IN THE COURT OF APPEALS OF IOWA

No. 6-154 / 05-0651
Filed May 24, 2006

MARY ARNOLD and KENNETH ARNOLD,
Plaintiff-Appellants,

vs.

LARRY LEE,
Defendant-Appellee.

Appeal from the Iowa District Court for Boone County, William Pattinson, Judge.

Mary Arnold appeals the district court's ruling denying her motion for a new trial. **AFFIRMED.**

Marc S. Harding, Des Moines, for appellant.

Sara J. Gayer, Constance Alt, and Tricia Hoffman-Simanek of Shuttleworth & Ingersoll, P.L.C. Cedar Rapids, for appellee.

Heard by Mahan, P.J., and Hecht and Eisenhauer, JJ.

MAHAN, P.J.

Mary Arnold appeals the district court's ruling denying her motion for a new trial. She argues the district court erred when it refused to admit into evidence a packaging insert from a medical device used during her surgery. We affirm.

I. Background Facts and Procedure

Arnold underwent laparotomy (stomach) surgery in October 2001. The surgery required general anesthesia. Larry Lee, a certified registered nurse anesthetist (CRNA), used an endotracheal tube to administer the anesthesia. An endotracheal tube is a tube that is inserted through the mouth and into the trachea. The tube is held in place by an inflated cuff, a small balloon on the exterior of the tube that is filled with air.

Arnold brought a medical malpractice suit against Lee alleging excessive pressure in the tube's cuff caused damage to her trachea. At trial, she sought to enter into evidence an insert from the tube's packaging. The insert is written by the tube's manufacturer. It contains various information and cautions about the tube and its use. The district court, however, refused to admit the insert. It concluded the written statement was hearsay.

At trial, several witnesses testified as to the use of the tube. The jury ultimately found for Lee. Arnold filed a motion for new trial, arguing the district court erred in not admitting the insert. Without a hearing, the district court denied her motion. Arnold appeals.

II. Standard of Review

Generally, we review the district court's rulings on the admission of evidence for abuse of discretion. *State v. Dullard*, 668 N.W.2d 585, 589 (Iowa 2003). We review hearsay rulings, however, for errors at law.[1] *Id.* Our supreme court has identified three reasons for the different treatment of hearsay evidence. First, hearsay evidence must be excluded unless it can be classified as an exception or exclusion under the hearsay rule or some other provision. *Id.* "Subject to the requirement of relevance, the district court has no discretion to deny the admission of hearsay if it falls within an exception, or to admit it in the absence of a provision providing for admission." *State v. Newell*, 710 N.W.2d 6, 18 (Iowa 2006). Second, whether a statement is hearsay is a legal question. *Dullard*, 668 N.W.2d at 589. Finally, hearsay evidence is presumed to be prejudicial. *McElroy v. State*, 637 N.W.2d 488, 493 (Iowa 2001).

However, "when the basis for admission of hearsay evidence is the expert opinion rule, which provides no hard and fast rule regarding admissibility, we will employ an abuse of discretion standard." *Kurth v. Iowa Dep't. of Transp.*, 628 N.W.2d 1, 5 (Iowa 2001) (evaluating rules 5.703 and 5.705).

III. Merits

Arnold argues the district court erred when it refused to admit the manufacturer's packaging insert. We note from the outset that (1) Arnold concedes the insert is hearsay; (2) she could not establish an author or a publication date for the insert; and (3) she could not establish that a copy of the

[1] The parties disagree about our standard of review in this case. The standard of review with respect to hearsay was settled in *State v. Long*, 628 N.W.2d 440, 444-45 (Iowa 2001), and clarified in *State v. Dullard*, 668 N.W.2d 585, 589 (Iowa 2003).

same insert came with the tube used in her surgery. Nonetheless, Arnold argues the insert is admissible under the learned treatise, residual, and expert exceptions to hearsay. *See* Iowa Rs. Evid. 5.703, 5.803(18), (24). She also argues the insert is admissible as evidence probative on Lee's standard of care. We review each of her claims below.

A. *Learned Treatise Exception*

According to rule 5.803(18), a statement that qualifies as a learned treatise is considered an exception to the hearsay rule. Rule 5.803(18) reads as follows:

> To the extent called to the attention of an expert witness upon cross-examination or relied upon by that witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.

Under rule 5.803(18), a learned treatise may be admitted into evidence as long as it is shown to be reliable authority. The party may show the treatise is reliable through its own witness, on cross-examination of another party's witness, or through judicial notice. *See* Iowa R. Evid. 5.803 advisory committee notes. The treatise itself, however, may not be received into evidence. Instead, statements from the treatise may be read into the record. *Ward v. Loomis Bros., Inc.*, 532 N.W.2d 807, 812 (Iowa Ct. App. 1995).

Arnold attempted to establish the requisite foundation through Lee and both parties' expert witnesses. Lee did not testify specifically about package inserts, but said that he read information from pharmaceutical and medical

device manufacturing companies. He testified that he used their warnings and recommendations as guidelines. Dr. Mitchell Sosis, an anesthesiologist called by Arnold, testified on direct examination that the package inserts constitute a reliable, accurate authority. On cross-examination, however, he admitted that he could not find a publishing date and did not know the author of the particular insert used at trial. Further, when asked if he relied on the insert in his practice of anesthesia medicine, he testified,

> A. Well, let me explain. Rely is not necessarily a word that I would use. I think it's a word with legal connotations probably you understand better than I do. I would say read it, find it interesting and useful, and I apply it to my practice.
>
> Q. As a guideline? A. You might say that.

William Miller, a CNRA called by Lee, testified that he did not and would not rely on information that comes from a manufacturer. Finally, Dr. Mark Kline, an anesthesiologist called by Lee, testified about his use of information from manufacturers as follows:

> Q. Would you consider the literature or the information put out by the company to be authoritative and reliable? A. I would hope it would not be unreliable, but to say that it's authoritative, it depends on who wrote it, how it was written, how it was reviewed. It may represent the company's own bias on how to use something, but not actually how it's used in the clinical practice.
>
> Q. And in fact, isn't it oftentimes true that physicians, and for that matter, maybe CRNAs take things and use them in a way that's off-label or different than what it's been approved for use as. Have you heard of off-label usage? A. Yes. That is primarily applied for medication; the approval basis for it is completely different for medication. We, of course, use medications off-label all the time.
>
> Q. Would you feel that it would be important to go ahead and use it as the manufacturer intended that these tubes be used? A. Well, I mean, we often have to modify the way we use something to meet the clinical situation. The manufacturer may give you some basic guidelines, but it doesn't really apply if you

> have a sick patient. So I don't think you can make that generalization.

Arnold also argues the insert is reliable and authoritative because the information it contains was approved by the Federal Drug Administration (FDA).

Iowa case law gives us little guidance in interpreting this rule of evidence. In reviewing other jurisdictions' case law regarding this particular question, we find that a slight majority do not allow the insert for the truth of the matters asserted within. *See Garvey v. O'Donoghue*, 530 A.2d 1141, 1144-46 (D.C. 1987) (refusing to admit evidence for truth); *Zweig v. E.R. Squibb & Sons, Inc.*, 536 A.2d 1280, 1282 (N.J. Supr. Ct. App. Div. 1988) (refusing to admit evidence for truth); *Whisenhunt v. Zammit*, 358 S.E.2d 114, 428-29 (N.C. Ct. App. 1987) (refusing to admit evidence under learned treatise exception because party could not show expert's reliance); *Spensieri v. Lasky*, 723 N.E.2d 544, 547 (N.Y. 1999) (noting parties conceded insert was hearsay but allowing the evidence to show standard of care). *But see Morlino v. Med. Ctr. Of Ocean Cty.*, 706 A.2d 721, 729-30 (N.J. 1998) (admitting insert under learned treatise exception to rebut inference expert was lone wolf); *Brambley v. McGrath*, 788 A.2d 861, 864-67 (N.J. Super. Ct. App. Div. 2002) (same). Given the facts of this particular case, we find the rationale against admitting the insert under rule 5.803(18) to be most persuasive.

First, no expert at trial could say that he relied upon the package insert as an authoritative instruction in using the tube. Instead, Lee and two of the experts testified they would use the insert for its guidelines. Essentially, we understand their testimony to mean they would take the warnings and information contained

in the insert into account when evaluating a patient, but that they might deviate from the manufacturer's recommendations if needed. Thus, we do not think any of the experts considered the information in the insert to be "authoritative" in the manner required by rule 5.803(18).

Second, we find Dr. Kline's testimony as to off-label use to be particularly persuasive. If we were to allow the package insert into evidence under rule 5.803(18), the jury would be allowed to consider the statements in the insert for the truth of what they assert: that there is only one way to use the tube. In an age where drugs are frequently used for purposes not approved by the FDA, we decline to set such a precedent. Therefore, we understand package inserts for pharmaceuticals and medical devices to represent recommendations by the manufacturer, not comprehensive instruction as to the use of the drug or device. *See Richardson v. Miller*, 44 S.W.3d 1, 12-16 (Tenn. Ct. App. 2000).[2]

Third, the manufacturer has its own reasons for the information contained in the package inserts. Those reasons are not limited to altruism or the education of the medical community. The manufacturer must gain FDA approval, sell its product, and avoid its own liability. While we do not intend to impugn the process in which manufacturers must engage to market a product, we do recognize it is a complicated process governed by motivations and methods that are not necessarily reflected in the publication of a textbook or an academic treatise or journal. *See id.* at 9-13.

[2] Arnold's argument relies heavily on cases involving the off-label use of pharmaceuticals.

Fourth, the insert Arnold seeks to have admitted lists no author or publication date. Thus, we do not know the education or qualifications of the author. We also do not know how current the information contained within the insert is. In addition, it was not established that this insert accompanied the devise in this surgery. Indeed, it was not established this insert was even in existence at the time of the surgery. We know that in order to accompany the tube, the insert was approved by the FDA. However, there is no indication the information in the insert was subjected to the type of competition and scrutiny required by, for example, peer-reviewed compilations or journals.

For these reasons, we conclude the district court did not err when it refused to admit the tube's packaging insert under rule 5.803(18).

B. *Residual Exception*

According to rule 5.803(24), another exception to the hearsay rule is

> A statement not specifically covered by any of the foregoing exceptions but having equivalent circumstantial guarantees of trustworthiness, if the court determines that (A) the statement is offered as evidence of material fact; (B) the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence. However, a statement may not be admitted under this exception unless the proponent of it makes known to the adverse party sufficiently in advance of the trial or hearing to provide the adverse party with a fair opportunity to prepare to meet it; the proponent's intention to offer the statement and the particulars of it, including the name and address of the declarant.

Five requirements must be met in order for a statement to be admitted under rule 5.803(24). Those five requirements are (1) trustworthiness; (2) materiality; (3) necessity; (4) service of the interests of justice; and (5) notice.

State v. Kone, 562 N.W.2d 637, 638 (Iowa 1997). Given the conjunctive within the requirements, failure to satisfy one requirement precludes a statement's admission into evidence.

While the insert may provide probative information, Arnold has not shown the insert itself is necessary to her case.[3] *See Kone*, 562 N.W.2d at 638. The insert is not the only means by which Arnold could introduce similar information. Dr. Sosis testified to substantially the same information as was contained in the insert: that a gauge should be used to measure the pressure within the tube's cuff. Further, as the district court correctly pointed out, Arnold could have called a representative of the manufacturer to testify to its own cautions and concerns. In any case, she has presented no facts to indicate the insert is necessary, or that reasonable efforts would not procure a non-hearsay basis for introduction of substantially similar evidence.

We therefore conclude the district court did not err when it refused to admit tube's packaging insert under rule 5.803(24).

C. *Basis of Expert Opinion Testimony*

According to rule 5.703,

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the trial or hearing. If of a type reasonably relied upon by the experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

[3] There are no Iowa cases interpreting "necessity" in the context of this rule. However, federal cases interpreting requirement B of the identical Federal Rule of Evidence 803(24) have indicated there must be some affirmative showing that reasonable efforts would not or could not have produced evidence superior to the hearsay statement. *See, e.g.*, *United States v. Sinclair*, 74 F.3d 753, 759-60 (7th Cir. 1996); *Larez v. City of Los Angeles*, 946 F.2d 630, 644 (9th Cir. 1991); *Noble v. Alabama Dep't of Envtl. Mgmt.*, 872 F.2d 361, 366 (11th Cir. 1989).

Our supreme court considered rule 5.703, read in conjunction with rule 5.705, as an exception to the hearsay rule in *Brunner v. Brown*, 480 N.W.2d 33, 35-37 (Iowa 1992). The court concluded that hearsay evidence which provides the underlying basis for an expert's opinion may be admitted under rules 5.703 and 5.705. Though it was somewhat unclear in *Brunner*, more recent decisions have made it clear that hearsay admitted under the expert testimony rules may only be admitted "for the limited purpose of showing the basis for the expert witnesses' opinions." *Gacke v. Pork Xtra, L.L.C.*, 684 N.W.2d 168, 183 (Iowa 2004). The evidence "is not admissible for the substantive evidence of the matters asserted therein." *Id.*; *see City of Dubuque v. Fancher*, 590 N.W.2d 493, 496 (Iowa 1999); *Brunner*, 480 N.W.2d at 37; *In re Estate of Kelly*, 558 N.W.2d 719, 721 (Iowa Ct. App. 1996); *CSI Chem. Sales, Inc. v. Mapco Gas Prods.*, Inc., 557 N.W.2d 528 531 (Iowa Ct. App. 1996).

The trial court has considerable discretion in admitting expert testimony. *Brunner*, 480 N.W.2d at 37. In order to be admitted as evidence under rules 5.703, and 5.705, the evidence must be of the type reasonably relied upon by experts in the field in reaching their conclusions. *Kelly*, 558 N.W.2d at 721-22. The trial court made no specific finding as to whether the insert was information of the type reasonably relied upon by experts in anesthesiology in reaching their conclusions. "Nevertheless, we review the trial court's decision under the assumption it was correct, and find an abuse of discretion only where we are unable to find support for the decision in the record." *Id.* at 722.

The court noted in its ruling that if the insert was allowed under rule 5.703, it would be for the limited purpose of explaining Dr. Sosis's opinion. The ruling expressed concern that, even with a limiting instruction, there would be substantial danger that the jury would misuse the evidence for substantive purposes. According to the court, "Since I did not find any compelling necessity to admit Exhibit 1 for the purpose of explaining Dr. Sosis's testimony or allowing the jury to evaluate that testimony, Exhibit 1 would have been more prejudicial than probative."

In *C.S.I. Chemical Sales*, we noted the important distinction between (1) introducing an opinion of a nontestifying expert as a basis for the opinion of a testifying witness and (2) introducing such evidence to corroborate the opinion. *C.S.I. Chem. Sales, Inc.*, 557 N.W.2d at 531. The first is allowed under rule 5.703, the second is not. *Id.*

Dr. Sosis testified to his opinion as to why it was necessary to monitor the pressure on the tube's cuff without reference to the packaging insert. He demonstrated the use of the tube and the pressure gauge, and explained the dangers of too little or too much pressure in the tube's cuff. He expressed the opinion that it was more difficult to manage the inflation of the cuff through the method Lee used that it is through the use of a pressure gauge. He then demonstrated how it was easy to increase the pressure on the cuff by only injecting a small amount of air. Through this testimony and through these demonstrations Dr. Solis provided the basis of his ultimate opinion: that Lee violated the standard of care by failing to correctly monitor the cuff's pressure.

The insert, however, simply reiterates Dr. Solis's opinion that a pressure gauge should be used because other methods are unreliable. There is no explanation, data, or diagrams to illustrate why a gauge should be used. Thus, the introduction of the insert would not have explained the basis of Dr. Solis's opinions, but simply corroborated them. *See Kim v. Nazarian*, 576 N.E.2d 427, 434 (Ill. Ct. App. 1991) ("The fact that a colleague agreed with the testifying expert's opinion is of dubious value in explaining the basis of the opinion."). Had the district court allowed the insert, there is a distinct danger that, because it provided nothing more than another opinion in agreement with Dr. Solis, the jury would have used it as substantive evidence. Further, it is an opinion Lee would be unable to cross-examine. *See id.* ("The party who is unable to cross-examine the corroborative opinion of the expert's colleague . . . will likely be prejudiced.").

We therefore agree with the district court that the risk for unfair prejudice outweighed the probative value of the insert. The court did not abuse its discretion in refusing to admit the evidence under rule 5.703.

D. *Standard of Care*[4]

An out-of-court statement may be considered not hearsay if it is not offered to show the truth of the matter asserted in the statement. *Roberts v. Newville*, 554 N.W.2d 298, 300 (Iowa Ct. App. 1996). In other words, "a

[4] There is no evidence in the record before us that this argument was made before the trial court. However, we except evidentiary rulings from our error preservation rule if the district court's ruling may be upheld on any theory, even though not urged in the district court. *DeVoss v. State*, 648 N.W.2d 56, 62 (Iowa 2002); *see, e.g.*, *Aller v. Rodgers Mach. Mfg. Co.*, 268 N.W.2d 830, 840 (Iowa 1979) ("Here, defendant's objection was sustained; therefore, the ruling will be upheld if the evidence could be held inadmissible on any theory, even though not urged in objections."); *State v. Hinkle*, 229 N.W.2d 744, 748 (Iowa 1975) ("We further note our rule there is no reversible error if the trial court's ruling which admitted the evidence in controversy may be sustained on any ground.").

statement that would ordinarily be deemed hearsay is admissible if it is offered for a non-hearsay purpose that does not depend upon the truth of the facts presented." *McElroy v. State*, 637 N.W.2d 488, 501 (Iowa 2001). For example, a statement might be offered to show the declarant's state of mind, the effect of the statement on the listener, or to show notice, motive, knowledge, reasonableness of behavior, good faith, or anxiety. *Id.*; *Roberts*, 554 N.W.2d at 300.

When a statement is offered for a non-hearsay purpose, the court must first determine whether the party's "true" purpose in offering the statement is to prove the truth of the statement. *McElroy*, 637 N.W.2d at 501-02. For example, if the facts asserted in the statement must be believed as true in order for the evidence to be relevant to the case, then the statement is being offered for the truth and is inadmissible hearsay. *Gacke*, 684 N.W.2d at 182. Second, the court must determine whether the statement is relevant. *McElroy*, 637 N.W.2d at 502. Finally, the court must limit the scope of evidence to that which is necessary to achieve the non-hearsay purpose. *Id.*

The only determination the district court made with regard to the insert's non-hearsay value is that its introduction was both unnecessary and more prejudicial than probative. No specific findings were made as to its value as evidence of a standard of care. Nevertheless, since Arnold urges us to accept the insert as non-hearsay, "we review the trial court's decision under the assumption it was correct, and find an abuse of discretion only where we are unable to find support for the decision in the record." *Kelly*, 558 N.W.2d at 722.

We have no cases in Iowa establishing that hearsay may be admitted for the limited purpose of establishing a standard of care. The majority of cases

from other jurisdictions that have faced this question, however, have either found an exception for the hearsay or otherwise allowed such evidence. *See, e.g., Garvey*, 530 A.2d at 1144-46; *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 886-887 (Minn. 1970), *Thompson v. Carter*, 518 So.2d 609, 611-612 (Miss. 1987); *Morlino*, 706 A.2d at 729-730 ; *Brambley*, 788 A.2d at 864-67; *Spensieri*, 723 N.E.2d at 547-549; *Richardson*, 44 S.W.3d at 15-17 (Tenn Ct. App. 2000). *But see Whisenhunt*, 358 S.E.2d at 116-17 (concluding insert was not admissible under learned treatise exception); *Zweig*, 536 A.2d at 1282 (concluding trial court correctly concluded insert was hearsay and inadmissible); *Reynolds v. Warthan*, 896 S.W.2d 823, 827-28 (Tex. Ct. App. 1995) (concluding trial court did not abuse discretion in refusing to admit insert under learned treatise exception). The fighting question in those cases is what weight a trial court should afford the evidence. A few jurisdictions follow the *Mulder* rule, that manufacturer inserts establish a prima facie standard of care. *See Richardson*, 44 S.W.3d at 16 n.19 (listing cases). The majority, however, have determined that the inserts may only be a factor in establishing a standard of care, and that they may only be accepted in conjunction with expert testimony. *See id.* (listing cases).

It would be unnecessary and inappropriate, however, for us to establish any new rule here. The district court did not abuse its discretion in determining the evidence was unnecessary and more prejudicial than probative. First, Dr. Solis testified to substantially the same evidence Arnold seeks to have admitted through the insert. He also testified that a national organization for professional nurse anesthetists recommended monitoring the tube's cuff pressure. Thus, Arnold was not prejudiced by the district court's refusal to admit

the insert. Second, we have no established rule for accepting hearsay for the non-hearsay purpose of establishing standard of care. We are uneasy with Arnold's argument and several of the cases cited above. Many seem to equate notice of risk with standard of care. *See, e.g.*, *Morlino*, 706 A.2d at 729-31; *Spensieri*, 723 N.E.2d at 548. The first has been accepted in Iowa, the second apparently has not. *See McElroy v. State*, 637 N.W.2d 488, 502 (Iowa 2001); *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 613 (Iowa 2000). Others accept the hearsay under an exception to hearsay, then accept it for the purposes of establishing a standard of care. *See, e.g.*, *Thompson*, 518 So.2d at 611-12 (accepting evidence under published compilation exception to hearsay); *Morlino*, 706 A.2d at 726-31 (accepting evidence under learned treatise exception to hearsay); *Brambley*, 788 A.2d at 865 (same). We, however, do not accept the evidence under any exception urged in this case. Without further guidance from our supreme court, we decline to set any new rule here.

We conclude the district court did not abuse its discretion in refusing to admit the insert for the limited purpose of showing standard of care.

IV. Conclusion

We conclude the district court did not err in refusing to admit the trachea tube packaging insert under the learned treatise or residual exceptions to the hearsay rule. We also conclude the district court did not abuse its discretion in refusing to admit the insert under the expert testimony rule or for the limited purposes of establishing a standard of care. Therefore, the district court's ruling denying Arnold's motion for a new trial is affirmed.

AFFIRMED.