FIFTH DIVISION
August 6, 2010

No. 1-09-1790

WILLIAM RALEIGH,	)	Appeal from the
	)	Circuit Court of
Plaintiff-Appellant,	)	Cook County.
	)	
v.	)	No. 06 L 5695
	)	
ALCON LABORATORIES, INC., and	)	
WEST SUBURBAN MEDICAL CENTER,	)	The Honorable
	)	Elizabeth Budzinski,
Defendants-Appellees.	)	Judge Presiding.

JUSTICE LAVIN delivered the opinion of the court:

This appeal involves the medical and legal sequellae from a cataract surgery in which an intraocular lens was implanted in a suburban man's eye almost 10 years ago. On October 11, 2000, plaintiff William Raleigh, D.D.S., underwent surgery on his right eye at the West Suburban Medical Center (West Suburban) in Oak Park, Illinois. Dr. Scott Rosen, an ophthalmologist, performed the procedure and implanted an ACRYSOF® intraocular lens (the ACRYSOF® Lens), developed, designed, and manufactured by Alcon Laboratories, Inc. (Alcon), in plaintiff's eye. While there were no complications during the surgery, plaintiff later experienced pain and vision problems in the eye. Weeks later, a rare fungus, phaeoacremonium rubrigenum, was found in plaintiff's right eye, requiring the surgical removal of the eye. In the trial court, plaintiff alleged that the product manufacturer should be held strictly liable, arguing that the lens in question was infected when it entered the stream of commerce, while simultaneously alleging that West Suburban should be held liable under the theory of *res ipsa loquitur*, arguing that the hospital was

in exclusive control of the instrumentality that injured the plaintiff. After lengthy discovery and motion practice, the trial court entered dispositive orders in favor of the defendants and this appeal followed. For reasons elucidated below, we affirm in all respects.

BACKGROUND

ACRYSOF®

An intraocular lens is defined in section 886.3600(a) of the Code of Federal Regulations (21 C.F.R. § 886.3600(a) (2000)) as a "device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye." Intraocular lenses are classified as Class III medical devices requiring premarket approval prior to being commercially distributed. 21 C.F.R. §§886.3600(b), (c) (2000).

On May 28, 1993, Alcon submitted a premarket approval application for ACRYSOF® to the United States Food and Drug Administration (the FDA). Alcon's application included design, manufacturing and labeling specifications, full reports of all known studies and investigations of ACRYSOF®'s safety and effectiveness, a statement of ACRYSOF®'s components, properties, and its principles of operation, and a description of the methods, controls, and facilities used in manufacturing ACRYSOF®. On December 22, 1994, the FDA notified Alcon that it had approved ACRYSOF® as a premarket-approved Class III medical device subject to certain conditions described in its approval letter. ACRYSOF® remains on the market as such today.

Alcon manufactured the ACRYSOF® Lens in August 2000 and shipped it to West Suburban on September 14, 2000. In its motion for summary judgment, Alcon included an affidavit from Sandra Budden, the regulatory compliance manager at Alcon, stating that it was her

opinion that Alcon complied with the federal manufacturing specifications and processes during the manufacture of the ACRYSOF® Lens, and that it was not defective at the time it left Alcon's manufacturing facility. Alcon's manufacturing documents demonstrate that Alcon complied with the FDA manufacturing specifications for sterilization, air and surface microbiological environmental testing, and packaging. The ACRYSOF® Lens was 1 of 5,176 intraocular lenses from Batch No. 002296 that met manufacturing specifications for release in August 2000. There were no other complaints of fungal contamination from Batch No. 002296.

The Surgical Procedure at West Suburban

Plaintiff's surgery, performed by Dr. Rosen, lasted approximately 30 minutes. Approximately 20 minutes into the surgery, the ACRYSOF® Lens was removed from its sealed packaging and placed on a plastic dish, still wrapped in sterile material. The ACRYSOF® Lens was then removed using forceps. Dr. Rosen then placed the ACRYSOF® Lens in plaintiff's right eye using the forceps. The eye was then sutured and covered with a patch and plaintiff was discharged. Within 24 hours of the surgery, plaintiff informed Dr. Rosen that he was having difficulty seeing out of the eye and experiencing pain. On November 5, 2000, Dr. Frank LaFranco performed a vitrectomy procedure, during which fluid was removed from the eye. A culture performed on the fluid revealed the presence of the aforementioned fungus.

Deposition Testimony Presented to the Trial Court

Dr. Rosen testified that he had performed approximately 6,000 cataract surgeries prior to plaintiff's procedure. Fungal endophthalmitis, he testified, is very rare and occurs in "significantly less than one percent" of cataract surgeries. No other patients that he performed cataract surgery

on that day developed any type of infection in the eye. There was nothing unusual noted about the storage or handling of the ACRYSOF® Lens by West Suburban. Dr. Rosen used approximately 10 surgical instruments and 9 ophthalmic solutions during and after the procedure. Dr. Rosen testified that any of these instruments or solutions could have been sources of plaintiff's infection.

Dr. LaFranco testified that "something that occurred in the operating room was the cause of this infection, whether it was a nonsterile instrument, a nonsterile fluid, a nonsterile [intraocular lens], and nonsterile surgeon's finger." Dr. LaFranco had "no way of knowing" that the infection occurred in the operating room, but it was his "belief is that this organism was put into Mr. Raleigh's eye in the operating room." Dr. LaFranco had no opinion to a reasonable degree of medical certainty as to the source of the fungus. Dr. LaFranco testified that the fungus "is such a rare organism [he] would speculate that its cause was not the normal breakdown of sterile technique."

Dr. Michael Bergman, plaintiff's expert, testified that "human error was involved in one way or the other. [E]nvironmental molds should not be contaminating prosthetic devices." Assuming that the ACRYSOF® Lens was contaminated by the forceps used during the procedure, Dr. Bergman believed that West Suburban deviated from the standard of medical care in the manner in which it sterilized the forceps, stating that "either the sterilization of the instrument was a problem or the ventilation in the unit was a problem. Neither of which is probable but either of which could have happened." Dr. Bergman opined that because the infection predominantly originated in the posterior chamber, "the problem began nearby which

would incriminate, number one, the lens and its manufacturing or postmanufacturing packaging, or two *** the forceps."

Another expert for plaintiff, Dr. Michael Rinaldi, testified that the most likely source of the fungus was the ACRYSOF® Lens, but acknowledged that other sources included the operating suite personnel, ophthalmic solutions used during the procedure, the surgical instruments, and the operating room environment. Dr. Rinaldi testified that a fungal infection is a risk of cataract surgery that does not necessarily mean that someone was negligent.

The Pleadings and the Trial Court's Dispositive Rulings

On January 20, 2009, plaintiff filed his amended complaint, alleging two counts against each defendant.[1] As to Alcon, plaintiff alleged state law claims for strict product liability (count I) and negligence (count II), asserting that the ACRYSOF® Lens contained the fungus which caused his infection at the time it was manufactured and prior to the time it was placed into the stream of commerce. As to West Suburban, plaintiff alleged a count for medical negligence (count III) and a count under the doctrine of *res ipsa loquitur*, alleging that West Suburban was in exclusive control of all potential sources of the fungus that led to and caused plaintiff's

[1] Plaintiff originally filed this cause of action against West Suburban, Alcon, and Dr. Rosen in 2002. In June 2005, plaintiff voluntarily dismissed the case. In June 2006, plaintiff re-filed this cause against those same three defendants. In September 2008, Dr. Rosen and his practice group, West Suburban Eye Associates, were granted summary judgment. That order is not a part of this appeal.

subsequent injuries (count IV). On May 15, 2009, the trial court entered two orders, the first order granting Alcon's motion for summary judgment as to counts I and II, and the second granting West Suburban's motion for summary judgment on count III and its motion to dismiss count IV pursuant to section 2–615 of the Code of Civil Procedure (735 ILCS 5/2–615 (West 2000)). On June 12, 2009, plaintiff filed a timely notice of appeal.

Plaintiff submits three issues on appeal. First, plaintiff contends that the trial court erred in dismissing count IV of his complaint because he established that he was injured while under the exclusive control of West Suburban and that the injuries would not have occurred in the absence of negligence as required by the doctrine of *res ipsa loquitur*. Next, plaintiff contends that the trial court erred in granting West Suburban's motion for summary judgment when the uncontradicted evidence established that West Suburban's conduct was negligent and that its negligence caused injury to him. Third, plaintiff contends that the trial court erred in granting Alcon's motion for summary judgment when the uncontradicted evidence established that a product manufactured by Alcon caused injury to him.

ANALYSIS

Res Ispa Loquitur

Plaintiff first contends that the trial court erred in dismissing count IV of his complaint because he established that he was injured while under the exclusive control of West Suburban and that the injuries would not have occurred in the absence of negligence as required by the doctrine of *res ipsa loquitur*. We review an order granting a section 2–615 motion to dismiss *de novo*. *Heastie v. Roberts*, 226 Ill. 2d 515, 530-31 (2007). Similarly, we review whether the *res*

ipsa loquitur doctrine should apply, which presents a question of law, *de novo*. *Heastie*, 226 Ill. 2d at 531. "In reviewing the sufficiency of a complaint, a court must accept as true all well-pleaded facts and all reasonable inferences that may be drawn from those facts." *Heastie*, 226 Ill. 2d at 531. A court must also construe the allegations in the complaint in the light most favorable to the plaintiff and should not dismiss a cause of action "unless it is clearly apparent that no set of facts can be proved that would entitle the plaintiff to recovery." *Heastie*, 226 Ill. 2d at 531.

In medical malpractice cases, where the plaintiff relies upon the doctrine of *res ipsa loquitur*, the court must determine whether that doctrine is applicable. 735 ILCS 5/2–1113 (West 2000). The court may rely upon common knowledge or expert medical testimony in determining that the medical result complained of would not have ordinarily occurred in the absence of negligence on the part of the defendant. 735 ILCS 5/2–1113 (West 2000). A plaintiff seeking to rely on the *res ipsa loquitur* doctrine must plead and prove that he was injured: (1) in an occurrence that ordinarily does not happen in the absence of negligence, (2) by an agency or instrumentality within the defendant's exclusive control. *Heastie*, 226 Ill. 2d at 531-32.

"Before *res ipsa loquitur* can be applied, it must be shown that the injury can be traced to a specific instrumentality or cause for which the defendant is responsible or that the defendant was responsible for all reasonable causes to which the accident could be attributed." *Napoli v. Hinsdale Hospital*, 213 Ill. App. 3d 382, 388 (1991) (*res ipsa loquitur* doctrine inapplicable where plaintiff failed to establish that the possibility of her injury occurring after arriving at hospital was greater than the possibility it occurred before her arrival); see *Smith v. Eli Lilly & Co.*, 137 Ill. 2d 222, 257 (1990) (in *res ipsa loquitur* actions, "all parties who could have been the

cause of the plaintiff's injuries are joined as defendants. This helps to preserve the identification element because liability will surely fall on the actual wrongdoer"). "Where there are differing possible causes of an accident and a plaintiff cannot establish that it was defendant's actions which caused the accident, *res ipsa loquitur* will not be applicable." *Napoli*, 213 Ill. App. 3d at 388. A plaintiff's failure to name as defendants all of the entities who might have caused his injuries is fatal to the action since the plaintiff must " 'eliminate the possibility that the accident was caused by someone other than any defendant.' " *Loizzo v. St. Francis Hospital*, 121 Ill. App. 3d 172, 178 (1984), quoting 3 J. Dooley, Modern Tort Law §48.19, at 347 (1977).

We conclude that plaintiff's own experts established that plaintiff has failed to prove that his injury was the type that would not have normally occurred in the absence of negligence on behalf of West Suburban. Looking at the same evidence, it is apparent that plaintiff has failed to prove that he was injured by an instrumentality within West Suburban's exclusive control. Among other causes, Dr. Bergman testified that the lens may have been infected when it left the control of the manufacturer. This testimony, in and of itself, would appear to render the *res ipsa loquitur* doctrine inapplicable as a matter of law. Further, although Dr. Bergman believed that human error may have caused the infection, he also stated that a resulting infection does not necessarily mean that someone was negligent during or after the surgery. This, to us, suggests that this type of injury can occur in the absence of negligence, which is another fatal flaw when one attempts to utilize this legal theory. Dr. Rinaldi, plaintiff's other expert, agreed that a fungal infection is a risk of cataract surgery and that its occurrence does not necessarily mean that

someone was negligent. Under these facts, we cannot conclude that plaintiff's injury would not have normally occurred in the absence of negligence on behalf of West Suburban.

While plaintiff's witnesses appeared to agree that the infection was most likely caused during the surgical procedure, they also testified that there were multiple potential sources of the fungus, including the surgical suite, surgical personnel, surgical instruments, and the ACRYSOF® Lens. Dr. Bergman's testimony revealed that he believed the most probable source of the fungus was the manufacturing or postmanufacturing of the ACRYSOF® Lens. That the surgical environment was the cause of the infection was only "a remote possibility." Plaintiff did not name any other potential defendants in his *res ipsa* count, including Alcon or the manufacturers or providers of any of the other instruments used during the procedure. Because plaintiff cannot trace the source of the fungus to a specific instrumentality in West Suburban's exclusive control and has not named as defendants all potential entities that may have reasonably caused his injury, *res ipsa* is not applicable. Accordingly, the trial court properly dismissed count IV of the amended complaint.

Negligence

Plaintiff next contends that the trial court erred in granting West Suburban's motion for summary judgment when the uncontradicted evidence established that West Suburban's conduct was negligent and that its negligence caused injury to him. We review the entry of summary judgment *de novo* and construe all evidence strictly against the movant and liberally in favor of the respondent. *Fitzgibbon v. National Broadcasting Co.*, 314 Ill. App. 3d 52, 54 (2000). Summary

judgment is appropriate if there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. 735 ILCS 5/2–1005(c) (West 2000); *Fitzgibbon*, 314 Ill. App. 3d at 54. A motion for summary judgment should be granted when the pleadings, depositions, affidavits, and admissions on file show that there is no genuine issue of material fact. 735 ILCS 5/2–1005(c) (West 2000).

In a medical malpractice action, the plaintiff must establish that the defendant owed a duty to the plaintiff, that the duty was breached, and that an injury and damages were directly and proximately caused by that breach. *Siwa v. Koch*, 388 Ill. App. 3d 444, 447 (2009). While the issue of proximate cause is ordinarily a question of fact for the jury, summary judgment is proper as a matter of law when the plaintiff fails to present affirmative evidence that the defendant's negligence was arguably a proximate cause of the plaintiff's injuries. *Wiedenbeck v. Searle*, 385 Ill. App. 3d 289, 292-93 (2008).

"Proximate cause must be established by expert testimony to a reasonable degree of medical certainty." *Wiedenbeck*, 385 Ill. App. 3d at 293. "The causal connection between treatment, or a delay and treatment, and the claimed injury '[must not be] contingent, speculative, or merely possible.' [Citation.]" *Wiedenbeck*, 385 Ill. App. 3d at 293. "An expert's opinion is only as valid as the reasons for the opinion. [Citations]. While testimony grounded in 'expert analysis of the known physical facts' is welcomed, conclusory opinions based on sheer, unsubstantiated speculation should be considered irrelevant." *Wiedenbeck*, 385 Ill. App. 3d at 293, quoting *Petraski v. Thedos,* 382 Ill. App. 3d 22, 31 (2008).

Plaintiff relies on the testimony of Dr. Bergman in asserting that the "undisputed evidence was that West Suburban medical staff failed to comply with the standard of medical care by allowing the fungus to be introduced into [his] eye." The record in no way supports this contention. Dr. Bergman testified that he had no reason to believe that any hospital policy or procedure was deficient or was a cause of plaintiff's injury. Dr. Bergman testified that he did not believe Dr. Rosen or either of the two nurses involved in the procedure, nurse Bando and nurse Shalikov, deviated from the standard of care. In fact, Dr. Bergman stated that Dr. Rosen "did nothing that was a deviation from the standard. That either he had received a contaminated lens or that there was contamination [postmanufacturer] of the lens, but neither [was] anything he could control but, unfortunately, his name was attached to the surgery."

An examination of the main expert testimony in this matter reveals that the opinions that plaintiff seeks to utilize to undo the orders of the trial court are built upon assumptions. Only after assuming the ACRYSOF® Lens was not the source of the fungus did Dr. Bergman opine that the forceps were the source of the fungus and that the hospital staff at West Suburban parted from the applicable standard of medical care in the way it sterilized the forceps. In other words, only when plaintiff's counsel asked Dr. Bergman to assume that the very source he believed contained the fungus– the ACRYSOF® Lens– was not the source of the fungus, could Dr. Bergman conclude that West Suburban deviated from the standard of care. Absent this speculation, Dr. Bergman could not testify to a reasonable degree of medical certainty that the forceps were the source of the fungus. Dr. Bergman's belief that it was a remote possibility that

the surgical environment caused the infection does not satisfy plaintiff's burden in establishing a causal connection, much less establish that there was any negligence on the part of hospital personnel during this procedure. Dr. Bergman could not testify to a reasonable degree of medical certainty that the forceps, the surgical suite, Dr. Rosen, or any other entity in West Suburban's control deviated from the standard of care or caused the injury to plaintiff. This evidence is a woefully insufficient basis upon which to proceed in a claim of professional negligence and the trial court was right to grant summary judgment.

Strict Liability and Express Federal Preemption

Plaintiff next contends that the trial court erred in granting Alcon's motion for summary judgment when the uncontradicted evidence established that a product manufactured by Alcon caused injury to him. Plaintiff alleged state law claims of strict liability and negligence against Alcon. Alcon moved for summary judgment arguing that plaintiff's state-law claims were preempted by the Medical Device Amendments of 1976 (the Amendments) (21 U.S.C. §360k (2006)) to the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §301 *et seq.* (2006)).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 169 L. Ed. 2d 8982, 128 S. Ct. 999 (2008), the Supreme Court considered whether the preemption clause enacted in the Amendments barred common law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA. There, the Court concluded that plaintiff's state-law claims against the manufacturer of a Class III premarket approved balloon catheter used in his angioplasty were preempted by the Act. *Riegel*, 552 U.S. at 330, 169 L. Ed. 2d at 906, 128 S. Ct. at 1011.

Under the Act's amended regulatory scheme, there are three classifications of medical devices, categorized by the risks they present. *Riegel*, 552 U.S. at 316, 169 L. Ed. 2d at 898, 128 S. Ct. at 1003. Class III devices, such as the ACRYSOF® Lens, receive the most federal oversight. *Riegel*, 552 U.S. at 317, 169 L. Ed. 2d at 898, 128 S. Ct. at 1003. After completing a rigorous review process, the FDA may grant or deny premarket approval. *Riegel*, 552 U.S. at 319, 169 L. Ed. 2d at 899, 128 S. Ct. at 1004. "Once a device has received premarket approval, [the Amendments] forbid[] the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319, 169 L. Ed. 2d at 900, 128 S. Ct. at 1005.

Section 360k(a) of the Act provides the following express preemption clause:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. §360k(a) (2006).

Pursuant to this preemption clause, we must determine (1) whether the federal government has established requirements applicable to ACRYSOF® and, if so, (2) whether

plaintiff's common law claims for strict product liability and negligence are based on requirements imposed by the State of Illinois with respect to ACRYSOF® that are different from or in addition to the federal requirements and related to safety and effectiveness. *Riegel*, 552 U.S. at 321, 169 L. Ed. 2d at 901, 128 S. Ct. at 1006.

Under the Act, state requirements are preempted only when the FDA has established specific requirements applicable to a particular device. *Riegel*, 552 U.S. at 322, 169 L. Ed. 2d at 901, 128 S. Ct. at 1006. Requirements concerning device regulation in general do not warrant preemption under the Act. *Riegel*, 552 U.S. at 322, 169 L. Ed. 2d at 901-02, 128 S. Ct. at 1006. In *Riegel*, the Supreme Court determined that premarket approval of Class III medical devices is specific to individual devices and constitutes federal safety review, explaining that "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323, 169 L. Ed. 2d at 902, 128 S. Ct. at 1007.

ACRYSOF® is a Class III premarket approved device, having received premarket approval from the FDA in 1994. The rigorous review process conducted by the FDA constitutes a specific federal determination of the safety of ACRYSOF®. Like the balloon catheter in *Riegel*, ACRYSOF® was subjected to, and was given, federal approval. Plaintiff does not challenge that the FDA approved the commercial distribution of the ACRYSOF® Lens.

We turn, then, to the second question: whether plaintiff's common law claims for strict

products liability and negligence are based on requirements imposed by the State of Illinois with respect to ACRYSOF® that are different from or in addition to the federal requirements and related to safety and effectiveness. The *Riegel* Court explained "that common-law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Riegel*, 552 U.S. at 323-24, 169 L. Ed. 2d at 902, 128 S. Ct. at 1007. The *Riegel* Court found that common law claims for strict liability and negligence constituted state requirements under the Act. *Riegel*, 552 U.S. at 324, 169 L. Ed. 2d at 902, 128 S. Ct. at 1007. As such, plaintiff's state-law claims of strict products liability and negligence are preempted under the Act, but "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330, 169 L. Ed. 2d at 906, 128 S. Ct. at 1011, quoting 21 U.S.C. §360k(a)(1) (2006). That is, plaintiff's claims would not be preempted if they were "parallel" to the federal requirements, such as if the claims were for damages premised upon a violation of FDA regulations. *Riegel*, 552 U.S. at 330, 169 L. Ed. 2d at 906, 128 S. Ct. at 1011. Here, plaintiff does not allege that his injuries were premised upon a violation of FDA regulations. Alcon has established that it complied with the FDA premarket approval process, received approval in 1994, and that the ACRYSOF® Lens was manufactured, packaged, and shipped in compliance with the federal requirements. Any conclusion holding Alcon liable under plaintiff's state-law claims despite Alcon's conformance with the federal requirements imposes a state requirement different from the applicable federal requirements. *Riegel*, 552 U.S. at 330, 169 L. Ed. 2d at 906-07, 128 S. Ct. at 1011.

Accordingly, plaintiff's claims are preempted by the Act and summary judgment in Alcon's favor was proper as a matter of law.

CONCLUSION

While it is readily apparent that plaintiff suffered a significant injury after the surgical implantation of this intraocular lens, it is also apparent that his strict liability claim is preempted by federal law and that his attempt to utilize *res ipsa loquitur* to avoid an understandable lack of proof of medical negligence is manifestly improper as a matter of law. The judgment of the circuit court is affirmed.

Affirmed.

TOOMIN, P.J., and HOWSE, J., concur.

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REPORTER OF DECISIONS – ILLINOIS APPELLATE COURT

(Front Sheet to be Attached to Each Case)

Complete TITLE of Case

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)
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v.)
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and WEST SUBURBAN MEDICAL)
CENTER,)
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Docket No.

COURT

Opinion Filed

No. 1-09-1790

Appellate Court of Illinois

First District, FIFTH Division

August 6, 2010

(Give month, day and year)

JUSTICES

JUSTICE LAVIN delivered the opinion of the court:

TOOMIN, P.J., and Howse, J., concur

APPEAL from the Circuit Ct. of Cook County.

Lower Court and Trial Judge(s) in form indicated in the margin:

The Honorable Elizabeth Budzinski, Judge Presiding.

Indicate if attorney represents APPELLANTS or APPELLEES and include attorneys of counsel. Indicate the word NONE if not represented.

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