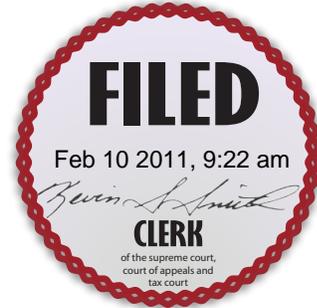


FOR PUBLICATION



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IN THE
COURT OF APPEALS OF INDIANA

CHRISTINE KOLOZSVARI and)
IVAN KOLOZSVARI,)
)
Appellants-Plaintiffs,)

vs.)

No. 32A04-1008-CT-525

JOHN DOE, M.D., JANE DOE, R.N.,)
KELLEY BRANCHFIELD, R.PH., and)
HOOK SUPERX, LLC,)
)
Appellees-Defendants.)

APPEAL FROM THE HENDRICKS SUPERIOR COURT
The Honorable David H. Coleman, Judge
Cause No. 32D02-0902-CT-4

February 10, 2011

OPINION - FOR PUBLICATION

BAILEY, Judge

Case Summary

Christine Kolozsvari (“Christine”) and Ivan Kolozsvari (“Ivan”; collectively, “the Kolozsvaris”) appeal from the trial court’s grant of summary judgment against them and in favor of Kelley Branchfield, R.Ph., (“Branchfield”) and Hook SuperX, LLC (“CVS”). The Kolozsvaris raise one issue for our review, whether the trial court erred when it held that pharmacists have no duty to warn of the side effects of prescribed medications, and therefore determined that Branchfield and CVS were entitled to judgment as a matter of law because they owed no duty either to warn Christine of the side effects of a medication Branchfield filled or to refuse to fill the prescription.

We reverse and remand for further proceedings.

Facts and Procedural History

In conformance with our standard of review, the facts and inferences favorable to the Kolozsvaris, the nonmovants at summary judgment, are as follows. Christine suffers from, among other ailments, ulcerative colitis. In 2006, Christine consulted John Doe, M.D., (“Dr. Doe”)¹ a gastroenterologist, for treatment. Pursuant to his treatment plan, Dr. Doe’s office notified Christine that she should undergo a colonoscopy, which was scheduled for September 25, 2007.

On September 18, 2007, Christine visited Dr. Doe’s office for a pre-colonoscopy

¹ The issues before us relate to potential liability of CVS and its employee pharmacist, Branchfield. The Kolozsvaris’ claims against Dr. Doe and his nurse, Jane Doe, R.N. (“Nurse Doe”), were before a medical review panel during the briefing of the case before this court. Pursuant to Ind. Code § 34-18-8-7(a)(1), which requires that a “complaint filed in court may not contain any information that would allow a third party to identify the defendant,” when a medical malpractice claim has been filed before the conclusion of a medical review panel, we refer to the other defendants as Dr. Doe and Nurse Doe throughout.

consultation. To ensure a clear view of the colon, Dr. Doe required Christine to take a laxative that would empty her colon. Because of her prior experience as a patient, Christine knew certain of these medications were difficult for her to take. Working along with Christine to determine the best colonoscopy preparation, Nurse Doe suggested, and Dr. Doe prescribed, OsmoPrep, a sodium phosphate-based laxative available in pill form instead of as a liquid.

Dr. Doe's office phoned the prescription to the CVS pharmacy in Danville, where Christine routinely took all of her prescriptions and which had a complete record of all such medications. Among these medications was Lisinopril, an ACE inhibitor Christine used at the time to treat her hypertension. CVS's monograph² for OsmoPrep instructs patients to contact a physician if they will use Lisinopril while also taking OsmoPrep, and in 2008 a U.S. Food and Drug Administration "black box" label was put on OsmoPrep regarding the drug's potential for causing kidney damage as a result of possible interactions with Lisinopril.

On September 20, 2007, Christine purchased the OsmoPrep, which was filled as prescribed by Dr. Doe. While Branchfield was working to fill the prescription, a notice appeared on the computer screen with a warning that use of OsmoPrep posed a risk of renal failure because of Christine's age. Branchfield dismissed the warning without conveying its

² A monograph is a short document often provided by a pharmacy that lists side effects, possible prescription interactions, and general precautions regarding use of a prescribed medication.

content to Christine.³

On September 24, 2007, the night before the scheduled procedure, Christine took the OsmoPrep pills per the instructions given to her by Nurse Doe. By the next day, Christine did not feel that the OsmoPrep had completely prepared her for the procedure. She called Dr. Doe's office to notify him and determine what course of action to take. During this call, Christine mentioned that she had experienced some tingling in her fingers and forearms and asked whether these sensations might be related to the OsmoPrep. Someone from Dr. Doe's office told her that these were not caused by the OsmoPrep. The colonoscopy was rescheduled for the following day and Christine was informed that another prescription for OsmoPrep would be called in to CVS; Christine found this surprising, as she expected to be told to just keep drinking water.

After concluding her phone call with Dr. Doe's office, Christine returned to CVS to obtain her second round of OsmoPrep. While Branchfield was filling the prescription, a second computer-generated notification alerted her that the prescribed dose of OsmoPrep would exceed the amount ordinarily considered safe in such a short period of time, increasing the risk to Christine of renal failure. Branchfield again dismissed the notice and filled the prescription without notifying Christine of the warning's content. During this visit, Christine told a pharmacy technician that she had been experiencing tingling running from her fingers to her elbows, and inquired whether these sensations might be a side-effect of the OsmoPrep.

³ Among the exhibits the Kolozsvaris designated in opposition to the motion for summary judgment are printed records from the CVS computer system showing that warnings were displayed to and dismissed by Branchfield.

The technician consulted with Branchfield, who said that OsmoPrep did not cause the tingling sensation.

That night, Christine took the second round of OsmoPrep as directed. Early in the morning on September 26, 2007, Christine awoke with her whole body “buzzing,” feeling “like if you push an electric lawnmower ... and ... you let go and your hands are vibrating.” (App. 115.) She gathered her wallet and keys and drove herself to the emergency room at Hendricks Regional Hospital.

Christine remained at the hospital from September 26, 2007, to October 10, 2007. Christine was diagnosed with kidney failure due to phosphate nephropathy. After undergoing hemodialysis for some time, Christine began to self-administer at-home peritoneal dialysis each night to clear her blood of toxins. This required the permanent placement of a peritoneal catheter and exposes her to the risk of peritonitis, an abdominal infection. She has twice suffered from peritonitis; each time, Christine was hospitalized for treatment. The damage to her kidneys requires that Christine undergo dialysis for the rest of her life or receive a kidney transplant, and she has been placed on a transplant waiting list.

On January 30, 2009, the Kolozsvaris filed suit against Dr. Doe, Nurse Doe, CVS, and Branchfield; on June 17, 2009, the Kolozsvaris amended their complaint, which alleges negligence and loss of consortium.

On March 10, 2010, CVS and Branchfield filed their Motion for Summary Judgment, arguing that CVS and Branchfield had no duty as a matter of law to warn Christine of the dangers posed by OsmoPrep or to decline to fill the prescription. On August 13, 2010, the

trial court granted CVS's and Branchfield's motion, dismissing the Koloszvaris' claims against them.

This appeal followed.

Discussion and Decision

Standard of Review

The Koloszvaris appeal from a grant of summary judgment to CVS and Branchfield. After submission of motions, arguments, affidavits, other evidence, and a hearing (if granted), a trial court must render summary judgment "forthwith if the designated evidentiary matter shows that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Ind. Trial Rule 56(C). Our standard of review in such cases is well established.

On appeal from a grant of summary judgment, our standard of review is the same as that of the trial court. We stand in the shoes of the trial court and apply a de novo standard of review. Our review of a summary judgment motion is limited to those materials designated to the trial court. Summary judgment is appropriate only where the designated evidence shows there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. For summary judgment purposes, a fact is "material" if it bears on the ultimate resolution of relevant issues. We view the pleadings and designated materials in the light most favorable to the non-moving party. Additionally, all facts and reasonable inferences from those facts are construed in favor of the nonmoving party.

Where a trial court enters specific findings and conclusions, they offer insight into the rationale for the trial court's judgment and facilitate appellate review, but are not binding upon this court.... When a trial court grants summary judgment, we carefully scrutinize that determination to ensure that a party was not improperly prevented from having his or her day in court.

Cox v. N. Indiana Pub. Serv. Co., 848 N.E.2d 690, 695-96 (Ind. Ct. App. 2006) (citations omitted).

Whether a Pharmacist has a Duty to Warn or Withhold Medication

The Kolozsvaris claim that Branchfield and, through her, CVS were negligent in failing to warn Christine about possibly serious side effects and contraindications associated with her use of OsmoPrep stemming from her age, the amount of OsmoPrep prescribed, and her prescription history as known to CVS and Branchfield. For the same reasons, the Kolozsvaris also allege that CVS and Branchfield were negligent in filling Christine's OsmoPrep prescription.

In Indiana, the tort of negligence is comprised of three elements: (1) a duty on the part of defendant in relation to the plaintiff; (2) the defendant's breach of that duty; and (3) an injury to the plaintiff resulting from that failure. Miller v. Griesel, 261 Ind. 604, 610-11, 308 N.E.2d 701, 706 (1974). The Kolozsvaris here, and CVS and Branchfield at summary judgment below, addressed only whether CVS and Branchfield had a duty of care toward Christine. A duty to exercise care "arises as a matter of law out of some relation existing between the parties, and it is the province of the court to determine whether such a relation gives rise to such duty." Id. (quoting Neal v. Home Builders, Inc., 232 Ind. 160, 111 N.E.2d 280 (1953)).

Part of any duty of care a pharmacist may owe a patient derives from our Legislature's regulation of the pharmacy as a profession. The General Assembly established the Board of Pharmacy in 1899 to license pharmacists engaged in selling any poison-containing

medication or compounding physician-issued prescriptions. See 1899 Ind. Acts 159-163. The General Assembly declared in 1977 that “the practice of pharmacy” is “a professional occupation ... affecting the public health, safety, and welfare” and that it is “a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the public.” I.C. § 25-26-13-1 (added by Acts 1977, P.L. 276, Sec. 1). To that end, our Legislature requires that pharmacists “exercise [their] professional judgment in the best interests of the patient’s health while engaging in the practice of pharmacy.” I.C. § 25-26-13-16(a). Since the enactment of these provisions in 1977, pharmacists have been required by law to fill all valid prescriptions unless an appropriate exercise of professional judgment indicates that honoring the prescription would be against the patient’s best interests or be contrary to the patient’s health or safety. I.C. § 25-26-13-16(b)(2) & (4) (as added by Acts 1977, P.L. 276, Sec. 1, and amended by P.L. 156-1986, Sec. 3.). In those situations where a pharmacist refuses in good faith to fill a prescription based on a professional judgment that the patient’s health and safety is at risk, the statute affords civil and criminal immunity to the pharmacist. I.C. § 25-26-13-16(b).

The Indiana Board of Pharmacy has interpreted this statute to require that a pharmacist “initiat[e] an offer ... to counsel the patient on matters that, in the pharmacist’s professional judgment, are significant to optimizing drug therapy.” Ind. Admin. Code tit. 856, r. 1-33-2(a). Information given in such counseling may include “[s]pecial directions and precautions” and “common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.”

856 IAC 1-33-2(a)(3) & (4). Such counseling may be waived, but a specific instance of waiver is applicable only for a specific offer of counseling and is not valid for waiver of future counseling offers. 856 IAC 1-33-2(d) & (e).

The evolution of pharmacy regulation in Indiana tracks the history of the evolution of the practice of pharmacy from small, local pharmacies to the growth of national chains like CVS from local or regional drug stores to nationwide retail chains. Cf. 1899 Acts 160-161 (requiring registered pharmacists to be “the proprietor or manager of a store or pharmacy in which physicians’ prescriptions are compounded” or to have worked in such a store for at least four years); History, CVS Caremark, <http://info.cvscaremark.com/our-company/history> (last visited January 20, 2011) (providing a timeline that documents the growth of CVS from a local store in Lowell, Massachusetts, in 1963, to a 7,000-store chain in 2009). In that time, the practice of medicine has become more specialized, and consumers have come to rely more and more upon pharmacists and pharmacies—which often have national resources to support their operations—for help in understanding the effects and interactions of various prescription and over-the-counter medications. See, e.g., Health: Advice from Your CVS Pharmacists on Various Health Topics and Medications, CVS, http://www.cvs.com/CVSAApp/health/consultation_corner.jsp (last visited January 20, 2011) (providing “Ask the Pharmacist” and “Drug Interaction Checker” features permitting consumers to email pharmacists questions about medications and to independently check drug interactions through an external Web site to which CVS directs its Web site visitors).

During this period of growth in the role of pharmacists and pharmacies in health care,

prior decisions of this court and our supreme court have recognized the contractual “relationship between pharmacist and customer as one that gives rise to a duty [of care]” in certain circumstances. Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 517 (Ind. 1994). Indiana statutes and regulations set forth some of the nature of the duty of care imposed upon pharmacists, although they do not of themselves give rise to such a duty. Id. at 518 (rejecting the “argument that the pharmacist’s duty arises by virtue of this statute alone”). While the provisions of the Indiana Code and Board of Pharmacy regulations do not give rise to a statutory duty of care, the Indiana Supreme Court has held that specific circumstances may give rise to a pharmacist’s duty to warn or withhold and that the Legislature’s policy concerns, as expressed in the statutes governing pharmacies and pharmacists, are central to determining when such a duty arises.

In McLaughlin, the court held that a pharmacist had a duty to withhold from a patient a narcotic medication that the pharmacist knew the patient had been refilling too quickly. Id. at 518. The pharmacist in McLaughlin learned of the refill rate from the pharmacy’s computer system, which provided him information about the rate at which McLaughlin was refilling the medication. Id. at 519. The McLaughlin court noted that a pharmacist has the statutory authority to refuse to honor a prescription where the pharmacist’s exercise of professional judgment leads him to conclude that a patient may be harmed. Id. at 518. The court recognized that there are many reasons that a patient “might have a prescription for a dangerous drug refilled at a rate unreasonably faster than that prescribed.” Id. But the public policy concerns as expressed by the Legislature in the statute—preventing pharmacists from

aiding or abetting an addiction or habit or otherwise harming the health and safety of a patient—together with the pharmacist’s knowledge of the prescription history, imposed a duty upon the pharmacist to withhold refills of the drug. Id. (citing I.C. § 25-26-13-16).

The case before us falls within McLaughlin’s interpretation and application of Indiana Code section 25-26-13-16. Here, Christine was prescribed OsmoPrep and sought to fill her prescriptions at CVS. Branchfield received two separate warnings from CVS’s computers while filling the two prescriptions: one alerting her to the risk of kidney damage as a result of someone Christine’s age using OsmoPrep, the other alerting her to the risk of kidney damage as a result of the amount of OsmoPrep Christine had been prescribed and would use in a short period of time. In addition, the entire history of Christine’s prescription medications—including her ongoing use of Lisinopril, an ACE inhibitor that had been associated with a risk of kidney damage when used along with OsmoPrep—was maintained by and therefore was or should have been known to CVS and Branchfield. Finally, Christine informed a pharmacy technician at the CVS pharmacy while Branchfield was working that she had experienced unusual sensations, and expressed concern that these symptoms were related to her use of OsmoPrep. Just as in McLaughlin, where the pharmacist knew that McLaughlin’s refill of his prescriptions was unreasonably rapid and this should have alerted the pharmacist to the substance abuse issues likely associated with this behavior, here, Branchfield had information that gave rise to a duty to exercise professional judgment under the statute. In light of this evidence, we hold that CVS and Branchfield had a duty of care to Christine either to warn Christine of the side effects of OsmoPrep or to withhold the medication in accordance with

Indiana Code section 25-26-13-16 and Pharmacy Board rule 1-33-2.

While we address whether CVS and Branchfield owed a duty of care to withhold or warn Christine about the potentially significant adverse effects of OsmoPrep under the facts of this case, our decision today reaches no further.⁴ Negligence actions are generally ill-suited to disposition upon summary judgment because of the fact-sensitive nature of such actions. Rhodes v. Wright, 805 N.E.2d 382, 387 (Ind. 2004). The question of the existence of a duty of care—a question of law, not fact—was the sole ground upon which summary judgment was granted; the designated evidence largely relates to that question, and our standard of review here dictates the facts as stated above.⁵ Having determined that a legal duty exists, we are presented with no other ground upon which the entry of summary judgment for CVS and Branchfield may be sustained on the evidence and arguments before us. We therefore remand this matter to the trial court for further proceedings consistent with our holding today.

Reversed and remanded.

NAJAM, J., and DARDEN, J., concur.

⁴ Despite CVS’s and Branchfield’s insistence to the contrary, pharmacists need not engage in the practice of medicine to provide counseling or warnings about medications or to withhold such from customers, and such actions need not impair the physician-patient relationship. Cf. McLaughlin, 642 N.E.2d at 519 (noting that “we do not perceive that physicians and pharmacists will become adversaries if pharmacists are expected to cease filling prescriptions where the customers are using the drugs much more rapidly than prescribed”).

⁵ CVS and Branchfield draw our attention to the question of whether OsmoPrep is contraindicated for patients taking Lisinopril, arguing that contraindication means that a patient should never be prescribed a medication. This argument addresses issues related to the standard of care owed Christine and whether that standard of care was breached, a matter not argued before the trial court upon summary judgment and not properly before this court.