

Karen L. Bartlett

v.

Civil No. 08-cv-00358-JL
Opinion No. 2010 DNH 148

Mutual Pharmaceutical
Company, Inc.

MEMORANDUM ORDER

This products liability case, which arises from injuries allegedly caused by the prescription drug Sulindac, is scheduled to begin trial next week. In advance of trial, this court ordered the parties to brief whether the defendant Mutual Pharmaceutical Company has sufficient evidence to support its affirmative defenses based on (1) plaintiff Karen Bartlett's failure to stop taking the drug Sulindac and/or to seek medical care as soon as she began feeling sick; and (2) her doctor Tahsin Ergin's failure to read Sulindac's warning label and/or to warn Bartlett of the drug's safety risks. After reviewing the parties' submissions, this court concludes that Mutual (which has not designated an expert to explain how any of those failures caused or contributed to Bartlett's injuries) does not have sufficient evidence to support those defenses and accordingly strikes them from the case.¹

¹The court initially announced this ruling during a conference call with the parties on August 11, 2010, and in a summary order later that day, see document no. 329. This order sets forth the court's reasoning in greater detail.

I. Applicable legal standard

"It is without question that district courts, in appropriate circumstances, are entitled to enter summary judgment sua sponte." P.R. Elec. Power Auth. v. Action Refund, 515 F.3d 57, 64 (1st Cir. 2008). To guard against any unfairness to the parties, our court of appeals has "required two conditions prior to the district court's exercise of such a right:" (1) "the discovery process must be sufficiently advanced that the parties have enjoyed a reasonable opportunity to glean the material facts," and (2) "the district court must provide the targeted party appropriate notice and a chance to present its evidence on the essential elements of the claim or defense." Id. at 64-65. Both of those conditions have been met here: the discovery process is over, and this court gave Mutual notice and an opportunity to present evidence on its defenses.² This court will therefore evaluate those defenses as it would in the context of a summary judgment motion filed by Bartlett.³

²See documents no. 296 (order), 322 (Mutual's brief), and 326 (Bartlett's brief). In addition to the briefing, this court discussed its concerns about the defenses with the parties during the final pre-trial conference. See document no. 301, at 29-42.

³Of course, this court would also have the authority at trial to refuse to instruct the jury on defenses for which Mutual has not presented sufficient evidence. See Fed. R. Civ. P. 50(a)(1). Mutual would not fare any better then, because (as explained infra) it lacks sufficient expert testimony to support

Summary judgment is appropriate where “the pleadings, the discovery and disclosure materials on file, and any affidavits show 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)(2). An issue is “genuine” if it could reasonably be resolved in either party’s favor at trial, and “material” if it could sway the outcome under applicable law. Mulvihill v. Top-Flite Golf Co., 335 F.3d 15, 19 (1st Cir. 2003). In making that determination, the “court must scrutinize the record in the light most flattering to the party opposing the motion, indulging all reasonable inferences in that party’s favor.” Id. The following factual summary is consistent with that approach.

II. Background⁴

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor, Tahsin Ergin, prescribed a non-steroidal anti-inflammatory drug (“NSAID”) called Clinoril. Dr. Ergin did not read the drug’s label before prescribing it.

its defenses, and the expert disclosure rules prevent it from remedying that defect by introducing new expert opinions at trial. See Fed. R. Civ. P. 26(a)(2)(B).

⁴For a more detailed summary of the case’s factual and procedural background, see this court’s recent summary judgment ruling. Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 3-8.

Even without reading the label, Dr. Ergin knew from his medical background that the drug could cause a serious and potentially fatal skin disease known as Stevens-Johnson syndrome ("SJS") or toxic epidermal necrolysis ("TEN"). But it was not his usual practice to discuss that risk with patients, and he did not do so with Bartlett. Instead, Dr. Ergin told Bartlett that if she developed any adverse symptoms or abnormal reactions, she should stop taking the drug and contact his office.

Bartlett took the prescription to a nearby pharmacy, which filled it with Sulindac, a generic version of the drug, manufactured by Mutual. The pharmacy gave Bartlett a "prescription advisor," which she read, that advised her to "check with your doctor" if certain possible side effects, including diarrhea, "continue or are bothersome," to "check with your doctor as soon as possible if you experience rash or other skin conditions," and to "contact your doctor immediately if you experience swelling of hands, face, lips, eyes, throat, or tongue" or certain other symptoms.

Within weeks of the prescription, Bartlett began to feel sick. Her symptoms started on a Saturday as a bout with diarrhea, which continued into Sunday. She then went to work on Monday, but did not feel well enough to work a full day. That was the first day she contacted Dr. Ergin or her primary care physician. She went to an emergency room the following day

(Tuesday), at which point she was complaining of a skin rash, fever, and eye irritation. She continued taking Sulindac until that point (and possibly a little longer, since there is a discrepancy between the number of pills she recalls taking and the number of pills left, see Bartlett, 2010 DNH 112, at 37-38). Soon thereafter, she was diagnosed with SJS/TEN. She spent about three months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries.

III. Analysis

A. *Defenses based on Bartlett's conduct*

Mutual has asserted four affirmative defenses based on Bartlett's failure to stop taking the drug Sulindac and/or to seek medical care as soon as she began feeling sick. The first defense is comparative negligence. See N.H. Rev. Stat. § 507:7-d. The second is plaintiff's misconduct, which is the strict liability equivalent of comparative negligence.⁵ See Thibault v. Sears, Roebuck & Co., 118 N.H. 802, 813 (1978). The third is apportionment of liability. See N.H. Rev. Stat. § 507:7-e; DeBenedetto v. CLD Consulting Eng'rs, Inc., 153 N.H. 793, 804 (2006). The fourth is superseding or intervening cause. See

⁵Mutual sometimes refers to this defense as "failure to follow instructions."

Marcotte v. Timberlane/Hampstead Sch. Dist., 143 N.H. 331, 347-48 (1999).

All of those defenses have at least one element in common: causation. Mutual must prove by a preponderance of the evidence that Bartlett's conduct caused or contributed to her injuries. See N.H. Rev. Stat. § 507:7-d (comparative negligence--defendant has "burden of proof as to the existence or amount of fault attributable" to the plaintiff); Thibault, 118 N.H. at 813 (plaintiff's misconduct--defense not available "if plaintiff's misconduct did not cause the loss or injury"); Tiberghein v. B.R. Jones Roofing, Co., 156 N.H. 110, 115 (2007) (apportionment--defense involves "fault allocation . . . between parties who have causally contributed to an accident"); Bruzga v. PMR Architects, P.C., 141 N.H. 756, 757-58 (1997) (superseding cause--defendant must show that superseding event "breaks the causal connection" between its conduct and plaintiff's injuries).

Although Mutual has not conceded the underlying premise that Sulindac caused Bartlett's SJS/TEN, see document no. 320, at 3 (noting that Mutual has no intent to challenge that point but will require Bartlett to prove it), its causation theory for these defenses seems to be that Bartlett's injuries would have been less severe if she had stopped taking Sulindac and gone to the emergency room immediately after she started to feel sick with diarrhea, rather than waiting a few days until she had

developed more serious symptoms. Mutual has not, however, designated any experts to testify in support of that theory. Instead, Mutual relies on the deposition testimony of various treating physicians (as well as one of Bartlett's experts), all of whom testified that immediate cessation of the offending drug is the first and most important aspect of treating a drug reaction.

None of those witnesses, however, explained how or to what extent (if any) Bartlett's conduct affected her actual injuries. To the contrary, some of the treating physicians suggested that medical knowledge of SJS/TEN has not advanced to the point where that question can be reliably answered. Dr. John Schulz, for example, testified that "the horse is out of the barn" after the initial "medication exposure" and that "once the syndrome is initiated, God knows where it will plateau." Similarly, Dr. Colleen Ryan acknowledged that while it "makes sense" to stop taking the drug immediately, "it's unclear the relationship of dose to the process." Mutual's counsel echoed those sentiments during oral argument on the summary judgment motions, representing to the court that a person could take only one Sulindac pill and "be struck to the same degree as Ms. Bartlett was in this case." Document no. 220, at 53.

The only witness who ventured an opinion on this causation theory is Mutual's expert Dr. Robert Stern, who testified at his

deposition that "there is a possibility that since Sulindac may have been the cause of [Bartlett's] reaction, . . . she may have had a somewhat less severe outcome" if she had stopped taking the drug earlier. He then repeated: "That's a possibility." But Mutual needs to prove more than a mere possibility; it needs to prove a probability. Thus, Dr. Stern's conclusory opinion is not enough to sustain Mutual's defenses. The court also notes that Dr. Stern's opinion was expressed for the first time at his deposition, not in his expert report, and thus was not properly disclosed under Fed. R. Civ. P. 26(a)(2)(B)(i).

Without expert testimony, the jury has no reliable way of determining whether, or to what extent, Bartlett's conduct caused or contributed to her injuries, which were far beyond the experience of average jurors. See Lemay v. Burtnett, 139 N.H. 633, 635 (1995) ("Expert testimony is required whenever the matter to be determined is so distinctly related to some science, profession, business or occupation as to be beyond the ken of the average layman."); Thorpe v. New Hampshire, 133 N.H. 299, 304 (1990) (explaining that expert testimony is necessary if "any inference of the requisite causal link must depend on observation and analysis outside the common experience of jurors"). Any finding of causation would be purely speculative on this record. See Lockridge v. Univ. of Me. Sys., 597 F.3d 464, 471 n.6 (1st

Cir. 2010) (“unsupported speculation . . . is insufficient to forestall summary judgment”).

Since Mutual has not presented sufficient evidence to establish a trialworthy defense of comparative fault, plaintiff’s misconduct, apportionment, or superseding cause based on Bartlett’s conduct, Bartlett is granted judgment as a matter of law on those defenses.

B. Defenses based on Dr. Ergin’s conduct

Mutual has also asserted two defenses based on Dr. Ergin’s conduct, including specifically his failure to read Sulindac’s warning label before prescribing the drug and/or his failure to warn Bartlett that the drug could cause SJS/TEN. The first defense is third-party negligence and apportionment of liability. See N.H. Rev. Stat. § 507:7-e; DeBenedetto, 153 N.H. at 793. The other is superseding or intervening cause. See Marcotte, 143 N.H. at 347-48. This court will address each defense in turn.

i. Apportionment

Under New Hampshire law, “[w]here the defendant seeks to reduce or eliminate the plaintiff’s recovery by apportioning professional liability” to a doctor who is not a party to the litigation, the defendant must “carry the plaintiff’s burden of proof outlined in . . . N.H. Rev. Stat. § 507-E:2,” which is the

statute applicable to medical malpractice cases. Goudreault v. Kleeman, 158 N.H. 236, 256 (2009). That statute requires “‘affirmative evidence which must include expert testimony of a competent witness’ of the standard of reasonable care, breach thereof and proximate causation of damages.” Id. (quoting N.H. Rev. Stat. § 507-E:2) (emphasis added).

Mutual has not designated any expert witnesses to opine on those three elements. Instead, Mutual relies on deposition testimony by two of Bartlett’s experts, Drs. Randall Tackett and Roger Salisbury. This court does not see how Mutual could elicit such testimony at trial consistent with the Federal Rules of Evidence and the Federal Rules of Civil Procedure. The testimony would be beyond the permissible scope of cross-examination (accepting Bartlett’s representation at the final pre-trial conference that she will not ask about such matters on direct examination). See Fed. R. Evid. 611(b). And to the extent that Mutual intends to call Drs. Tackett and Salisbury in its own case, it failed to make the timely expert disclosures required by Fed. R. Civ. P. 26(a)(2)(A).

This court recognizes that, under some circumstances, “a trial court has discretion to decide whether to require a witness to testify for an opposing party” at trial, including an expert witness. Jasty v. Wright Med. Tech., Inc., 528 F.3d 28, 39 (1st Cir. 2008). But there is no requirement that the court do so,

especially “[i]n the absence of any showing of a need for [the opposing party] to call the witness.” Id. (affirming trial court’s decision not to allow one party to call the other party’s damages expert). This court is not inclined to exercise its discretion to allow such testimony here. Any “need” that Mutual may have to call Bartlett’s witnesses is entirely of its own making, in that it failed to designate its own expert to testify about the standard of care (despite long ago disclosing an apportionment defense based on Dr. Ergin’s conduct, see documents no. 11 and 322-1). Allowing Mutual to bypass the strictures of Rule 26 by simply posing out-of-scope questions to Bartlett’s experts at their depositions would put Bartlett at an unfair disadvantage, since her expert proof on this issue was confined by Rule 26.

In any event, even if Mutual could use the testimony of Bartlett’s experts, that testimony would still be insufficient to sustain Mutual’s apportionment defense. One of Bartlett’s experts, Dr. Tackett, is a pharmacologist, not a treating physician. Thus, he is not qualified to express an expert opinion on the standard of care that Dr. Ergin, an orthopedic surgeon, should have followed in prescribing a drug like Sulindac. See Fed. R. Evid. 702. Moreover, even if he were qualified, Dr. Tackett did not testify that the standard of care required Dr. Ergin to read Sulindac’s label or to warn Bartlett

that the drug could cause SJS/TEN. At most, his testimony suggests that Dr. Ergin should have "provided [Bartlett] with a sufficient warning about if she had side effects to contact him." That is precisely the warning that Dr. Ergin gave, so Dr. Tackett's testimony is of no help to Mutual in proving these defenses.

Bartlett's other expert, Dr. Salisbury, is a burn surgeon who has some experience prescribing drugs that carry a risk of SJS/TEN, so he arguably is qualified to opine about the applicable standard of care. See id. But his testimony also fails to establish that Dr. Ergin breached the standard of care in a way that caused or contributed to Bartlett's injuries. See Goudreault, 158 N.H. at 256. Dr. Salisbury opined in his expert report that Sulindac's label should have included the following statement: "patients should be warned to discontinue NSAID should they develop any rash, fever without an alternative explanation, or mucosal symptoms." Again, however, Dr. Ergin did advise Bartlett to stop taking the medication and contact his office if she developed any adverse symptoms or abnormal reactions. And in any event, there is no expert testimony regarding how, or to what extent, earlier cessation of the drug would have changed Bartlett's injuries. See Part III.A, supra.

Dr. Salisbury also testified at his deposition that physicians "have the responsibility," as a matter of "generally

accepted practice in medicine," to review the warning label or Physician's Desk Reference entry (which also contains the warning) for drugs that they prescribe. He explained that the "reason for that" is "not only to help them in understanding the drug, but in order to counsel the patient what to look for and what problems may occur with stopping the drug." But Dr. Ergin already knew, even without reading Sulindac's warning label, that the drug could cause SJS/TEN, which is essentially all that the label said in that regard.⁶ There is no evidence to suggest that his failure to read the label affected his decisionmaking process and thus no evidence to suggest that it caused or contributed to Bartlett's injuries.

This defense ultimately stands or falls on whether the standard of care required Dr. Ergin, knowing that Sulindac could cause SJS/TEN, to warn Bartlett specifically of that remote but serious risk and what it could entail. Dr. Salisbury expressed no opinion on that issue. His statement that the "reason" for reading the drug's label is to help the doctor "counsel the patient what to look for [i.e., early symptoms] and what problems may occur with stopping the drug [i.e., as opposed to taking it]"

⁶Dr. Salisbury's opinion that Dr. Ergin was "underinformed . . . about the known and scientifically knowable risks of Sulindac" was relative to what Sulindac's label should have said (in his view), not what the label actually said. It is thus irrelevant here.

does not address which types of risks should be conveyed to the patient, whether Sulindac's risk of SJS/TEN falls in that category, or how that risk should have been conveyed.

This court has no doubt that Mutual's evidence of Dr. Ergin's negligence, if presented by a plaintiff in a medical malpractice case, would be considered insufficient as a matter of law. Under Goudreault, that means it is also insufficient as a matter of law to sustain Mutual's apportionment defense.

ii. Superseding cause

Mutual's superseding cause defense fares no better. In order to establish that defense, Mutual must prove that the superseding cause was not reasonably foreseeable. See, e.g., Marcotte, 143 N.H. at 348. Mutual has not even attempted to argue, nor could any reasonable jury find, that Dr. Ergin's failure to read the Sulindac label and/or his failure to warn Bartlett of the drug's risk of SJS/TEN were unforeseeable to Mutual. Indeed, as Mutual emphasized in arguing for summary judgment on Bartlett's failure-to-warn claims, and as this court noted in its order granting summary judgment to Mutual, there are many cases with very similar facts. See Bartlett, 2010 DNH 112, at 14 (citing examples).

Since Mutual has not presented sufficient evidence to establish a trialworthy defense of apportionment or superseding cause based on Dr. Ergin's conduct, Bartlett is granted judgment as a matter of law on those defenses as well.

IV. Conclusion

For the reasons set forth above, Bartlett is granted judgment as a matter of law on Mutual's affirmative defenses of comparative fault, apportionment, plaintiff's misconduct, and superseding cause.

SO ORDERED.



Joseph N. Laplante
United States District Judge

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cc: Keith M. Jensen, Esq.
Bryan Ballew, Esq.
Patrick J. O'Neal, Esq.
Eric Roberson, Esq.
Christine M. Craig, Esq.
Timothy P. Beaupre, Esq.
Joseph P. Thomas, Esq.
Paul J. Cosgrove, Esq.
Jeffrey D. Geoppinger, Esq.
Linda E. Maichl, Esq.
Stephen J. Judge, Esq.
Pierre A. Chabot, Esq.