UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical
Company, Inc.

MEMORANDUM ORDER

Plaintiff Karen Bartlett has moved for a jury instruction stating that she does not have to prove that Sulindac had an inadequate warning to prevail on her defective design claim, but that such evidence may be considered by the jury as a factor in determining whether Sulindac was unreasonably dangerous to consumers. She relies on the following passage from Vautour v. Body Masters Sports Industries, Inc., 147 N.H. 150 (2001):

> Under a risk-utility approach, a product is defective as designed if the magnitude of the danger outweighs the utility of the product.... In order to determine whether the risks outweigh the benefits of the product design, a jury must evaluate many possible factors including the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.

Id. at 154 (emphasis added). Nearly identical language appears in a series of earlier New Hampshire Supreme Court cases. See Price v. BIC Corp., 142 N.H. 386, 390 (1997); LeBlanc v. Am.

Honda Motor Co., 141 N.H. 579, 585 (1997); Chellman v. Saab-Scania AB, 138 N.H. 73, 77-78 (1993).

Mutual argues, in response, that Bartlett cannot present any evidence regarding Sulindac's warning, because this court recently granted summary judgment on Bartlett's failure-to-warn claims due to a lack of causation between the warning and her injuries. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, at 11-22 (finding no causation because, among other things, Bartlett's doctor did not read or rely upon the drug's warning).[1] In light of that ruling, Mutual argues that Sulindac's warning is no longer relevant and that Bartlett, to prevail on her defective design claim, must prove that Sulindac was unreasonably dangerous regardless of what its warning said.

After reviewing the relevant case law, discussing this matter with the parties during a conference call on August 13, 2010, and reviewing their written submissions,[2] this court concludes that the warning is still relevant to Bartlett's

[1] Mutual recently withdrew its "comment k" defense, which depended in part on the warning's adequacy. See Bartlett, 2010 DNH 112, at 24-25 (describing the requirements of that defense) (citing Restatement (Second) of Torts § 402A, cmt. k (1965)); document no. 332 (withdrawing the defense). Until that defense was withdrawn, there was no dispute that evidence of the warning's adequacy could be presented at trial, which is why this issue has not been resolved until now. See Bartlett v. Mut. Pharm. Co., 2010 DNH 131, 13 n.5 (reserving judgment on this issue); see also Bartlett v. Mut. Pharm. Co., 2010 DNH 123, 4 n.1 (same).

[2] Documents no. 339, 341, 342, and 344.

defective design claim, but not in the same way that it would be in the context of a failure-to-warn claim. For Bartlett to prevail on her defective design claim, she must prove that Sulindac was unreasonably dangerous despite its warning, not because of it. Evidence regarding the warning may be admitted for that purpose.

I. Legal framework

The New Hampshire Supreme Court has made clear that "design defect and failure to warn claims are separate" ways of establishing that a manufacturer is strictly liable for a defect in a product. See LeBlanc, 141 N.H. at 586. Our court of appeals, applying New Hampshire law, has said the same thing. See Cheshire Med. Ctr. v. W.R. Grace & Co., 49 F.3d 26, 32 (1st Cir. 1995) (stating that "manufacturing defect, design defect, and warning defect [are] three different ways of proving product defect, not just … factors bearing upon one way of proving product defect"); see also Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 657 (1st Cir. 1981) (separately analyzing design defect and failure-to-warn claims involving a prescription drug). The standard jury instructions in New Hampshire also include a separate section for each type of strict liability claim; there is no mention of warnings in the design defect section. See

Walter L. Murphy & Daniel C. Pope, New Hampshire Civil Jury Instructions §§ 23.2 and 23.4, at 23-3 and 23-5 (2007).

Nevertheless, as our court of appeals has observed, "New Hampshire case law supports the proposition that evidence concerning the existence and adequacy of a warning is relevant not only to a warning defect claim, but also to a design defect claim." Cheshire, 49 F.3d at 32 (citing Reid v. Spadone Mach. Co., 119 N.H. 457, 463 (1979)); see also Duford v. Sears, Roebuck & Co., 833 F.2d 407, 411-12 (1st Cir. 1987) ("The jury might have based liability solely on the inadequacy of the warnings .... Alternatively, or perhaps in conjunction with a belief that the warnings were only marginally sufficient, the jury might have found" the product unreasonably dangerous). Since that observation, three more New Hampshire Supreme Court cases have expressly stated that one of many factors the jury may consider in a defective design case is "the presence and efficacy of a warning to avoid an unreasonable risk of harm." Vautour, 147 N.H. at 154; see also Price, 142 N.H. at 390; LeBlanc, 141 N.H. at 585.

II. Analysis

The question here, which has not been answered in any of the previous cases, is whether a warning's adequacy is still relevant to a defective design claim where the court has granted summary

judgment on the plaintiff's failure-to-warn claim due to a lack of causation between the warning and the plaintiff's injuries. See Bartlett, 2010 DNH 112, at 11-22. Mutual argues that if an inadequate warning is part of the reason why a product is deemed to be unreasonably dangerous, and the warning did not cause the plaintiff's injuries, then the design defect claim too must fail for lack of causation. Mutual's reasoning is that the warning would then constitute part of the product's defective condition, and it is black-letter law that the defective condition must cause the plaintiff's injuries. See Vautour, 147 N.H. at 154.

This court agrees with that reasoning, at least to some extent. Bartlett cannot be allowed to circumvent this court's summary judgment ruling by using Sulindac's warning to establish that the drug is unreasonably dangerous (i.e., arguing that Sulindac is unreasonably dangerous because of its warning), where this court has already ruled that any inadequacy in the warning did not cause Bartlett's injuries. That would effectively turn this case back into a failure-to-warn case, rendering the summary judgment ruling meaningless.

But that is not how the New Hampshire Supreme Court seems to have envisioned the warning's role in a design defect case. Instead, the cases suggest (on a close reading) that the jury, if it determines that the product would be unreasonably dangerous without any warning, may consider "the presence and efficacy of a

warning to avoid an unreasonable risk of harm." Vautour, 147 N.H. at 154 (emphasis added); Price, 142 N.H. at 390; LeBlanc, 141 N.H. at 585; cf. also Bellotte v. Zayre Corp., 116 N.H. 52, 55 (1976) (distinguishing "the initial question of whether the product was unreasonably dangerous" from the question of the "adequacy of warning of a product unreasonably dangerous without warnings"). In other words, the plaintiff must prove that the product was unreasonably dangerous despite any warning in place at the time of its sale.

Under that approach, the inadequacy of the warning is not a part of the product's defective condition and thus need not be causally connected to the plaintiff's injuries. Indeed, the adequacy of the warning is not really the issue that the jury is being asked to decide. The issue is whether the warning, adequate or not, avoids the product's otherwise unreasonable danger. The jury could conclude that a product is unreasonably dangerous even if its warning is adequate, or better than adequate. See, e.g., Duford, 833 F.2d at 411 ("a suitable warning is not necessarily a conclusive defense in a defective design case"); accord LeBlanc, 141 N.H. at 586.

Mutual argues that unless Bartlett can show that "no warning accompanying the product would have removed [its] unreasonable danger," then her defective design claim effectively turns on the strength of Sulindac's warning, making it a failure-to-warn claim

for which Bartlett cannot prove causation. But that argument is problematic for at least two reasons.

First, it would mean that, because Bartlett's doctor did not read Sulindac's warning, Mutual would not only be shielded from liability for having an inadequate label (i.e., failure-to-warn), but also would get credit for having the best possible warning for purposes of the defective design analysis, even though this court has ruled that the warning's adequacy is a matter of genuine dispute on the current record. See Bartlett, 2010 DNH 112, at 8-11. Indeed, under Mutual's reasoning, it would get credit for having the best possible warning even if its warning were gibberish.

Second, it assumes that a warning, even a legally adequate one, which fails to avoid a product's unreasonable danger automatically becomes the product's defect (and hence must be causally connected to the plaintiff's injuries) if the jury can imagine "any warning [that] would have removed the unreasonably dangerous nature of the product." Assume, for example, that the jury found that Sulindac had a legally adequate warning, but that the product was still unreasonably dangerous. Under Mutual's reasoning, if the jury could imagine some hypothetical "super-warning" that would have avoided the unreasonable danger (e.g., sending a personal messenger to every doctor's home and office in America), the legally adequate warning would thereby become the

product's defect. This court cannot accept either of those propositions.

Mutual alternatively suggests that the jury could be instructed to determine whether Sulindac was unreasonably dangerous "without regard to the warning." But that strikes the court as an empty and artificial instruction. To the extent that a warning affects a product's level of dangerousness and/or utility, it is impossible to analyze whether a product is unreasonably dangerous "without regard to the warning," unless that means analyzing the product "as if there were no warning." Mutual is unwilling to accept that sort of instruction as a means of keeping the warning out of the case (even if that were permissible, which is an issue on which this court expresses no opinion).

For all of these reasons, this court concludes that the best course, and the one most faithful to New Hampshire precedent, is to give a jury instruction that tracks the language of the New Hampshire Supreme Court cases (i.e., that the jury, if it determines Sulindac would be unreasonably dangerous without any warning, may consider "the presence and efficacy of a warning to avoid an unreasonable risk of harm") and to allow evidence and argument about Sulindac's warning, provided it is properly directed at whether the warning in place at the time of

Bartlett's prescription avoided an otherwise unreasonable danger (and not whether it created unreasonable danger).[3]

Bartlett's motion for a jury instruction[4] is therefore DENIED, without prejudice to any objections or counter-proposals that either party may make in response to this court's proposed jury instructions.

SO ORDERED.

Joseph N. Laplante
United States District Judge

[3] Bartlett argues that "if the evidence of Sulindac's inadequate label is relevant ... such relevance makes all the relevant evidence admissible, not a small portion" of it. If she means, by that tautology, that any evidence relevant to her former failure-to-warn claim is automatically relevant to her defective design claim, then she is incorrect. Much of that evidence (especially the evidence relating to causation) is no longer relevant. Indeed, Bartlett seemed to acknowledge that point in withdrawing her prescribing doctor Tahsin Ergin as a witness, saying that she is "unaware of any relevant testimony he may give" now that the failure-to-warn claims and Mutual's third-party apportionment defense are no longer part of the case. Document no. 334.

To give another example not tied to Dr. Ergin, whether Mutual hypothetically could or should have filed a citizen's petition with the FDA regarding Sulindac, and how the FDA hypothetically would have responded to such a petition, have no relevance to whether Sulindac's warning in place at the time of Bartlett's prescription avoided an otherwise unreasonable danger, or to any other issue remaining in the case. Conversely, the fact that FDA actually required changes to all NSAID labels shortly after Bartlett's injuries, and the fact that it instituted a "black box" warning for Bextra, are relevant to that issue.

[4] Document no. 339.

Dated: August 15, 2010

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