

DA 19-0102

IN THE SUPREME COURT OF THE STATE OF MONTANA

2019 MT 244

KATHY HOWARD,

Plaintiff and Appellant, and Cross-Appellee,

v.

ROBERT EDWARD REPLOGLE, M.D.,

Defendant, Appellee, and Cross-Appellant.

APPEAL FROM: District Court of the Thirteenth Judicial District,
In and For the County of Yellowstone, Cause No. DV 13-0244
Honorable Gregory R. Todd, Presiding Judge

COUNSEL OF RECORD:

For Appellant:

James G. Edmiston, Tanis M. Holm, Edmiston & Colton, Billings, Montana

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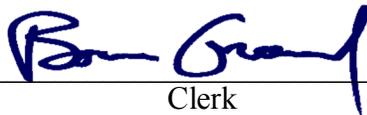
For Appellee:

Gary Kalkstein, Travis Dye, Kalkstein & Dye, P.C., Missoula, Montana

Submitted on Briefs: August 28, 2019

Decided: October 15, 2019

Filed:


Clerk

Justice Ingrid Gustafson delivered the Opinion of the Court.

¶1 Plaintiff, Appellant, and Cross-Appellee Kathy Howard (Howard) appeals the Order Denying Plaintiff's Renewed Motion for Judgment as a Matter of Law/Motion for New Trial issued by the Thirteenth Judicial District Court, Yellowstone County, on January 17, 2019. Defendant, Appellee, and Cross-Appellant Robert Edward Replogle, M.D. (Dr. Replogle) cross-appeals the District Court's October 25, 2018 Order Denying Defendant's Motion to Exclude Plaintiff's Damages for Future Medical Expenses and Loss of Ability to Enjoy Life.

¶2 We affirm, addressing the following dispositive issues:

1. *Did the District Court err by denying Howard's Motion for Judgment as a Matter of Law?*
2. *Did the District Court err by denying Howard's Motion for New Trial?*

FACTUAL AND PROCEDURAL BACKGROUND

¶3 In approximately 2000, Howard was injured in a car accident. A short time later, she slipped and fell down a set of stairs. After dealing with back pain from these incidents for years, Howard was referred to Dr. Replogle in 2008. Dr. Replogle is a board-certified neurosurgeon and a member of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), who was practicing in Billings at the time of Howard's referral. In late 2008, Dr. Replogle performed a decompression procedure on Howard's spine, but Howard did not find relief. After the decompression procedure was not as effective as hoped, Dr. Replogle performed a multilevel fusion of

Howard's spine in early 2009 using PEEK grafts and a bone substitute. This fusion provided some pain relief to Howard for several months.

¶4 In late 2009, Howard was again experiencing back pain. In early 2010, Dr. Replogle recommended that Howard undergo a minimally invasive fusion of her L5-S1 vertebrae. Dr. Replogle recommended that this fusion be performed using unilateral pedicle screws and an OptiMesh graft. OptiMesh is a medical device designed, manufactured, and marketed by Spineology, Inc. OptiMesh is an "expandable bone graft synthetic containment device," or essentially a mesh bag which is inserted into the disc space and then filled with bone graft material to fuse the vertebrae. Spineology invented OptiMesh to be used in interbody fusions. Due to FDA regulations, however, Spineology was not allowed to market OptiMesh for interbody fusions. The FDA-approved marketing language for OptiMesh stated that "OptiMesh is intended to maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (e.g. tumor) that does not impact the stability of the vertebral body and does not include the vertebral endplates." The FDA does not regulate the use of the device, however, and spinal surgeons have been using OptiMesh "off-label" for interbody fusions in the United States and Europe since approximately 2003.

¶5 Dr. Replogle first used OptiMesh in a minimally-invasive interbody fusion in 2007. In 2008, Dr. Replogle bought \$110,000 worth of Spineology stock and also entered into a consulting agreement with Spineology. Prior to Howard's surgery, Dr. Replogle had used OptiMesh in approximately 30 procedures. Before surgery, Dr. Replogle discussed the

risks of the procedure with Howard as part of the informed consent process. Howard signed two consent forms stating that she understood the risks and wanted to proceed with the surgery. During the informed consent process, Dr. Replogle did not inform Howard of either his Spineology stock or his Spineology consulting agreement.

¶6 On March 11, 2010, Dr. Replogle performed the minimally invasive L5-S1 fusion procedure using OptiMesh. At a follow-up appointment after the surgery, Howard complained of pain, but Dr. Replogle observed no indications of abnormalities which required immediate intervention. Dr. Replogle observed Howard's complaints to be normal following a spinal fusion procedure. At Howard's last appointment with Dr. Replogle, on June 17, 2010, he informed Howard that further reconstructive spine surgery would not provide a benefit and referred her to a pain clinic. Howard did not follow up on this referral.

¶7 Howard continued to experience pain and was eventually referred to Dr. Judson Cook, a board-certified neurosurgeon who was then practicing in Cheyenne, Wyoming. In 2012, Dr. Cook performed a revision surgery and discovered problems with the OptiMesh fusion. Dr. Cook removed as much of the OptiMesh as he could when he performed the revision surgery.

¶8 In 2013, Howard filed suit against Spineology. In 2014, Howard filed a separate suit against Dr. Replogle and Northern Rockies Neurosurgeons. In 2016, Howard dismissed her claims against Northern Rockies Neurosurgeons and moved to consolidate the remaining claims against Spineology and Dr. Replogle. On July 31, 2018, Dr. Replogle

filed a motion in limine seeking, in relevant part, to exclude evidence that Dr. Replogle owned shares of Spineology stock and preclude Howard from arguing that Dr. Replogle used OptiMesh for personal financial gain. In her brief opposing Dr. Replogle's motion, Howard argued that the "jury should be allowed to hear this relevant evidence and decide for itself whether this presented an ethical conflict of interest which should have been disclosed by Dr. Replogle to Plaintiff or not." At a hearing on the motion, Howard similarly argued that the issue of informed consent was a "battle of experts," involving a "disputed issue of fact" which made the matter "an issue for the jury to decide[.]" The District Court denied Dr. Replogle's motion in limine on this issue. Before trial, Howard settled with Spineology, leaving only her claims against Dr. Replogle pending. Howard contended that Dr. Replogle did not obtain her informed consent for the March 2010 procedure because he did not disclose his financial interest in Spineology to her, and that Dr. Replogle departed from the standard of care in performing the procedure.

¶9 The matter went to trial beginning on October 29, 2018. Dr. Allan Hamilton, Howard's expert witness, testified that Dr. Replogle did not meet the standard of care for obtaining informed consent when he did not disclose his financial ties to Spineology. Dr. Hamilton based his opinion on a set of guidelines issued by the AANS and CNS in 2008 regarding when a doctor should disclose his or her financial interest to a patient. Dr. Hamilton did not disclose the existence of these guidelines at his deposition before trial, but Howard did disclose them in a supplemental expert witness disclosure approximately two weeks before trial. Dr. Replogle moved to exclude the guidelines due

to their untimely disclosure, but the District Court declined to exclude them, and Dr. Hamilton was allowed to testify about them at trial. Dr. Replogle, called as part of the Plaintiff's case-in-chief, testified that he did not disclose his Spineology interest to Howard. After the close of Howard's case-in-chief, she moved for judgment as a matter of law regarding the informed consent issue. The District Court denied the motion.

¶10 Trial continued, and Dr. Replogle's expert witness, Dr. Michael Levy, testified that Dr. Replogle was not required to disclose his financial ties to Spineology to obtain Howard's informed consent for the L5-S1 fusion procedure. Both Dr. Levy and Dr. Replogle further testified that they were not aware of the AANS and CNS guidelines. At the close of all evidence in the case, Howard again moved for judgment as a matter of law regarding her informed consent claim. The District Court again denied Howard's motion.

¶11 On November 2, 2018, the jury returned a verdict in favor of Dr. Replogle, finding that he was not negligent in either obtaining Howard's informed consent or the way he performed surgery. Howard then filed her renewed motion for judgment as a matter of law and motion for a new trial on December 5, 2018. After the matter was briefed, the District Court denied Howard's motions in its January 22, 2019 Order Denying Plaintiff's Renewed Motion for Judgment as a Matter of Law/Motion for New Trial. This appeal followed.

STANDARD OF REVIEW

¶12 We review a district court's M. R. Civ. P. 50 decision denying judgment as a matter of law de novo. *Johnson v. Costco Wholesale*, 2007 MT 43, ¶ 18, 336 Mont. 105, 152 P.3d 727. A district court should grant judgment as a matter of law only when there is a

complete lack of any evidence which would justify submitting an issue to the jury, considering all evidence and any legitimate inferences that might be drawn from it in a light most favorable to the party opposing the motion. *Wagner v. MSE Tech. Applications, Inc.*, 2016 MT 215, ¶ 15, 384 Mont. 436, 383 P.3d 727 (citing *Deonier & Assocs. v. Paul Revere Life Ins. Co.*, 2004 MT 297, ¶ 18, 323 Mont. 387, 101 P.3d 742).

¶13 Where the basis of a motion for a new trial is insufficiency of the evidence, we review a district court's ruling de novo, determining whether there was substantial evidence to support the verdict. *Giambra v. Kelsey*, 2007 MT 158, ¶ 27, 338 Mont. 19, 162 P.3d 134 (citing *Renville v. Taylor*, 2000 MT 217, ¶ 14, 301 Mont. 99, 7 P.3d 400).

DISCUSSION

¶14 1. *Did the District Court err by denying Howard's Motion for Judgment as a Matter of Law?*

¶15 “[T]he existence of a legal duty presents a question of law to be determined by the court.” *Dick Irvin, Inc. v. State*, 2013 MT 272, ¶ 17, 372 Mont. 58, 310 P.3d 524 (citing *State v. Butte-Silver Bow Cty.*, 2009 MT 414, ¶ 20, 353 Mont. 497, 220 P.3d 1115).

¶16 Howard asks this Court to find, as a matter of law, that Dr. Replogle was required to disclose to her that he owned Spineology stock and had a consulting agreement with Spineology before she could give informed consent to the 2010 surgery. In the Final Pretrial Order, Howard did not specifically identify Dr. Replogle's financial disclosures as an issue of law. Howard did identify “[w]hether Dr. Replogle failed to obtain Mrs. Howard's informed consent before performing the Procedure” as an issue of fact in the Final Pretrial Order. Before and during trial, Howard repeatedly argued that Dr.

Replogle's financial interest in Spineology and its relation to the informed consent process was an issue for the jury to decide, before ultimately moving for judgment as a matter of law on the issue at the end of her case, and then again after the settling of jury instructions at the close of all evidence. The District Court found that the issue of Dr. Replogle's disclosures during the informed consent process was a matter for the jury to decide.

¶17 The plaintiff in a medical malpractice action must establish the following elements: (1) the applicable standard of care, (2) the defendant departed from that standard of care, and (3) the departure proximately caused the plaintiff's injury. *Estate of Willson v. Addison*, 2011 MT 179, ¶ 17, 361 Mont. 269, 258 P.3d 410 (citation omitted). Expert testimony is required to establish these elements. *Horn v. St. Peter's Hosp.*, 2017 MT 298, ¶ 20, 389 Mont. 449, 406 P.3d 932 (citing *Labair v. Carey*, 2012 MT 312, ¶ 29, 367 Mont. 453, 291 P.3d 1160). "A medical malpractice plaintiff must establish that a physician's conduct breached a national standard of care." *Norris v. Fritz*, 2012 MT 27, ¶ 44, 364 Mont. 63, 270 P.3d 79 (citation omitted). The disclosures required to obtain an informed consent are a matter of medical judgment. *Collins v. Itoh*, 160 Mont. 461, 467-68, 503 P.2d 36, 40 (1972) (citing *Doerr v. Movius*, 154 Mont. 346, 349, 463 P.2d 477, 478 (1970)).

¶18 At trial, the jury heard competing testimony from expert witnesses regarding financial disclosures in general, and specifically regarding whether Dr. Replogle was required to disclose his Spineology ties. Dr. Hamilton testified that Dr. Replogle was required to disclose this information, and Dr. Levy testified that he was not. Because the

District Court twice denied Howard's motion for judgment as a matter of law, the matter went to the jury.

¶19 The District Court gave two jury instructions specifically related to the informed consent issue at trial. Howard's proposed instruction No. 5 stated:

It is the duty of a doctor to obtain a patient's consent before treatment. To obtain consent a doctor is required to disclose all material facts relating to the proposed treatment so that the necessary consent to treatment can be based on an intelligent exercise of judgment. He must explain, in terms a layperson can understand, the nature of any significant risks that may be encountered as a result of the treatment and any other information skilled practitioners would disclose to the patient under the same or similar circumstances. Treatment without consent renders the doctor liable for any injury which resulted from the treatment.

The District Court refused Howard's proposed instruction, and instead gave Instruction No. 18, which stated:

It is the duty of a doctor to obtain a patient's consent before treatment. To obtain consent a doctor is required to disclose all material facts relating to the proposed treatment so that the necessary consent to treatment can be based on an intelligent exercise of judgment. The doctor must explain, in terms a layperson can understand, the nature of any significant risks that may be encountered as a result of the treatment. Treatment without consent renders the doctor liable for any injury which resulted from the treatment.

The District Court refused Howard's proposed instruction No. 5 as it contained language from a California pattern jury instruction, and instead gave Defendant's proposed instruction No. 25, which came from the Montana pattern jury instructions, as Instruction No. 18. The District Court also gave Instruction No. 19, identical to that proposed by Howard, which stated:

If you find from expert medical evidence that a standard of practice existed among doctors as to the amount of information which a doctor would

disclose to a patient such as plaintiff under the circumstances of this case, and if you also find from your evaluation of all the evidence that the doctor failed to disclose to plaintiff the information required by such standard, then the consent obtained from plaintiff was not an informed consent.

¶20 The jury ultimately found that Dr. Replogle did obtain Howard's informed consent to the surgery he performed on March 11, 2010, and therefore he was not negligent in not informing Howard of his financial interest in Spineology. The jury heard competing expert testimony about a matter beyond the scope of normal experience—the financial ties of neurosurgeons to the products they may use in surgery—and determined that Dr. Replogle's informed consent disclosure met the standard of care.

¶21 Howard argues that the AANS and CNS guidelines discussed by Dr. Hamilton at trial made it mandatory for Dr. Replogle to disclose his financial interest in Spineology to Howard as part of the informed consent process. At trial, there was conflicting expert testimony from three neurosurgeons—Dr. Hamilton, Dr. Levy, and Dr. Replogle—about what disclosures were required to obtain Howard's informed consent to the spinal fusion procedure. All three doctors are, or were at one time, members of both the AANS and CNS, and testimony elicited at trial resulted in an estimation that approximately 85 percent of practicing neurosurgeons are a member of one or both groups. Testimony also demonstrated that membership in both the AANS and CNS is voluntary, as neither group licenses neurosurgeons. Both Dr. Levy and Dr. Replogle, members of both the AANS and CNS at the time, testified that they had no knowledge of the 2008 AANS and CNS guidelines regarding financial disclosures until it was disclosed to them by Howard approximately two weeks before trial. Prior to disclosing these guidelines, Howard

consistently argued that the informed consent issue presented a disputed factual issue which must go to the jury. From the conflicting expert testimony presented at trial, it is apparent that there was not a complete lack of any evidence which would justify submitting the issue to the jury. *Wagner*, ¶ 15. As such, the matter is properly one before the jury and the District Court correctly denied Howard's motion for judgment as a matter of law.

¶22 2. *Did the District Court err by denying Howard's Motion for New Trial?*

¶23 Howard, pursuant to Rule 50(b), requested a new trial when she filed her renewed motion for judgment as a matter of law. As we have determined that the District Court correctly denied Howard's motion for judgment as a matter of law regarding Dr. Replogle's financial disclosure requirements, we need only determine whether substantial evidence exists to support the jury's verdict in favor of Dr. Replogle.

¶24 We review a jury verdict to determine whether substantial evidence exists to support the jury's findings. *Covey v. Brishka*, 2019 MT 164, ¶ 20, 396 Mont. 362, 445 P.3d 785 (citing *Wise v. Ford Motor Co.*, 284 Mont. 336, 339, 943 P.2d 1310, 1312 (1997)). Substantial evidence is evidence that a reasonable mind might accept as adequate to support a conclusion. *Suzor v. Int'l Paper Co.*, 2016 MT 344, ¶ 40, 386 Mont. 54, 386 P.3d 584. We review evidence in the light most favorable to the prevailing party, and reversal is rarely warranted. *Suzor*, ¶ 40 (citations omitted).

¶25 At trial, Howard was able to fully present her case to the jury that she did not give informed consent to the procedure due to Dr. Replogle's failure to inform her of his financial interest in Spineology. The jury heard conflicting expert testimony on whether

such a disclosure was required, and ultimately ruled in favor of Dr. Replogle. A reasonable mind could accept the testimony presented at trial that Dr. Replogle was not required to disclose his financial interest in Spineology to obtain Howard's informed consent prior to surgery. The parties characterized the trial as a "battle of experts" below, and presented opposing expert testimony on the issue. The jury believed Dr. Replogle. Substantial evidence exists to support the jury's verdict and neither reversal of that verdict nor a new trial is warranted.

¶26 Finally, Dr. Replogle cross-appealed the District Court's Order Denying Defendant's Motion to Exclude Plaintiff's Damages for Future Medical Expenses and Loss of Ability to Enjoy Life, as well as the District Court's decision to allow Howard to use the AANS and CNS guidelines at trial. In light of our decision upholding the District Court's denial of both Howard's Rule 50 motion for judgment as a matter of law and her motion for a new trial, Dr. Replogle's cross-appealed issues are moot and we decline to address them.

CONCLUSION

¶27 The District Court correctly denied both Howard's motion for judgment as a matter of law and her motion for a new trial. Because these issues are dispositive, we decline to address the issues raised by Dr. Replogle in his cross-appeal.

¶28 Affirmed.

/S/ INGRID GUSTAFSON

We concur:

/S/ JAMES JEREMIAH SHEA

/S/ LAURIE McKINNON

/S/ BETH BAKER

/S/ JIM RICE