Court of Claims of Ohio

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ENID BLACK

Plaintiff

٧.

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Defendant

Case No. 2012-03379

Magistrate Anderson M. Renick

DECISION OF THE MAGISTRATE

{¶1} Plaintiff filed this action alleging medical negligence based upon treatment provided to her at the University of Toledo Medical Center (UTMC). The issues of liability and damages were bifurcated and the case proceeded to trial on the issue of liability.¹

{¶2} On January 28, 2011,² plaintiff presented to her primary care physician complaining of pain in her hip and abdomen, difficulty urinating, diarrhea, and fever. Plaintiff, who was 72 at the time and taking a prescription corticosteroid known as Prednisone, was examined by Nurse Practitioner Carolyn Badenhop. Badenhop determined that plaintiff's symptoms indicated a urinary tract infection (UTI) and she advised plaintiff to seek further evaluation and treatment at the emergency room (ER) at UTMC. Plaintiff arrived at the UTMC ER where she was seen by Physician Assistant Sara Martino. Martino took plaintiff's history and ordered blood and urine tests to identify the exact organism causing the UTI, which Martino classified as

¹Plaintiff's February 10, 2014 motion for an extension of time to file a reply brief is GRANTED instanter.

²All dates shall refer to 2011 unless otherwise noted.

complicated. Martino also began an intravenous (IV) infusion of Levaquin, a broad based antibiotic which is part of a class known as fluoroquinolones. Martino also ordered IV fluids and Tylenol for relief of both pain and fever.

- {¶3} Subsequent to the treatment, plaintiff's condition began to improve. Martino presented plaintiff with two options: she could be admitted to the hospital with additional IV antibiotic treatment, or plaintiff could return home with an antibiotic prescription for ciprofloxacin (Cipro), which is in the same class of drugs as Levaquin. Martino explained that the advantage of Cipro is that it can be taken orally, does not require a hospitalization, and it has the same effect as Levaquin. Plaintiff chose to be discharged with a prescription for Cipro and she was provided instructions detailing signs and symptoms of potential complications which would require further medical attention.
- {¶4} Plaintiff returned to her home in the evening and a friend obtained the prescription of Cipro from a local pharmacy which had also filled her Prednisone prescription. The next day, on January 29, plaintiff took two doses of Cipro; one in the morning and one in the evening. Plaintiff read the product insert that was provided with the prescription which contained the following "black boxed warning:" "Fluoroquinolones, including ciprofloxacin, are associated with an increased risk of tendinitis and tendon rupture in all ages. The risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants." (Joint Exhibit L.)
- {¶5} During the morning of January 30, plaintiff experienced a dull pain in her ankle. Plaintiff spoke with the physician on call at her primary care physician's office, who instructed her to stop taking Cipro and switched her prescription to Bactrim. On January 31, Badenhop switched plaintiff's prescription to a third antibiotic. Later that day, plaintiff received a phone call informing her that Escherichia coli (E. coli) had been

detected in her urine and directing her to return to UTMC for further treatment. Plaintiff was subsequently admitted to the hospital where she received treatment with IV Ceftriaxone for several days. Prior to her discharge, a consulting physician who specializes in infectious disease recommended that plaintiff take Cipro; however, the order was changed to Keflex after the physician learned of plaintiff's ankle pain.

{¶6} On February 4, 2011, after plaintiff had been discharged from the hospital, she was referred to Nabil Ebraheim, M.D., an orthopedic surgeon, for treatment related to plaintiff's ankle pain. Dr. Ebraheim noted that plaintiff's pain was anterior to her Achilles tendon, diagnosed her condition as retrocalcaneal bursitis, and recommended physical therapy. During her next visit, on March 17, 2011, plaintiff reported that her pain was "much better than before" and Dr. Ebraheim noted her ankle exhibited good range of motion. (Joint Exhibit D.)

{¶7} On March 28, 2011, plaintiff sought a second opinion from Roger Kruse, M.D., an orthopedic surgeon at Sports Medicine at Wildwood. Dr. Kruse performed an ultrasound evaluation of the ankle which confirmed Dr. Ebraheim's diagnosis of retrocalcaneal bursitis and determined that there was "no significant deficit seen in the tendon itself and no significant thickening of note." (Joint Exhibit E.) Dr. Kruse treated her with an injection of a corticosteroid for pain relief. On May 4, plaintiff returned to Dr. Ebraheim who added tendinitis to his assessment based upon plaintiff's report of pain on palpation to both the retrocalcaneal area as well as the Achilles tendon itself. Dr. Ebraheim performed another injection and recommended that plaintiff return to physical therapy. On May 11, 2011, plaintiff returned to Dr. Kruse's office and reported that "she was getting some improvement" until she tripped on uneven gravel while walking, causing significant swelling and bruising and discomfort in her ankle. Dr. Kruse recommended that plaintiff wear a "Cam walker boot" for two to three weeks. On May 16, 2011, plaintiff reported "that she was getting up off the toilet yesterday without

wearing her Cam walker boot, felt a pop in the posterior portion of her left ankle/ Achilles area." (Joint Exhibit H.) An ultrasound confirmed that plaintiff had experienced an acute Achilles tendon rupture and she was fitted with a cast. Plaintiff subsequently received physical therapy to treat the tendon rupture.

- {¶8} Plaintiff alleges that Martino's actions fell below the standard of care by:
 1) prescribing fluoroquinolones for her UTI; 2) failing to admit her to the hospital; and
 3) failing to warn her of all the risks associated with fluoroquinolones. Plaintiff further alleges that the administration of fluoroquinolones in January 2011 proximately caused plaintiff's tendon rupture on May 15, 2011.
- {¶9} "In order to establish medical malpractice, it must be shown by a preponderance of the evidence that the injury complained of was caused by the doing of some particular thing or things that a physician or surgeon of ordinary skill, care and diligence would not have done under like or similar conditions or circumstances, or by the failure or omission to do some particular thing or things that such a physician or surgeon would have done under like or similar conditions and circumstances, and that the injury complained of was the direct result of such doing or failing to do some one or more of such particular things." *Bruni v. Tatsumi*, 46 Ohio St.2d 127 (1976), paragraph one of the syllabus. The appropriate standard of care must be proven by expert testimony. *Id.* at 130. "[E]xpert opinion regarding a causative event, including alternative causes, must be expressed in terms of probability irrespective of whether the proponent of the evidence bears the burden of persuasion with respect to the issue." *Stinson v. England*, 69 Ohio St.3d 451 (1994), paragraph one of the syllabus.
- {¶10} Plaintiff presented the expert testimony of Eugene Saltzberg, M.D., who is board-certified in emergency medicine. According to Dr. Saltzberg, the standard of care requires prescribing the "safest" medication. Dr. Saltzberg testified that it was a breach of the standard of care to prescribe fluoroguinolones to plaintiff inasmuch as

she was over the age of 60, was taking corticosteroids, and there were safer alternatives available. Dr. Saltzberg based his opinion on the black box warning, which explains that fluoroquinolones are associated with an increased risk of tendonitis. Plaintiff also presented the testimony of Walid Mahmoud, M.D., who is a board-certified emergency room physician.³ Dr. Mahmoud reviewed the results of plaintiff's urine culture and noted that E. coli was present. According to Dr. Mahmoud, E. coli is susceptible to a number of medications.

{¶11} Defendant's expert, Andra Blomkalns M.D., who is board-certified in emergency medicine, testified that the administration of Levaguin and Cipro to plaintiff met the standard of care. Dr. Blomkalns explained that Levaquin and Cipro are excellent first line of defense medications that reach high levels of concentration necessary to quickly combat an infection. According to Dr. Blomkalns, the primary consideration in the risk benefit analysis performed when prescribing an antibiotic is choosing the medication that will be most effective in treating the infection. Blomkalns further explained that the risk of tendon rupture was far outweighed by the benefit offered by the fluoroquinolones—treating plaintiff's complicated UTI and preventing further infection. Dr. Blomkalns asserted that other choices, such as gentamicin, do not reach the same level of concentration making such drugs an inferior choice to combat a complicated UTI. Dr. Blomkalns testified that plaintiff's pathogen was resistant to penicillin, meaning plaintiff's infection would have likely worsened had Martino prescribed such a drug. Additionally, such drugs are rarely used to treat UTIs. Dr. Blomkalns further explained that the black box warning is intended to remind physicians to be cautious when prescribing fluoroguinolones and that the warning does not convey that the drug is contraindicated for patients who are over the age of 60 and

³Dr. Mahmoud's deposition is ADMITTED as Plaintiff's Exhibit 10.

taking corticosteroids such as Prednisone. Dr. Blomkalns concluded that the administration of fluoroquinolones met the standard of care.

{¶12} Dr. Saltzberg opined that Martino committed a breach of the standard of care by failing to admit plaintiff to the hospital given the diagnosis of complicated UTI and the potential pyelonephritis, which is a UTI that affects the kidneys. Martino explained that she would have preferred to have admitted plaintiff to the hospital, but that admission was not required given plaintiff's response to the fluoroquinolones administered in the ER, the option to take Cipro orally at home, and plaintiff's access to her primary care provider. Martino testified that both pyelonephritis and a complicated UTI are treated in the same manner, by the administration of antibiotics.

{¶13} Dr. Blomkalns testified that several factors are considered in determining whether to discharge a patient or to admit the patient to the hospital. Dr. Blomkalns explained that the patient's intelligence and her access to a primary care physician are two relevant factors in making such a decision. Given plaintiff's ability to self-medicate with an oral medication such as Cipro and access to a primary care physician, Dr. Blomkalns testified that the standard of care did not require plaintiff to be admitted to the hospital. Instead, Dr. Blomkalns opined that a hospital admission would have exposed plaintiff to potential risks not present in her home environment. Dr. Blomkalns explained that IV antibiotics carry a risk of clostridium difficile, or c. diff, a potentially fatal bacterial infection of the colon. As a result, Dr. Blomkalns concluded that Martino's decision to allow plaintiff to go home on oral antibiotics met the standard of care.

{¶14} Regarding, plaintiff's claim that Martino failed to inform her of the risks associated with fluoroquinolones, a medical claim premised upon the lack of informed consent requires proof that:

{¶15} "(a) The physician fails to disclose to the patient and discuss the material risks and dangers inherently and potentially involved with respect to the proposed therapy, if any;

{¶16} "(b) the unrevealed risks and dangers which should have been disclosed by the physician actually materialize and are the proximate cause of the injury to the patient; and

{¶17} "(c) a reasonable person in the position of the patient would have decided against the therapy had the material risks and dangers inherent and incidental to treatment been disclosed to him or her prior to the therapy." *Nickell v. Gonzalez*, 17 Ohio St.3d 136 (1985), syllabus.

{¶18} Plaintiff testified that Martino never explained the risks of taking fluoroquinolones. Martino was unable to recall whether such a conversation took place. Dr. Saltzberg testified that the standard of care requires a physician to inform a patient of the risks associated with fluoroquinolones. Jonathan Feibel, M.D., a board-certified orthopedic surgeon who specializes in foot and ankle surgery, testified that physicians routinely prescribe medications to patients without discussing all of the the risks of the medications. Dr. Feibel explained that once a physician determines the correct medication for a given situation, it is not necessary for the physician to discuss all the risks associated with the medication. Dr. Feibel asserted that, under the circumstances presented in this case, the risk of a tendon rupture was "so small and so remote" that it would be "unfair" to a patient to discuss such a risk inasmuch as it could complicate rendering appropriate treatment. (Defendant's Exhibit Q, page 105.)

{¶19} Upon review, the court concludes that plaintiff has failed to prove that Martino deviated from the standard of care by prescribing fluoroquinolones, allowing plaintiff to return to her home, and not warning plaintiff of the risks associated with the fluoroquinolones. The court finds that Dr. Blomkalns and Martino both credibly testified

that fluoroquinolones were an appropriate choice of medication to treat plaintiff's complicated UTI. Indeed, as acknowledged by Dr. Blomkalns, other medications suggested by plaintiff also carried risk and would not have been appropriate to treat plaintiff's UTI. The fact that plaintiff's condition improved once she began treatment persuades the court that Martino's choice of medication was appropriate. Although plaintiff argues that Dr. Mahmoud reviewed the results of plaintiff's urine culture and testified that he would not give Cipro to a "high risk" patient if he "had a choice," Dr. Mahmoud also testified that he had no opinion regarding plaintiff's treatment inasmuch as he was not aware of her physical characteristics and medical history. Furthermore, upon admission to the hospital, plaintiff's infectious disease physician recommended a prescription of Cipro before learning of plaintiff's ankle pain. Finally, there is nothing in the black box warning that indicates fluoroquinolones are contraindicated for a patient such as plaintiff. As Dr. Feibel explained, the black box warning merely cautions the physician to consider the potential side effects of the medication so that the physician can engage in a risk benefit analysis prior to administering fluoroquinolones. Martino engaged in a risk benefit analysis and chose a medication with minimal risk and a significant benefit. The evidence showed that the benefit of treating plaintiff's complicated UTI far outweighed any potential risk of a tendon rupture. Accordingly, the court concludes that Martino met the standard of care by prescribing fluoroquinolones.

{¶20} Additionally, the court finds that that standard of care did not require Martino to admit plaintiff to the hospital on January 28, 2011. As stated before, once plaintiff began a course of treatment with Levaquin, she began to improve. Plaintiff was an intelligent patient who was fully capable of understanding and following detailed discharge instructions. Plaintiff did not live alone and had access to a primary care provider. Cipro is an oral antibiotic that is unique in that it is able to reach the same level of concentration as IV Levaquin. Furthermore, upon learning of plaintiff's ankle

pain on January 30, 2011, plaintiff's primary care provider merely changed her antibiotic prescription and did not direct plaintiff to return to the hospital. Moreover, as Dr. Blomkalns explained, hospitalization is not without risks and Cipro offered plaintiff the benefit of treating while at home. In short, the court finds the testimony of Dr. Blomkalns to be credible and persuasive. Therefore, the court concludes that the standard of care did not require plaintiff's hospitalization on January 28, 2011.

{¶21} Regarding plaintiff's claim of lack of informed consent, the court finds that Martino was not required to discuss with plaintiff the remote risk of a tendon rupture. As Dr. Feibel credibly explained, the risk of a tendon rupture is so remote that requiring a physician to discuss such a risk could potentially complicate treatment. Dr. Feibel, who routinely treats Achilles tendinitis, testified that he has never seen a case of tendinitis caused by the administration of fluoroquinolones. Furthermore, the law of informed consent does not require a physician inform a patient of all potential risks. Bedel v. Univ. of Cincinnati Hosp., 107 Ohio App.3d 420, 427 (10th Dist.1995). Finally, the court cannot conclude that a reasonable person would have decided against the proposed therapy had such a risk been disclosed. The risk of not treating plaintiff's complicated UTI, or selecting an inappropriate medication, far outweighed the risk of tendon rupture associated with the fluoroquinolones. In short, plaintiff has failed to prove her claim of lack of informed consent.

{¶22} Finally, even if the court were to find that Martino's care breached the standard of care or that Martino failed to disclose the material risks associated with fluoroquinolones, plaintiff failed to prove that any alleged breach of the standard of care proximately caused plaintiff's injury or that the risk that Martino failed to disclose materialized and proximately caused plaintiff's injury. Dr. Saltzberg testified that the administration of fluoroquinolones proximately caused plaintiff's tendon inflammation and rupture. Dr. Saltzberg's opinion is based upon the black box warning, temporal

proximity of administration and injury, and several article abstracts; however, Dr. Saltzberg, who is not an orthopedic surgeon, admitted that Prednisone is known to cause Achilles tendon weakness. Dr. Saltzberg further admitted that he does not read orthopedic literature.

{¶23} Dr. Feibel, who specializes in foot and ankle surgery, testified that he treats Achilles tendonitis on a daily basis and that it is not possible to say to a reasonable degree of medical probability that fluoroquinolones proximately caused plaintiff's tendonitis. Additionally, Dr. Feibel noted that he has never seen a patient develop tendonitis after taking Levaquin and Cipro. Furthermore, after plaintiff first began to complain of ankle pain, she was diagnosed with retrocalcaneal bursitis, an inflammation of the sack that sits in front of the Achilles tendon. Plaintiff reported additional problems with her ankle after stumbling on uneven gravel in early May 2011, after which she was prescribed a walking boot. Plaintiff ruptured her tendon when she stood up while not wearing her walking boot. Moreover, tendon ruptures are a known complication of Prednisone, which plaintiff had been taking for an extended period of time prior to the rupture. The court finds the testimony of Dr. Feibel to be more convincing and persuasive than that of Dr. Saltzberg. In short, the court finds that plaintiff has failed to prove by a preponderance of the evidence that any breach of the standard of care proximately caused plaintiff's injury or that any failure to inform plaintiff of the risk associated with fluoroquinolones materialized and proximately caused plaintiff's injury.

{¶24} Based upon the foregoing, the court finds that plaintiff has failed to prove any of her claims by a preponderance of the evidence and accordingly, judgment is recommended in favor of defendant.

{¶25} A party may file written objections to the magistrate's decision within 14 days of the filing of the decision, whether or not the court has adopted the decision

during that 14-day period as permitted by Civ.R. 53(D)(4)(e)(i). If any party timely files objections, any other party may also file objections not later than ten days after the first objections are filed. A party shall not assign as error on appeal the court's adoption of any factual finding or legal conclusion, whether or not specifically designated as a finding of fact or conclusion of law under Civ.R. 53(D)(3)(a)(ii), unless the party timely and specifically objects to that factual finding or legal conclusion within 14 days of the filing of the decision, as required by Civ.R. 53(D)(3)(b).

ANDERSON M. RENICK Magistrate

CC:

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