ARIZONA COURT OF APPEALS DIVISION ONE

IDA JUANITA ROMERO, Plaintiff/Appellant,

v.

BRIAN D. STEINKE, M.D. and ROMA MARIE COLWELL-STEINKE, husband and wife; ARIZONA SPINE CARE, P.L.C., an Arizona professional limited liability company, *Defendants/Appellees*.

No. 1 CA-CV 15-0862 FILED 5-18-2017

Appeal from the Superior Court in Maricopa County No. CV2011-055755 The Honorable John R. Hannah, Jr., Judge

AFFIRMED COUNSEL

Jeffrey L. Victor, PC, Scottsdale By Jeffrey L. Victor Co-Counsel for Plaintiff/Appellant

Law Office of Scott E. Boehm, PC, Phoenix By Scott E. Boehm Co-Counsel for Plaintiff/Appellant Dickinson Wright, PLLC, Phoenix By Frederick M. Cummings, Anne L. Tiffen, Bradley A. Burns Counsel for Defendants/Appellees

MEMORANDUM DECISION

Presiding Judge Diane M. Johnsen delivered the decision of the Court, in which Judge Margaret H. Downie and Judge James P. Beene joined.

JOHNSEN, Judge:

¶1 Ida Juanita Romero appeals from the superior court's entry of summary judgment in favor of Dr. Brian D. Steinke, Roma Marie Colwell-Steinke and Arizona Spine Care, P.L.C. For the reasons that follow, we affirm.

FACTS AND PROCEDURAL BACKGROUND

¶2 Romero, then 48, went to Steinke complaining of lower back, leg and thigh pain; numbness; and worsening bowel and bladder incontinence. To relieve her symptoms, she decided to undergo spinal fusion and decompression surgery. Steinke performed the surgery at Banner Estrella Medical Center. Also present in the operating room was David Bettes – a sales representative for Medtronic Sofamor Danek, USA, Inc. ("Medtronic"), a medical instruments provider—who was "covering" the surgery for Medtronic.¹ About halfway through the six-hour surgery, Bettes asked Steinke if he would like to use a Medtronic product called a "Crosslink," a metal implant that attaches to the spine and stabilizes vertebrae. Steinke told Bettes he would use a Crosslink if one were available. Although no Crosslink was available at Banner Estrella, Bettes called Joshua Calimpong, a Medtronic sales representative at Banner Boswell Medical Center to arrange to have a Crosslink transported from Banner Boswell to Banner Estrella.

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Bettes described "covering" in the following way: "[I]f a doctor chooses to use the products . . . that I sell, common practice is for that sales representative or sales consultant . . . to attend the case and be support for the ancillary hospital personnel during the administration . . . of those products."

- ¶3 Calimpong was covering a surgery at Banner Boswell that same day, and had asked ahead of time that a Crosslink be available for that procedure. In preparation for use in that surgery, a Crosslink had been placed in Banner Boswell's "sterile core" presumably after being sterilized in accordance with Banner Boswell procedure. The Banner Boswell surgeon, however, had chosen not to use the Crosslink. After receiving Bettes's call, Calimpong agreed to deliver the Crosslink to Banner Estrella.
- Sterilization processing department for two transport bags. Bags in hand, he then proceeded to the sterile core area. There, Calimpong inspected the "tray" containing the Crosslink to ensure its sterility had not been visibly compromised.² The tray was packaged in a blue sterilization wrapper, which was taped at each fold to seal any openings. The tape itself served as an indicator of the tray's sterility prior to sterilization, the tape is white, but upon sterilization, black lines appear on the tape. After confirming the tape had black lines through it and remained intact, Calimpong examined the transport bags for holes. Finding no holes in either bag, Calimpong placed the tray in the first bag and double-knotted it; then he placed the first bag inside the second and double-knotted the second bag.
- Once the tray was double-bagged, Calimpong carried it to his car and placed it on the front seat next to him. From Banner Boswell, he drove 15 minutes to Banner Estrella. After he arrived at Banner Estrella, Calimpong carried the tray directly to a door just outside Banner Estrella's operating rooms, where he handed the tray, still double-bagged, to Bettes. Because Calimpong delivered the tray directly to the operating rooms, it bypassed Banner Estrella's Central Sterilization Processing Department, in breach of Banner Estrella protocol, which requires outside vendors to bring all trays directly to the Central Sterilization Processing Department.
- After taking the tray from Calimpong, Bettes returned to the operating room where Steinke was operating on Romero. There, Bettes removed the wrapped tray from the double bags with his bare hands and placed the tray, still taped and packaged in blue sterilization wrap, on an unsterile stand in the operating room. When the doctors signaled they were ready for the Crosslink, Bettes approached the tray on the stand, and with his bare hands, pulled a tab on the blue sterilization wrapper that caused

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Medtronic sales representatives deliver medical instruments to hospitals in metal trays, each of which might contain hundreds of instruments. The Crosslink in this case was in a tray that weighed approximately 10 to 15 pounds.

the wrapper to unwrap "like . . . a present," revealing the tray's contents and allowing a scrub nurse wearing sterile gloves to lift the Crosslink from the tray. Doctors then attached the Crosslink to Romero's spine.

- Three days after surgery, Romero complained of worsening pain and weakness, as well as nausea and vomiting. A CT scan performed a day later did not reveal anything out of the ordinary. A day after that, however, Romero notified nurses that she could not feel her lower extremities. An MRI that day, August 30, 2009, revealed "significant fluid collection in her epidural space." Steinke presumed the fluid build-up was the result of an infection (referred to as an "epidural abscess"), and made a record to that effect. Accordingly, medical staff collected blood samples to test for the presence of bacteria and administered antibiotics. The same day, Steinke performed surgery to drain the fluid. During the procedure, he collected multiple specimens, all of which were tested for bacteria.
- ¶8 Around the same time, two infectious disease specialists examined Romero. Like Steinke, each presumed that, based on her symptoms, Romero suffered from an epidural abscess. For that reason, one of the infectious disease specialists prescribed two additional broad-spectrum antibiotics.
- Meanwhile, Steinke performed additional irrigation and debridement procedures on Romero on September 1, 3 and 7. On September 1 and 3, additional specimens were collected for culture and Gram stain. Additionally, on September 3, Steinke removed and replaced the Crosslink with another; the original was tested for the presence of bacteria.
- ¶10 After none of the cultures or Gram stains revealed the presence of any infectious organisms in the fluid or on the Crosslink, Steinke added an addendum to his original diagnosis of infection. The addendum stated:

None of the cultures from any of the cervical, thoracic or lumbar I and Ds grew out anything, nor were there any organisms seen on Gram stain. As such the preop and postop diagnoses of epidural abscess mentioned here were presumptive and apparently inaccurate. This appears to have been an inflammatory process of unknown origin at this point.

¶11 Romero, who remained paralyzed after the series of procedures, sued Steinke, his spouse and his employer, alleging medical

malpractice. The defendants (collectively referred to here as "Steinke") moved for summary judgment. After briefing and oral argument, the court granted the motion, concluding Romero had failed to offer evidence sufficient to show that negligence by Steinke caused her injury. Romero timely appealed. We have jurisdiction pursuant to Article 6, Section 9, of the Arizona Constitution and Arizona Revised Statutes section 12-2101(A) (2017).³

DISCUSSION

A. Standard of Review.

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law." Ariz. R. Civ. P. 56(a). We review a grant of summary judgment *de novo*, viewing the facts and inferences drawn therefrom in the light most favorable to the party against whom judgment was entered. *Corbett v. ManorCare of Am., Inc.*, 213 Ariz. 618, 621-22, ¶ 2 (App. 2006). Summary judgment is appropriate "if the facts produced in support of the claim or defense have so little probative value, given the quantum of evidence required, that reasonable people could not agree with the conclusion advanced by the proponent of the claim or defense." *Orme School v. Reeves*, 166 Ariz. 301, 309 (1990).

¶13 "Causation is generally a question of fact for the jury unless reasonable persons could not conclude that a plaintiff had proved this element." *Barrett v. Harris*, 207 Ariz. 374, 378, ¶ 12 (App. 2004). In a medical malpractice lawsuit, "a plaintiff . . . must prove the causal connection between an act or omission and the ultimate injury through expert medical testimony, unless the connection is readily apparent to the trier of fact." *Id.* To that end, "the plaintiff's expert is generally required to testify as to probable causes of the plaintiff's injury." Benkendorf v. Advanced Cardiac Specialists Chartered, 228 Ariz. 528, 530, ¶ 8 (App. 2012). It is not sufficient, however, for the expert to simply recite that he or she holds an opinion "to a reasonable medical probability." *See Crawford v. Indus. Comm'n*, 23 Ariz. App. 578, 583 (1975). Rather, an expert's opinion will be admitted only if it is "based on sufficient facts or data" and is "the product of reliable principles and methods" and "if the expert has reliably applied the principles and methods to the facts of the case." See Ariz. R. Evid. 702; Ariz. State

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Absent material revision after the relevant date, we cite a statute's current version.

Hosp./Ariz. Cmty. Prot. & Treatment Ctr. v. Klein, 231 Ariz. 467, 471, ¶ 14 (App. 2013).

- ¶14 On appeal, Steinke characterizes entry of summary judgment in this case as a product of a decision by the superior court as "gatekeeper" that Romero's causation expert failed to satisfy Arizona Rule of Evidence 702. Because ordinarily this court would review a ruling under Rule 702 for an abuse of discretion, see Sandretto v. Payson Healthcare Mgmt., Inc., 234 Ariz. 351, 356, ¶ 11 (App. 2014), Steinke argues our review is limited to whether the superior court abused its discretion.
- In its written order, the superior court meticulously examined the testimony of Romero's causation expert, Dr. Larry W. Rumans, and closely considered the facts and data on which Rumans based his opinion that negligence by Steinke caused Romero's injuries. Although the court referenced Rule 702, it did not rule on Steinke's motion to exclude Romero's expert under that rule. In the end, the analysis by which the court determined that Romero had offered insufficient evidence to create a genuine issue of fact about causation was the same analysis it might have performed in considering whether Romero's expert testimony was adequately supported by facts and data under Rule 702. But based on that analysis, the court granted Steinke's motion for summary judgment, and we will review that decision *de novo. See Orme School*, 166 Ariz. at 309.

B. Merits of the Motion for Summary Judgment.

- ¶16 To defeat Steinke's motion for summary judgement on causation, Romero needed to provide evidence sufficient to enable a reasonable juror to find (1) the Crosslink was contaminated; (2) Romero's fluid build-up was caused by an infection; and (3) the contaminated Crosslink caused the infection. Thus, her expert, Rumans, testified that "to a reasonable degree of medical certainty," the Crosslink that Steinke implanted in Romero was contaminated, causing her to contract an infection that resulted in her injuries.
- ¶17 In support of his opinion that the Crosslink was contaminated, Rumans cited violations of hospital and Medtronic protocols that occurred during the delivery of the Crosslink device to Steinke's operating room on the day of the surgery. It is undisputed that Calimpong violated hospital protocol when he bypassed the Banner Estrella's Central Sterilization Processing Department and delivered the Crosslink directly to Bettes; likewise undisputed is that Bettes violated Medtronic's protocol when he unwrapped the tray containing the Crosslink with his bare hands.

But as Rumans admitted, "[t]here is no direct evidence" that the protocol violations caused the Crosslink to be non-sterile or contaminated. Rumans's opinion that the Crosslink caused an infection seemingly assumed that the Crosslink must have been contaminated as a result of the protocol violations: He testified it "has to be that it's not sterile when it's handled in this way. You just don't have any verification that it is." But given the evidence, Rumans had no opinion about how the Crosslink actually became contaminated.

- As noted, the Crosslink came from Banner Boswell's sterile core, and the only evidence is that upon its arrival in the operating room at Banner Estrella, the tray's sterile wrap (banded with black lines) remained intact. Moreover, Romero offered no evidence that in unwrapping the Crosslink tray in the operating room, Bettes did anything differently than would have been done by a circulating nurse, who is normally tasked with opening trays during surgical procedures.⁴ Further, as noted, when the Crosslink was removed from Romero's spine several days after the surgery, it was tested and revealed no evidence of infection.
- Moving on to the nature of the fluid build-up that Romero developed after her surgery, to defeat summary judgment, Romero needed to offer evidence that the build-up was the result of an infection, rather than some other post-surgical inflammation. Rumans conceded that fluid build-up can occur from inflammation absent infection, but based his opinion that Romero suffered an infection on the presence of pus-like fluid observed after the surgery, drainage, pain and fever.
- Dr. Peter Kotona, Steinke's causation expert, testified that he uses seven data points when evaluating whether a patient has incurred a post-surgical infection: (1) positive culture results; (2) positive Gram stain results; (3) elevated white blood cells; (4) fever; (5) presence of frank pus; (6) pain out of the ordinary; and (7) wound drainage out of the ordinary. Analyzing the first three factors, neither the cultures nor Gram stains showed the presence of bacteria. The vast majority of tests of Romero's surgical wound revealed "few" or "rare" white blood cells, and blood tests taken five days after the surgery showed Romero's white-cell count to be normal. Rumans asserted that the antibiotics prescribed almost immediately after Romero complained of post-surgery discomfort would

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⁴ Although Romero argued that Bettes conceded during his deposition that he touched the Crosslink with his bare hands in the Banner Estrella operating room, Bettes actually testified that he touched the non-sterile outside of the wrap that enveloped the tray.

have killed infection-causing bacteria, but no dead organisms were found on the Gram stains.

- All the other symptoms Rumans identified pus-like fluid, drainage, pain, fever can be the product of non-infectious inflammation, and Rumans offered no facts to support his conclusion that, based on the presence of those symptoms, Romero more likely suffered from an infectious epidural abscess rather than a non-infectious inflammatory process. And he acknowledged that other factors, including Romero's weight, the surgery itself, the simple presence of the Crosslink, a catheter, and a fall Romero suffered after the surgery, could have caused the fluid build-up. *See Emp'rs Mut. Liab. Ins. v. Indus. Comm'n*, 17 Ariz. App. 516, 519 (1972) ("[I]f there are two or more possible causes for a disability and the medical testimony adduced to establish causality is couched only in terms of possibilities, then the claimant has not met his burden of proof.").
- Finally, as to the third element of causation, Rumans failed to identify facts sufficient to support his conclusion that the alleged infection was caused by the Crosslink, rather than by any of the other possible causes he identified, including, among others: the length of surgery, the presence of people in the operating room, the patient's own skin, the patient's own blood, and trauma. In fact, Rumans acknowledged that an overwhelming majority of infectious spinal epidural abscesses do not develop as a result of contaminated instruments.
- ¶23 In sum, after examining the record with care, we conclude the superior court correctly determined that Romero offered insufficient evidence to create a genuine issue of fact in support of her allegation (and her expert witness's opinion) that the Crosslink implanted during her surgery was contaminated, that she suffered from an infectious abscess rather than non-infectious inflammation, and that a contaminated Crosslink caused her infection.
- \P 24 The defects in Romero's causation analysis are illustrated by this comment by her expert witness:

[W]hen you have a situation where there's been a violation of policies and procedures and protocol and you don't know the status of the Crosslink and then you have a series of events that do occur, leading to concern about infection, certainly, and then it does, in fact, occur, those hoofbeats are, you know, not from Africa.

This approach suggests that when an event (Romero's post-surgical fluid build-up) follows a series of unusual circumstances, one may presume that the unusual circumstances caused the event. That logic may be appropriate for some purposes, but not for purposes of summary judgment and Arizona Rule of Civil Procedure 56(a). Romero's expert's opinion – on which her case depended – that the Crosslink was contaminated and that contamination caused her to incur an infection was simply unsupported by sufficient facts.

CONCLUSION

¶25 Because Romero failed to present evidence that would enable a reasonable juror to conclude that Steinke attached a contaminated Crosslink to her spine that caused an infection, we affirm the superior court's order granting Steinke's motion for summary judgment.



AMY M. WOOD • Clerk of the Court FILED: AA