

- [Cite as *Kerpelis v. Pfizer, Inc.*, 2004-Ohio-3049.]

STATE OF OHIO, MAHONING COUNTY  
IN THE COURT OF APPEALS  
SEVENTH DISTRICT

MARIA KERPELIS,	)	
	)	CASE NO. 03 MA 17
PLAINTIFF-APPELLANT,	)	
	)	
- VS -	)	OPINION
	)	
PFIZER, INC., et al.,	)	
	)	
DEFENDANTS-APPELLEES.	)	

CHARACTER OF PROCEEDINGS: Civil Appeal from Common Pleas Court, Case No. 01 CV 1310.

JUDGMENT: Affirmed.

JUDGES:

Hon. Mary DeGenaro  
Hon. Cheryl L. Waite  
Hon. Joseph J. Vukovich

Dated: June 7, 2004

APPEARANCES:

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DeGenaro, J.

{¶1} This timely appeal comes for consideration upon the record in the trial court and the parties' briefs. Plaintiff-Appellant, Maria Kerpelis, appeals the decision of the Mahoning County Court of Common Pleas which granted summary judgment to Defendants-Appellees, Pfizer, Inc., Janssen Pharmaceutica, Inc., Bristol-Myers Squibb Company, St. Elizabeth Medical Center, and Ying Amorn, M.D. Kerpelis argues that the trial court erred when it granted summary judgment since her affidavit and evidence she discovered after the trial court granted summary judgment demonstrates that Appellees are liable for her injuries. Kerpelis relied on her own lay opinion to establish her medical malpractice and product liability claims against Appellees rather than producing an expert witness who could testify regarding causation. Since Kerpelis never produced an expert witness in response to Appellees' motions for summary judgment, the trial court's decision must be affirmed.

## Facts

{¶2} Kerpelis underwent a colonoscopy performed by Dr. Amorn at the St. Elizabeth Medical Center and was discharged the next day. At that time, Dr. Amorn prescribed Populsid, a medication manufactured by Janssen.

{¶3} Kerpelis claims that while she was in the hospital she was infected due to unsanitary conditions. Shortly after leaving the hospital Kerpelis visited another doctor, complaining of fever, chills, muscle aches, fatigue, and abdominal pains. That doctor prescribed Trimox, an antibiotic manufactured by Bristol-Myers Squibb. Kerpelis still suffered from those symptoms one week after her colonoscopy and she visited her doctor a second time. That doctor then gave Kerpelis several one-dose packets of Trovan, a medication manufactured by Pfizer.

{¶4} Kerpelis took each of these medications that day. At around midnight Kerpelis had what she claims to be an acute reaction to the medications. During that time, she suffered from extreme respiratory distress and her symptoms included shortness of breath, racing heart, severe abdominal pain, aching joints, and fatigue. The symptoms lasted for hours that night and Kerpelis claims she still suffers from them. Although Kerpelis believes the medications she took caused the episode she never asked a doctor to confirm her belief.

{¶5} After filing and dismissing complaints against each of the defendants, Kerpelis filed a new complaint against all of the defendants. That complaint alleged that the hospital and Dr. Amorn committed medical malpractice and that the pharmaceutical companies were liable under a theory of products liability.

{¶6} On December 5, 2001, the trial court entered a pre-trial order. It ordered, among other things, that Kerpelis provide the names and addresses of her

prospective expert witnesses to the defendants by August 1, 2002. On July 26, 2002, Kerpelis moved for an extension of this deadline to September 15, 2002, which was granted by the trial court on August 19, 2002. On September 16, 2002, Kerpelis filed a second motion to extend this deadline to October 20, 2002. The trial court never specifically ruled on this motion. Regardless, Kerpelis never notified the defendants that she had found an expert witness to testify on her behalf.

{¶7} Between October 15, 2002, and December 4, 2002, each of the defendants filed a motion for summary judgment. In those motions, the defendants argued that they were entitled to summary judgment since Kerpelis did not have an expert witness to support her claims. Kerpelis filed her brief in opposition on November 14, 2002. The only evidence Kerpelis could produce to establish her claims was her affidavit describing her symptoms and beliefs and printouts from the internet which showed that the FDA restricted the use of Propulsid and Trovan after 1999. On January 7, 2003, the trial court granted the defendants' motions for summary judgment, noting that Kerpelis had failed to present a prima facie case of medical malpractice. On February 7, 2003, the trial court modified its judgment to reflect that it was granting summary judgment on Kerpelis' products liability and negligence claims as well as her medical malpractice claims.

#### Summary Judgment Standard of Review

{¶8} In her sole assignment of error, Kerpelis' argues:

{¶9} "The trial court erred in sustaining Defendants-Appellees' motion for summary judgment."

{¶10} Kerpelis argues that the trial court improperly granted summary judgment to Appellees. When reviewing a trial court's decision to grant summary judgment, an appellate court applies the same standard used by the trial court and,

therefore, engages in a de novo review. *Parenti v. Goodyear Tire & Rubber Co.* (1990), 66 Ohio App.3d 826, 829. Under Civ.R. 56, summary judgment is only proper when the movant demonstrates that, viewing the evidence most strongly in favor of the non-movant, reasonable minds must conclude no genuine issue as to any material fact remains to be litigated and the moving party is entitled to judgment as a matter of law. *Doe v. Shaffer* (2000), 90 Ohio St.3d 388, 390. A fact is material when it affects the outcome of the suit under the applicable substantive law. *Russell v. Interim Personnel, Inc.* (1999), 135 Ohio App.3d 301, 304.

{¶11} When moving for summary judgment, a party must produce some facts that suggest that a reasonable fact-finder could rule in her favor. *Brewer v. Cleveland Bd. of Edn.* (1997), 122 Ohio App.3d 378, 386. “[T]he moving party bears the initial responsibility of informing the trial court of the basis for the motion, and identifying those portions of the record which demonstrate the absence of a genuine issue of fact on a material element of the nonmoving party's claim.” *Dresher v. Burt* (1996), 75 Ohio St.3d 280, 296. The nonmoving party has the reciprocal burden of specificity and cannot rest on mere allegations or denials in the pleadings. *Id.* at 293.

#### Newly Discovered Evidence

{¶12} Before this Court addresses the merits of Kerpelis’ argument, we must determine what evidence may be considered when reviewing the trial court’s decision. Kerpelis argues we can and should consider the newly discovered evidence that she attached to her appellate brief. In support of this argument, she cites *Domanski v. Woda* (1937), 132 Ohio St. 208. But *Domanski* is clearly distinguishable. In *Domanski*, the appellant asked the trial court for a new trial based upon newly discovered evidence, a motion which is now covered by Civ.R. 59(A)(8). Neither

*Domanski* nor Civ.R. 59(A)(8) allow an appellant to challenge a trial court's decision to grant summary judgment by presenting the appellate court with new evidence which was not submitted to the trial court.

{¶13} The Ohio Supreme Court clearly held a reviewing court cannot add material to the record before it, which was not part of the trial court proceedings, and then decide the appeal on the basis of the new matter. See *State v. Ishmail* (1978), 54 Ohio St.2d 402, paragraph one of the syllabus. "Since a reviewing court can only reverse the judgment of a trial court if it finds error in the proceedings of such court, it follows that a reviewing court should be limited to what transpired in the trial court as reflected by the record made of the proceedings." *Id.* at 405-406.

{¶14} This Court has repeatedly and unconditionally followed the Ohio Supreme Court's mandate on this issue in both criminal and civil cases. See *Hager v. Waste Technologies Industries*, 7th Dist. No. 2000-CO-45, 2002-Ohio-3466; *State v. Budrovic* (Oct. 31, 2001), 7th Dist. No. 00 CA 5. On December 12, 2003 this Court struck Kerpelis' supplement to her brief, noting that evidence not before the trial court may not be added to the record. Accordingly, even though Kerpelis argues that we must consider the evidence attached to her appellate brief, we cannot do so.

#### Medical Malpractice

{¶15} Kerpelis next argues that the trial court erred when it granted summary judgment to the hospital and Dr. Amorn since the room where the colonoscopy was performed and the personnel she dealt with were unsanitary. In response, both the hospital and Dr. Amorn argue that Kerpelis' claim must fail since she did not support her claim with expert testimony. In addition, Dr. Amorn argues that Kerpelis did not specifically contest the trial court's decision to grant summary judgment to him in her

brief. Accordingly, Dr. Amorn argues that this court does not need to address whether the trial court's decision regarding his motion for summary judgment was correct.

{¶16} Although Dr. Amorn is correct in a certain sense, we will not disregard any error in the trial court's decision to grant him summary judgment. Although Kerpelis was represented by counsel in the trial court, she is acting pro se on appeal. And it is clear that she intended to challenge the trial court's decision to grant summary judgment to each of the defendants. Furthermore, it is possible to interpret her argument as a challenge to the trial court's decision to grant summary judgment to him. She alleges that he performed the colonoscopy and that the room she was in and the people she dealt with were unsanitary. Clearly, this is an attack on Dr. Amorn's actions. Kerpelis clearly challenges the trial court's decision in this regard.

{¶17} However, the substance of Kerpelis' argument must fail. The Ohio Supreme Court has long held that in order to establish medical malpractice, the plaintiff must show: 1) the standard of care recognized by the medical community; 2) the failure of the defendant to meet the requisite standard of care; and, 3) a direct causal connection between the medically negligent act and the injury sustained. *Bruni v. Tatsumi* (1976), 46 Ohio St.2d 127, paragraph one of the syllabus. And it further held that expert testimony is generally required to establish the standard of care and to establish whether the defendant satisfied that standard in a medical malpractice case. *Id.* at 130. "Failure to establish the recognized standards of the medical community has been fatal to the presentation of a prima facie case of malpractice by the plaintiffs." *Id.* at 131.

{¶18} The exception to that rule is "in cases where the nature of the case is such that the lack of skill or care of the physician and surgeon is so apparent as to be within the comprehension of laymen and requires only common knowledge and



experience to understand and judge it.” *Id.* This exception has a limited scope in a world of increasing medical complexity. *Buerger v. Ohio Dept. of Rehab. & Corr.* (1989), 64 Ohio App.3d 394, 399. And the cases which apply this exception generally deal with instances of gross inattention during patient care or miscommunication with the patient, such as leaving a medical instrument inside the body or operating on the right knee versus the left knee. *Lipp v. Kwyer*, 6th Dist. No. L-02-1150, 2003-Ohio-3988, ¶14-15.

{¶19} In this case, Kerpelis does not have any expert testimony supporting her claim that the hospital and Dr. Amorn have violated the appropriate standard of care. Unless her case is of such a kind that the lack of skill or care is so apparent that it is within the comprehension of laymen, the trial court properly granted summary judgment to the hospital and Dr. Amorn. Kerpelis has not attempted to argue at any stage of the proceedings that the common knowledge exception to the requirement for an expert applies and a review of Kerpelis’ claims demonstrates that she would need expert testimony to establish the standard of care and causation. Kerpelis’ claim cannot survive summary judgment merely because she believes that the hospital and Dr. Amorn were negligent. Accordingly, the trial court properly granted summary judgment to the hospital and Dr. Amorn. Kerpelis’ arguments to the contrary are meritless.

#### Products Liability

{¶20} Kerpelis finally argues that the trial court erred when it granted the pharmaceutical companies’ motions for summary judgment since two of the medications she took, Propulsid and Trovan, have been removed from the market by the Food and Drug Administration. She argues that the fact that the FDA removed these medications from the market demonstrates that they were defective and were

more dangerous than she could reasonably foresee. In response, each of the pharmaceutical companies makes a similar argument that Kerpelis failed to establish a cognizable products liability claim since she did not produce any expert testimony supporting her claim.

{¶21} In a products liability action, the plaintiff bears the burden of proving: 1) there was, in fact, a defect in the product manufactured and sold by the defendant; 2) the defect existed at the time the product left the hands of the defendant; and 3) the defect was the direct and proximate cause of the plaintiff's injuries or loss. *State Auto Mut. Ins. Co. v. Chrysler Corp.* (1973), 36 Ohio St.2d 151, paragraph two of the syllabus; R.C. 2307.73(A). The pharmaceutical companies argue Kerpelis' needs expert testimony to establish there was a defect and the defect was the proximate cause of her injuries.

{¶22} Clearly, whether a prescription drug is defective and whether it is the proximate cause of an injury are questions which lie outside the knowledge of lay witnesses. Accordingly, Kerpelis would have to introduce expert testimony to establish these elements of her claim.

{¶23} “[W]here an issue in a case involves a question of scientific inquiry which is not within the knowledge of lay witnesses or members of the jury, expert testimony is required to furnish the answers, and, if the issue relates to a causal connection between an injury and a subsequent physical condition which involves only a scientific inquiry, such causal connection must be established by the testimony of medical witnesses competent to testify on the subject, and the proof in such case must establish a probability and not a mere possibility of such causal connection.” *Stacey v. Carnegie-Illinois Steel Corp.* (1951), 156 Ohio St. 205, 210; see, also, Evid.R. 702.

**{¶24}** Kerpelis did not produce any expert testimony supporting her claims that the medications were defective or that they caused her injuries. The only evidence she introduced which could demonstrate a defect is that the FDA took Propulsid off the market and has ordered that Trovan be used only as a drug of last resort.

**{¶25}** It is questionable whether the fact that the FDA took action to restrict the use of Propulsid and Trovan creates a genuine issue regarding whether these medications were defective. But even if it does, Kerpelis has failed to introduce any evidence that these medications proximately causes her injuries. In her deposition, Kerpelis freely admitted that she never asked a doctor or any other type of expert whether her medications could have caused her symptoms. The only reason she thinks that these medications injured her is because of the temporal proximity between when she began taking these medications and the onset of her symptoms. This belief establishes nothing more than the mere possibility that these medications caused Kerpelis' injuries. This is insufficient to survive summary judgment in favor of Pfizer and Bristol-Myers Squibb.

**{¶26}** Further, this does not demonstrate that Trimox, manufactured by Bristol-Myers Squibb, was defective in any way. Without some evidence that Trimox was defective, Kerpelis' claim against Bristol-Myers Squibb could not survive summary judgment.

**{¶27}** Kerpelis clearly has serious medical issues which were caused by something. She believes those issues were caused by the medications manufactured by these pharmaceutical companies. But the manufacture and design of a prescription drug and how it acts once it is ingested is clearly outside lay expertise. Since Kerpelis did not produce an expert to testify on her behalf, the trial court properly granted summary judgment to the pharmaceutical companies. Kerpelis'

arguments to the contrary are meritless.

{¶28} Accordingly, Appellant's sole assignment of error is meritless and the judgment of the trial court granting summary judgment to Appellees is affirmed.

Waite, P.J., concurs.

Vukovich , J., concurs.