UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-358-JL
Opinion No. 2011 DNH 004

Mutual Pharmaceutical Company, Inc.

OPINION & ORDER

This products liability case arises out of severe and permanent injuries, including blindness, that plaintiff Karen Bartlett suffered after ingesting sulindac, a prescription drug manufactured by the defendant, Mutual Pharmaceutical Company. Bartlett brought claims against Mutual for strict liability (defective design), strict liability (failure to warn), fraud, and negligence under New Hampshire law. This court granted summary judgment to Mutual on nearly all of the claims. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 2010 WL 2765358, 2010 U.S. Dist. LEXIS 69825 (failure to warn, fraud, and part of negligence claim); Bartlett v. Mut. Pharm. Co., 2010 DNH 164, 2010 WL 3659789, 2010 U.S. Dist. LEXIS 96711 (remainder of negligence claim). Bartlett proceeded to trial and prevailed on her sole remaining claim, for defective design. The jury found in her favor and awarded her $21.06 million in compensatory damages.

Mutual has now renewed its motion for judgment as a matter of law, see Fed. R. Civ. P. 50(b), arguing that Bartlett presented insufficient evidence to support her claim and that the claim is pre-empted by federal law. Mutual has also moved, in the alternative, for a new trial, see Fed. R. Civ. P. 59, arguing that numerous errors at trial tainted the jury verdict and that the damages award was excessive. Both motions are denied. Bartlett presented sufficient evidence for a reasonable jury to conclude that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers. Federal law does not prohibit states from imposing liability on that basis. In light of the severe injuries that Bartlett suffered, the damages award (though substantial) was within the acceptable range. And while no three-week trial is perfect, Mutual has not identified any errors that would warrant setting aside the jury verdict or retrying the case.

To a large extent, Mutual's post-trial motions attempt to escape the consequences of its own tactical decisions. For example, Mutual accuses this court of expanding the scope of manufacturer liability for injuries caused by products that cannot be made safer. But Mutual voluntarily withdrew an affirmative defense, recognized by this court in its summary judgment ruling, that would have relieved Mutual of liability if it proved that sulindac was unavoidably unsafe and had an

adequate warning. See Bartlett, 2010 WL 2765358, at *10, 2010 U.S. Dist. LEXIS 69825, at *31-32. Mutual also accuses Bartlett of giving the jury an unbalanced view of sulindac's risks and benefits. But Mutual chose not to call any of its own witnesses at trial, foregoing the opportunity to rebut Bartlett's evidence and put sulindac in a better light. Of course, Mutual was entitled to employ any trial strategy it wished. But, having made those tactical decisions, it must live with the consequences. It is not entitled to another trial where it can try a different strategy.

I. Applicable legal standard

"The standard for granting a Rule 50 motion [for judgment as a matter of law] is stringent." Malone v. Lockheed Martin Corp., 610 F.3d 16, 20 (1st Cir. 2010). Courts may set aside a jury's verdict and award judgment as a matter of law "only when the evidence points so strongly and overwhelmingly in favor of the moving party that no reasonable jury could have returned a verdict adverse to that party." Id. In making that determination, the court must "view the evidence in the light most favorable to the verdict, making no determination[] of [its] own as to the credibility of witnesses or the weight of the evidence." Rodriguez-Garcia v. Miranda-Marin, 610 F.3d 756, 765 (1st Cir. 2010). It is the moving party's burden to "specify ...

the law and facts that entitle [it] to the judgment." Coons v. Indus. Knife Co., 620 F.3d 38, 44 (1st Cir. 2010) (quoting Fed. R. Civ. P. 50(a)(2)).

The standard for granting a motion for new trial under Rule 59 is more flexible. "The district court has the power and duty to order a new trial whenever, in its judgment, the action is required to prevent injustice." Rodriguez-Garcia, 610 F.3d at 765. In making that determination, the court "is free to independently weigh the evidence," including "the credibility of the witnesses." Jennings v. Jones, 587 F.3d 430, 436 (1st Cir. 2009). But the court "cannot displace a jury's verdict merely because [it] disagrees" with the outcome. Id. A new trial may be granted "only if the verdict is against the law, against the weight of the credible evidence, or tantamount to a miscarriage of justice." Crowe v. Marchand, 506 F.3d 13, 19 (1st Cir. 2007). It is the moving party's burden to show that any "errors and defects" at trial affected its "substantial rights." Fed. R. Civ. P. 61; see also Cabral v. U.S. Dep't of Justice, 587 F.3d 13, 22 (1st Cir. 2009).

II. Background

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril. A nearby

pharmacy filled the prescription with sulindac, a generic version of the drug manufactured by Mutual. Within weeks, Bartlett went to the emergency room complaining of skin blisters, eye irritation, and other symptoms. She was soon diagnosed with Stevens-Johnson Syndrome ("SJS") progressing to toxic epidermal necrolysis ("TEN"), a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. See Dorland's Illustrated Medical Dictionary 1872 (31st ed. 2007). Her doctors concluded that the SJS/TEN was caused by sulindac. She spent about three months in the hospital recovering--two of them in a medically induced coma--and emerged with permanent injuries, including blindness.

Bartlett brought suit against Mutual in New Hampshire Superior Court in January 2008, asserting claims for strict liability (defective design), strict liability (failure to warn), fraud, and negligence under New Hampshire law. She had three principal theories of liability: (1) that Mutual failed to warn adequately about sulindac's risk of SJS/TEN; (2) that Mutual failed to survey the medical literature for information about sulindac's risks and to report that information to the Food & Drug Administration ("FDA"); and (3) that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers. Mutual removed the case to this court, see 28 U.S.C. § 1441, which has subject-matter

jurisdiction based on diversity of citizenship, see 28 U.S.C. § 1332(a)(1).

At first, the litigation focused primarily on Bartlett's failure-to-warn theory. Mutual moved for judgment on the pleadings, see Fed. R. Civ. P. 12(c), arguing that the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and related FDA regulations barred a manufacturer from unilaterally changing the warning for a generic drug, which must remain identical to that of the brand-name drug, and therefore pre-empted Bartlett's claims. This court denied the motion, concluding that federal law allowed such changes and did not pre-empt Bartlett's claims. See Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279 (D.N.H. 2009); accord Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010), cert. granted, 78 U.S.L.W. 3745 (U.S. Dec. 10, 2010) (No. 09-1501); Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009), cert. granted, 78 U.S.L.W. 3522 (U.S. Dec. 10, 2010) (No. 09-993).

Mutual then moved for summary judgment, see Fed. R. Civ. P. 56, arguing that sulindac's warning was adequate as a matter of law and that, in any event, Bartlett could not prove that any defect in the warning caused her injuries because her doctor admittedly never read the warning before prescribing sulindac. This court rejected the first argument, finding that the adequacy of sulindac's warning was for the jury to decide (sulindac's

label expressly mentioned SJS/TEN in its list of potential adverse reactions, but not in its warnings section). See Bartlett, 2010 WL 2765358, at *3-4, 2010 U.S. Dist. LEXIS 69825, at *10-14. But this court agreed with the second argument, as to the lack of causation, and therefore granted summary judgment to Mutual on Bartlett's claims for strict liability (failure to warn) and fraud, as well as her negligence claim to the extent it was based on a failure-to-warn theory. Id. 2010 WL 2765358, at *5-8, 2010 U.S. Dist. LEXIS 69825, at *14-27.

After that ruling, this court sua sponte ordered the parties to brief whether Bartlett had a trialworthy claim for negligence based on her second theory: that Mutual failed to survey the medical literature for information about sulindac's risks and to report that information to the FDA. Bartlett's brief made clear that the theory depended on speculation that the FDA, if advised of that information, would have withdrawn its approval of sulindac in whole or in part, contrary to what had actually happened (sulindac remains on the market to this day, with FDA approval). Accordingly, this court granted summary judgment to Mutual on the remainder of Bartlett's negligence claim. See Bartlett, 2010 WL 3659789, at *4-12, 2010 U.S. Dist. LEXIS 96711, at *12-36. As a result, Bartlett also lost any ability to recover enhanced compensatory damages, since her claim for those damages was based on her failure-to-warn and failure-to-survey

theories. Id. 2010 WL 3659789, at *12-13, 2010 U.S. Dist. LEXIS 96711, at *36-40.[1]

Those rulings left Bartlett with only one theory for trial: that sulindac's risk outweighed its benefits, making it a defective product unreasonably dangerous to consumers. Mutual challenged that theory as well (albeit not until a motion for reconsideration of this court's summary judgment ruling), arguing that New Hampshire law requires a plaintiff to prove, in addition to the product's risks outweighing its benefits, some other "defect" in design. See Buckingham v. R.J. Reynolds Tobacco Co., 142 N.H. 822 (1998). But this court disagreed, explaining that under more recent New Hampshire Supreme Court cases "a product is defective as designed if the magnitude of the danger outweighs the utility of the product," Bartlett v. Mut. Pharm. Co., 2010 DNH 130, 2010 WL 3239247, at *3, 2010 U.S. Dist. LEXIS 77902, at *7 (quoting Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 154 (2001)), and "the plaintiff is not required to present evidence of a safer alternative design," Bartlett v. Mut. Pharm. Co., 2010 WL 3303634, at *1, 2010 U.S. Dist. LEXIS 84924, at *3

[1]Using a similar sua sponte procedure, this court also granted summary judgment to Bartlett on certain of Mutual's affirmative defenses that were based on the alleged misconduct of Bartlett and her doctor, concluding that the defenses were not sufficiently supported by the necessary expert testimony. See Bartlett v. Mut. Pharm. Co., 2010 DNH 148, 2010 WL 3210763 (document no. 340).

(document no. 336) (quoting Kelleher v. Marvin Lumber & Cedar Co., 152 N.H. 813, 831 (2005)).

Nevertheless, this court agreed with Mutual that if a drug cannot be redesigned to make it safer, the manufacturer's liability must be limited. Following the view set forth in the Restatement (Second) of Torts § 402A, *cmt. k* (1965), this court ruled that Mutual could "avoid liability for defective design if it can prove, as an affirmative defense, that sulindac is unavoidably unsafe and had an adequate safety warning." Bartlett, 2010 WL 2765358, at *10, 2010 U.S. Dist. LEXIS 69825, at *31-32; see also 1 Louis R. Frumer & Melvin I. Friedman, Products Liability §8.07[5], at 8-296 (2010) (noting that because comment k "is traditionally viewed as an exception and a defense to strict liability, courts generally place the initial burden of proving the various ... factors on the defendant"). Mutual, however, voluntarily withdrew that "comment k" defense on the eve of trial, without explanation. See document no. 332.

With Bartlett's failure-to-warn theory and Mutual's "comment k" defense out of the case, the adequacy of sulindac's warning (meaning whether it reasonably informed doctors of the drug's risks, see Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 657 (1st Cir. 1981))[2] was no longer an issue for trial. Mutual argued

[2]Brochu is one of just a handful of decisions, all of them by federal courts, that have applied New Hampshire products liability law to prescription drugs. It is also one of the

that this court should therefore exclude all warning-related evidence and instruct the jury to analyze sulindac's risks and benefits "without regard to the warning." But since a warning can affect a drug's risks and benefits (e.g., by explaining how to use the drug safely, or by identifying certain patients who should not take it), this court concluded that the proposed instruction would provide no real guidance to the jury; either the drug's risks and benefits must be weighed as if it had no warning at all,[3] or they must be weighed in light of the warning that actually accompanied it. See Bartlett v. Mut. Pharm. Co., 2010 WL 3303864, at *3, 2010 U.S. Dist. LEXIS 102603, at *10 (document no. 345).

Following a line of New Hampshire Supreme Court cases, which expressly stated that the jury in a defective design case may consider "the presence and efficacy of a warning to avoid an unreasonable risk of harm," Vautour, 147 N.H. at 154, this court ruled that warning-related evidence could be admitted at trial for a limited purpose: if the jury found that sulindac's risks

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leading cases establishing that drug manufacturers can be held liable not only on a failure-to-warn theory, but also on a defective design theory. 642 F.2d at 655 (rejecting the view "that under New Hampshire's balancing test no drug can ever be classified as unreasonably dangerous").

[3]Mutual would not accept this approach as a means of keeping warning-related evidence out of the case. Instead, Mutual wanted the jury to assume that sulindac had the best possible warning, which was contrary to the evidence.

outweighed its benefits, then it could consider whether the warning--regardless of its adequacy--reduced those risks or increased those benefits to such an extent that it eliminated the unreasonable danger. In other words, the warning could operate only to Mutual's benefit. Bartlett needed to prove that sulindac's risks outweighed its benefits "despite its warning, not because of it." Bartlett, 2010 WL 3303864, at *1, 2010 U.S. Dist. LEXIS 102603, at *4.

This court also ruled on many other evidentiary and procedural issues in advance of trial, including nearly 50 challenges to expert witnesses and testimony, see Bartlett v. Mutual Pharm. Co., 2010 DNH 123, 2010 WL 2889114, at *1, 2010 U.S. Dist. LEXIS 111959, at *3 (ruling that "[t]he parties' experts have sufficient qualifications and a sufficient foundation to support most of their proffered opinions"), and nearly 50 motions in limine, see Bartlett v. Mut. Pharm Co., 2010 DNH 125, 2010 WL 3156555 (document no. 278) (ruling on Bartlett's limine motions); Bartlett v. Mut. Pharm. Co., 2010 DNH 131, 2010 WL 3092649, 2010 U.S. Dist. LEXIS 111259 (ruling on Mutual's limine motions), as well as Mutual's motion to bifurcate the trial into separate liability and damage phases, see Bartlett v. Mut. Pharm. Co., 2010 WL 3210724 (document no. 320) (denying the motion because bifurcation would result in duplication of evidence and other inefficiencies).

Trial began in August 2010 and lasted nearly three weeks. Bartlett presented testimony from herself, her sister (Barbara Mourikas), two friends who were with her on the day she fell ill (Lynda Mailhot and Rebecca Padulo), eight doctors who treated her for various different injuries resulting from SJS/TEN (primary care physician Leo Lane, burn surgeons Nam Kim, Colleen Ryan, and John Schulz, eye surgeons Claes Dohlman and James Chodosh, pulmonologist Bijan Sadrnoori, and gynecologist Steven Pliskow), two Mutual employees (Robert Dettery and Andria Werynski), two retained expert witnesses who opined about sulindac's risks and benefits (pharmacologist Randall Tackett and burn surgeon Roger Salisbury), and two retained experts who opined about Bartlett's economic damages (economist Thomas Barocci and life care planner Carol Hyland).

Mutual cross-examined Bartlett's witnesses, but chose not to present any witnesses of its own (aside from designating additional testimony by certain unavailable fact witnesses whose testimony Bartlett presented by deposition). At the close of evidence, Mutual moved for judgment as a matter of law, see Fed. R. Civ. P. 50(a)(2), which this court orally denied. On the fourth day of deliberations, the jury returned a verdict in Bartlett's favor, finding that she had proven her claim for strict liability (defective design) by a preponderance of the evidence and awarding her $21.06 million in damages, consisting

of $1.25 million for past medical expenses (to which the parties had stipulated), $2.377 million for future medical expenses, $933,000 for lost wages, and $16.5 million for pain, suffering, and loss of enjoyment of life. See document no. 381.

This court entered judgment in accordance with the verdict and the earlier summary judgment rulings. See document no. 389. Mutual then renewed its motion for judgment as a matter of law, see Fed. R. Civ. P. 50(b), arguing that Bartlett presented insufficient evidence to support her claim and that the claim is pre-empted by federal law. Mutual also moved, in the alternative, for a new trial, see Fed. R. Civ. P. 59, arguing that numerous errors at trial tainted the jury verdict and that the amount of damages was excessive. The execution of judgment has been stayed pending the resolution of those post-trial motions and any subsequent appeal. See Bartlett v. Mut. Pharm. Co., 2010 WL 4174591, 2010 U.S. Dist. LEXIS 114978 (document no. 406) (applying Fed. R. Civ. P. 62). This court will now analyze each of Mutual's arguments in turn.

III. Analysis

A. *Sufficiency of the evidence*

i. Risks outweighing benefits

The first issue raised by Mutual's Rule 50 motion is whether Bartlett presented sufficient evidence for a reasonable jury to

find that sulindac's risks outweighed its benefits. The New Hampshire Supreme Court has stated that, "barring a determination that the utility of the product completely outweighs the risk associated with its use or that the risk of harm is so remote as to be negligible," the weighing of risks and benefits is a "question[] of fact to be decided by the jury." Price v. BIC Corp., 142 N.H. 386, 390 (1997) (citing Thibault v. Sears, Roebuck & Co., 118 N.H. 802, 809 (1978)).[4] As explained below, this court cannot make either of those risk-benefit determinations as a matter of law in light of the evidence that Bartlett presented. Mutual's challenge to the sufficiency of that evidence is therefore rejected.

As an initial matter, Mutual argues that Bartlett's experts (Drs. Tackett and Salisbury) were not qualified to testify at all about sulindac's risks and benefits, because neither works directly with sulindac and other NSAIDs. "It is not required," however, "that experts be 'blue-ribbon practitioners' with optimal qualifications," United States v. Vargas, 471 F.3d 255, 262 (1st Cir. 2006), or that they have "an intimate level of familiarity with every component of a [product] as a prerequisite to offering expert testimony," Crowe, 506 F.3d at 18. They need only be "qualified as an expert by knowledge, skill, experience,

[4]State law governs the sufficiency inquiry in a diversity case. See, e.g., Soto-Lebron v. Fed. Express Corp., 538 F.3d 45, 55 (1st Cir. 2008).

training, or education." Fed. R. Evid. 702; see also Levin v. Dalva Bros., Inc., 459 F.3d 68, 78 (1st Cir. 2006) ("Rule 702 has been interpreted liberally in favor of the admission of expert testimony.").

Both of Bartlett's experts easily met that standard. Dr. Tackett has been a pharmacologist for more than 30 years and is a pharmacology professor at the University of Georgia. Dr. Salisbury has been a burn surgeon for more than 35 years and has treated more than 400 patients with SJS/TEN. Both have demonstrated familiarity with the medical literature on sulindac's risks and benefits, as well as NSAIDs and SJS/TEN more generally. They were qualified to testify on those topics. See Bartlett, 2010 WL 2889114, at *13, 2010 U.S. Dist. LEXIS 111959, at *36-38 (deeming Drs. Tackett and Salisbury qualified before trial); Lofton v. McNeil Consumer & Specialty Pharms., No. 05-cv-1531, 2008 WL 4878066, at *9-10, 2008 U.S. Dist. LEXIS 94391, at *28-30 (N.D. Tex. July 25, 2008) (allowing them to testify in a similar case involving an NSAID that allegedly caused SJS/TEN, citing their "extensive experience").

Mutual also argues that Bartlett's experts should have been prohibited from testifying about sulindac's risks and benefits because their expert reports--like much of the early litigation--focused primarily on Bartlett's failure-to-warn theory, not her defective design theory. See Fed. R. Civ. P. 26(a)(2)(B)(I)

(requiring pre-trial disclosure of "all opinions that the witness will express"). But the reports were filled with opinions about sulindac's risks and benefits, which were clearly relevant to the defective design theory as well. "The purpose of expert reports is to ... convey the substance of the expert's opinion ... so that the opponent will be ready to rebut [and] cross examine." Metavante Corp. v. Emigrant Sav. Bank, 619 F.3d 748, 762 (7th Cir. 2010). Bartlett's expert reports accomplished that purpose, as evidenced by Mutual's "able cross-examination" of the experts at trial. Id.

Mutual notes that Bartlett's experts never opined that sulindac was "unreasonably dangerous," which is the ultimate issue in a defective design case. That is true; this court prohibited them from using that particular phrase at trial because they had not used it in their expert reports. But they did expressly state in their reports, and testify at trial, that sulindac's risks outweighed its benefits, which is what the phrase "unreasonably dangerous" means in this context. See Vautour, 147 N.H. at 154. There is no requirement that experts utter the magic words "unreasonable danger" for a plaintiff to recover for defective design.[5] Cf. Kelleher, 152 N.H. at 832

[5]Indeed, before this court granted summary judgment on Bartlett's negligence claim, Mutual argued--successfully--that no expert should be allowed to utter the word "negligent." See Bartlett, 2010 WL 2889114, at *12, 2010 U.S. Dist. LEXIS 111959, at *35-36.

(rejecting "the defendant's assertion that the plaintiff was required to use the exact phrase, 'unreasonably dangerous,' to adequately plead" a defective design claim).

As for the opinion that sulindac's risks outweighed its benefits, Mutual argues that it was merely a "passing reference, without support." But Bartlett's experts supported the opinion with a litany of specific facts, most of them drawn directly from the medical literature or published FDA analyses. They testified, for example, to the following:

- ***Causation of SJS/TEN.*** Sulindac is one of many drugs, including nearly every NSAID and nearly every antibiotic, that can cause SJS/TEN. This causal link has been confirmed by positive re-challenges, i.e., cases where patients who had previously developed SJS/TEN after taking sulindac developed it again after re-administration of the drug. See, e.g., Glen D. Park et al., Serious adverse reactions associated with sulindac, 142 Archives of Internal Medicine 1292-94 (1982).[6]

- ***Background rate of SJS/TEN.*** The background rate of SJS associated with drug therapy is 1.2 to 6 per million prescriptions, and the background rate of TEN (the more serious form of the disease) is 0.4 to 1.2 per million prescriptions, according to FDA estimates. See Letter from Steven K. Galson, Director, FDA Center for Drug Evaluation & Research, to Dr. Salisbury, at 5 (June 22, 2006) (document no. 310-1) (citing medical literature).

- ***Group risk of SJS/TEN.*** While no controlled study has measured its individual risk of SJS/TEN, sulindac is part of a group of NSAIDs, known as acetic acid NSAIDs, that has been shown to have a greater risk of SJS/TEN than another

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[6]Bartlett's experts were permitted to express opinions based on the medical literature, see Fed. R. Evid. 703, but the articles themselves were not admitted as exhibits because they were hearsay not subject to any identified exception, see Fed. R. Evid. 801-803.

group, known as propionic acid NSAIDs, in a controlled study. See Maja Mockenhaupt et al., SJS and TEN: assessment of medication risks with emphasis on recently marketed drugs; the EuroSCAR-study, 128 Journal of Investigative Dermatology 35, 41 (2008). In addition, sulindac is one of the NSAIDs with longer half-lives, which are suspected of having a greater risk of SJS/TEN because they stay in the body longer. See, e.g., Pierre E. Wolkenstein et al., Drug-induced TEN, 16 Clinics in Dermatology 399, 403 (1998).

- ***Adverse event reports of SJS/TEN.***[7] From 1980 to 1997, the FDA's adverse event reporting database--which collects spontaneous reports of drug side effects from doctors, manufacturers, patients, etc.--received 89 reports of SJS/TEN attributed to sulindac, more than the number of reports for any other NSAID on the market and all but four drugs of any kind. See Maja Mockenhaupt et al., The risk of SJS and TEN associated with NSAIDs: a multinational perspective, 30 Journal of Rheumatology 2234 (2003) (document no. 230-4). Through 2004, the number of SJS/TEN reports attributed to sulindac had increased to 134.[8] In 39

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[7]Consistent with a pre-trial ruling, this court allowed Bartlett's experts to "testify based on the [adverse event] reports," Bartlett, 2010 WL 3092649, at *1, 2010 U.S. Dist. LEXIS 111259, at *1-4, but excluded the reports themselves from evidence because they were hearsay not subject to any identified exception, see Fed. R. Evid. 801-803. The pre-trial ruling left open the possibility that the reports themselves could be admitted to show notice to Mutual (i.e., not for their truth), but that became irrelevant once Bartlett's negligence claim was dismissed. Mutual seems to misunderstand that ruling as limiting the experts' reliance on adverse event reports to notice issues, which by its plain language it did not.

[8]Bartlett's experts originally miscounted the number of reports at 176, which included many duplicates. They corrected the number at trial. This court instructed the jury that it could draw an inference against Dr. Tackett's credibility because he failed to disclose the errors before trial. Mutual argues that this court should have gone further and excluded all of the experts' testimony as unreliable. But, as this court explained in rejecting Bartlett's pre-trial motion to exclude one of Mutual's experts who made a computational error, such errors generally go to the weight, not the admissibility, of expert testimony. See Bartlett, 2010 WL 2889114, at *11, 2010 U.S. Dist. LEXIS 111959, at *30-31 (citing cases). Moreover, even

of those cases, the patient died. According to FDA estimates, more than 90 percent of adverse events go unreported.

- ***Reporting rate of SJS/TEN.*** Sulindac's rate of SJS/TEN reports from 1980 to 1997, per million prescriptions, was the highest of any NSAID, according to an unpublished manuscript (document no. 230-2) prepared for the drug company Pharmacia by the authors of the Journal of Rheumatology article just mentioned (one of whom was Mutual's own expert, dermatologist Robert Stern).[9]

- ***Risks other than SJS/TEN.*** According to a recent FDA analysis, there is no evidence that any one NSAID--including sulindac--is more or less risky than other NSAIDs with regard to various other known side effects, including gastrointestinal bleeding, renal toxicity, hepatic enzyme elevation, bronchospasm, fluid retention, and edema. See John K. Jenkins, Director, FDA Office of New Drugs, Analysis and recommendations for Agency action regarding NSAIDs and cardiovascular risk 12 (Apr. 6, 2005) (document no. 309-1).[10]

- ***Benefits.*** Sulindac has been approved by the FDA for treatment of acute painful shoulder and various arthritic

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without their own count, Bartlett's experts had an independent and reliable basis for testifying about sulindac's high number of SJS/TEN reports: the Journal of Rheumatology article. If anything, the errors helped Mutual by giving it a way to counter that evidence (which is presumably why Mutual waited until trial to expose the errors, rather than seeking exclusion when it, too, noticed them before trial).

[9]Mutual argues that Bartlett's experts failed to disclose this opinion in their expert reports. See Fed. R. Civ. P. 26(a)(2)(B)(i). But Dr. Tackett expressly stated in his report that the authors of the Journal of Rheumatology article "found when analyzing the number of reports per physician office visits with a prescription, sulindac had significantly and substantially higher rates of reported SJS/TEN reactions ... compared to other NSAIDs." So the opinion was disclosed.

[10]This court admitted the FDA analysis into evidence as a full exhibit, since it was a self-authenticating public record available on the FDA's website. See Fed. R. 803(8) (hearsay exception) and 902 (self-authentication).

conditions (acute gouty arthritis, rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis). It is the only NSAID approved to treat the first two conditions. Nevertheless, according to a recent FDA analysis, there is no evidence that any one NSAID--including sulindac--provides greater relief of pain and inflammation than other NSAIDs. See Jenkins, supra, at 2.[11]

- ***Risk/benefit profile.*** The FDA has recommended that five NSAIDs be removed from the market due, in part, to their risk of SJS/TEN as demonstrated by adverse event reports (sometimes fewer than 15). While sulindac has not been removed from the market, it has a similar "risk/benefit profile" to valdecoxib (known by the brand name Bextra), one of the removed NSAIDs, in that neither drug has a demonstrated advantage over other NSAIDs with regard to their benefits or various known risks other than SJS/TEN, see id. at 2, 12, both drugs had a higher reporting rate of SJS/TEN than other NSAIDs, see id. at 17, and sulindac had more reported deaths from SJS/TEN (39) than did Bextra (7), see id.[12]

- ***Safer alternative products.*** Two alternatives to sulindac, aspirin and acetaminophen (known by the brand name Tylenol),

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[11]Mutual argues that Bartlett's experts failed to disclose this opinion and the one discussed in the previous paragraph. See Fed. R. Civ. P. 26(a)(2)(B)(I). But both experts expressly cited the FDA's analysis in their reports and quoted its statement that Bextra, another NSAID, lacked "any demonstrated advantage over other NSAIDs." Their reports then stated that sulindac had a similar "risk/benefit profile" to Bextra. So Mutual was on notice that Bartlett's experts would testify, based on the FDA's analysis, that sulindac also lacked any demonstrated advantage over other NSAIDs.

[12]Mutual argues that this Bextra comparison should have been excluded as unreliable because, as Bartlett's experts acknowledged, Bextra had been on the market for a much shorter period of time (about 3.5 years, compared to sulindac's then-27) and had more SJS/TEN reports (189) than sulindac (133). But those differences went to the weight of the comparison, not its admissibility. The jury could weigh both the similarities and the differences between Bextra and sulindac.

carry no risk of SJS/TEN, at least in adults,[13] and are equally effective as sulindac, at least in treating conditions like shoulder pain (for which Bartlett took sulindac). While they carry some additional risks that sulindac does not (e.g., aspirin can cause Reye's syndrome) and may not be equally effective in treating every condition that sulindac treats, they also provide additional benefits that sulindac does not. Overall, they are safer alternative products.

Mutual faults Bartlett's experts for focusing primarily on sulindac's risk of SJS/TEN and failing to consider all of its other risks and its benefits. As just mentioned, however, Bartlett's experts (while acknowledging sulindac's approved uses) testified broadly that there is no evidence that sulindac has any greater benefit than other NSAIDs, or any lesser risk of various known side effects other than SJS/TEN. They based that testimony on a recent FDA analysis, see Jenkins, supra, at 2, 12, which resulted from what the FDA called "a comprehensive review of the risks and benefits, including the risks of SJS and TEN, of all approved NSAID products," Galson, supra, at 2, and which was admitted into evidence as a full exhibit. So their risk/benefit analysis was sufficiently comprehensive.[14]

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[13]Dr. Tackett acknowledged on cross-examination that a recent study indicated a possible link between Tylenol and SJS/TEN in children. See Natacha Levi et al., Medications as risk factors of SJS/TEN in children: a pooled analysis, 123 Pediatrics 297 (2009).

[14]Bartlett's experts also relied on another piece of evidence that contained an extensive summary of sulindac's risks and benefits, and that was admitted into evidence as a full exhibit: sulindac's label, or "package insert." The label described in detail each of sulindac's approved uses, including

Mutual argues that this court should have prohibited Bartlett's experts from relying on the FDA's analysis, in light of their testimony that the FDA has insufficient resources to monitor the safety of all drugs, which is how Bartlett's experts attempted to downplay the FDA's approval of sulindac. See Wyeth v. Levine, 129 S. Ct. 1187, 1202 (2009) (noting that "FDA has limited resources to monitor the 11,000 drugs on the market" and that, as discussed in Part III.B.i, infra, FDA approval does not preclude state tort liability). That was indeed a theoretical tension in Bartlett's case, and one that Mutual highlighted for the jury during closing argument.[15] But it went to the weight, not the admissibility, of the experts' opinions. A reasonable jury could have agreed with Bartlett's experts that the FDA was right about some things, but wrong about others.[16]

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the benefits it had been shown to have in controlled studies, and each of its known side effects other than SJS/TEN, including their estimated rates of occurrence.

[15]Of course, Mutual faced the opposite theoretical tension: attacking the FDA's recent analysis of NSAIDs as unreliable, while simultaneously emphasizing the FDA's approval of sulindac to suggest it was not unreasonably dangerous.

[16]Mutual also argues that Bartlett's experts lacked a reliable basis for testifying about the FDA's limited resources. But their testimony was based primarily on two government reports, see U.S. Gov't Accountability Office, GAO-06-402, Improvement Needed in FDA's Postmarket Decision-making and Oversight Process (2006); H. Subcomm. on Science and Technology, FDA Science and Mission at Risk (2007), which were admitted into evidence as full exhibits, see Fed. R. Evid. 803(8) (hearsay exception) and 902 (self-authentication); see also Fed. R. Evid. 703 (permissible bases of expert testimony).

If Mutual had evidence to refute the FDA's analysis, such as evidence that sulindac is more beneficial than other NSAIDs or that it has less risk of certain side effects other than SJS/TEN, then Mutual could have presented that evidence at trial in its own case (or, at the very least, confronted Bartlett's experts with it). A plaintiff bringing a claim for defective design cannot be expected to sing the praises of the allegedly defective product, or to put the product in the best possible light. So far as this court can tell, Mutual chose not to present its own experts because it feared that they would actually strengthen, not weaken, Bartlett's case.[17]

Next, Mutual argues that Bartlett presented insufficient evidence for the jury to evaluate sulindac's risk of SJS/TEN. As just mentioned, however, Bartlett's experts testified at length on that issue, opining that sulindac has been confirmed to cause SJS/TEN; that the background rate of SJS/TEN is as many as six cases per million prescriptions; that sulindac is part of two groups of NSAIDs (acetic acid NSAIDs and longer half-life NSAIDs) believed to have a higher risk of SJS/TEN; that the FDA received 133 reports of SJS/TEN attributed to sulindac over the last 25 years; that 39 of those reported cases resulted in death; that

[17]Indeed, one of Mutual's designated experts, Dr. Stern, co-authored the Journal of Rheumatology article, on which Bartlett's experts relied, that noted sulindac's high number and rate of SJS/TEN reports.

sulindac had both a higher number, and a higher rate, of reported cases than any other NSAID from 1980 to 1997 (and the fifth-most of any drug); and that some alternatives to sulindac carry no risk of SJS/TEN.

Mutual argues that this court should have prohibited Bartlett's experts from relying on adverse event reports, since such reports are anecdotal, sometimes unverified or incomplete, and can be influenced by non-random factors.[18] "To be sure, [both parties] agree that adverse event reports--whether published in safety databases or the medical literature--have significant limitations." In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig., 612 F. Supp. 2d 116, 153 (D. Mass. 2009) (Saris, J.). For precisely the reasons that Mutual cites, they "do not provide as much information as controlled epidemiological studies do." Id. (quoting McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1254-54 (11th Cir. 2005), and also citing In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1040 (D. Minn. 2007), both of which excluded expert testimony based on adverse event reports).

[18]One such influence, which Bartlett's experts acknowledged at trial, is known as the "Weber effect." See J.C.P. Weber, Epidemiology of adverse reactions to NSAIDs, 6 Advances in Inflammation Research 1-7 (1984) (finding that adverse event reporting peaks about two years after a drug enters the market).

As in many cases involving rare side effects, however, no controlled study of sulindac's SJS/TEN risk is currently available. Under such circumstances, "[c]ourts may, and often do, rely on ... adverse event data" to inform the analysis of a drug's risks. Id. at 153 (citing In re PPA Prods. Liab. Litig., 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003)); see also, e.g., In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 200 (S.D.N.Y. 2009) (noting that the admissibility of such data "may depend on case-specific circumstances," and stressing the "rarity" of the disease and the "relatively high number" of reports as reasons for admitting it). Despite its limitations, such data has significant probative value and is "reasonably relied upon by experts in the [pharmacological] field in forming opinions and inferences." Fed. R. Evid. 703.

Indeed, Mutual's own designated expert Dr. Stern (and his co-authors) expressly relied on adverse event data in their peer-reviewed Journal of Rheumatology article on "The risk of SJS/TEN associated with NSAIDs," which served as the basis for much of Bartlett's expert testimony on this issue. See, e.g., Mockenhaupt 2003, supra, at 2238 ("To identify NSAID[s] widely used in the US ... that have risks of SJS and TEN comparable to those of piroxicam [which had a "high risk" in a controlled study], we compared spontaneous reporting rates for all NSAID[s]," per million prescriptions, and "identified four

NSAID[s] ... with spontaneous reporting rates comparable to those of piroxicam: diflunisal, sulindac, oxaprozin, and etodolac.") (emphasis added).[19]

The FDA also expressly relied on adverse event data in its recent risk/benefit analysis of NSAIDs. See, e.g., Jenkins, supra, at 17 (noting that the "reporting rate of [SJS/TEN] appears to be greater for Bextra than other" NSAIDs). This court is not prepared to deem it unreasonable, as a matter of law, for Bartlett's experts to have done the same thing that a peer-reviewed medical journal, Mutual's own expert, and the FDA have all done. See, e.g., Crowe, 506 F.3d at 18 ("Rule 703 was enacted in part 'to bring the judicial practice into line with the practice of the experts themselves when not in court.'") (quoting Fed. R. Evid. 703, advisory committee notes (1972)); Ramirez v. Debs-Elias, 407 F.3d 444, 449 (1st Cir. 2005) ("scholarly literature is information reasonably relied upon by medical experts").

[19]As this quotation makes clear, there is no basis for Mutual's assertion that "the [unpublished] Pharmacia report's conclusion about sulindac's reporting rate was, essentially, abandoned by Dr. Stern and his co-authors in [their] subsequent, peer-reviewed article." The article expressly mentioned that sulindac had one of the five highest reporting rates among NSAIDs.

It is important to note, moreover, that Mutual extensively cross-examined Bartlett's experts about the limitations of adverse event data, and this court also took a number of steps to prevent them from overstating its significance as a measure of a drug's risk. The experts were required, for example, to use the phrase "reporting rate" in describing adverse event data, rather than "incidence rate," "occurrence rate," "rate" alone, or "relative risk."[20] This court also gave a strong cautionary instruction to the jury, both during the expert testimony and again in the final jury charge:

> You have heard testimony about the alleged number of adverse event reports of SJS/TEN associated with sulindac and other drugs, and about their alleged "reporting rates." In the context of this trial, a "reporting rate" means the number of adverse event reports for a drug divided by the number of prescriptions for a drug. You should not confuse "reporting rate" with the rate at which SJS/TEN actually occurs with a drug. Those are two different concepts. You have not heard any testimony about the actual occurrence rate of SJS/TEN with sulindac individually, as compared with other individual drugs, except for those drugs that allegedly do not have any risk of SJS/TEN.

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[20]This court orally vacated a pre-trial ruling to the extent that it would have allowed Bartlett's experts to testify about "relative risk" based on adverse event reports. See Bartlett, 2010 WL 2889114, at *14, 2010 U.S. Dist. LEXIS 111959, at *40-41. Mutual complains that this court nevertheless allowed Bartlett's experts to compare sulindac's "risk-benefit profile" to that of Bextra based, in part, on such reports. As this court explained in front of the jury, however, "risk/benefit profile" means the available information on "all risks and all benefits," not the incidence rate of SJS/TEN in particular. To the extent that there may have been any confusion on that point, this court cured it with the cautionary instruction set forth infra.

Document no. 378, at 18.

Mutual argues that, without any evidence of sulindac's actual incidence rate of SJS/TEN, the jury had no reasonable basis to "quantify" the risk. But that assumes that the only way to quantify risk is through a controlled study of the individual drug (Bartlett's experts did testify about a controlled study of acetic acid NSAIDs as a group, which found a higher risk of SJS/TEN), and hence that a plaintiff cannot prevail without such a study. It is easy to understand why Mutual would prefer such a requirement, since controlled studies can be hard for plaintiffs to come by, especially for side effects as rare as SJS/TEN. But this court is not persuaded that the New Hampshire Supreme Court would set the bar so high. Cf. Vautour, 147 N.H. at 157 (allowing jury to make risk/benefit determination despite limitations in expert testimony).

Bartlett's experts quantified sulindac's risk of SJS/TEN in other ways. They testified, for example, that the FDA received 133 reports of SJS/TEN attributed to sulindac over the past 25 years, 39 of which resulted in death, and that more than 90 percent of cases go unreported, according to FDA estimates. From that testimony, the jury reasonably could have inferred that sulindac probably caused more than a thousand cases of SJS/TEN, and hundreds of deaths, over the past 25 years (roughly 50 cases and 15 deaths per year). That is enough quantification to enable

a risk/benefit analysis, even if the jury inferred a very high number of prescriptions for sulindac.[21] While the jury certainly could have drawn other inferences from the data, or rejected some of the data for the reasons argued by Mutual, that was not the only rational approach permitted by the evidence.

Next, Mutual argues that sulindac's risk of SJS/TEN is simply too remote to result in liability for defective design. As support for that argument, Mutual invokes dicta from an old New Hampshire Supreme Court case that "in the absence of adequate warning a one-in-a-million risk of adverse reaction" to a drug is not "a sufficient basis on which to impose strict liability." Thibault, 118 N.H. at 808 (citing Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968), a failure-to-warn case). As that quote suggests, however, Thibault actually made that comment in reference to failure-to-warn claims, not defective design claims. See also Price, 142 N.H. at 390 (citing Thibault's comment in a defective design case, but with a "cf." signal, meaning that the case supported a different but analogous proposition).[22] The

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[21]Dr. Tackett testified that, at one time (1987), sulindac had been the 44th-most prescribed drug in the country, but that it had been prescribed less in other years.

[22]Indeed, the "one-in-a-million" comment has been incorporated into New Hampshire's standard jury instruction for failure-to-warn claims. See Walter L. Murphy & Daniel C. Pope, New Hampshire Civil Jury Instructions, § 23.4, at 23-5 (2007) ("This does not mean that a manufacturer must warn a user/consumer of a one-in-a-million chance of injury."). Mutual argues, in its Rule 59 motion, that this court erred by refusing

fact that a manufacturer need not have warned of a particular risk does not necessarily mean that the risk did not render its product unreasonably dangerous.

But even accepting arguendo Mutual's premise that a "one-in-a-million risk of adverse reaction" to a drug is never actionable under a defective design theory, and its further premise that the jury had no basis for concluding that sulindac's SJS/TEN risk was any greater than the background rate for all drugs, Mutual's conclusion still does not follow: per the FDA, even the background rate of SJS/TEN is greater than one-in-a-million, and the top end of the range is six-in-a-million, or one in less than 175,000. (Mutual appears to be ignoring the SJS rate and looking solely at the rate for the more serious TEN, which is lower, but still exceeds one-in-a-million at the top end.) So even if the risk-benefit analysis were strictly a quantitative mathematical calculation, without any qualitative component involving the severity of the side effect, Mutual would not be entitled to judgment as a matter of law on that basis.

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to give that instruction. But there was no failure-to-warn claim left in the case, and this court specifically instructed the jury (at Mutual's request) that Mutual's conduct in responding to sulindac's risks was "not at issue" in the case. Document no. 378, at 22. Giving the jury part of the failure-to-warn instruction, and thereby suggesting that "a manufacturer must warn a user/consumer of" certain risks, would have been inconsistent and confusing.

Of course, the risk/benefit analysis is not just a mathematical calculation. Even with perfect information about all of sulindac's risks and benefits, no mathematical formula could determine to a legal certainty how many cases of SJS/TEN, how many deaths, how many losses of sight, or how many severe skin burns is a reasonable price to pay for the relief of shoulder pain, arthritis, and other conditions that sulindac provides. It is, at bottom, a judgment call on which reasonable people could disagree. As the New Hampshire Supreme Court has explained, making those sorts of difficult risk/benefit judgments "is the very essence of the jury's function." Vautour, 147 N.H. at 157; see also 2 Frumer & Friedman, supra, § 11.03[4][d], at 11-101 ("The determination of a product's risks and benefits as a matter of law ... will rarely be granted in design defect cases if any of the elements is disputed.").

Again, under New Hampshire law, courts may override the jury's risk/benefit judgment in only two circumstances: where "the risk of harm is so remote as to be negligible," or where the "the utility of the product completely outweighs the risk." Price, 142 N.H. at 390. Neither circumstance is present here. While certainly remote, sulindac's risk of SJS/TEN cannot be considered "negligible," particularly given the severity of the disease and the estimated number of cases and deaths. See Webster's Third New International Dictionary 1514 (2002)

(defining negligible to mean "of so little consequence as to require or deserve little or no attention: trifling"). And while reasonable people could certainly conclude that sulindac's benefits outweigh its risks, the comparison is not so "completely" one-sided that no one could reasonably conclude otherwise.[23]

In sum, Mutual has not met the "stringent" standard for relief under Rule 50. Malone, 610 F.3d at 20. Viewing the evidence in the light most favorable to the verdict, this court concludes that Bartlett presented sufficient evidence for a reasonable jury to find that sulindac's risks outweighed its benefits, making it an unreasonably dangerous product. Mutual has not shown any errors or defects in the admission of that evidence that would entitle it to relief under Rule 59 either. The evidence supporting the jury's verdict was sufficiently reliable to be admitted into evidence, see, e.g., notes 8, 12,

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[23]Mutual argues that Bartlett's experts conceded that sulindac's benefits outweighed its risks by testifying that, if not removed from the market, sulindac should at least be reserved for patients who fail to respond to alternative treatments, rather than being used as a "first-line therapy." At most, however, that means that sulindac's benefits might outweigh its risks for a certain subset of patients. Under New Hampshire law, a product's design must "meet risk-utility balancing standards as seen from the point of view of the public as a whole," not just a subset of it. Price, 142 N.H. at 389 (emphasis added). Moreover, the jury was free to disregard what was essentially the experts' "backup" position. See document no. 378, at 6 (instructing the jury, without objection, that "[y]ou may accept all, part, or none of the testimony of an expert").

16, and 19, supra, and was properly disclosed to Mutual before trial where required, see, e.g., notes 9 and 11, supra. Mutual has not suffered anything "tantamount to a miscarriage of justice." Crowe, 506 F.3d at 19.

ii. Safer alternative design

The next issue raised by Mutual's Rule 50 motion is whether, in addition to proving that sulindac's risks outweighed its benefits, Bartlett needed to prove that sulindac had some other "defect" in design. Mutual argues that proof of some other "defect" is required by Buckingham, 142 N.H. at 822, and that Bartlett could not satisfy that requirement because sulindac is incapable of being designed any other way.[24] This court has already analyzed that argument at length in two prior orders. See Bartlett, 2010 WL 3239247, 2010 U.S. Dist. LEXIS 77902; Bartlett, 2010 WL 3303634, 2010 U.S. Dist. LEXIS 84924. As explained there, while Buckingham arguably supports Mutual's position, two more recent cases from the New Hampshire Supreme Court make clear that "a product is defective as designed if the

[24]Mutual also objects to this court's use of the phrase "defective condition," rather than "defect," throughout the final jury charge. But the New Hampshire Supreme Court commonly uses the phrase "defective condition" when setting forth the elements of a defective design claim, see, e.g., Vautour, 147 N.H. at 154, and so do New Hampshire's model jury instructions, see Murphy & Pope, supra, §§ 23.1 and 23.2. Indeed, even Mutual's proposed instructions repeatedly used that phrase. See document no. 254, at 4.

magnitude of the danger outweighs the utility of the product," Vautour, 147 N.H. at 154, and that "the plaintiff is not required to present evidence of a safer alternative design," Kelleher, 152 N.H. at 831.

As a federal court exercising diversity jurisdiction over a state-law action, this court "must apply the most recent statement of state law by the state's highest court." Vitkus v. Beatrice Co., 127 F.3d 936, 941-42 (10th Cir. 1997); see also, e.g., Brunner v. Hampson, 441 F.3d 457, 465 (6th Cir. 2006); Lamarque v. Mass. Indem. & Life Ins. Co., 794 F.2d 194, 196 (5th Cir. 1986); Middle Atl. Utils. Co. v. S.M.W. Dev. Corp., 392 F.2d 380, 384 (2d Cir. 1968); cf. Smith v. F.W. Morse & Co., 76 F.3d 413, 429 (1st Cir. 1996) (following the more "recently decided" New Hampshire Supreme Court case that "speaks directly to the question," rather than an older opinion). Thus, even assuming arguendo that the earlier Buckingham decision conflicts with Vautour and Kelleher, this court must follow the express language of the more recent cases.

Mutual, taking its rhetoric to new heights (or perhaps new lows), describes this court's reading of Vautour and Kelleher as "bizarre" and "tortured." But Mutual still has not been able to explain how, under its reading of those cases, a plaintiff could prove a "defect" without having to prove some safer alternative design. Mutual's position appears to be that, as stated at the

final pre-trial conference, "there has to be an alternative [design]; you just don't have to prove up the alternative." Document no. 302, at 46. Proof, though, is all that counts in determining a plaintiff's prima facie burden. And Vautour expressly states that "[t]he plaintiffs' burden was to present evidence regarding the risk-utility factors; they did not have a burden of proving a safer, alternative design."[25] 147 N.H. at 154; see also id. at 157 ("plaintiffs presented sufficient evidence that the [product] was unreasonably dangerous pursuant to the risk-utility balancing test"). As discussed in Part III.A.i, supra, Bartlett satisfied that burden.

Mutual also describes this court's reading of Vautour and Kelleher as an act of "social engineering" and predicts that, if plaintiffs can recover for defective design even where a product is unavoidably unsafe and has an adequate warning, no "prudent manufacturer would sell any product in New Hampshire."[26] Mutual

[25]In its post-trial motions, Mutual resorts to dicta from the Superior Court decision in Vautour in an unpersuasive attempt to demonstrate that the New Hampshire Supreme Court meant something other than what it expressly said. If anything, that approach strikes this court as the more unusual one, particularly where the Supreme Court reversed the Superior Court decision.

[26]As this court previously observed, Mutual's position is itself a call for social policymaking, in that it "would have the practical effect of immunizing nearly all drug manufacturers from [defective design] liability, no matter how dangerous the drug, no matter how minimal its benefits, ... and even if other, similar drugs offer the same benefits with less risk." Bartlett, 2010 WL 3303634, at *1, 2010 U.S. Dist. LEXIS 84924, at *4-5 (noting that the only exception would be drugs whose dosage or design could be altered to avoid the unreasonable danger).

seems to have forgotten, however, that this court ruled that Mutual would "avoid liability for defective design if it can prove, as an affirmative defense, that sulindac is unavoidably unsafe and had an adequate safety warning." Bartlett, 2010 WL 2765358, at *10, 2010 U.S. Dist. LEXIS 69825, at *31-32. That is the very limitation for which Mutual has been advocating (albeit in the form of a defense, not a prima facie burden). It was Mutual, not this court, that "engineered" a broader scope of liability by voluntarily withdrawing that defense on the eve of trial. See document no. 332. Presumably, not every "prudent manufacturer" will choose to follow the same strategy.

Recognizing, apparently, that its withdrawal of the "comment k" defense undermines its position, Mutual argues in its Rule 59 motion that it withdrew the defense only because this court allegedly "confirmed" that doing so would render inadmissible any evidence regarding sulindac's warning, and that this court went back on that promise at trial, in violation of Mutual's due process rights. But that is not what happened. This court expressly reserved judgment on that evidentiary issue, both in its limine rulings, see Bartlett, 2010 WL 3092649, at *5 n.5, 2010 U.S. Dist. LEXIS 111259, at *14-15, and at the final pre-trial conference, during which Mutual first suggested that it might withdraw the defense (and another defense, known as "state of the art," see N.H. Rev. Stat. § 507:8-g), and Bartlett

responded that warning-related evidence could be presented at trial anyway. See document no. 301, at 98-99; document no. 302, at 30-32, 52-54.

After the final pre-trial conference, this court expressly ordered that "[i]f Mutual withdraws the [state of the art] defense, then [its] procedures [for monitoring sulindac's risks] will no longer be relevant and thus will not be presented to the jury." Bartlett v. Mut. Pharm. Co., 2010 WL 3219357, at *2 n.5, 2010 U.S. Dist. LEXIS 92403, at *5 (document no. 329). This court never made any such statement with regard to the "comment k" defense and warning-related evidence. A few days before trial, Mutual informed the court during a conference call that it would decide "by the end of the day with regard to both [its] state of the art and unavoidably unsafe [defenses] whether we're withdrawing those defenses so that what is left is only no label issues and only the issue about unreasonably dangerous." Document no. 353, at 37. This court replied with a one-word "understood," id., and moved on to other pressing topics.

Mutual announced its withdrawal of both defenses later that day, see document no. 332, and Bartlett responded by immediately seeking a pre-trial ruling on the admissibility of warning-related evidence, see document no. 339. Mutual quickly filed two briefs arguing against the admission of such evidence, see documents no. 341, 342, and this court held another conference

call with the parties devoted specifically to that issue. Not once did Mutual suggest, either in its briefs or during the conference call, that it believed this court (apparently by saying the word "understood" on the earlier conference call) had already promised to exclude warning-related evidence if Mutual withdrew its "comment k" defense. That fact alone belies Mutual's argument that it withdrew its "comment k" defense based on this court's ruling that doing so would eliminate any warning-related evidence from trial.

On the day before trial, this court ruled that warning-related evidence would be admissible, to a limited extent, with regard to the issue of whether sulindac was unreasonably dangerous. See Bartlett, 2010 WL 3303864, 2010 U.S. Dist. LEXIS 102603. Thus, while Mutual was indeed left with "only the issue about unreasonably dangerous" (to use its phrase from the earlier conference call), the warning still had some potential relevance to that issue. The first footnote of that same order explained that "Mutual recently withdrew its 'comment k' defense," and that "[u]ntil 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." Id. 2010 WL 3303864, at *1 n.1, 2010 U.S. Dist. LEXIS 102603, at *3-4 (citing Bartlett, 2010 WL 3092649, at *5 n.5, 2010 U.S. Dist. LEXIS 111259, at *14-15).

Mutual never moved for reconsideration of that ruling, never disputed the order's account of the procedural history (until its Rule 59 motion), and even more importantly, never sought to reinstate its "comment k" defense on the ground that the withdrawal had been contingent on the exclusion of warning-related evidence (even throughout the trial, as Bartlett introduced the very evidence that Mutual now says it thought was inadmissible). Indeed, Mutual did not even ask this court to instruct the jury on the "comment k" defense. By failing to raise the issue in a timely manner, when this court easily could have afforded relief, Mutual waived its due process argument. See, e.g., United States v. Carpenter, 494 F.3d 13, 30 (1st Cir. 2007) ("the raise-or-waive rule ... precludes a party from making a tactical decision to refrain from objecting, and subsequently, should the case turn sour, assigning error," without having "afford[ed the trial court] an opportunity to correct the problem").

Even if Mutual's argument not been waived, it would be difficult for this court to view the argument as anything more than an unfounded, post hoc attempt to shirk responsibility for a voluntary strategic decision. Mutual has not shown any unfairness whatsoever relating to its withdrawal of the "comment k" defense, and certainly is not entitled to a new trial on that basis. Nor, in light of that withdrawal, is Mutual entitled to

judgment as a matter of law on the ground that sulindac is unavoidably unsafe, which (together with the adequacy of sulindac's warning) is an issue that Mutual itself chose to remove from the case.

iii. Safer alternative product

The next issue raised by Mutual's Rule 50 motion is whether Bartlett needed to present evidence of a safer alternative product (as opposed to a safer alternative design). Mutual argues that such proof is also required under New Hampshire law and that Bartlett failed to provide it. But Mutual has not cited, nor can this court find, any authority for such a requirement. Cf. Heath v. Sears, Roebuck & Co., 123 N.H. 512, 530 (1983) (noting that "mere compliance with current industry practice" is not "a defense to [to defective design] liability" under New Hampshire law). Moreover, Mutual's argument is undermined by the fact that it objected--successfully--to this court's proposed instruction that the jury, in weighing sulindac's risks and benefits, could "consider whether there were alternative products on the market that provided the same benefits as sulindac, but with less risk."

Mutual argued, at the time, that the proposed instruction was inconsistent with a later instruction, included in the final jury charge, that "a manufacturer is not obliged to design the

safest possible product, ... or one as safe as others make, so long as the design it has adopted is not unreasonably dangerous." Document no. 378, at 15-16 (quoting Thibault, 118 N.H. at 808). But there was no inconsistency: a jury can consider a factor without it being dispositive.[27] That is clearly the role that a safer alternative design plays under New Hampshire case law, see Vautour, 147 N.H. at 156 ("proof of an alternative design is ... neither a controlling factor nor an essential element"), and there is no reason to believe that a safer alternative product would be treated any differently.

While not required to do so, Bartlett presented considerable evidence for the jury to consider with regard to safer alternative products. See Part III.A.i, supra. For example, her experts testified that sulindac is part of two NSAID groups--acetic acid NSAIDs and longer half-life NSAIDs--believed to have a greater risk of SJS/TEN than other NSAIDs, with no greater benefits (aside from the "longer benefit" associated with having a longer half-life). In addition, they testified that aspirin and Tylenol, while perhaps not perfect alternatives to sulindac, have no risk of SJS/TEN, are equally effective in treating conditions like shoulder pain (for which Bartlett took sulindac),

[27]Out of an abundance of caution, this court nevertheless granted Mutual's request to exclude the proposed instruction, allowing Bartlett to argue the point in her closing, but not instructing on it.

have additional benefits that sulindac does not have, and are safer alternative products overall.

Mutual argues that, to be considered a safer alternative, a product must be equally effective and less dangerous in all respects, not just overall. But in Vautour, where the plaintiffs' expert testified that "under similar circumstances [to those encountered by the plaintiff], machines with [an alternative] design would be, overall, less dangerous," the New Hampshire Supreme Court concluded that it "was up to the jury to assess the weight to be given this testimony." 147 N.H. at 157 (emphases added). Again, there is no reason to believe that safer alternative products would be treated any differently from safer alternative designs. So it was up to the jury, in assessing sulindac's risks and benefits, to determine how much weight (if any) to give Bartlett's evidence regarding safer alternative products.

iv. Causation

The next issue raised by Mutual's Rule 50 motion is whether Bartlett presented sufficient evidence of causation. See, e.g., Vautour, 147 N.H. at 154 (requiring proof that the product's defective "condition caused injury to the user"). Mutual argues that Bartlett failed to do so, because she presented "no evidence whatsoever that any alternative design would have avoided [her]

injury."[28] As already explained, however, the New Hampshire Supreme Court has expressly ruled that "the plaintiff is not required to present evidence of a safer alternative design." Kelleher, 152 N.H. at 831. By the same token, a plaintiff is not required to prove that the alternative design would have avoided her injuries. See Vautour, 147 N.H. at 153 (ruling that plaintiffs presented trialworthy claim even though their "expert failed to offer any testimony regarding ... how his proposed alternative design would prevent the type of injuries suffered").

Mutual also argues that, since this court allowed the jury to consider whether sulindac's warning avoided an otherwise unreasonable danger, see Bartlett, 2010 WL 3303864, at *4, 2010 U.S. Dist. LEXIS 102603, at *11 (citing Vautour, 147 N.H. at 154), there was no causation because Bartlett's doctor never read that warning.[29] But Mutual never "distinctly articulated" that

[28]Mutual also argues that this court's use of a general verdict form made it "impossible to determine if [the jury] concluded that plaintiff satisfied each element of a design defect claim," including causation. But the final jury charge made clear that "to recover on her claim for strict products liability, Mrs. Bartlett must prove each of the ... elements by a preponderance of the elements." Document no. 378, at 14. Given that instruction, there is no reason to doubt that the jury found Bartlett had proven each element. See, e.g., United States v. Gentles, 619 F.3d 75, 82 (1st Cir. 2010) ("It is a well established tenet of our judicial system that juries are presumed to follow [the court's] instructions."); Goulet v. New Penn Motor Express, Inc., 512 F.3d 34, 43 n.6 (1st Cir. 2008) (finding no fault with the use of general verdict form where "the jury was amply instructed" on the requirements for liability).

[29]As discussed supra, that was why this court granted summary judgment to Mutual on Bartlett's failure-to-warn theory.

argument in its close-of-evidence motion for a directed verdict under Rule 50(a), so it cannot be raised now. Parker v. Gerrish, 547 F.3d 1, 12 (1st Cir. 2008) (explaining that a Rule 50(b) motion "is bounded by the movant's earlier Rule 50(a) motion"). Indeed, this court cannot find any warning-related arguments that Mutual "distinctly articulated" in its Rule 50(a) motion and then renewed in its Rule 50(b) motion.[30] So for Rule 50 purposes, at least, sulindac's warning is no longer at issue.

Moreover, even if properly raised, Mutual's warning-related causation argument would fail on the merits. The warning was not sulindac's defective condition; the unreasonable danger was. See document no. 378, at 16 (instructing the jury that it could consider the warning only if it determined, first, that sulindac was unreasonably dangerous, and even then, only to determine whether the warning avoided the unreasonable danger); Bartlett, 2010 WL 3303864, 2010 U.S. Dist. LEXIS 102603. The fact that Bartlett's doctor never read a warning that, in the jury's view, did not eliminate sulindac's unreasonable danger, was of no consequence. The chain of causation on a defective design claim does not run through the warning. See, e.g., Vautour, 147 N.H.

See Bartlett, 2010 WL 2765358, at *5-8, 2010 U.S. Dist. LEXIS 69825, at *14-27.

[30]See Part III.B.iii, infra (discussing Mutual's warning-related pre-emption argument, which was raised in the Rule 50(a) motion but not again until the Rule 50(b) reply).

at 154 (requiring only proof that the defective "condition caused injury to the user").

Mutual argues, finally, that "unreasonable danger does not cause an injury." Again, however, Mutual never "distinctly articulated" that argument in its Rule 50(a) motion, so it cannot be raised now under Rule 50(b). Parker, 547 F.3d at 12. Moreover, even if properly raised, the argument would fail on the merits. What made sulindac unreasonably dangerous, according to Bartlett, was "its inherent propensity to cause SJS/TEN." That was the (sole) theory that Bartlett presented to the jury, both in her opening statement and her closing argument (using the quoted language both times).[31] The evidence was overwhelming, and essentially uncontested, that Bartlett suffered SJS/TEN as a side effect of sulindac. So there was sufficient evidence for the jury to find causation.

B. *Federal pre-emption*

The other issue raised by Mutual's Rule 50 motion, in addition to the sufficiency of the evidence, is federal pre-emption. "A fundamental tenet of our federalist system is that constitutionally enacted federal law is supreme to state law.

[31]Mutual protests that this court never instructed the jury on that theory. But Bartlett sought such an instruction in the final jury charge, and Mutual successfully opposed it, persuading this court that it might be misconstrued as implicitly endorsing the theory.

See U.S. Const. art. VI cl. 2. As a result, federal law sometimes pre-empts state law either expressly or by implication." N.H. Motor Transp. Ass'n v. Rowe, 448 F.3d 66, 74 (1st Cir. 2006), aff'd, 552 U.S. 364 (2008). Federal "pre-emption is an affirmative defense upon which [the] defendant bears the burden of proof." Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co., 510 F.3d 77, 102 (1st Cir. 2007); see also Wyeth, 129 S. Ct. at 1193 (characterizing a manufacturer's argument that federal drug law pre-empted the plaintiff's claims as a defense). Here, Mutual has made essentially four different pre-emption arguments. This court will address each of them in turn.

i. "Second-guessing" the FDA

First, Mutual argues that federal law (specifically, the FDCA and related FDA regulations) impliedly pre-empts any state-law tort claim that requires the jury to "second-guess" the FDA's risk/benefit analysis of a drug, because such claims "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[32] Good v. Altria Group, Inc., 501 F.3d 29, 47 (1st Cir. 2007), aff'd, 555 U.S. 70 (2008)

[32]It is worth noting that Mutual did not raise this pre-emption argument in its earlier motions for judgment on the pleadings or for summary judgment, which raised the other pre-emption arguments discussed infra.

(describing the doctrine of obstacle pre-emption). As support for that argument, Mutual relies on Geier v. American Honda Motor Co., 529 U.S. 861 (2000), where the Supreme Court held that a federal regulation that called for a gradual phase-in of airbags in cars pre-empted state-law tort claims based on a manufacturer's failure to install airbags earlier, because such claims presented an obstacle to achieving Congress's objectives, which included winning consumer acceptance of airbags and spurring further technological innovation during the phase-in period.

This case, however, has very little (if anything) in common with Geier. It has much more in common with Wyeth, 129 S. Ct. at 1187, a more recent case where a drug manufacturer argued--much like Mutual does here--that "because the FDCA requires the FDA to determine that a drug is safe and effective under the conditions set forth in its labeling, the agency must be presumed to have performed a precise balancing of risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments." Id. at 1200. The Supreme Court rejected that argument, concluding that the regulatory framework applicable to prescription drugs is "quite different" from the one in Geier and that "the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." Id. at 1202-03.

Wyeth is arguably not directly controlling here, because it involved a failure-to-warn claim, not a defective design claim. But this court cannot see, nor has Mutual articulated, any reason why Wyeth's logic would not extend to this closely analogous context. Cf. Wimbush v. Wyeth, 619 F.3d 632, 645 (6th Cir. 2010) (concluding that Wyeth's "rationale extends beyond the realm of failure-to-warn claims to apply to all pre-approval state law claims," including, in that case, a claim of negligence in bringing an FDA-approved drug to the market). Mutual has not cited any cases, before or since Wyeth, that interpreted federal law as prohibiting juries from deeming an FDA-approved drug to be more risky than beneficial. See Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528, 537 (6th Cir.), cert. denied, 510 U.S. 914 (1993) ("reject[ing] the argument that FDA approval pre-empts state product liability claims based on design defect," and

noting that the "great majority" of courts had done the same[33]). Mutual's pre-emption argument is therefore rejected.

Relatedly, Mutual argues in its Rule 59 motion that this court violated due process by allowing Bartlett to "attack" the FDA's decision to approve sulindac, thereby "putting the FDA on trial" even though it was not a party to the case and even though "plaintiff's claims were not related to FDA or its actions related to sulindac." But even assuming, dubitante, that Mutual has standing to raise the due process rights of a non-party, that argument clearly has no merit. The FDA's "actions related to sulindac" were quite relevant to Bartlett's claim. See Fed. R. Evid. 401 (evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence ... more or less probable"). Indeed, Mutual repeatedly emphasized the FDA's approval of sulindac throughout the trial. If anything, it would have violated Bartlett's due process rights to allow Mutual to

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[33]Tobin, incidentally, belies Mutual's repeated refrain that this case is unprecedented in holding a drug manufacture liable for defective design under a risk/benefit analysis. In that case, which involved injuries caused by the drug ritodrine, the Sixth Circuit agreed with the manufacturer that (as here) the plaintiff could not recover on her failure-to-warn theory due to a lack of causation, id. at 536, but nevertheless upheld a jury verdict of liability on a defective design theory, where (as here) "evidence of the risks and benefits associated with ritodrine were a main focus" at trial, id., and the plaintiff's theory was that the drug posed a risk of "disturbing" side effects, id. at 539, with only "some benefit," id. at 537 n.8. The Sixth Circuit ruled that there was sufficient evidence for the jury to disagree with the FDA's risk/benefit analysis. Id. at 538.

use the FDA's approval as a shield to liability, without allowing Bartlett to challenge it.

ii. Design pre-emption for generic drugs

Second, Mutual argues that federal law (again, the FDCA and related FDA regulations) prohibited manufacturers from unilaterally changing the design of a generic drug, thus making "compliance with both state and federal law ... impossible." Good, 501 F.3d at 47 (describing the doctrine of impossibility pre-emption). As already explained, however, Mutual was not held liable for failing to change sulindac's design; it was held liable for selling an unreasonably dangerous product, with greater risks than benefits. Federal law did not require Mutual to sell sulindac. Nor, for that matter, did state law require Mutual to stop selling it, or to redesign it. See Bartlett, 2010 WL 3092649, at *8, 2010 U.S. Dist. LEXIS 111259, at *24 ("what strict products liability requires is that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market" or "retrofit" them) (citing 5 Frumer & Friedman, supra, § 57.01[4], at 57-9). So it was not "impossible" for Mutual to comply with both federal and state law. Cf. Barnett Bank of Marion County, N.A. v. Nelson, 517 U.S. 25, 31 (1996) (explaining that impossibility pre-emption arises

"if the federal law said, 'you must sell insurance,' while the state law said, 'you may not'").

iii. Warning pre-emption for generic drugs

Third, Mutual attempts in its reply brief on its Rule 50 motion to raise the pre-emption argument that it advanced unsuccessfully earlier in this case: that federal law (again, the FDCA and related FDA regulations) prohibited manufacturers from unilaterally changing the warning for a generic drug, thus making it impossible for Mutual to comply with both federal and state law. See Bartlett, 659 F. Supp. 2d at 279 (concluding that federal law allowed such changes and therefore did not pre-empt Bartlett's claims); accord Demahy, 593 F.3d at 428; Mensing, 588 F.3d at 603. Mutual failed, however, to raise that warning-related pre-emption argument in its opening brief in support of either of its post-trial motions. The argument is therefore waived. See, e.g., Doe v. Friendfinder Network, Inc., 540 F. Supp. 2d 288, 303 n.16 (D.N.H. 2008); L.R. 7.1(e)(1) (reply is "restricted to rebuttal of factual and legal arguments raised in the objection").[34]

[34]The same is true of Mutual's argument that this court erred by failing to instruct the jury that Mutual could not change its warning, which also appeared for the first time in the reply brief. Moreover, such an instruction would have been inconsistent with the instruction set forth in the next paragraph, infra, which is presumably why Mutual did not object to the final jury charge on that basis.

The argument is also moot, since this court granted summary judgment to Mutual on Bartlett's failure-to-warn theory, see Bartlett, 2010 WL 2765358, at *5-8, 2010 U.S. Dist. LEXIS 69825, at *10-14, and Mutual withdrew its "comment k" defense, see document no. 332, thereby eliminating from the case the issue of whether Mutual could have or should have strengthened sulindac's warning. Indeed, this court expressly instructed the jury (at Mutual's request) that Mutual's "conduct in ... responding" to sulindac's safety risks, which included any failure to change its warning, was "not relevant to this case, and you should put [it] out of your mind." See document no. 378, at 22.[35] Mutual protests that the warning was still a part of the case, which is true, but not in the sense that Mutual could have been held liable for failing to change it. See Bartlett, 2010 WL 3303864, at *1, 2010 U.S. Dist. LEXIS 102603, at *4 ("Bartlett "must prove that sulindac was unreasonably dangerous despite its warning, not because of it.").

Moreover, even if it were neither waived nor moot, this court would reject Mutual's argument on the merits, for the

[35]As this court explained in a previous ruling, strict liability "claims focus on the product itself rather than the defendant's conduct." Bartlett, 2010 WL 3659789, at *12, 2010 U.S. Dist. LEXIS 96711, at *38 (citing 2 Frumer & Friedman, supra, § 14.03[1][b], at 14-35, and Racer v. Utterman, 629 S.W.2d 387, 395 (Mo. App. Ct. 1981), which noted that "most ... courts have treated strict liability in tort as a doctrine which looks to the product not to the conduct of the manufacturer" and that "liability arises because of the condition of the product regardless of the care exercised by the manufacturer").

reasons explained at length in its earlier opinion. See Bartlett, 659 F. Supp. 2d at 279. Mutual argues that a recent amicus brief filed by the United States Solicitor General in Mensing calls this court's reasoning into question. See Brief of the United States as Amicus Curiae, 2010 WL 4339894, at *13, Pliva, Inc. v. Mensing, No. 09-993 (U.S. Nov. 2, 2010) (stating, albeit with limited discussion, that the manufacturer of a generic drug "may not unilaterally change its approved labeling"). But the Solicitor General's view is not dispositive. See Wyeth, 129 S. Ct. at 1201-04 (disagreeing with Solicitor General's view on a similar issue). This court still finds the reasoning in its earlier opinion--and later adopted in Demahy, 593 F.3d at 440--to be more persuasive.

iv. *Buckman* pre-emption

Finally, in what amounts to a fourth pre-emption argument, Mutual argues in its Rule 59 motion that this court erred by allowing the jury, in determining whether sulindac's warning avoided an otherwise unreasonable danger, to consider whether the warning complied with FDA labeling requirements, because only the federal government has authority to enforce those requirements. See 21 U.S.C. § 337(a) ("all such proceedings for the enforcement [of the FDCA] "shall be by and in the name of the United States"). As support for that proposition, Mutual relies on

Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), where the Supreme Court held that state-law claims for fraud-on-the-FDA were impliedly pre-empted by the FDCA, in part because they would interfere with the FDA's statutory power to enforce its own disclosure requirements. Id. at 349.

Buckman pre-emption, however, applies where a state-law claim arises "solely from the violation of FDCA requirements." Id. at 352-53. That is not even close to the situation here. This court instructed the jury that "compliance or non-compliance with FDA labeling requirements is not necessarily conclusive or controlling" on the issue of whether sulindac's warning avoided an otherwise unreasonable danger, and could be given "as much or as little weight as you think it deserves, in light of all the evidence." Document no. 378, at 19. Moreover, this court instructed the jury that it could not even consider sulindac's warning and the FDA requirements unless it determined, first, that sulindac was unreasonably dangerous. Id. at 16, 19. So Bartlett's claim did not arise from a violation of FDA requirements at all (much less "solely"); it arose from sulindac's unreasonable danger.

Mutual has not cited any authority for extending Buckman pre-emption to this very different context. Indeed, there is a split of authority regarding whether Buckman pre-emption even extends to negligence claims where FDA regulations establish a

per se standard of care. See Bartlett, 2010 WL 2765358, at *13-14, 2010 U.S. Dist. LEXIS 69825, at *42 (citing cases on both sides of that issue). This case is far removed even from that. Moreover, even assuming dubitante that this court erred by instructing the jury on the FDA's labeling requirements, Mutual has not shown that doing so was "tantamount to a miscarriage of justice." Crowe, 506 F.3d at 19. Mutual made the FDA's approval of sulindac's warning a point of emphasis throughout the trial. It was not unjust for the jury to be told what the FDA's standards for approval were and to be able to consider them in evaluating the warning.[36]

C. *Judicial conduct*

Having determined that Bartlett presented sufficient evidence to support her claim and that the claim is not pre-empted by federal law, this court will now turn to the remaining issues raised by Mutual's Rule 59 motion. The first such issue relates to this court's conduct. Mutual argues that a new trial is necessary because "the proceedings were not being conducted in an impartial fashion," but rather in such a way as to favor Bartlett and disfavor Mutual. As support for that argument, Mutual points to a handful of comments and actions by this court

[36]Mutual has not made any Rule 50 argument for Buckman pre-emption, either at the close of evidence or post-trial, so to that extent the argument is waived. See Parker, 547 F.3d at 12.

that, in its view, suggest judicial bias. As explained below, however, Mutual has taken those comments and actions out of context, or otherwise misconstrued them. This court sincerely meant what it said in the final jury charge: that it "is neutral and impartial in this matter and does not take sides." Document no. 378, at 32.

It is important, in considering Mutual's specific allegations of bias, to keep in mind the bigger picture. See, e.g., United States v. DeCologero, 530 F.3d 36, 56 (1st Cir. 2008) ("Charges of partiality should be judged not on an isolated comment or two, but on the record as a whole."). This is a case where the court granted summary judgment to Mutual on nearly all of Bartlett's claims, one of them sua sponte. See Bartlett, 2010 WL 2765358, 2010 U.S. Dist. LEXIS 69825; Bartlett, 2010 WL 3659789, 2010 U.S. Dist. LEXIS 96711. Moreover, this court kept a tight rein on Bartlett's counsel throughout the trial, as described in Part D, infra. It is understandable, then, that Bartlett's counsel regard Mutual's judicial bias argument as "totally contrary to the plaintiff's experience during the entirety of this case including every minute of trial." Document no. 409-1, at 4.

Moreover, it should be noted that Mutual's purported examples of judicial bias--culled from a nearly three-year litigation requiring hundreds of pre-trial rulings, and

culminating in a three-week trial--come nowhere near the kind of conduct that our court of appeals has deemed insufficient to demonstrate judicial bias or require a new trial. See United States v. Rodriguez-Rivera, 473 F.3d 21, 28 (1st Cir. 2001) (collecting cases where "stern[] rebukes of counsel or litigants [were] insufficient to demonstrate judicial bias," including trial judges' calling plaintiff "an absolute and incorrigible liar," referring to defense counsel's cross-examination as "very devious," and warning counsel he was being reported for violating the rules of professional conduct).

i. Ruling on motion before sur-reply

First, Mutual points to a ruling that this court made on a motion to strike filed by Bartlett, before Mutual had filed its sur-reply.[37] The motion sought to strike Mutual's expert Dr. Stern for failing to produce the Pharmacia report (discussed in Part III.A.i, supra). After reviewing Bartlett's motion, Mutual's objection, and Bartlett's reply, this court granted the motion in part. See document no. 251. While not striking Dr. Stern altogether, this court agreed with Bartlett that the report should have been disclosed earlier and, given its potential significance, ordered that Dr. Stern (and one other defense

[37]To the extent that Mutual refers to other unidentified "motions," its argument is conclusory and insufficiently developed.

expert) be made available for supplemental depositions regarding the report. At that point, only one month remained until trial, so time was of the essence.

Shortly after this court's order, Mutual sought leave to file a sur-reply. While not required to accept a sur-reply on a non-dispositive motion, see L.R. 7.1(e)(3) ("leave to file a surreply will only be granted under extraordinary circumstances"), this court nevertheless granted Mutual's request and then issued another order--longer than the first--analyzing and rejecting the arguments raised in Mutual's sur-reply. See Bartlett v. Mut. Pharm. Co., 2010 WL 2990824 (document no. 272). This court gave the sur-reply full consideration, and did so with an open mind. Mutual may have disliked the result, but neither the result nor the process leading up to it reflects judicial bias. See also, e.g., Bartlett, 2010 WL 3303634, 2010 U.S. Dist. LEXIS 84924 (giving full consideration to Mutual's motion to reconsider the denial of an earlier motion to reconsider).

ii. Comments during discovery hearing

Next, Mutual points to this court's statement, made during a discovery-related hearing in October 2009, that Mutual is a "giant corporation" represented by "experienced counsel" from a "huge law firm." It is important to put those statements in their proper context. The issue before the court during that

hearing was whether to sanction Mutual under Fed. R. Civ. P. 37(c)(1) for failing to timely produce certain FDA filings that Bartlett had specifically requested in discovery. See Bartlett v. Mut. Pharm. Co., 2009 DNH 166, 2009 WL 3614987, 2009 U.S. Dist. LEXIS 102494 (imposing some, but not all, of the sanctions Bartlett sought); but see document no. 125 (disallowing the monetary part of the sanctions after Bartlett failed to timely submit an itemized bill).

Mutual, as part of its argument against sanctions, alleged that Bartlett, too, had failed to produce certain documents kept in her home, but explained that Mutual had declined to seek sanctions on that basis, considering it unprofessional. This court responded that "your point is well taken," but noted that the analysis of whether a discovery error is substantially justified under Rule 37(c)(1) might be "a little bit different" for "Mutual with its ... experienced counsel with 20 years experience in this type of litigation" than for "a plaintiff who is disabled and has probably never been ... in a litigation before." This court went on to clarify:

> I'm not going to hold [Bartlett] to a different standard than you. That's not what I mean to say. You probably get sick of hearing that you're the giant corporation with the huge law firm, but you deal with this every day, and to me there's a difference between dropping the ball on this discovery request and a plaintiff who left some [documents in her house]."

Document no. 99, at 46-47.

As that context makes clear, this court was not denigrating Mutual as a "giant corporation with [a] huge law firm;" to the contrary, it was acknowledging that such characterizations can be tiresome. Nevertheless, this court was expressing skepticism about Mutual's suggested analogy between its failure to produce its FDA filings, which "are standard fare for discovery in pharmaceutical litigation of this sort," Bartlett, 2009 WL 3614987, at *4, 2009 U.S. Dist. LEXIS 102494, at *12, and Bartlett's failure, as a blind plaintiff, to locate certain documents in her home and produce them. Whatever one may think of that analogy and this court's response to it, neither had any bearing on the sanctions ruling (which was based on Mutual's discovery error, not how it compared with Bartlett's alleged error) or any other ruling in this case.

iii. Comments during trial conference

Next, Mutual points to this court's comment, made during a trial conference conducted outside the presence of the jury, that "I want you to prove your case if you can." Mutual interprets that statement to mean that this court wanted Bartlett to prevail on the merits. But that is not at all what the court was saying, as the context again makes clear. The court was in the process of explaining to Bartlett that one of the opinions given by her expert Dr. Tackett (regarding sulindac's risk of liver toxicity)

had not been properly disclosed in his expert report and that the court would be instructing the jury to disregard that testimony. In other words, the court was in the process of granting relief requested by Mutual.

Before granting that relief, this court asked Bartlett if she could identify "anything remotely representing [a disclosure of Dr. Tackett's opinion] to try to give you the benefit of the doubt because you are the plaintiff and I want you to prove your case if you can--I want you to be able to prove your case without barriers from me." This court did not mean, by that statement, that it wanted Bartlett to prevail over Mutual in the end. Rather, this court meant only that it wanted Bartlett to be able to present her case without any artificial barriers from the court--provided she stayed within the confines of the Federal Rules of Evidence and Civil Procedure. Perhaps, in retrospect, the point could have been better worded, but it was not reflective of judicial bias.

iv. "Smoking gun"

Next, Mutual complains that this court, outside the presence of the jury, referred to the Pharmacia report as a "smoking gun." That was how Bartlett referred to the report in her filings. See document no. 230-1, at 6 ("This document, quite literally, is the smoking gun of smoking guns."). This court did not agree with

that over-the-top characterization; to the contrary, it told the parties early in the trial that "I am much less inclined to think that [the report] has anything approaching the smoking gun." Nevertheless, this court used the phrase "smoking gun," or "so-called smoking gun," as a shorthand that the parties would instantly recognize. The jury never heard that phrase, so it obviously had no affect on the trial or the verdict. Nor did its use reflect judicial bias.

v. Rephrasing questions

Next, Mutual points to a few occasions during trial when this court rephrased questions by Bartlett's counsel that were leading or lacking in foundation. But this court did not intervene on those occasions out of favor for Bartlett; it did so to fulfill its responsibility to "exercise reasonable control over the mode ... of interrogating witnesses and presenting evidence so as to (1) make the interrogation and presentation effective for the ascertainment of the truth," and "(2) avoid needless consumption of time." Fed. R. Evid. 611(a); see also Nat'l R.R. Passenger Corp. v. Certain Temporary Easements, 357 F.3d 36, 42 (1st Cir. 2004) ("Decisions regarding the mode ... of witness questioning lie within the district court's broad discretion").

Contrary to what Mutual suggests, this court's involvement in questioning was quite minimal; it did not "advantage or disadvantage a party unfairly," or indeed at all. United States v. Angulo-Hernandez, 565 F.3d 2, 10 (1st Cir. 2009) (concluding that even a "court's rather frequent questioning and commentary" did not cross the line, where the court's intent was "to clarify testimony, respond to defense counsels' objections, ... and expedite the trial, all legitimate purposes"); cf. also Rodriguez-Rivera, 473 F.3d at 27-28 (similar); Raviart v. Yates, No. 03-0164, 2007 WL 2505575, *14, 2007 U.S. Dist. LEXIS 64712, at *38 (E.D. Cal. Aug. 31, 2007) (concluding that "the trial judge's involvement in the questioning of witnesses did not bespeak a bias in favor of the prosecution or otherwise render petitioner's trial fundamentally unfair").

vi. Blowing nose and wiping eyes

Finally, Mutual argues that this court gave at least an appearance of partiality by blowing its nose and wiping its eyes during some emotional testimony by Bartlett's sister. But this court specifically addressed that issue with the jury (after Mutual raised concerns the next morning), explaining that "as a matter of fact I did not have an emotional reaction to that testimony. I was merely blowing my nose and dealing with a little allergic, itchy eye." Many of the jurors nodded in

understanding. This court further instructed the jury that even if someone observing the trial were to have an emotional reaction to the evidence presented, it would not have "any bearing upon this case" and "wouldn't be something you should consider one way or the other." Those frank instructions cured any possible prejudice to Mutual. See, e.g., Rodriguez-Rivera, 473 F.3d at 28-29 ("such a charge usually mitigates any perceived partiality from the bench").

D. *Counsel's conduct*

The next issue raised by Mutual's Rule 59 motion relates to the conduct of Bartlett's counsel. Mutual argues that a new trial is necessary because, from voir dire to closing argument, Bartlett's counsel "engaged in conduct designed to improperly inflame and influence the jury." In determining whether allegedly improper conduct by counsel warrants a new trial, "the court must examine the totality of the circumstances, including (1) the nature of the comments; (2) their frequency; (3) their possible relevance to the real issues before the jury; (4) the manner in which the parties and the court treated the comments," including any curative instructions; "(5) the strength of the case; and (6) the verdict itself." Granfield v. CSX Transp., Inc., 597 F.3d 474, 490 (1st Cir. 2010).

As explained below, there is no question that Bartlett's counsel made this court's job at trial more difficult than it needed to be, repeatedly testing the limits of this court's rulings (not to mention its patience). Anticipating just such an approach, however, this court kept a tight rein on Bartlett's counsel throughout the trial, imposing various restrictions to prevent misconduct, stopping counsel whenever they pushed too far (sometimes in response to Mutual's objections, but often sua sponte), giving curative instructions or other relief where appropriate (again, often sua sponte), and even reprimanding counsel in front of the jury a few times. As a result, whether or not counsel's conduct was "designed to improperly inflame and influence the jury," this court is confident that it did not have that effect.

i. Voir dire

First, Mutual argues that Bartlett's counsel improperly asked prospective jurors, during attorney-conducted voir dire, whether they would be unable to award damages greater than $20 million. But this court sustained Mutual's objection to that question and prohibited Bartlett's counsel from using specific dollar figures from that point forward. Bartlett had expressly disclosed before trial that she intended to ask such questions and, indeed, argued that she was entitled to do so. See document

no. 259, at 3 (citing Geehan v. Monahan, 382 F.2d 111, 115 (7th Cir. 1967)). So if Mutual wanted to prevent the questions from being asked at all, it should have filed a specific objection before trial, rather than merely objecting in general to Bartlett's request for attorney-conducted voir dire, and then waiting to object to specific questions after they had already been asked.

In any event, this court is not persuaded that the limited questioning about a specific damage figure caused any prejudice to Mutual, especially in light of this court's immediate intercession.[38] This court expressly instructed the jury, in the final charge, that any amount mentioned by Bartlett's counsel was "not evidence in this case" and that any damage award needed to be "based solely on the evidence presented during the course of the trial." Document no. 378 at 28.[39] As explained in Part

[38]Indeed, there is a split of authority on whether such questioning is even improper in the first place. See Richard L. Ruth, Propriety of inquiry on voir dire as to juror's attitude toward amount of damage awards, 63 A.L.R.5th 285, §§ 2[a] and 3[a] (1998) (noting that "several courts have established as a general rule that a party may inquire on voir dire as to prospective jurors' attitudes toward specific damage figures," though some courts have disagreed, as this court did by sustaining Mutual's objection).

[39]During an in-chambers conference before the final jury charge, Bartlett's counsel disclosed that they also planned to request a specific amount in closing (which turned out to be "between $20 and $30 million"). The parties agreed to the instruction set forth above as a means of addressing that request. Mutual did not object to the request then, or when it happened, and has not raised it as an issue in its Rule 59 motion. In light of that, it is nearly impossible to imagine

III.F, supra, this court has no reason to believe that the jury ignored that instruction.

ii. Demonstrative aids

Next, Mutual argues that Bartlett's counsel misused two demonstrative aids: a visual presenter known as an "Elmo," on which Bartlett's counsel allegedly left exhibits for longer than necessary, and an easel, on which Bartlett allegedly summarized evidence in a misleading fashion. But this court, after noticing some initial misuse of those aids, severely restricted Bartlett's counsel in the use of both (in addition to correcting, by way of a contemporaneous instruction, the misleading information on the easel). Specifically, this court restricted Bartlett's counsel to publishing exhibits on the Elmo only while asking the witness a question to which the exhibit related. And this court prohibited Bartlett's counsel from referring back to the easel during closing argument. Those restrictions prevented any possible prejudice to Mutual.

iii. Staging dramatic moments

Next, Mutual argues that Bartlett's counsel improperly staged two dramatic moments designed to elicit sympathy from the

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that Mutual could have been prejudiced by counsel's mentioning the $20 million figure during jury selection.

jury: (1) having Bartlett return late to the courtroom after one break in testimony, with the hope that the jury would see her walk, with assistance, to counsel's table; and (2) having Bartlett's husband Greg sob in view of the jury while Bartlett's sister was testifying, and then leave the gallery. But the first moment never happened. Mutual brought Bartlett's absence to this court's attention, the jury was briefly excused (without being told why), and Bartlett returned to the courtroom before the jury did, so that the jury never saw her walking (except when she walked to and from the witness stand). So that incident had no effect on the jury whatsoever.

As for the sobbing by Bartlett's husband, this court cannot recall it (or any objection by Mutual, which would have made a record of it), but takes Mutual at its word that it did. Indeed, one can hardly be surprised that a husband would cry at some point during a three-week trial relating to severe injuries suffered by his wife. Most courts have concluded, however, that a brief emotional reaction of that sort does not warrant a new trial, "at least if the judge admonished the jury to disregard such manifestation in reaching their verdict." L.S. Tellier, Manifestation of emotion by party during civil trial as ground for new trial, 69 A.L.R.2d 954, § 2 (1960); see also, e.g., Malandris v. Merrill Lynch, 703 F.2d 1152, 1179 (10th Cir. 1981). This court gave precisely such an instruction on the day

following Bartlett's sister's testimony, as discussed in Part III.C.vi, supra.[40]

iv. Net sales figure

Next, Mutual argues that Bartlett's counsel improperly allowed the jury to see Mutual's annual net sales figure during videotaped testimony by Mutual employee Robert Dettery.[41] This court ruled before trial that Bartlett could not present any evidence of Mutual's financial condition, see Bartlett, 2010 WL 3092649, at *8, 2010 U.S. Dist. LEXIS 111259, at *25-27 (explaining that such evidence was not relevant), and specifically ruled that Bartlett could not show the jury the following question-and-answer from Dettery's videotaped testimony: "Q. And '07 sales were greater than $480 million? A. I'm not sure." Document no. 352, at 5. Bartlett's counsel modified the video presentation so that those words were not audible, but the question (without the answer) nevertheless appeared briefly in the subtitles, before the video and subtitles jumped ahead to the next admissible question-and-answer.

[40]Mutual also complains that Bartlett's husband violated this court's witness sequestration order by observing part of his sister-in-law's testimony. See Bartlett, 2010 WL 3092649, at *9, 2010 U.S. Dist. LEXIS 111259, at *28-29 (citing Fed. R. Evid. 615). But Bartlett's husband never testified at trial, so sequestration was not necessary.

[41]Mutual moved for a mistrial on that basis shortly after Dettery's testimony. See document no. 358. This court heard argument on the motion and then denied it orally.

The parties disagree about whether that error was intentional. At trial, Bartlett's counsel told this court that it was a computer glitch, resulting from the way that their software program synched up the video/audio file and the separate text file shown in the subtitles. They attempted to replicate the glitch for this court a number of times, but were unable to do so. Mutual, with the support of an affidavit from the managing director of the software company that made the program, claims that a glitch of that sort is impossible and therefore must have been a deliberate act (if not a criminal one). Bartlett's counsel, in turn, claim that they have now replicated the glitch, having figured out through discussions with the software company that it resulted from the difference in screen-size ratios between their laptop computer and the court's televisions.

This court need not resolve that debate, however, because--even if intentional--the brief, silent display of a question containing Mutual's net sales figure still would not warrant a new trial. The jury already knew, from Mutual's own statement during voir dire, that Mutual had 500 employees (which itself elicited a note of caution from this court, since Mutual's statement came close to implying to the jurors that employee jobs might be at stake, making it potentially prejudicial to Bartlett). And the jury knew, from Dettery's admissible

testimony, that Mutual had a portfolio of about 250 generic drugs, as well as a few brand-name drugs. So with or without seeing the net sales figure, the jury surely assumed that Mutual had substantial annual sales. See, e.g., Simek v. J.P. King Auction Co., 160 Fed. Appx. 675, 685 (10th Cir. 2005) (unpublished) (finding no prejudice from question about net worth where the "evidence already tended to show [the party's] wealth").

Moreover, this court expressly instructed the jury that "[q]uestions ... by lawyers are not evidence, unless the witness adopts the facts set forth in the question," and that "[t]estimony that has been excluded ... is not evidence and must not be considered." Document no. 378, at 9-10. To the extent that the jurors even noticed the net sales figure (which is unknown), they surely also noticed that it was contained in a question that was neither spoken aloud nor answered by the witness, indicating that, pursuant to this court's instructions, it was not evidence and could not be considered. Under the totality of the circumstances, this court does not believe that Mutual suffered any significant prejudice from the brief, silent display of the annual sales question.[42]

[42]This case is nothing like the one on which Mutual relies, City of Cleveland v. Peter Kiewit Sons' Co., 624 F.2d 749 (6th Cir. 1980), where counsel "almost continuously sought to plant the seed in the minds of the jurors that [defendant] was a very large corporation with international operations" and "to inject into the trial the idea that [defendant] had insurance which

v. Expert's "script" or "notes"

Next, Mutual argues that Bartlett's counsel improperly prepared a document (Mutual calls it a "script," Bartlett calls it "notes") for one of Bartlett's experts, Dr. Tackett, to use during his testimony. See document no. 394-1. The document contained hundreds of typed questions, some with handwritten answers next to them and/or citations to expert reliance materials. The document also contained about a dozen points for Dr. Tackett to make during cross-examination. Dr. Tackett testified at trial that Bartlett's counsel typed up the document based on their telephone conversations before trial and gave it to him the day before his testimony. Mutual noticed the document during Dr. Tackett's direct examination and used it to challenge his credibility on cross-examination, asking detailed questions about how the document was prepared and how Dr. Tackett had used it. Indeed, that was Mutual's opening salvo on both days of Dr. Tackett's cross-examination.

While Bartlett claims that it is "common witness preparation" to discuss questions and answers with expert witnesses before their testimony, and sometimes even to write them out in a "script," LeCroy v. Sec'y, Fla. Dep't of Corr., 421

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would cover any damages." Id. at 756-58. Bartlett's counsel did not invoke Mutual's financial condition at all, much less "continuously," after the silent display of the sales figure.

F.3d 1237, 1267 (11th Cir. 2005), it is a strange practice, if not an improper one, for the witness to carry such a document with him to the stand and refer to it while testifying. Indeed, it is rather like walking into a punch, given how bad it looks to the jury on cross-examination. This court is not persuaded, however, that the document resulted in Dr. Tackett's giving opinions that were not his own, or that were not reliably based on his knowledge and expertise.[43] Nor is this court persuaded that the document's use caused any prejudice to Mutual, especially in light of Mutual's effective cross-examination of Dr. Tackett, based on the "script" itself.

vi. Leading questions

Next, Mutual complains that Bartlett's counsel repeatedly asked leading questions on direct examination. See Fed. R. Evid. 611 ("Leading questions should not be used on the direct examination of a witness except as may be necessary to develop the witness' testimony."). That is true, but the other half of

[43]This case is nothing like the one on which Mutual relies, In re Scrap Metal Antitrust Litig., No. 02-cv-0844, 2006 WL 2850453, 2006 U.S. Dist. LEXIS 75873 (N.D. Ohio Sept. 30, 2006), where counsel used a script "to educate [a fact witness] about facts which, whether he ever knew them or not, he did not presently recall, and then put him on the stand to testify ... that he did presently recall all of the topics covered in the outline," which the court deemed "tantamount to suborning perjury." Id. 2006 WL 2850453, at *7, 2006 U.S. Dist. LEXIS 75873, at *31.

the story is that Bartlett's counsel met with repeated rebukes from this court when they did so, sometimes in response to Mutual's objections (which were mostly sustained) and sometimes sua sponte (since Mutual often did not object). Some of those rebukes came in the presence of the jury. It is well established that trial courts have "extensive discretion over the phrasing of questions." United States v. Hansen, 434 F.3d 92, 105 (1st Cir. 2006). This court exercised that discretion throughout trial to prevent Bartlett from using leading questions to gain an unfair advantage over Mutual.[44]

If anything, this court may have been too hard on Bartlett's counsel, since some of their leading questions appear, in hindsight, to have been designed to elicit disclosed opinions from Bartlett's experts, while keeping the experts away from related topics that this court had deemed off-limits. In such instances, Mutual still had the opportunity to test the experts' opinions through cross-examination. See id. (noting that "thorough cross-examination" may eliminate any prejudice from leading questions).

[44]"There is, of course, a degree of tolerance for leading questions under certain circumstances." Hansen, 434 F.3d at 105. One such circumstance, which arose a few times during this trial, is where an unavailable witness's testimony is presented by deposition, and the leading questions cannot simply be rephrased as they would be during live testimony.

vii. Undisclosed expert opinions

Mutual also argues that Bartlett's counsel repeatedly attempted to elicit undisclosed expert opinions. See Fed. R. Civ. P. 26(a)(2)(B)(I) (requiring pre-trial disclosure of "all opinions that the [expert] witness will express"). Again, however, this court went to great lengths to prevent Bartlett's experts from giving such opinions. For example, this court required an advance, written proffer of all opinions that Bartlett's counsel intended to elicit from Dr. Tackett, and went through those opinions one-by-one with the parties to rule out any that had not been properly disclosed before trial (then cautioning Dr. Tackett, before his testimony and outside the presence of the jury, about the opinions deemed off-limits). This court also required Bartlett's counsel to obtain prior approval before eliciting opinions to which they believed Mutual's cross-examination had "opened the door."

Where Bartlett's counsel strayed from the pre-approved opinions, this court did not hesitate to stop them (again, sometimes sua sponte) and to strike the testimony or grant other appropriate relief. To the extent that any undisclosed opinions may nonetheless have squeaked past, it happened without objection from Mutual and thus is not a basis for post-trial relief. See, e.g., Fonten Corp. v. Ocean Spray Cranberries, Inc., 469 F.3d 18, 21 (1st Cir. 2006) ("Failure to timely object to an attorney's

misconduct will frequently result in the denial of a motion for new trial."). Moreover, Mutual has not shown that any of the key opinions regarding sulindac's risks and benefits were undisclosed, see Part III.A.i, supra, so it did not suffer any prejudice.

viii. Other attempts to present inadmissible evidence

Mutual also argues that Bartlett's counsel improperly attempted to admit other inadmissible evidence, including testimony that Mutual failed to survey the medical literature for information about sulindac's safety risks, as well as copies of the medical literature and the unpublished Pharmacia report. Again, however, this court rebuffed those attempts, so Mutual suffered no prejudice. Moreover, this court expressly instructed the jury (at Mutual's request) that Mutual's "conduct in seeking ... knowledge" of sulindac's risks was "not relevant to this case." Document no. 378, at 22.

ix. "Missing witness" argument

Next, Mutual argues that Bartlett's counsel violated one of this court's orders by making a "missing witness" argument, i.e., commenting during closing argument on Mutual's failure to call any witnesses. See Bartlett, 2010 WL 3156555, at *7 (document no. 278) (stating that parties "may not comment on ... uncalled

witnesses unless and until [they] lay[] a proper foundation and obtain[] this court's permission to do so"). But Bartlett's counsel raised that issue with this court before the closing and obtained permission to make limited comments in that regard. In fact, Mutual conceded that Bartlett's counsel "can comment on the fact that [Mutual] didn't call any witnesses," provided "that's as far as they can go." Document no. 439, at 14.

This court is not persuaded that Bartlett's counsel exceeded the scope of that permission, or otherwise strayed into improper argument. Even if they did, however, this court reminded the jury (sua sponte) immediately after the closing that "while it is accurate to say Mutual did not call witnesses after the plaintiff rested her case, Mutual's counsel did put on a defense in this case, through cross-examination of the plaintiff's witnesses and through its presentation of its own portions of the videotape deposition testimony or read testimony from a transcript that immediately followed the plaintiff's presentation, with respect to witnesses like [Mutual's employee] Dettery." In light of that instruction, Mutual suffered no prejudice.

x. Other improper comments

Finally, Mutual argues that Bartlett's counsel made a number of other improper comments during trial:

- During opening statement, Bartlett's counsel mentioned their own experience in the United States military, which

obviously was not relevant. See Fed. R. Evid. 401, 402. But this court sustained Mutual's immediate objection to that comment, cutting off Bartlett's counsel before they had finished the point, and instructed Bartlett's counsel, in the presence of the jury, to "talk about the evidence," not to "describe [their] experience, background." Document no. 430, at 89-90. So Mutual suffered no prejudice.

- During opening statement, Bartlett's counsel also noted that Mutual had never apologized to Bartlett. Id. at 128. Again, that was not relevant. See Fed. R. Evid. 401, 402. But Mutual did not object to that comment, either as it happened or during the sidebar after the opening (when Mutual raised other objections to Bartlett's opening statement). Moreover, this court expressly instructed the jury that Mutual's conduct was "not at issue" and should not be considered. Document no. 378, at 22. Mutual again suffered no prejudice.

- During both opening and closing, Bartlett's counsel commented that sulindac "stole" Bartlett's freedom, see document no. 430, at 89, 91, which Mutual considers an improper reference to its conduct. But, on its face, the comments referred to the drug's effect, not Mutual's conduct. And again, Mutual did not object to the comments. In any event, Mutual suffered no prejudice in light of the instruction just described (regarding Mutual's conduct not being at issue).

- On a number of occasions, Bartlett's counsel referred to the Pharmacia report as the work of Mutual's expert Dr. Stern, who never testified at trial, and as a "draft" of the Journal of Rheumatology article. Mutual argues that those comments were unfair and misleading, but this court disagrees. Dr. Stern was, in fact, the report's author and one of Mutual's designated experts. Until the end of trial, when Mutual rested without calling any witnesses, it was unclear whether Mutual would call Dr. Stern. And Dr. Stern acknowledged at his deposition that the published article was based on data from the Pharmacia report, such that he even sought Pharmacia's permission to publish the article.

- During closing argument, Bartlett's counsel incorrectly stated that the FDA "didn't have" the Pharmacia report (whereas the evidence was only that Dr. Stern had not personally provided the report to the FDA). But this court granted Mutual's request for a curative instruction on that point, explaining to the jury that Bartlett's counsel had

mischaracterized the record. In light of that instruction, Mutual suffered no prejudice.

- Bartlett's counsel also argued, during closing argument, that sulindac's warning violated FDA labeling regulations. Again, however, this court granted Mutual's request for a cautionary instruction on that point, telling the jury (consistent with the final jury charge) that "compliance or noncompliance with FDA labeling ... is not necessarily controlling" on the issue of whether sulindac's warning avoided an unreasonable danger, and that "you may give such evidence as much or little weight as you think it deserves." Subject to that instruction (and probably even without it), the argument was permissible. See Part III.B.iv, supra.

- Bartlett's counsel also stated, during closing argument, that questions by attorneys are not evidence.[45] But that comment tracked this court's jury instructions, see document no. 378, at 8-9 ("Questions ... by lawyers are not evidence, unless the witness adopts the facts set forth in the question."), which in turn tracked controlling case law, see United States v. Cudlitz, 72 F.3d 992, 1002-03 (1st Cir. 1996) ("questions of counsel are not evidence"). To the extent that it differed at all, this court instructed the jury to "take the law from the court." Document no. 378, at 9. So, again, Mutual suffered no prejudice.

E. *Cumulative evidence*

The next issue raised by Mutual's Rule 59 motion is whether this court allowed Bartlett to present too much evidence of her severe injuries. Mutual argues, first, that this court should have bifurcated the trial into separate liability and damages phases to prevent such evidence from improperly influencing the

[45]Mutual seems to be concerned primarily with a set of questions about whether Bartlett's experts knew that sulindac was listed as a preferred drug on various drug formularies. But the experts' "no" answers to those questions were not evidence that the formularies actually listed sulindac; they were merely evidence that the experts did not know either way.

liability determination. See Fed. R. Civ. P. 42(b) ("For convenience, to avoid prejudice, or to expedite or economize, the court may order a separate trial of one of more separate issues"). This court has already addressed that argument at length in a pre-trial order. See Bartlett, 2010 WL 3210724 (document no. 320). As explained there, the party seeking bifurcation bears the burden of proving that it will satisfy the rule's objectives, see, e.g., 8 Moore's Federal Practice, § 42.20[8], at 42-55 (3d ed. 2007), and the court has broad discretion in determining whether bifurcation is appropriate, see, e.g., Lisa v. Fournier Marine Corp., 866 F.2d 530, 531 (1st Cir. 1989).

Mutual failed to show that bifurcation was appropriate in this case. Even if the trial had been bifurcated, evidence of SJS/TEN's severity still would have been admissible at the liability phase, to inform the jury's risk/benefit analysis. See Fed. R. Evid. 402; Price, 142 N.H. at 389 (jury may consider "the risk of danger posed by [the product's] use). Moreover, since Mutual put Bartlett to her proof on causation (even though, as already mentioned, that point was essentially undisputed), some evidence of her particular injuries also would have been admissible on that issue, if not also to "paint[] the backdrop" of the case. Faigin v. Kelly, 184 F.3d 67, 81 (1st Cir. 1999).

As a result, bifurcation likely would have resulted in "duplication of evidence" and would have "force[d] busy doctors from Boston hospitals to make two trips to New Hampshire for this trial," which would have been inefficient. Bartlett, 2010 WL 3210724, at *2 (document no. 320); see also 8 Moore's, supra, § 42.20[4][a], at 42-46 (bifurcation is "not the normal course of events, and a single trial will usually be more expedient and efficient").

Short of bifurcation, Mutual argues that "evidence of plaintiff's injuries ... only needed to be presented one time," and that this court erred by allowing "witness after witness to testify, often in graphic detail, about plaintiff's injuries and medical treatment." See Fed. R. Evid. 403 (allowing exclusion of relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice ... or needless presentation of cumulative evidence"). Each witness, though, had something different to add. Bartlett's ordeal with SJS/TEN caused many different injuries, requiring the involvement of many doctors (with various specialties), and impacting many aspects of her life. No single witness, even Bartlett herself, could have given the jury a full picture of what happened.[46]

[46]Indeed, Bartlett spent months of her recovery in a medically induced coma. Mutual contested whether Bartlett could feel pain during that period, which obviously did not help to reduce the amount of pain-related testimony.

It is true that some of the witnesses went into graphic detail about Bartlett's injuries, and that some of the pictures shown to the jury were unpleasant, but that is because Bartlett's injuries were so horrific and, in many respects, far beyond the experience of the average juror. See Part III.F, infra. There was really no other way for Bartlett to convey to the jury the full extent of her pain and suffering. See United States v. Morales-Aldahondo, 524 F.3d 115, 120 (1st Cir. 2008) ("The trial judge's job is to avoid unfair prejudice," not "to scrub the trial clean of all evidence that may have an emotional impact."). This court "balanced the competing concerns of Rule 403 by," for example, reviewing proffered photographs in open court (outside the presence of the jury) and "limiting the number of images presented," as well as by excluding proffered video footage of the type of eye surgery that Bartlett underwent, among other things. Id. Mutual has not shown any miscarriage of justice in that regard.

F. *Damages award*

The next issue raised by Mutual's Rule 59 motion is whether the jury awarded Bartlett an excessive amount of compensatory damages. As mentioned earlier, the jury awarded a total of $21.06 million, consisting of $4.56 in special damages that were largely uncontested ($1.25 million for past medical expenses

stipulated by the parties, $2.377 million for future medical expenses, and $933,000 for lost wages) plus $16.5 million for pain, suffering, and loss of enjoyment of life. Mutual argues that the amount, and particularly the pain and suffering component, was so high as to be "undoubtedly punitive" and "based purely on the jury's passion and prejudice." This court disagrees. While substantial, the award was within the acceptable range, in light of the horrific injuries that Bartlett suffered. Given this court's instruction on the issue in the final jury charge, there is no reason to think that the pain and suffering award was punitive.[47]

"District courts may grant a motion for new trial" based on the amount of damages "only if the award exceeds any rational appraisal or estimate of the damages that could be based on the evidence before the jury and is grossly excessive, inordinate, shocking to the conscience of the court, or so high that it would be a denial of justice to permit it to stand." Franceschi v. Hosp. Gen. San Carlos, Inc., 420 F.3d 1, 5 (1st Cir. 2005); see also Bielunas v. F/V Misty Dawn, Inc., 621 F.3d 72, 80 (1st Cir. 2010) ("only rarely and in extraordinary circumstances will

[47]This court instructed the jury (at Mutual's request) that it was "not permitted to award punitive damages or any other money damages for the purpose of punishing Mutual or making an example of it for the public good or for the purpose of preventing Mutual and others from similar conduct." Document no. 378, at 27; see also Gentles, 619 F.3d at 82 ("juries are presumed to follow [the court's] instructions").

[courts] veto the jury's decision"). That is a "weighty burden" for Mutual to meet. Bielunas, 621 F.3d at 80. This court cannot "jettison a damage award simply because" it is "generous in comparison to other (hand-picked) cases," or in comparison to what the court might have awarded. Id. at 80-82.

No one who witnessed the trial in this case could deny the horror of Bartlett's injuries. To name just some of them: Bartlett suffered burns and lost skin over nearly two-thirds of her body; she was in a medically induced coma for months; she lost her sight (despite 12 eye surgeries, to date, attempting to save it, and likely many more to come); she lost the ability to have sexual intercourse due to vaginal injuries; she lost the ability to eat normally due to esophageal stricture (requiring multiple surgeries to stretch the esophagus so that she can eat safely at all); she lost the ability to engage in aerobic activities (in which she had previously been an avid participant) due to lung injuries; she suffered scarring to her face, back, anus, and vagina; and she suffers from post-traumatic stress disorder. Children, she said, are scared of her appearance. And at 50 years old, she is expected to live with her injuries for more than 30 years.

"There is," of course, "no mathematical formula for determining the monetary equivalent of non-economic injuries." Bielunas, 621 F.3d at 80. Nor is there any "one 'correct' sum,

but, rather, a range of acceptable awards." Blinzler v. Marriott Int'l, Inc., 81 F.3d 1148, 1161-62 (1st Cir. 1996). In many cases, "the spread between the high and low ends of the range will be great. The choice within the range" is "largely within the jury's ken." Id. at 1162. That is indeed the case here. The jury's choice to award $16.5 million for Bartlett's pain and suffering--less than four times her special damages--was a rational response to the evidence. While Mutual has cited cases where juries awarded much less for similar injuries, Bartlett has cited cases where juries awarded much more. Her award fell within the "wide universe of acceptable awards," id., and was neither shocking to the conscience nor unjust to Mutual.[48]

G. *Cumulative error*

The final issue raised by Mutual's Rule 59 motion is cumulative error. Mutual argues that the combined effect of the errors discussed above warrants a new trial, even if none of the errors individually would. As already discussed, however, many

[48]Our court of appeals ruled in Whitfield v. Melendez-Rivera, 431 F.3d 1 (1st Cir. 2005), that $3 million was the most a plaintiff could recover for pain and suffering after being shot in the leg and thereafter dealing with a "weak knee" and "limited range of motion" (albeit not enough to prevent him from "pass[ing] the Navy's physical readiness test"). Id. at 16-17. Having witnessed Bartlett's testimony firsthand and considered the other evidence presented at trial, this court has no doubt that her pain and suffering surpasses that endured by the Whitfield plaintiff by many orders of magnitude.

of the errors that Mutual cites were not errors at all. See, e.g., Williams v. Drake, 146 F.3d 44, 49 (1st Cir. 1998) ("cumulative-error analysis is inappropriate when a party complains of the cumulative effect of non-errors"). Moreover, to the extent that errors occurred, they did not cause any significant prejudice. Mutual has not "come close to [showing] the critical mass [of errors] necessary to cast a shadow upon the integrity of the verdict." United States v. Sepulveda, 15 F.3d 1161, 1196 (1st Cir. 1993).

IV. Conclusion

For the reasons set forth above, Mutual's motion for judgment as a matter of law[49] and its motion for a new trial[50] are both DENIED.

SO ORDERED.

Joseph N. Laplante
United States District Judge

Dated: January 5, 2011

cc: Keith M. Jensen, Esq.
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[49]Document no. 395.

[50]Document no. 394.

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