

Dennis D. Ferri, Esquire (*argued*) and Allyson Britton DiRocco, Esquire, Morris, James LLP, Wilmington, Delaware, for Appellant, Cross Appellee, Christiana Care Health Services, Inc.

Randall E. Robbins, Esquire (*argued*) and Carolyn S. Hake, Esquire, Ashby & Geddes, Wilmington, Delaware, for Appellees, Cross-Appellees, John Houghton and Evelyn Houghton.

BERGER, Justice:

This is an appeal from a jury verdict in favor of the patient in a medical malpractice action. The patient alleged that his physician negligently performed a surgical procedure and breached his duty to obtain informed consent. The patient also sued the supervising health services corporation based on vicarious liability and independent negligence. The jury found both the physician and the corporation negligent and apportioned liability between them. On appeal, the physician and corporation assert that the trial court erred in several evidentiary rulings, incorrectly instructed the jury on proximate cause, and wrongly awarded pre- and post-judgment interest. In cross appeals, the physician and corporation seek review of the trial court's decision to submit a supplemental question to the jury, as well as its failure to alter the damages award based on the jury's response to that supplemental question.

We affirm the judgment in favor of the patient. The trial court should not have requested supplemental information from the jury after the verdict. Although the trial court decided not to modify the verdict, the jury's response to the supplemental question arguably could affect other proceedings between the physician and corporation. As a result, the judgment below is **AFFIRMED** and the case is **REMANDED** with instructions to the Superior Court to vacate the supplemental verdict.

FACTUAL AND PROCEDURAL BACKGROUND

In December 2009, John Houghton¹ fell from a ladder and suffered multiple non-displaced rib fractures, among other injuries. He was admitted to Christiana Hospital,² where he experienced severe chest pain despite receiving oral pain medication. Because of his persistent chest pain, Houghton's physicians requested a consult with Dr. Nadiv Shapira, a thoracic surgeon affiliated with Christiana Hospital who performs the "On-Q procedure." The procedure, intended to treat pain caused by rib fractures, involves the insertion of a catheter, known as the "On-Q," under the patient's skin and over the ribs using a metal tunneling device. The catheter is approximately five inches long and contains several holes. When liquid analgesic is infused through the catheter, it soaks the surrounding tissue. The goal is to place the catheter in such a way that it can be used to continuously soak the nerves around the ribs with analgesic in order to relieve the pain associated with the rib fracture. The On-Q procedure has not been approved by the FDA and is thus an "off-label" use of the On-Q catheter.

Shapira evaluated Houghton and determined that he was a candidate for the On-Q procedure because of his high level of chest pain, his inability to breathe deeply, and his poor response to the oral pain medication. Shapira discussed the

¹ His wife, Evelyn Houghton, joined in this action, but there are no issues on appeal related to her claims. Accordingly, we will refer only to John Houghton unless the context requires otherwise.

² Appellant and cross-appellee, Christiana Care Health Services, Inc. ("CCHS"), owns and operates Christiana Hospital.

On-Q procedure with Houghton. Although he did not have an “exact recollection” of the conversation at trial, Shapira testified that he would always talk to patients about the “aims, risks and alternatives” of the On-Q procedure.³ Shapira would explain that the purpose of the procedure was to provide pain relief in order to prevent “further deterioration” and to ameliorate the risks associated with continued reliance on a breathing tube and respirator.⁴ Shapira would also mention the risks of bleeding, infection, injury to adjacent organs or tissues, and side effects of the medication being transmitted through the catheter.

Finally, Shapira would explain that oral and intravenous pain medications are alternatives to the On-Q procedure. Shapira testified that he normally would tell patients that epidural anesthesia, while a “very effective” treatment for rib fracture pain, is “not an option” because it carries a “very significant risk” and “has its limitations.”⁵ According to Shapira, epidural anesthesia is not an alternative often used at Christiana Hospital, and he did not present epidural anesthesia as a treatment option to Houghton.

Shapira also failed to advise Houghton that Shapira had an independent interest in the On-Q procedure. In 2007, Shapira entered into a contract with the On-Q’s manufacturer, I-Flow Corporation, under which Shapira became a member

³ App. to CCHS’s Opening Br. at A-539.

⁴ App. to CCHS’s Opening Br. at A-539.

⁵ App. to CCHS’s Opening Br. at A-542-43.

of I-Flow's speaker's bureau. I-Flow paid Shapira to give presentations to other physicians about the On-Q procedure, and Shapira created a promotional pamphlet about the procedure. Also in 2007, Shapira created a database at Christiana Hospital to collect information about his patients' responses to the On-Q procedure. Around that time, the number of patients on whom Shapira performed the On-Q procedure began to increase significantly. In 2009, Shapira requested and received approval from CCHS's Institutional Review Board ("IRB") to study the effectiveness of the On-Q procedure using the patient data he was collecting. By mid-2009, Shapira had labeled himself, in addition to a thoracic surgeon, an "interventional pain management physician" based on his frequent performance of the On-Q procedure at Christiana Hospital.⁶

Houghton agreed to the On-Q procedure, and Shapira inserted two On-Q catheters into Houghton's rib fracture area on December 8, 2009. The next day, Houghton inadvertently removed the catheters. Shapira then performed another surgery to insert two new On-Q catheters. One of those catheters became displaced and perforated some of Houghton's internal organs. As a result, Houghton spent significant additional time in the hospital and underwent several surgeries to remove the catheter and repair the organ damage.

⁶ App. to the Houghtons' Answering Br. at B-393-94.

Houghton's action alleges that Shapira negligently failed to obtain informed consent before performing the On-Q procedure, and negligently performed the procedure. Houghton also alleges that CCHS is liable for Shapira's negligence because Shapira was CCHS's agent. Finally, Houghton claims that CCHS negligently failed to properly manage Shapira's On-Q study, and negligently granted "expedited review" of Shapira's application to conduct the study.

After an eight day trial, the jury returned a verdict finding both Shapira and CCHS liable in negligence. The verdict sheet did not ask the jury to address Houghton's medical negligence and informed consent claims against Shapira separately. It asked only whether Shapira was negligent. The jury awarded \$3.75 million in damages to Houghton and \$650,000 to Evelyn Houghton for loss of consortium. The jury apportioned 65% of the total liability to Shapira, and 35% to CCHS.

After the verdict, CCHS requested that the jury be asked to apportion CCHS's 35% liability. CCHS argued that it needed to know how much of the 35% liability was attributed to CCHS in its capacity as Shapira's employer, and how much was attributed to CCHS's independent failure to adequately manage Shapira's data collection and study. The Superior Court granted the request for the supplemental question but refused to reform the original verdict based on the jury's

answer. The Superior Court also awarded the Houghtons costs, pre-judgment interest, and post-judgment interest. This appeal and cross-appeal followed.

DISCUSSION

1. Informed Consent Claim

Houghton's informed consent claim against Shapira has two main components. First, he alleges that Shapira breached the standard of care for informed consent by failing to adequately disclose the risks and alternatives of the On-Q procedure, including the fact that the On-Q procedure was "experimental" and that an epidural was a viable alternative. Second, Houghton alleges that Shapira breached the standard of care by failing to disclose significant personal conflicts of interest regarding the On-Q procedure, including his business relationship with I-Flow.

Although Shapira's appeal focuses on Houghton's second claim, Shapira conceded at trial that he never presented Houghton with the option to receive an epidural rather than undergo the On-Q procedure.⁷ Delaware's informed consent statute expressly requires a physician to disclose "alternatives to treatment . . . which a reasonable patient would consider material to the decision whether or not to undergo the treatment"⁸ Shapira, himself, acknowledged that epidural

⁷ App. to the Houghtons' Answering Br. at B-410.

⁸ 18 Del. C. § 6801(6).

anesthesia can be a “very effective” treatment method for rib fracture pain.⁹ Because receiving an epidural was a viable alternative to the On-Q procedure, and Shapira did not tell Houghton about it, the jury could have found that Shapira breached the standard of care on that basis.

As to the I-Flow/conflict evidence, Shapira mischaracterizes the Superior Court’s ruling. The Superior Court did not hold that Shapira was required to disclose that information as a matter of law. Rather, it held that Shapira’s relationship with I-Flow (and his failure to disclose that relationship) was relevant to the jury’s determination of whether Shapira met the standard of care for informed consent. The Superior Court relied primarily on this Court’s decision in *Barriocanal v. Gibbs*,¹⁰ in which we construed Delaware’s informed consent statute. We agree with the Superior Court’s application of *Barriocanal*.

Delaware’s informed consent statute defines informed consent as:

. . . the consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.¹¹

⁹ App. to CCHS’s Opening Br. at A-542.

¹⁰ 697 A.2d 1169 (Del. 1997).

¹¹ 18 *Del. C.* § 6801(6).

In short, a physician must provide the patient with information necessary to understand (1) the nature of the proposed procedure, and (2) the material risks and alternatives to the procedure. The physician must supply such information “to the extent [that it is] customarily given to patients . . . by other licensed health care providers in the same or similar field of medicine as the defendant.”¹² Under *Barriocanal*, whether the physician has met the standard of care required by the informed consent statute is a question of fact for the jury.

In *Barriocanal*, this Court interpreted “material risks and alternatives” to include information about a doctor’s inexperience with a procedure, a hospital’s being understaffed on the day of the procedure, and the existence of a nearby hospital in which the procedure also could be performed.¹³ While the Court did not hold that such information was necessarily required to be disclosed under the statute, the Court found that it was relevant.¹⁴ Shapira argues that *Barriocanal* should not be read broadly to apply here. He points out that all of the undisclosed information in that case directly addressed medical risks and alternatives. By contrast, the undisclosed information at issue relates only to Shapira’s alleged conflict of interest. Moreover, if doctors are required to disclose their potential conflicts, Shapira claims that no one will know how much personal financial

¹² 18 *Del. C.* § 6852(a)(2).

¹³ *Barriocanal*, 697 A.2d at 1171-72.

¹⁴ *Id.* at 1173 (“We find that the type of ‘qualification’ information at issue in this case was relevant to the issue of informed consent.”).

information must be included.

Shapira's argument fails because his relationship to I-Flow directly relates to the procedure he performed. The conflict information is relevant because it bears on "risks and alternatives." The conflict created a risk that Shapira wanted to perform the procedure because it would benefit him personally, and not because it was the most appropriate procedure. Likewise, the conflict created a risk that Shapira did not disclose or consider all reasonable alternatives.

This is not a case where a doctor fails to disclose that she owns some stock in a publicly-traded medical company. Shapira was making a name for himself, and earning money, by promoting the On-Q procedure. In addition, he was gathering data about the procedure's efficacy. He had a strong incentive to play down the risks of the On-Q procedure and play up the problems with alternative treatments.

Under these circumstances, the conflict evidence was relevant to the informed consent claim and admissible. The trial court properly permitted the jury to consider this evidence when reaching its determination as to whether Shapira met the standard of care under Delaware's informed consent statute.

2. Evidence of the Procedure's "Experimental" Nature

Shapira argues that the Superior Court erred by permitting Houghton's expert witnesses to testify at trial that the On-Q procedure was experimental while prohibiting four defense witnesses from testifying that the procedure was not experimental. This argument lacks merit because it ignores the fact that only Houghton's witnesses were qualified as experts. The witnesses who testified that the On-Q procedure was experimental were giving expert opinions regarding the standard of care for treating rib fracture pain. They possessed "specialized knowledge" about what treatments for rib fracture pain were generally accepted in the medical community and what treatments were not.¹⁵ The defense witnesses, on the other hand, were presented as "fact witnesses," not experts.¹⁶ They were bound by Delaware Rule of Evidence 701, which states:

If [a] witness is not testifying as an expert, the witness' testimony in the form of opinions . . . is limited to those opinions . . . which are . . . not based on scientific, technical or other specialized knowledge within the scope of Rule 702.¹⁷

The Superior Court correctly ruled that the question of whether a procedure is experimental is an opinion requiring specialized knowledge and cannot be given

¹⁵ See D.R.E. 702 ("If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise . . .").

¹⁶ App. to Shapira's Opening Br. at AA-108.

¹⁷ D.R.E. 701.

unless the witness is qualified as an expert.¹⁸

3. Pre-judgment and Post-judgment Interest

The Superior Court awarded pre-judgment and post-judgment interest under 6 *Del. C.* § 2301(d). That provision entitles a plaintiff who has made a pre-trial settlement demand on the defendant to recover pre-judgment and post-judgment interest under certain circumstances. Section 2301(d) states:

In any tort action . . . in the Superior Court . . . for bodily injuries, death or property damage, interest shall be added to any final judgment . . . provided that prior to trial the plaintiff had extended to defendant a written settlement demand valid for a minimum of 30 days in an amount less than the amount of damages upon which the judgment was entered.

The statute is unambiguous. It plainly states that a plaintiff is entitled to interest if (1) the plaintiff extended the defendant a written settlement demand before trial, (2) the demand was valid for at least 30 days, and (3) the amount of damages recovered in the judgment was greater than the amount the plaintiff had demanded. Shapira does not dispute that those requirements were met. Instead, he advances an interpretation of § 2301(d) that would require the settlement demand to be made at least 30 days before trial. We decline to read such a requirement into the statute. The statute requires only that the demand be “valid for a minimum of 30 days,” not

¹⁸ See App. to Shapira’s Opening Br. at AA-132-33. Shapira also argues that the Superior Court abused its discretion by limiting him to four experts. But this is simply another version of the claim that his fact witnesses should have been allowed to testify that the On-Q procedure is not experimental.

that the 30 day period must elapse prior to the start of trial.

Shapira argues alternatively that 6 *Del. C.* § 2301(d) is unconstitutional because it “unduly inhibits [the] exercise of [his] fundamental right to resort to the courts in defense of claims made against [him and] creates an irrebuttable presumption that [he is] responsible for causing delay”¹⁹ This argument lacks merit. A legislative enactment is “presumed to be constitutional”²⁰ and “should not be declared invalid unless its invalidity is beyond doubt.”²¹ Shapira presents nothing to rebut the presumption of § 2301(d)’s constitutionality other than conclusory statements about the statute’s perceived one-sidedness. He ignores the fact that § 2301(d) applies only when a plaintiff recovers more in a judgment than it demanded in settlement negotiations. The statute incentivizes plaintiffs to make less aggressive settlement demands, but it does nothing to restrict a defendant’s right of access to the courts or its ability to present a defense. As the Superior Court noted, we have interpreted § 2301(d) in the past without questioning its constitutionality.²² We adhere to that view.

¹⁹ Shapira’s Opening Br. at 34.

²⁰ *Hoover v. State*, 958 A.2d 816, 821 (Del. 2008).

²¹ *Snell v. Engineered Sys. Designs, Inc.*, 669 A.2d 13, 17 (Del. 1995) (quoting *Justice v. Gatchell*, 325 A.2d 97, 102 (Del. 1974)).

²² *See, e.g., Rapposelli v. State Farm Mut. Auto. Ins. Co.*, 988 A.2d 425, 427-29 (Del. 2010).

4. Supplemental Jury Question

In its original verdict sheet, the jury apportioned liability between Shapira and CCHS, finding that Shapira was 65% at fault while CCHS was 35% at fault. CCHS then requested that the jury provide a supplemental verdict explaining how much of the 35% CCHS liability was attributable to CCHS's agency relationship with Shapira and how much was attributable to CCHS's failure to properly manage Shapira's study. The Superior Court granted CCHS's request but made clear that apportionment of liability given in the original verdict sheet would not be modified.²³ The supplemental verdict apportioned 25% of CCHS's liability to the failure to properly oversee Shapira's study and 75% to CCHS's agency relationship with Shapira. CCHS then moved to reform the original verdict based on the jury's supplemental verdict. The Superior Court denied that motion.

CCHS argues that the jury's 75/25 sub-apportionment of CCHS's liability is inconsistent with the jury's overall 65/35 apportionment between Shapira and CCHS. We need not reach that argument because we find that there was no basis for granting the request for a supplemental jury verdict in the first place. "Under Delaware law, enormous deference is given to jury verdicts,"²⁴ and they should not be disturbed unless "the evidence preponderates so heavily against the jury verdict

²³ App. to the Houghtons' Answering Br. at B-574-75.

²⁴ *Young v. Frase*, 702 A.2d 1234, 1236 (Del. 1997).

that a reasonable jury could not have reached the result.”²⁵

Here, no one argues that the original verdict was unreasonable, let alone against the great weight of the evidence. CCHS did not object to the form of the original jury verdict sheet. Nor did CCHS object to the jury instructions, which explained how the jury was to apportion liability. The Superior Court further noted that the jury did not appear to be confused either by the original verdict sheet or by the jury instructions. Quite simply, it was too late for CCHS to move to supplement the jury’s verdict once the verdict had been returned. We find that the supplemental verdict is invalid and instruct the Superior Court to strike that verdict.

5. Jury Instruction on Proximate Cause

Shapira argues that the Superior Court’s jury instruction on proximate cause contained an error of law. The Superior Court instructed the jury in relevant part as follows:

Proximate cause is a cause that directly produces the harm, and but for which the harm would not have occurred. A proximate cause brings about, *or helps to bring about*, the plaintiff’s injuries, and it must have been necessary to the result. There may be more than one proximate cause of an injury.²⁶

Shapira says that the inclusion of the phrase “or helps to bring about” renders the instruction legally incorrect because it is “inconsistent with the ‘but for’ causation

²⁵ *Storey v. Camper*, 401 A.2d 458, 465 (Del. 1979).

²⁶ App. to CCHS’s Opening Br. at A-580 (emphasis added).

standard that the Delaware Courts have adopted.”²⁷ Under settled law, this argument fails. This Court repeatedly has found that the phrase “helps to bring about” can be part of an accurate statement of the “but for” causation standard.²⁸ Here, taking the jury instructions as a whole, we conclude that the Superior Court properly instructed the jury on the standard for proximate cause.

CONCLUSION

The judgment of the Superior Court is **AFFIRMED** and the case is **REMANDED** with instructions to the Superior Court to vacate the supplemental verdict. Jurisdiction is not retained.

²⁷ CCHS’s Opening Br. at 34.

²⁸ See, e.g., *Ireland v. Gemcraft Homes, Inc.*, 29 A.3d 246, 2011 WL 4553166, at *3 (Del. Oct. 3, 2011) (TABLE); *Pesta v. Warren*, 888 A.2d 232, 2005 WL 3453825, at *2 (Del. Dec. 14, 2005) (TABLE).