

No. 71616-6

COURT OF APPEALS, DIVISION I
OF THE STATE OF WASHINGTON

RAUL SWAIN and KATHLEEN SCHONS, individually and as
guardians of minor child, JAXOM SWAIN-SCHONS,

Respondents,

v.

SWEDISH HEALTH SERVICES d/b/a SWEDISH MEDICAL
CENTER, and MICHAEL C. SHANNON, M.D.,

Appellants.

APPEAL FROM THE SUPERIOR COURT
FOR KING COUNTY
THE HONORABLE MARIANE C. SPEARMAN

BRIEF OF APPELLANTS

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2014 OCT 27 AM 9:31
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I. INTRODUCTION

The Civil Rules are designed to prevent a party from ambushing an opponent with expert testimony disclosed for the first time during trial, after that party has rested, on rebuttal. At the end of a two-week medical malpractice trial against appellants Michael Shannon M.D. and Swedish Medical Center, the trial court allowed respondents Raul Swain, Kathleen Schons, and their son Jaxom,¹ to present on rebuttal undisclosed expert testimony by one of Jaxom's subsequent treating physicians who testified that she had conducted post-treatment experiments to conclude that Jaxom's injury could not have occurred in the manner that Dr. Shannon and his experts asserted.

This previously undisclosed expert testimony crippled Dr. Shannon's defense that the pieces of medical guidewire that had been found in Jaxom's vein came from the wire's thin outer wrapping, which unbeknownst to Dr. Shannon, had separated from its inner core while he was inserting a catheter into the vein. Neither Dr. Shannon nor his experts could address this undisclosed expert testimony disclosed and presented for the first time on

¹ Dr. Shannon and Swedish Medical Center are referred to collectively as "Dr. Shannon," and the plaintiffs are referred to as Swain-Schons.

rebuttal. Though the wire was surgically removed with no lasting injuries to Jaxom, the jury returned a \$1 million verdict in favor of Swain-Schons.

The trial court also refused to allow Dr. Shannon's expert to testify regarding reports of similar guidewire failures, allowed Swain-Schons to present evidence regarding the length of Dr. Shannon's shift and that a different hospital used a checklist for procedures involving guidewires, evidence that Swain-Schons conceded was irrelevant to whether Dr. Shannon violated the standard of care. The trial court erroneously denied Dr. Shannon's motion for a new trial. This Court should vacate the judgment and remand for a new trial.

II. ASSIGNMENTS OF ERROR

1. The trial court erred in allowing the plaintiffs to offer undisclosed expert testimony of Dr. Chapman on rebuttal and then refusing to strike that testimony. (12/18 RP 78-83)

2. The trial court erred in preventing Dr. Shannon's expert witness Mr. Cline from referring to Manufacturer and User Facility Device Experience (MAUDE) reports he relied on in forming his expert opinions. (12/16 RP 70-72)

3. The trial court erred in denying Dr. Shannon's motion in limine to exclude evidence regarding Dr. Shannon's shift length or the procedure checklist used by a different hospital. (12/9 RP 91-92)

4. The trial court erred in entering its Order Denying Defendants' Motion For A New Trial. (CP 1105-06)

5. The trial court erred in entering judgment on the jury's verdict against Dr. Shannon and Swedish Health Services. (CP 1100-02)

III. ISSUES

1. May a medical malpractice plaintiff introduce on rebuttal undisclosed expert testimony from a subsequent treating physician based not on the physician's treatment of the plaintiff, but on the physician's post-treatment experiments?

2. Did the trial court err by excluding under ER 703 an expert metallurgist's testimony regarding reports of medical guidewire failures commonly relied on by other metallurgists and used by that expert to form his opinion on how a medical guidewire failed without any negligence of the treating physician?

3. Did the trial court err by admitting in a medical malpractice trial evidence of the length of time the defendant

physician was on call and the procedure checklist used by a different hospital, where plaintiffs' own experts conceded that neither established a violation of the standard of care?

IV. STATEMENT OF THE CASE

A. On August 15, 2011, Dr. Shannon placed a catheter in Jaxom Swain-Schons using a medical guidewire.

Since 2009 Dr. Michael Shannon has practiced as a pediatric intensive care physician at Swedish Medical Center on First Hill in Seattle, Washington. (12/17 RP 109) Before practicing at Swedish, Dr. Shannon spent 13 years as a pediatric intensive care physician at Presbyterian Hospital in Albuquerque, New Mexico. (12/17 RP 119-21) Dr. Shannon started Swedish's critical care transport program, in which physicians travel to sick children who need support en route to the hospital. (12/17 RP 128)

On August 14, 2011, 20 month old Jaxom Swain-Schons experienced febrile seizures, a common malady in children. (Ex. 101 at 1-2; 12/17 RP 13-14, 126) Jaxom's parents, Raul Swain and Kathleen Schon, took Jaxom to the emergency room at the Swedish Mill Creek Emergency Department. (12/10 RP 92) After examining Jaxom, the emergency room physician, Dr. Lawrence Chu, recommended that Jaxom be transferred to Swedish First Hill.

(12/12 RP 67-68; Ex. 101 at 2) Dr. Chu contacted Dr. Shannon to arrange the transfer. (12/12 RP 68; Ex. 101 at 2)

Dr. Shannon immediately left from the First Hill facility to pick up and transport Jaxom via ambulance. (12/17 RP 127-28) Upon arriving at the Mill Creek emergency room, Dr. Shannon learned that the nurses at Mill Creek were having great difficulty placing an IV in Jaxom. (12/17 RP 128) The nurse accompanying Dr. Shannon managed to place an IV in Jaxom; however the IV failed on the trip back to Swedish First Hill. (12/12 RP 130)

When they returned to Swedish First Hill, Dr. Shannon was concerned that Jaxom was dehydrated and had been unable to obtain fluids through an IV line. (12/17 RP 132-33; Ex. 102 at 28) Dr. Shannon recommended to Swain-Schons that he perform a procedure called a central line placement that would place a catheter in Jaxom's blood vein, allowing the delivery of fluids and medications, as well as blood sampling. (12/17 RP 132-33; 12/11 RP 20; Ex. 102 at 28) Swain-Schons consented to the procedure. (12/17 RP 154; Ex. 102 at 28)

In a central line placement the physician inserts a guidewire into the vein then uses it to thread a catheter into the vein. (12/11 RP 25-28) Guidewires are extremely thin; the wire Dr. Shannon

used had a diameter of .018 of an inch. (12/16 RP 127; 12/17 RP 159, 185) Guidewires consist of a solid inner wire core covered by a thin outer wire wrapped and coiled around the length of the inner wire. (12/16 RP 78-79; Ex. 118) The outer wrapping is held onto the inner wire by a weld at each end. (12/16 RP 79) Guidewires also have a “J hook” welded onto one end that straightens out during placement in the vein, but then curls back into a hook to prevent damaging the vein. (12/11 RP 26, 142; 12/16 RP 81) The outer wrapping of a guidewire is not apparent to the naked eye; for all intents and purposes it appears to be a solid wire. (12/16 RP 78-79)

In the early morning hours of August 15, 2011, using a 4 French 8 centimeter catheter kit made by Cook Medical containing a 40 centimeter length guidewire, Dr. Shannon placed the catheter in Jaxom without complication. (12/12 RP 145; 12/17 RP 154, 176, 185; 12/18 RP 138; Ex. 102 at 28) Doctors at Swedish instructed Swain-Schons on febrile seizures and discharged Jaxom the next day. (12/10 RP at 97; Ex. 102 at 1)

B. After discovering that pieces of the guidewire had been retained in Jaxom, Swain-Schons sued Dr. Shannon and Swedish Medical Center.

Six months after the central line procedure, Jaxom's parents took Jaxom to the Everett Clinic for what appeared to be a cyst on his neck. (12/10 RP 102; Ex. 103 at 12) Physicians at the Everett Clinic x-rayed Jaxom and determined that wire pieces were present in his vein. (12/10 RP 102-03) Jaxom was transported to Children's Hospital in Seattle where physicians removed the wire pieces without complication. (12/10 RP 111) Jaxom suffered no long-term consequences from the presence of the guidewire pieces. (12/10 RP 147; 12/12 RP 39, 44; 12/17 RP 101-02) The pathologist who inspected the removed guidewire pieces described them as "two silver metal wires with a coil architecture." (Ex. 6 at 16; 12/16 RP 37)

On May 7, 2012, Swain-Schons filed a complaint for medical negligence against Dr. Shannon and Swedish Medical Center. (CP 1-4) Trial commenced before King County Superior Court Judge Mariane Spearman ("the trial court") on December 9, 2012, and lasted through December 18. Dr. Shannon denied any negligence because he reasonably believed that he had removed an intact guidewire and that the thin outer coil of the wire and the J hook

separated from the wire's inner core due to a latent and unobservable defect.

C. The trial court refused to allow Dr. Shannon's expert metallurgist to explain the significance of reports documenting instances of guidewire failure.

To support his defense that the components of the guidewire had separated, Dr. Shannon hired an expert metallurgist, Keith Cline, to analyze how the guidewire could have failed. In an offer of proof, Mr. Cline testified that metallurgists rely on any reports that document the failure of a metallic device. (12/16 RP 41, 54-55, 58) Mr. Cline explained that by reviewing previous reports of failure metallurgists avoid "reinvent[ing] the wheel" every time they start a failure analysis. (12/16 RP 55) Mr. Cline testified that Manufacturer and User Facility Device Experience (MAUDE) reports, which document adverse experiences with medical devices to the Food and Drug Administration, are the type of reports that he and other metallurgists rely on, and that "any responsible metallurgist performing a failure analysis of a medical device would search for MAUDE reports." (12/16 RP 41-42, 60) Mr. Cline relied on MAUDE reports that documented failures of Cook guidewires, the type used by Dr. Shannon, including by separating, fraying, and

breaking, in forming his opinions in this case. (12/16 RP 42, 54-55; Ex. 119)

Dr. Shannon offered Mr. Cline's expert testimony regarding the MAUDE reports to rebut the Swain-Schons' position that the welds on a guidewire are incapable of breaking. In their case in chief, Swain-Schons presented testimony from their expert and a treating physician that they had never heard of the welds on a guidewire breaking. (12/11 RP 100-02, 159) During the defense case, however, the trial court refused to allow Mr. Cline to mention the MAUDE reports to the jury and refused to allow Dr. Shannon to use them as illustrative exhibits. (12/16 RP 70-72) The trial court reasoned that "Mr. Cline didn't say that in his normal course of being a metallurgist he relies on MAUDE reports." (12/16 RP 70)

D. The trial court refused to exclude evidence regarding Dr. Shannon's shift length and the procedure checklist used by a different hospital.

Dr. Shannon moved in limine to exclude evidence regarding Dr. Shannon's 48-hour on-call shift on the night he treated Jaxom and to exclude evidence that Seattle's Children's Hospital, where Swain-Schons' expert practiced, employed a procedure checklist.

(CP 61-62)² The trial court denied that motion. (12/9 RP 91-92) At trial, Swain-Schons' expert, Dr. Kenneth Schenkman, testified that a physician does not violate the standard of care by working a 48-hour on-call shift, but that no physicians at Children's Hospital work 48-hour on-call shifts. (12/11 RP 71, 91) Swain-Schons' expert also testified that the standard of care does not require using a procedure checklist but that a checklist is an important tool to avoid "mess[ing] up" and that they are especially important when the physician is tired. (12/11 RP 70-71, 91-92; Exs. 9-10)

E. At the end of the two week trial, the trial court allowed one of Jaxom's treating physicians to give her undisclosed expert opinion, based on her post-treatment experiments, that the wire pieces could not have been the outer coil of the guidewire.

Prior to trial, Swain-Schons disclosed only one expert witness, Dr. Schenkman. (CP 782) Swain-Schons also disclosed a list of "treating healthcare providers" who "may be called to testify regarding their care and treatment of Jaxom Swain-Schons." (CP 781-82) Swain-Schons included Dr. Theresa Chapman, Jaxom's subsequent treating physician, in the list of treating healthcare providers. (CP 782) They did not disclose that Dr. Chapman was

² While Dr. Shannon is on-call, he sleeps, runs errands, and otherwise relaxes when he is not needed at the hospital. (12/17 RP 195; 12/18 RP 26)

the radiologist at Seattle Children's hospital that reviewed Jaxom's radiology images prior to surgery or that Dr. Chapman would offer any expert testimony. (CP 782) Swain-Schons never updated or amended their disclosure of expert witnesses nor did they provide a summary of Dr. Chapman's opinions.

On the last day of trial, the trial court permitted Dr. Chapman to testify on rebuttal, over Dr. Shannon's objection. (12/11 RP 176-77) In her report written after reviewing the radiology images, Dr. Chapman wrote that the images showed "2 thin metallic densities in the chest, consistent with wires." (Ex. 6 at 10) However, at trial, Dr. Chapman went beyond her report and testified that in her expert opinion "[i]t is not possible" that what she saw on radiology images were "coils," and that the outer coil of the guidewire would not have had the strength to perforate through the skin. (12/18 RP 68, 74)

Dr. Chapman based those opinions on experiments she had run on an exemplar guidewire given to her by Swain-Schons' counsel. (12/18 RP 74, 82; 2/14 RP 11, 31) The Swain-Schons did not supplement discovery responses or otherwise disclose these experiments despite Dr. Shannon's discovery request that the Swain-Schons identify each expert, "[t]he subject matter of any

investigation or study conducted by him/her,” and “[t]he substance of the fact and opinions to which the expert is expected to testify at trial.” (CP 755) Dr. Shannon’s counsel immediately objected to Dr. Chapman’s testimony and asked that it be stricken. (12/18 RP 73, 78-80) The trial court refused to strike Dr. Chapman’s testimony. (12/18 RP 83)

F. The trial court denied Dr. Shannon’s motion for a new trial.

The jury found Dr. Shannon negligent and awarded \$250,000 to each of Jaxom’s parents, and \$500,000 to Jaxom. (CP 676-77) Dr. Shannon moved for a new trial arguing that the trial court erred by allowing Dr. Chapman to present undisclosed expert opinions on rebuttal, precluding Mr. Cline from referring to the MAUDE reports, and allowing evidence regarding Dr. Shannon’s shift length and the checklist used by Children’s Hospital. (CP 705-36) The trial court denied the motion. (CP 1105-06) The trial court entered judgment on the jury’s verdict against Dr. Shannon. (CP 1100-02)

Dr. Shannon timely appealed. (CP 1107-16)

V. ARGUMENT

A. **The trial court erred in allowing Dr. Chapman's undisclosed expert testimony in violation of the discovery rules.**

Swain-Schons never disclosed that Dr. Chapman, a treating physician, would provide expert testimony based on post-treatment experiments with a guidewire that “[i]t is not possible” that what she saw on radiology images were “coils” and that coils would not have been strong enough to perforate the skin. The trial court exacerbated the prejudicial impact of this previously undisclosed testimony by allowing it on rebuttal. This Court should vacate the judgment and remand for a new trial.

Washington courts long ago abandoned the “blindman’s bluff” version of trial in favor of “a fair contest with the basic issues and facts disclosed to the fullest practicable extent.” *Gammon v. Clark Equip. Co.*, 38 Wn. App. 274, 280, 686 P.2d 1102 (1984) (quoting *United States v. Procter & Gamble Co.*, 356 U.S. 677, 682, 78 S.Ct. 983, 986, 2 L.Ed.2d 1077 (1958)), *aff’d*, 104 Wn.2d 613, 707 P.2d 685 (1985). “Requiring parties to disclose witnesses allows the opposing party time to prepare for trial and conduct the necessary discovery in a timely fashion.” *Lancaster v. Perry*, 127 Wn. App. 826, 833, ¶ 10, 113 P.3d 1 (2005).

King County Local Rule 26(k)(1) codifies these principles by requiring disclosure of experts: “Each party *shall* . . . disclose all persons with relevant factual or *expert knowledge* whom the party reserves the option to call as witnesses at trial.” (emphasis added) This disclosure must include “[a] summary of the expert’s opinions and the basis therefore and a brief description of the expert’s qualifications.” KCLR 26(k)(3)(C); *see also Jones v. City of Seattle*, 179 Wn.2d 322, 343, ¶ 45, 314 P.3d 380 (2013) (defense’s “reservation of rights” to call any witness on plaintiff’s list was improper disclosure under KCLR 26; plaintiff was prejudiced because he had “no ability to respond to [witness’s] ‘explosive’ allegations”).

Civil Rule 26(e)(1) likewise requires parties to seasonably supplement discovery responses regarding “the identity of each person expected to be called as an expert witness at trial, the subject matter on which he is expected to testify, and the substance of his testimony.” Where a party fails to timely disclose a witness or her testimony, that testimony should be excluded if (1) the party willfully violated the discovery rules, (2) there is substantial prejudice to the opposing party, and (3) sanctions less than exclusion are insufficient. *Jones*, 179 Wn.2d at 343, ¶ 33 (citing

Burnet v. Spokane Ambulance, 131 Wn.2d 484, 494, 933 P.2d 1036 (1997)); *see also* KCLR 26(k)(4).

Washington courts recognize the distinction between a treating physician called to testify to purely factual matters and those called to offer expert opinions. When treating physicians are allowed to give expert opinions those opinions must be “limited to the medical judgments and opinions *which were derived from the treatment.*” *Smith v. Orthopedics Int’l, Ltd., P.S.*, 170 Wn.2d 659, 668, ¶ 14, 244 P.3d 939 (2010) (emphasis in original) (internal quotation omitted). *See also Johnson v. State, Dep’t of Transp.*, 177 Wn. App. 684, 691, 700-05, ¶¶ 11, 29-37, 313 P.3d 1197 (2013) (plaintiff could not recover costs associated with treating physician as expert witness costs because physician was “neither retained nor listed as an expert witness”), *rev. denied*, 179 Wn.2d 1025, 320 P.3d 718 (2014).

Here, Swain-Schons undisputedly failed to disclose that Dr. Chapman would testify as an expert witness. They disclosed only that Dr. Chapman might “be called to testify regarding [her] care and treatment of Jaxom Swain-Schons.” (CP 782) Dr. Chapman’s “care and treatment” consisted only of reviewing radiology images and writing a report based on those images that stated she observed

“2 thin metallic densities in the chest, consistent with wires.”
(12/18 RP 63; Ex. 6 at 10)

As Swain-Schons conceded below, Dr. Chapman gave expert opinions – not included in her report – that “[i]t is not possible” that what she saw on radiology images were “coils,” and that the outer coil of the guidewire would not have had the strength to perforate through the skin. (CP 998; 12/18 RP 68, 74) Dr. Chapman derived these opinions not from her treatment of Jaxom, but from the experiments she ran with a guidewire given to her by Swain-Schons’ counsel. (*Compare Smith*, 170 Wn.2d at 668, ¶ 14 with 12/18 RP 74, 82; 2/14 RP 11, 31) Swain-Schons never disclosed these “expert[] opinions and the basis therefore,” nor did they supplement their discovery response to Dr. Shannon’s request they disclose “[t]he subject matter of any investigation or study conducted” by an expert, as required by KCLR 26(k)(3)(C) and CR 26(e)(1).

The trial court erred by not excluding Dr. Chapman’s testimony as a willful and prejudicial discovery violation that could not be cured with lesser sanctions. *Jones*, 179 Wn.2d at 343, ¶ 33. Swain-Schons knew before trial the expert opinions they would elicit from Dr. Chapman. Indeed, Swain-Schons’ counsel met with

Dr. Chapman, outlined the defense theory, and gave her an exemplar guidewire to aid in developing her opinions. (12/18 RP 74, 82; 2/14 RP 11, 31) Lacking any reasonable excuse for their failure to disclose Dr. Chapman's expert opinions and their bases, Swain-Schons willfully violated the discovery rules. *Casper v. Esteb Enterprises, Inc.*, 119 Wn. App. 759, 769, 82 P.3d 1223 (2004) ("A violation of the discovery rules is willful if done without reasonable excuse."); *In re Estate of Foster*, 55 Wn. App. 545, 548, 779 P.2d 272 (1989) ("an inadvertent error in failing to disclose an expert witness" is willful when done without reasonable excuse), *rev. denied*, 114 Wn.2d 1004, 788 P.2d 1079 (1990).

While Swain-Schons willful failure to comply with the discovery rules severely prejudiced Dr. Shannon, that prejudice was exacerbated by the trial court's decision to allow this undisclosed expert testimony for the first time on rebuttal. Rebuttal evidence is, by definition, evidence offered to rebut new matters presented in the defense's case. "The plaintiff, therefore, is not allowed to withhold substantial evidence supporting any of the issues which it has the burden of proving in its case in chief in order to present this evidence cumulatively at the end of defendant's case." *Kremer v.*

Audette, 35 Wn. App. 643, 648, 668 P.2d 1315 (1983) (quoting *State v. White*, 74 Wn.2d 386, 394–95, 444 P.2d 661 (1968)).

Here, both Jaxom’s surgeon Dr. Drugas and their expert Dr. Schenkman testified for Swain-Schons in their case in chief that the defense theory that Jaxom’s injury was caused by the coiled exterior portion of the wire was not a viable one. (12/11 RP 99-102, 144-46) Swain-Schons cross-examined Dr. Shannon’s defense experts challenging that theory. Dr. Chapman’s eleventh hour testimony that “[i]t is not possible” that she saw coils on radiology images or that coils could perforate the skin was not proper rebuttal.

Moreover, Dr. Chapman’s untimely testimony eviscerated the defense theory that the wire pieces were retained not as the result of Dr. Shannon’s negligence, but because the wire’s outer wrapping separated from its inner core without Dr. Shannon’s knowledge. Because Swain-Schons did not disclose Dr. Chapman’s expert opinions until the moment she offered them in rebuttal, neither Dr. Shannon nor his experts could effectively anticipate or address them. Dr. Chapman’s undisclosed rebuttal testimony was classic “sandbagging” that deprived Dr. Shannon of the chance to fairly present his defense.

Dr. Shannon asked for, but the trial court erroneously denied, the least severe sanction that would remedy the prejudice caused by Swain-Schons' failure to properly disclose Dr. Chapman's expert opinions – excluding or striking Dr. Chapman's testimony that went beyond the opinions actually disclosed in her report. (12/18 RP 78-80) No lesser sanction would have cured the prejudice caused by Dr. Chapman's surprise testimony. *Jones*, 179 Wn.2d at 345, ¶ 52 (witness exclusion was appropriate remedy for “ambush” from failure to disclose witness).

The trial court manifestly abused its discretion in allowing Dr. Chapman's undisclosed expert testimony on rebuttal. Its ruling, if allowed to stand, will only encourage the type of gamesmanship that Washington courts consistently reject as incompatible with the rules of discovery. This Court should vacate the judgment and remand for a new trial preceded by proper disclosure of all expert opinions.

B. The trial court erred in refusing to allow Dr. Shannon's expert metallurgist to explain the significance of the MAUDE reports that documented similar instances of guidewire failure.

The trial court further erred in precluding Dr. Shannon's expert metallurgist Mr. Cline from dispelling the false impression

created by Swain-Schons that guidewires are incapable of failing in the manner alleged by Dr. Shannon. Mr. Cline had reviewed twenty reports of similar failures in forming his opinion that the welds on a guidewire could fail, allowing the solid inner core of the guidewire to separate from the outer coil of the wire. The trial court committed prejudicial and reversible error in refusing to allow Mr. Cline to refer to the MAUDE reports in his testimony and in refusing to allow the jury to review them as illustrative exhibits that supported his expert opinion that Dr. Shannon was fault free.

Expert testimony is admissible where it “will assist the trier of fact to understand the evidence or to determine a fact in issue.” ER 702. *See also Carlton v. Vancouver Care LLC*, 155 Wn. App. 151, 169, ¶42, 231 P.3d 1241 (2010) (trial court committed reversible error in excluding expert testimony that would have assisted jury). Evidence Rule 703 allows experts to base their opinions on facts or data “perceived by or made known to the expert at or before the hearing.” Those facts or data need not be admissible in evidence so long as they are “of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.” ER 703; *see also* Karl Tegland, 5B Washington Practice: Opinions & Expert Testimony § 703.5 at 231

(5th ed. 2007). ER 703 does not require that experts have personal, firsthand knowledge of the facts or data relied upon. *Sunbreaker Condo. Ass'n v. Travelers Ins. Co.*, 79 Wn. App. 368, 374, 901 P.2d 1079 (1995), *rev. denied*, 129 Wn.2d 1020, 919 P.2d 600 (1996).

Experts – in all fields – routinely rely on prior research on a subject as an aid in forming their opinions. *See, e.g., Deep Water Brewing, LLC v. Fairway Res. Ltd.*, 152 Wn. App. 229, 275, ¶ 118, 215 P.3d 990 (2009) (appraiser correctly allowed to explain reliance on past appraisals in forming valuation opinion; “quality work previously done should not be disregarded”), *rev. denied*, 168 Wn.2d 1024, 230 P.3d 1038 (2010); *Rogers Potato Serv., L.L.C. v. Countrywide Potato, L.L.C.*, 152 Wn.2d 387, 392, 97 P.3d 745 (2004) (experts correctly “relied upon forensic reports from reputable sources”); *In re Young*, 122 Wn.2d 1, 58, 857 P.2d 989 (1993) (experts correctly allowed to testify based on “psychological reports and criminal history” compiled by others).

Here, the trial court erred in precluding Mr. Cline from discussing the MAUDE reports and from presenting them to the jury as illustrative exhibits. In forming his opinions, Mr. Cline relied on twenty MAUDE reports documenting failures of Cook guidewires, the type used by Dr. Shannon, including by separating,

fraying, and breaking. (12/16 RP 42, 54-55; Ex. 119) The MAUDE reports supported Mr. Cline's opinion that guidewires were capable of failing in the manner alleged by Dr. Shannon. Further, allowing Mr. Cline to refer to the reports would have rebutted the false impression created by Swain-Schons' expert and treating physician that guidewires cannot fail. (12/11 RP 100-02, 159) The trial court's exclusion of admissible evidence that was crucial to Dr. Shannon's case was an abuse of discretion requiring reversal. *See Grigsby v. City of Seattle*, 12 Wn. App. 453, 457, 529 P.2d 1167, *rev. denied*, 85 Wn.2d 1012 (1975); *see also Thomas v. French*, 99 Wn.2d 95, 104, 659 P.2d 1097 (1983) (error is prejudicial if "it affects, or presumptively affects, the outcome of the trial").

The record squarely contradicts the basis for the trial court's exclusion of Mr. Cline's testimony regarding the MAUDE reports – its belief that Mr. Cline relied on the reports solely for litigation purposes and that metallurgists do not rely generally on such reports. (12/16 RP 70 ("Mr. Cline didn't say that in his normal course of being a metallurgist he relies on MAUDE reports")) Mr. Cline testified that metallurgists rely on all reports – including MAUDE reports – that document the failure of a metallic device. (12/16 RP 41, 54-55, 58) By reviewing previous reports of failure

metallurgists avoid “reinvent[ing] the wheel” when they start a failure analysis. (12/16 RP 55, 58; *see Deep Water Brewing*, 152 Wn. App. at 275, ¶ 118) The information contained in MAUDE reports is “reasonably relied upon by experts in [his] particular field of metallurgical engineering.” (12/16 RP 41-42; *see also* 12/16 RP 60 (“any responsible metallurgist performing a failure analysis of a medical device would search for MAUDE reports”))

Testimony concerning the MAUDE reports was not inadmissible, as Swain-Schons argued below, under 21 U.S.C. § 360i, which governs records and reports on medical devices.³ The statutory prohibition on the use of reports in civil litigation applies “only in civil actions involving the maker of the report,” *e.g.*, when a patient sues a doctor for malpractice and then seeks to establish that malpractice by using a report submitted by the doctor. *Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 596 (N.D. Cal. 2004). This interpretation fulfills the statute’s purpose of encouraging reports of medical device malfunctions by “allow[ing] a doctor or hospital to freely report an adverse event involving a patient

³ “No report made under paragraph (1) by [users of medical devices] shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.” 21 U.S.C. § 360i(b)(D)(3)

without worrying about the report being used against them in litigation.” *Contratto*, 225 F.R.D. at 597.

The trial court committed reversible error in excluding testimony concerning the MAUDE reports and their use as illustrative exhibits, preventing Dr. Shannon’s expert from explaining to the jury that guidewires can and do regularly fail. This Court should reverse and remand for a new trial for this reason, as well.

C. The trial court erred in allowing evidence of Dr. Shannon’s on-call shift length and the checklist used by a different hospital – both of which Swain-Schons conceded did not support their theory that Dr. Shannon violated the standard of care.

Swain-Schons presented irrelevant and prejudicial testimony regarding the length of Dr. Shannon’s on-call shift and a checklist used at Children’s Hospital, neither of which established a standard of care violation. This irrelevant evidence invited the jury to speculate that Dr. Shannon had violated the standard of care without the requisite expert testimony under RCW 7.70.030(1). This Court should vacate the judgment and remand for a new trial.

To establish a medical malpractice claim a plaintiff must prove that his or her “injury resulted from the failure of a health care provider to follow the accepted standard of care.” RCW

7.70.030(1). A plaintiff establishes a standard of care violation by proving that “[t]he health care provider failed to exercise that degree of care, skill, and learning expected of a reasonably prudent health care provider at that time in the profession or class to which he or she belongs, in the state of Washington, acting in the same or similar circumstances.” RCW 7.70.040(1). A medical malpractice plaintiff must generally produce expert testimony to establish the standard of care. *Young v. Key Pharm., Inc.*, 112 Wn.2d 216, 228, 770 P.2d 182 (1989) (“What is or is not standard practice and treatment in a particular case, or whether the conduct of the physician measures up to the standard is a question for experts and can be established only by their testimony.”) (quotation omitted). Thus, criticisms of a physician’s care from an expert that do not rise to the level of a violation of the standard of care are irrelevant under RCW 7.70.030(1). See *First State Ins. Co. v. Kemper Nat. Ins. Co.*, 94 Wn. App. 602, 614-15, 971 P.2d 953 (evidence that did not establish claims pleaded was irrelevant), *rev. denied*, 138 Wn.2d 1009, 989 P.2d 1136 (1999); ER 401.

Here, plaintiffs’ expert conceded that neither the length of Dr. Shannon’s on-call shift nor his failure to use the checklist used at Children’s Hospital violated the standard of care. (12/11 RP 70-

71) The trial court nonetheless invited the jury to create its own standard of care and to speculate that Dr. Shannon violated this lay standard without the requisite expert testimony, in direct contravention of RCW 7.70.030-040 and *Young*. Swain-Schons argued below that this evidence was akin to “motive” evidence (CP 709), but medical negligence has no “motive” element. The trial court’s error in admitting this irrelevant and prejudicial evidence requires a new trial. *First State*, 94 Wn. App. at 615 (trial court committed reversible error in admitting irrelevant evidence that “changed the focus of the trial” to irrelevant issues).

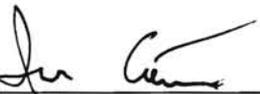
VI. CONCLUSION

Any one of the trial court’s prejudicial rulings justifies a new trial. In combination, they severely crippled Dr. Shannon’s defense. This Court should vacate the judgment and remand for a new trial.

Dated this 24th day of October, 2014.

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DECLARATION OF SERVICE

The undersigned declares under penalty of perjury, under the laws of the State of Washington, that the following is true and correct:

That on October 24, 2014, I arranged for service of the foregoing Brief of Appellants, to the court and to the parties to this action as follows:

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DATED at Seattle, Washington this 24th day of October, 2014.



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