was the likely cause of these symptoms. Flesner continued to complain to his doctors about this pain through June and July 2001.

In August 2001, after taking Baycol for nearly five months, Flesner discontinued his use of Baycol after reading in a newspaper article that Bayer had withdrawn Baycol from the market. Continuing to experience muscle pain and fatigue, Flesner sent a letter to Dr. Brandon in which he hypothesized that Baycol was causing his symptoms. On August 13, 2001, Dr. Brandon performed a blood test, which indicated that Flesner's creatine kinase ("CK")<sup>3</sup> levels were slightly above normal—Flesner's CK level was 234; up to 200 is considered normal. Dr. Brandon informed Flesner that his elevated CK level was consistent with Flesner's suspicion that Baycol was the cause of his symptoms, but that "[a]ny pains related to Baycol should have long passed." Since discontinuing Baycol treatment, Flesner has had four CK tests, three of which have been outside of the normal range.

In July 2002, Flesner filed suit in the Southern District of California, alleging that, due to inadequate warnings, Baycol caused the various symptoms he suffered and continues to suffer. He asserted five claims under California law: (1) strict liability; (2) negligence; (3) breach of express warranty; (4) breach of implied warranty; and (5) unjust enrichment.

As a part of the consolidated Baycol litigation, Flesner's case was transferred from the Southern District of California to the District of Minnesota. Bayer subsequently brought a number of Daubert<sup>4</sup> motions to exclude expert testimony. See generally, In re Baycol Prods. Litig., 532 F. Supp. 2d 1029 (D. Minn. 2007). As it pertains to Flesner, the district court barred plaintiffs' experts Dr. Samuel Mayer and Dr. Stephen Raskin from testifying that Baycol was more toxic than other statins. Id. at 1047, 1068. In addition, the district court barred Dr. Mayer from testifying as to

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<sup>3</sup>CK is a chemical released into the bloodstream when muscles die. A rise in CK level is one indication of the presence of myopathy.

<sup>4</sup>Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

Baycol's long-term effects. Id. at 1048–51. Finally, the court barred Dr. Raskin from testifying as to the sufficiency of the Baycol warning label. Id. at 1068–69.

Three weeks after the district court's Daubert opinion, seven months after Dr. Mayer's deposition, and nearly a year after the court-imposed deadline for submission of case-specific discovery, Flesner submitted a supplemental expert report from Dr. Mayer. Bayer filed a motion to strike Dr. Mayer's supplemental report as untimely. The district court granted the motion to strike, finding that Flesner could not show good cause for the late submission and that Bayer would be prejudiced by the admission of Dr. Mayer's supplemental report. In the same opinion, the district court granted Bayer's motion for summary judgment on each of Flesner's claims. Flesner appeals both of these rulings. We affirm.

## II.

District courts have broad discretion in establishing and enforcing deadlines and in maintaining compliance with discovery and pretrial orders. See Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 758–59 (8th Cir. 2006). We review a district court's ruling only for "clear and prejudicial abuse of discretion." Wegener v. Johnson, 527 F.3d 687, 690 (8th Cir. 2008). In this case, there is no question that Dr. Mayer's supplemental report was late—Flesner submitted the report nearly a year after the court-imposed deadline. The question is whether he was justified in doing so.

Flesner's only proffered reason for the delay was that Dr. Mayer "reviewed the records of Mr. Flesner in greater detail." This explanation is insufficient, as there is nothing in the record to indicate that Dr. Mayer could not have reviewed Flesner's records in detail at the time of his initial report. See id. at 693 ("[Plaintiff's] failure to exercise due diligence with respect to her expert's review of relevant medical records . . . does not substantially justify her untimely disclosure."). In addition, it is not unreasonable to conclude that Bayer would be prejudiced by Flesner's late

submission, given that Bayer had already deposed Dr. Mayer and moved for summary judgment based on his initial report and deposition. See Marmo, 457 F.3d at 760; accord Trost v. Trek Bicycle Corp., 162 F.3d 1004, 1008–09 (8th Cir. 1999) (stating that because defendant had prepared its summary judgment motion, in part, on initial disclosure of expert-witness testimony, the district court did not abuse its discretion in excluding plaintiff's untimely disclosed expert). For these reasons, the district court did not abuse its discretion.

### III.

"We review the district court's grant of summary judgment de novo and may affirm on any basis supported by the record." Tenge v. Phillips Modern Ag. Co., 446 F.3d 903, 906 (8th Cir. 2006). Summary judgment is appropriate when the evidence, viewed in the light most favorable to the nonmoving party, demonstrates "that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Henerey v. City of St. Charles, Sch. Dist., 200 F.3d 1128, 1131 (8th Cir. 1999). "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). We review for abuse of discretion the district court's decision to exclude expert testimony for purposes of determining whether there exists an issue of material fact. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142–43 (1997); Ahlberg v. Chrysler Corp., 481 F.3d 630, 635 (8th Cir. 2007). We first address Flesner's strict liability, negligence, and warranty claims, and then address Flesner's unjust-enrichment claim.

A.

The district court granted summary judgment on Flesner's claims for strict liability, negligence, and express and implied warranty. In regard to the strict liability and negligence claims, the district court found that Flesner could not meet his causation burden because he failed to present an expert capable of testifying with a reasonable degree of medical probability that Baycol contributed to his injuries. The court found that Flesner's warranty claims failed because the Baycol labels "warned of the side effects [Flesner] alleges." On appeal, we limit our analysis to whether Flesner has met his burden of proving causation on each of these claims. We find that he has not.

To succeed in his strict liability and negligence claims, Flesner has the burden of proving medical causation through the use of a medical expert. Bockrath v. Aldrich Chem. Co., Inc., 980 P.2d 398, 403 (Cal. 1999) ("In cases . . . presenting complicated and possibly esoteric medical causation issues, the standard of proof ordinarily required is 'a reasonable medical probability based upon competent expert testimony that the defendant's conduct contributed to [the] plaintiff's injury.'") (citation omitted). Causation is also a required element in a claim for breach of express or implied warranty. Pisano v. Am. Leasing, 194 Cal. Rptr. 77, 80 (Cal. Ct. App. 1983). Under California law, proof of causation in this context requires that Flesner demonstrate to a "reasonable medical probability based upon competent expert testimony that the defendant's conduct contributed to [his] injury." Rutherford v. Owens-Illinois, Inc., 941 P.2d 1203, 1219 n.11 (Cal. 1997) (citation omitted). Probability is a higher standard than possibility, requiring Flesner to prove that, "in the absence of other reasonable causal explanations, it [is] more likely than not that the injury was a result of [Bayer's] action. This is the outer limit of inference upon which an issue may be submitted to the jury." Jones v. Ortho Pharm. Corp., 209 Cal. Rptr. 456, 460 (Cal. Ct. App. 1985). While Flesner points to the testimony of various "generic causation experts" who are able to testify as to general causation—that is, whether Baycol is *capable* of causing myopathy—the issue on appeal is specific causation—whether

Baycol caused Flesner's alleged injuries. See Whiteley v. Philip Morris Inc., 11 Cal. Rptr. 3d 807, 863 (Cal. Ct. App. 2004) ("[P]laintiffs must establish, *to a reasonable medical probability, their illnesses* were caused by the toxic exposure. The fact the chemicals increased the possibility of sickness in the overall population does not suffice to provide a causal link with plaintiffs' illnesses.") (citation omitted).

On this point, Flesner relies on the testimony of Dr. Mayer, his case-specific expert.<sup>5</sup> Specifically, he relies on two reports: (1) Dr. Mayer's generic expert-witness report, which Dr. Mayer submitted in the consolidated Baycol litigation; and (2) Dr. Mayer's case-specific expert report. Dr. Mayer's generic report concluded only that Baycol is capable, as a general matter, of causing myopathy. Because this is not at issue on appeal, we focus on Dr. Mayer's case-specific expert report in determining whether the district court abused its discretion in excluding Dr. Mayer's testimony on causation.<sup>6</sup> We find that Dr. Mayer had inadequate factual evidence on which to base his opinion.

Dr. Mayer's case-specific expert report fails to provide competent evidence on specific medical causation, particularly in light of Dr. Mayer's deposition testimony. Upon reviewing the record, it is apparent that Dr. Mayer's testimony on causation is devoid of the factual basis necessary to render it sufficient to create a triable issue of fact. See McGonnell v. Kaiser Gypsum Co., Inc., 120 Cal. Rptr. 2d 23, 29 (Cal. Ct.

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<sup>5</sup>In addition to excluding Dr. Mayer's testimony, the district court found that Flesner's treating physicians, Drs. Miller and Brandon, could not testify to a reasonable medical probability on causation. Flesner does not appear to rely on testimony from Drs. Miller and Brandon on appeal. Rather, Flesner focuses on Dr. Mayer's testimony. In any event, the record is clear that neither Dr. Miller nor Dr. Brandon could testify with the requisite degree of certainty that Baycol contributed to Flesner's alleged injuries.

<sup>6</sup>Bayer has not, as Flesner claims, conceded that there is a question of material fact as to specific causation. The context of Bayer's "concession" reveals that Bayer was arguing in the alternative.



App. 2002) ("Plaintiffs cannot manufacture a triable issue of fact through use of an expert opinion . . . devoid of any basis, explanation, or reasoning."). Neither Dr. Mayer's sparse objective medical evidence nor the conclusory remarks in his case-specific expert-report form are sufficient to overcome the abuse-of-discretion standard with which we are presented.

First, Flesner fails to demonstrate that the district court abused its discretion because Dr. Mayer cannot present any objective scientific evidence—other than Flesner's slightly elevated CK level—that Baycol caused Flesner's injuries. In Dr. Mayer's generic report, he stated that, while each is flawed, there are numerous tests for diagnosing myopathy, including testing for increased CK and myoglobinuria levels, muscle biopsies, and electromyography tests. He testified in his deposition, however, that, other than testing for elevated CK levels, none of these scientific tests was performed on Flesner. Further, he testified that Flesner's above-normal CK level could have alternative causes and the elevation was so slight it would not, under the standards of the American College of Cardiology, require discontinuation of Baycol therapy out of concern for myopathy.

In addition, although Flesner's CK levels were above normal in his first CK test, the record does not contain a measure of Flesner's CK level prior to his taking Baycol. Without this baseline reading, there is no evidence to suggest that this elevated level has any link to Flesner's Baycol ingestion. This problem is exacerbated by the high degree of variance exhibited in Flesner's post-Baycol CK readings. On September 18, 2001—approximately one month after he stopped taking Baycol—Flesner had a CK level of 167, which, as Dr. Mayer testified, is within the normal range. But he subsequently had three readings, again after he stopped taking Baycol, in which his CK level was outside of the normal range.

Finally, Dr. Mayer himself stated in his generic report that CK readings are an "inaccurate and crude 'snapshot' of muscle damage" that "tell us little about prognosis." Thus, the limited objective evidence available to Dr. Mayer was—as he

describes it—a poor indicator of muscle damage, had alternative explanations, and presented, at best, a weak causal link between Flesner's alleged injuries and his ingestion of Baycol. We are not persuaded, therefore, that Flesner's slightly elevated CK level calls into question the district court's decision that Dr. Mayer could not present evidence that demonstrates, to a reasonable medical probability, that Baycol contributed to Flesner's alleged injuries.

Second, Dr. Mayer's conclusory remarks in his case-specific report are insufficient to show that the district court abused its discretion in excluding his expert testimony. In addition to noting Flesner's elevated CK level, Dr. Mayer based his conclusion on his observations that: (1) Flesner's pain was of "new onset" with ingestion of Baycol; (2) Dr. Mayer had no other explanation for the injury; (3) Flesner suffered pain "reasonably contemporaneous" with ingesting Baycol; and (4) Flesner's injury did not grow worse after he stopped taking Baycol.

Dr. Mayer's deposition testimony, along with the remainder of the record, calls into question his first and second observations in which he stated that the pain was of "new onset" with Baycol ingestion and that there was "no other explanation" for Flesner's pain. Flesner's medical history reveals a long battle with muscle pain, dating back to 1988 when he suffered an on-the-job injury. Since that time, Flesner's doctors have prescribed a number of pain medications to address Flesner's ongoing pain. Thus, the record contains evidence that Flesner's pain was not of new onset and that there were, indeed, alternative explanations for the pain. In his deposition, Dr. Mayer acknowledged this history of muscle pain, but concluded that this prior pain was "certainly of a different nature and character than it was after approximately August 2001." In this context, such conclusory statements without sufficient evidentiary support do not call into question the district court's broad discretion in the area of expert testimony.

Dr. Mayer's third and fourth observations are best categorized as an argument for causation by temporal association—the third observation addressing when the

condition started, the fourth addressing when the condition stopped. Temporal association, in this case, is not sufficient to prove it was "more likely than not," that Baycol caused Flesner's injuries. We have held, "Under some circumstances, a strong temporal connection is powerful evidence of causation." Bonner v. ISP Techs., Inc., 259 F.3d 924, 931 (8th Cir. 2001). For example, in Bonner, we referenced Heller v. Shaw Industries, Inc., 167 F.3d 146 (3d Cir. 1999), a case in which the Third Circuit stated, "if a person were doused with chemical X and immediately thereafter developed symptom Y," this temporal relationship might constitute strong evidence of causation. Id. (quoting Heller, 167 F.3d at 154). Flesner's case does not fit within this narrow category. "The temporal relationship often will be only one of several factors, and the weight to be given to the temporal relationship 'will differ depending on the strength of that relationship.'" Bland v. Verizon Wireless, (VAW) LLC, 538 F.3d 893, 899 (8th Cir. 2008) (quoting Heller, 167 F.3d at 154). In this case, the additional factors on which Dr. Mayer relied are either unsupported by the record or have alternative explanations. Further, Flesner has suffered muscle aches for many years and taken a number of medications for a variety of ailments—some of them contemporaneously with Baycol—thus reducing the strength of a causal link based on a temporal relationship between his alleged pain and his Baycol ingestion. Given this, temporal proximity does not render the district court's decision to disregard Dr. Mayer's testimony an abuse of discretion.

This case is not, as Flesner suggests, like Bonner, where there are "questions of conflicting" expert testimony. 259 F.3d at 930; see also Andrews v. Foster Wheeler LLC, 41 Cal. Rptr. 3d 229, 239 (Cal. Ct. App. 2006) ("[T]he court may not weigh the plaintiff's evidence or inferences against the defendants' as though it were sitting as the trier of fact.") (citation omitted). Rather, it is a case in which Flesner failed to put forth competent evidence with which to create a conflict. Without competent evidence on both sides, there can be no "battle of the experts" in which a fact-finder could weigh competing claims. Simply put, this case presents us with an expert opinion based on conclusory statements, weak scientific evidence, and temporal proximity in the face of alternative explanations. See Bushling v. Fremont Med. Ctr.,

11 Cal. Rptr. 3d 653, 664 (Cal. Ct. App. 2004) ("[A]n expert opinion is worth no more than the reasons and facts on which it is based."). Dr. Mayer's opinion on causation simply lacks the factual basis to rise above the level of speculation. See McGonnell, 120 Cal. Rptr. 2d at 29 ("[A] court is not bound by expert opinion that is speculative or conjectural."). Given the broad discretion afforded to district courts in matters of expert testimony, we cannot find that the district court abused its discretion in finding that Dr. Mayer could not competently testify as to medical causation in Flesner's case. Flesner has therefore failed to establish the existence of an element of his claims—causation—that he would have the burden of proving at trial. As a result, summary judgment is appropriate and we affirm the district court. See Celotex, 477 U.S. at 322.

## B.

The district court also granted Bayer's motion for summary judgment on Flesner's unjust-enrichment claim, finding that Flesner received what he bargained for and therefore could not demonstrate that Bayer was unjustly enriched as a result of Flesner purchasing Baycol. As with the previous claims, we affirm.

Under California law, an unjust-enrichment plaintiff must show "receipt of a benefit and unjust retention of the benefit at the expense of another." Lectrodryer v. SeoulBank, 91 Cal. Rptr. 2d 881, 883 (Cal. Ct. App. 2000). There is no question that Bayer received a benefit when Flesner purchased Baycol. The issue is whether retention of that benefit was unjust. See Marina Tenants Ass'n v. Deauville Marina Dev. Co., 226 Cal. Rptr. 321, 328 (Cal. Ct. App. 1986) ("The 'mere fact that a person benefits another is not itself sufficient to require the other to make restitution therefor.'") (quoting Restatement (First) of Restitution § 1, cmt. c (1937)). We find that it was not. The record illustrates not only that Flesner's cholesterol level fell after he took Baycol, but, as our analysis in the previous section demonstrates, that there is no competent medical evidence showing that Flesner suffered any harm as a result of taking Baycol. Thus, he received the benefit of his bargain. In light of this, we

affirm the district court's grant of summary judgment on Flesner's unjust-enrichment claim. Peterson v. Cellco P'ship, 80 Cal. Rptr. 3d 316, 323 (Cal. Ct. App. 2008) ("There is no equitable reason for invoking restitution when the plaintiff gets the exchange which he expected.") (quoting Comet Theatre Enters., Inc. v. Cartwright, 195 F.2d 80, 83 (9th Cir. 1952)).

#### IV.

For the foregoing reasons, we affirm the judgment of the district court.

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