Brill v Lenox Hill Hosp.
2023 NY Slip Op 30188(U)
January 11, 2023
Supreme Court, New York County
Docket Number: Index No. 805307/2018
Judge: John J. Kelley
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SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

PRESENT: **HON. JOHN J. KELLEY** **PART** **56M**

Justice

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DIANA BRILL,

Plaintiff,

- v -

LENOX HILL HOSPITAL, JACK RESNICK, M.D., DUANE READE INC., and JOHN DOE R.Ph., also known as V.C.M., R.Ph., true name being fictitious and unknown at this time,

Defendants.

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INDEX NO. 805307/2018

MOTION DATE 09/12/2022

MOTION SEQ. NO. 002

DECISION + ORDER ON MOTION

The following e-filed documents, listed by NYSCEF document number (Motion 002) 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 111, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 145, 146, 148, 150, 151

were read on this motion to/for SUMMARY JUDGMENT/AFTER JOINDER.

I. INTRODUCTION

In this action to recover damages for medical malpractice based upon alleged departures from good and accepted medical care and lack of informed consent, and for negligent hiring and training of hospital and pharmacy personnel, the defendant Jack Resnick, M.D., moves pursuant to CPLR 3212 for summary judgment dismissing the complaint insofar as asserted against him. The plaintiff, Diana Brill, opposes the motion. The motion is denied.

II. BACKGROUND

The crux of the plaintiff's claim against internist Resnick is that, in late November and early December 2016, he continued her on the antibiotic Levaquin (levofloxacin) to complete her treatment for community acquired bacterial pneumonia, that she was more than 60 years old and on a regimen of the corticosteroid Prednisone at the time, that it was known in the medical community as of 2016 that the administration of Levaquin to a person of her age who was on steroids presented a high risk of tendonitis and tendon rupture, and that, subsequent to the administration of Levaquin, she sustained bilateral gluteal tendon ruptures that left her

permanently disabled. She further asserted that Resnick failed to obtain her fully informed consent to the administration of Levaquin, as he did not inform her about the known risks and dangers of that drug, particularly when prescribed at the same time as Prednisone, and failed to educate her about alternative, equally effective antibiotic treatments that posed lesser dangers.

Sometime between 2004 and 2006, rheumatologist Steven Meed, M.D., diagnosed the plaintiff with rheumatoid arthritis, and she treated with him until at least early 2016. As of 2016, the plaintiff was on a five milligram (mg) per day regimen of the corticosteroid Prednisone to compensate for the effects of a pituitary tumor that had caused adrenal insufficiency. The plaintiff had treated with Resnick on occasion for various ailments beginning in August 2012, when she presented with an earache, and then again in July 2014, secondary to a cat bite, as well as on March 16, 2016, when she needed pre-operative clearance for hand surgery, on May 9, 2016, when she had been suffering from a productive cough for three weeks, and on November 15, 2016, when she complained of hip pain that had migrated to her groin. After the May 9, 2016 visit, Resnick prescribed the decongestant Sudafed and the antibiotic Augmentin. In a July 12, 2016 note, Resnick updated the plaintiff's chart to reflect that she responded well to that treatment, although she had developed bronchitis in June 2016 that had been treated in Italy. After the November 15, 2016 visit, Resnick noted discrete tenderness of the plaintiff's left inguinal ligament, and recommended testing to rule out thrombosis.

According to Resnick, it was his understanding during 2016 that the plaintiff had been taking Prednisone on a daily basis for a significant period of time at a dosage of 5 mg per day, inasmuch as she had had her pituitary gland removed, there thus was no gland "instructing" the adrenal gland to make cortisone and, therefore, she needed to take Prednisone as a replacement. In late November 2016, the plaintiff contacted Resnick and complained of high fever, weakness, and difficulty moving. Resnick recommended that she go to a hospital emergency room (ER), after which she presented to the ER of the defendant Lenox Hill Hospital (Lenox Hill) on November 24, 2016.

On November 24, 2016, Christina Mannino, M.D., examined the plaintiff at Lenox Hill. Dr. Mannino noted that the plaintiff complained of shortness of breath and fever, and presented with a prior history of stroke, hypertension, high cholesterol, hypothyroidism, rheumatoid arthritis, resection of a brain tumor, and diabetes. Upon her examination of the plaintiff, Dr. Mannino reported that the plaintiff was suffering from shortness of breath, abnormal breath sounds, crackling and rhonchi in the left lung, and an oxygen saturation rate of 86%, indicating hypoxia. Dr. Mannino's made a differential diagnosis that the plaintiff was suffering from severe community acquired pneumonia, sepsis secondary to pneumonia, and effusion, based upon her vital signs, temperature of 101.5, respiratory rate greater than 22 breaths per minute, abnormal breath sounds, and low oxygen saturation rate. She consulted with intensive care unit physician and pulmonologist Charles Carpati, M.D., who recommended treating the plaintiff with Levaquin.

Dr. Mannino ordered testing and intravenous fluids, Tylenol, and Levaquin. According to Resnick, Dr. Mannino wished to administer antibiotics to the plaintiff within 60 minutes of diagnosis to address the bacterial infection. Resnick further asserted that, based on his review of Dr. Mannino's deposition testimony, Dr. Mannino would have prescribed Levaquin regardless of whether the plaintiff was on a maintenance dosage of Prednisone. The plaintiff was admitted to Lenox Hill hospital as an inpatient for five days, with Resnick identified as the admitting physician. During that admission, the plaintiff was administered 750 mg of Levaquin every 48 hours for five days, and initially was continued on her regular medications, including Prednisone, at the existing dosages which, for Prednisone, was 5 mg per day. The Levaquin initially was administered intravenously at the hospital, and thereafter in the form of a pill.

According to the plaintiff, Resnick, as the admitting physician, examined her in the hospital between November 24, 2016 and November 26, 2016 and wrote a note by hand on her chart on November 25, 2016.

Although the plaintiff received 5 mg of Prednisone on November 25, 2016, one day later, on November 26, 2016, hospitalists evaluated her and noted that she had recently discontinued

the hydroxychloroquine that she had been taking for her rheumatoid arthritis. Since there were findings consistent with an inflammatory response to poorly controlled rheumatoid arthritis, the plaintiff's dosage of Prednisone was increased to 60 mg per day, which was administered on November 26, 2016 and November 27, 2016, then tapered to 40 mg per day on November 28, 2016, after which the plaintiff's arthritis improved. The plaintiff was discharged from the hospital on November 28, 2016 in stable condition, with a prescription for Prednisone at 40 mg per day, and instructions to follow up with Resnick and her rheumatologist in one to two days.

On November 29, 2016, or one day after the plaintiff's discharge from Lenox Hill, she saw Resnick, and he provided her with a continuation prescription for Levaquin, at one 750 mg tablet every 48 hours for six days, totaling three tablets. She filled the prescription at the Walgreen's/Duane Reade pharmacy on Roosevelt Island and took the entire round of antibiotics. Nobody from Walgreens/Duane Reade contacted Resnick to discuss any contraindication of taking Levaquin and Prednisone together and, according to Resnick, when he looked up the dosage for Levaquin to prescribe to her, he "did not notice" whether there was anything identified as a contraindication for administering Levaquin and Prednisone simultaneously. According to Walgreen's/Duane Reade, there were no drug utilization reports in the plaintiff's pharmacy records indicating the possibility of a severe drug interaction if the plaintiff were administered Levaquin and Prednisone simultaneously. There were, however, references in the Walgreen's/Duane Reade pharmacy records that the plaintiff had been prescribed Prednisone over several years, although those records did not indicate that she was on any round of Prednisone that had been dispensed by Walgreen's/Duane Reade at the time that the Levaquin prescription was filled.

On November 30, 2016, by which time the plaintiff's daily dosage of Predisone had been tapered down to 30 mg per day, she presented to rheumatologist Michael Colin, M.D., who noted her recent hospitalization for pneumonia. She thereafter presented to Dr. Colin for a refill of her Prednisone, and his plan was gradually to taper down the 30 mg dosage over a period of

two weeks, and for her to follow up with Dr. Meed with respect to her rheumatoid arthritis. On December 5, 2016, several days after the plaintiff had discontinued the Levaquin, she met with Dr. Meed, whose records noted that her joints were stable, albeit with bilateral trochanter bursa tenderness with full range of motion in the bilateral hips. Dr. Meed recommended steadily reducing the dosage of Prednisone down to 10 mg a day by January 15, 2017. On December 6, 2016, the plaintiff presented to Resnick for the final time, complaining of a rash on her buttocks, for which Resnick prescribed an antiviral medication.

Resnick claims that the plaintiff fell during the 2016 Christmas holiday, but the plaintiff vigorously denied it. She had X-rays taken on December 26, 2016. On December 27, 2016, the plaintiff returned to see Dr. Meed, complaining of continuing hip pain. Dr. Meed informed the plaintiff that the X-rays revealed the presence of rheumatoid demineralization of the joint and probable aseptic necrosis of the femoral head. In his note, Dr. Meed diagnosed the plaintiff with "*acute dramatic deterioration* and pain of left hip especially on weight bearing; *onset without trauma approximately 3 weeks ago*" (emphasis added). A December 30, 2016 magnetic resonance imaging (MRI) scan showed an "acute/subacute" rupture of the gluteus medius tendon and chronic tearing and scarring of the gluteus minimus tendon.

III. THE PLAINTIFF'S ALLEGATIONS

In her complaint, the plaintiff asserted that, between November 24, 2016 and November 28, 2016, Lenox Hill treated her for pneumonia, and that between November 29, 2016 and December 2016, Resnick provided her with follow-up treatment. She averred that Resnick negligently treated her, failed timely and properly to take an accurate history from her, and failed to account for her prior medical and pharmaceutical history, and thus negligently prescribed Levaquin at high doses despite being contraindicated for a patient who, like the plaintiff, also was taking corticosteroids. She further alleged that Resnick failed timely and properly to stop, change, or adjust her medication regimen, and instead continued the prescription and administration of Levaquin after her discharge from the hospital, despite the

fact that she remained on Prednisone. In addition, the plaintiff alleged that Resnick failed timely and properly to perform a cross-check to ensure that no contraindicated medications were being ordered or administered to her.

The plaintiff further alleged in her complaint that Resnick committed malpractice in failing to inform her of the contraindicated nature of the use of Levaquin while simultaneously taking Prednisone, the risks and benefits inherent in taking those two drugs simultaneously, and the alternatives to the administration of Levaquin to treat the pneumonia She asserted that a reasonable patient in her position would not have consented to the use of Levaquin had she known of the risks, benefits, and alternatives.

The plaintiff also asserted that she would be relying on the doctrine of res ipsa loquitur.

In her bill of particulars as to Resnick, she reiterated many of the allegations in her complaint, adding specifically that Resnick departed from good and accepted medical practice in prescribing her a continuation of Levaquin beginning on November 29, 2016, despite the fact that she was then taking Prednisone, and had been taking Prednisone for a number of years on a daily basis, and in failing to recognize the increased risk for tendon injury for a patient simultaneously taking Levaquin and Prednisone. She also asserted that Resnick committed malpractice in failing timely and properly to review her medication history before dispensing the Levaquin and in failing to take into consideration that she had been administered Levaquin during her hospitalization at Lenox Hill from November 24, 2016 through November 28, 2016. The plaintiff averred that Resnick ultimately prescribed an excessive amount of Levaquin, causing her to “become overdosed with Levaquin” and further faulted Resnick for failing timely and properly to monitor the her while she was simultaneously taking Levaquin and Prednisone.

With respect to her lack of informed consent cause of action, the plaintiff asserted that Resnick failed to disclose the risks and benefits of taking Levaquin while simultaneously taking Prednisone. She asserted that Renick failed to disclose to her that she was placed at a much

higher risk for tendon rupture by taking Levaquin and Prednisone simultaneously than if she had been prescribed and administered a different antibiotic, contending that Resnick failed to offer or disclose any alternative methods of treatment or medications other than Levaquin that she could take. She thus contended that Resnick failed to inform her of the potential risks and complications associated with the treatment rendered, and that she would not have undergone the treatment and would not have taken the Levaquin had she been fully and properly informed of those risks and complications, including increased susceptibility to tendon ruptures.

In her bill of particulars, the plaintiff alleged that, as a consequence of Resnick's malpractice, she sustained a rupture of both the left and right gluteal tendons, with a tear of both the left and right hip gluteus medius, and a complete detachment from the facet of the greater trochanter in both tendons. She asserted that, by reason of the hip injuries, she was required to undergo surgeries under general anesthesia on November 7, 2017 and September 12, 2018, respectively, consisting of left and right hip open gluteus maximus transfers, with gluteus medius repairs, utilizing Arthrex suture bridge fixation with six swivel locks in each of the two procedures. The plaintiff further asserted that she sustained torn ligaments in her right ankle, necessitating surgical interventions under general anesthesia on March 6, 2018 and May 29, 2018, respectively, as well a hematoma and collapsed arch in the right foot. She averred that her injuries caused a limitation of her ability to ambulate, necessitating the use of a wheelchair or walker, and that the surgeries left deforming and disfiguring post-operative scarring. With respect to the September 12, 2018 surgery, the plaintiff claimed to have suffered acute hypoxic respiratory failure, hypercapnia, sepsis due to aspiration pneumonia, acute encephalopathy, atrial fibrillation, acute chronic congestive heart failure, urinary retention, acute kidney injury, urinary tract infections, post-operative anemia due to acute blood loss, systemic inflammatory response syndrome, coma, and shock.

IV. THE SUMMARY JUDGMENT MOTION

In support of his motion, Resnick submitted the pleadings, the plaintiff's bill of particulars, relevant medical, hospital, and pharmacy records, transcripts of the parties' deposition testimony, the note of issue, and the expert affirmation of internist, Mitchell H. Charap, M.D. Dr. Charap opined that Resnick did not depart from good and accepted medical practice in his treatment of the plaintiff, and that nothing that Resnick did nor failed to do caused or contributed to any of the plaintiff's injuries.

Dr. Charap asserted that, with respect to the plaintiff's November 29, 2016 visit, Resnick appreciated her recent hospitalization for pneumonia and treatment with Levaquin, which he claimed had "resulted in the immediate defervescence of her fever." He further asserted that Resnick also appreciated that the plaintiff had been administered Prednisone to treat a multisystem inflammatory response. Dr. Charap stated that Resnick properly reviewed and appreciated the plaintiff's medication history at the time of this visit. He averred that, based on her residual complaints of shortness of breath, tiredness, and weakness during her hospitalization for pneumonia, Resnick exercised reasonable medical judgment in prescribing a proper dosage of Levaquin at 750 mg every 48 hours for six days, a dosage that Dr. Charap described as neither excessive nor contraindicated, despite the plaintiff's age and history of Prednisone use. As he explained it,

> "[i]n 2016, Levaquin was one of the primary first line antibiotics prescribed for the treatment of pneumonia. In addition, for a patient who is hospitalized with pneumonia, such as plaintiff, the standard dose for Levaquin is 750mg by IV or orally for 5-7 doses. Here, plaintiff received three doses of Levaquin while hospitalized, thus she did not complete the standard course of the antibiotic before she was discharged. As plaintiff reported feeling better but was still experiencing residual symptoms consistent with pneumonia on November 29th, it is my opinion that Dr. Resnick exercised reasonable medical judgment to continue plaintiff's previously prescribed Levaquin dosage for three additional doses."

Dr. Charap characterized the plaintiff's claim that Levaquin was contraindicated as "inaccurate," and asserted that, in light of her positive response to Levaquin, "an internist would not change a

patient to a new antibiotic in light of a prior positive response to the medication." He asserted that she ultimately received a total of six doses of Levaquin at 750 mg per administration, and that both the dosage and duration of use were consistent with the standard of care and standard for a patient who is hospitalized with pneumonia.

Dr. Charap opined that Resnick exercised reasonable medical judgment in continuing the plaintiff's prescription of Levaquin despite her history of taking Prednisone. He asserted that, contrary to plaintiff's claim that Resnick failed to be aware of the higher risk for tendon injury in a patient simultaneously taking Levaquin and Prednisone, "this risk is exceedingly rare and was not widely reported in 2016." Dr. Charap concluded that, given the plaintiff's residual complaints consistent with pneumonia, and the fact that she had not completed a full course of the antibiotic by the time she presented to Resnick after her hospital stay, "it was reasonable medical judgment to continue plaintiff on Levaquin in light of the rarity of the risk of gluteal tendon rupture." He continued that, "[b]ased on the rarity of this risk, as well as the limited dose and duration of Levaquin prescribed to plaintiff, it is my opinion that Levaquin was a reasonable medication to prescribe based on plaintiff's complaints."

With respect to the plaintiff's contention that Resnick failed timely and properly to monitor her while she was taking Levaquin and Prednisone, Dr. Charap noted that, on November 29, 2016, Resnick advised her to return to see him in two to three days, but that the plaintiff did not see Resnick again until December 6, 2016, "at which time she was without complaint but for a mild rash on her buttock."

Dr. Charap asserted that the "[p]laintiff was otherwise without complaint until late December when she first reported left hip pain to her internist, Dr. Meed," and that "[a]ccording to the MRI report, plaintiff had sustained a fall one week earlier," an event that the plaintiff allegedly reiterated when she contacted Dr. Randolph Pearlstein in California on February 3, 2017. Dr. Charap opined that, although the December 28, 2016 MRI showed chronic tearing and scarring of the gluteus minimus tendon, the plaintiff did not allege that condition as an injury

caused by Resnik's alleged malpractice, and he thus concluded that "there was no negligent action or inaction by Dr. Resnick that was a substantial factor in causing plaintiff's alleged injuries." Dr. Charap noted that the plaintiff had a history of rheumatoid arthritis, a condition that affects a patient's joints and tendons, and that this condition was a likely contributor any tendon rupture that "would explain plaintiff's chronic, meaning not recent, tearing and scarring of the gluteus minimus tendon and could also contribute to an acute rupture of the gluteus medius tendon." He pointed to repeated documentation in the plaintiff's subsequent treatment records indicating that she sustained a fall in approximately mid-December 2016, and thereafter experienced hip pain and was diagnosed with a tendon rupture. Dr. Charap concluded that it would be "wholly speculative" to link the reasonable administration of Levaquin to the plaintiff's gluteus medius tendon rupture, and that the records and medical testimony established that Resnick's prescription of Levaquin "to complete the standard dosing" was not the proximate cause of any of the plaintiff's alleged injuries, including the gluteus medius tendon rupture.

Dr. Charap asserted that there was "absolutely no merit" to the plaintiff's claims that Resnick failed to obtain her informed consent to the continued administration of Levaquin because it was his understanding that New York law requires a lack of informed consent claim to be associated with an "invasive procedure," and that Resnick performed no such procedure.

In opposition to Resnick's motion, the plaintiff relied upon the same documents that Resnick submitted. She also submitted her own affidavit and the expert affidavit of Rebecca A. Andrews, M.D., an internist and professor of medicine at the University of Connecticut, as well as the United States Food and Drug Administration (FDA) warning concerning the use of Levaquin.

Dr. Andrews explicitly disagreed with Dr. Charap's affirmation and his conclusion that Resnick did not depart from the applicable standard of care. She stated that

> "the defendants deviated and departed from the accepted standards of care by simultaneously prescribing high doses Levaquin (antibiotic) and high levels of Prednisone (corticosteroid) to Ms. Brill thereby placing her at a greatly increased

> risk for the development of tendon rupture and for failing to inform her of the risks associated with Levaquin use. Unfortunately for Ms. Brill, within a month of taking the medications she suffered bilateral gluteal tendon ruptures which have left her permanently disabled."

As Dr. Andrews explained it, Levaquin is considered part of the fluoroquinolone family of antibiotics, also known as quinolones. She averred that, as early as 1983, it had been known in the medical community that fluoroquinolone antibiotics carried certain potentially devastating risks, most notably the risk of spontaneous tendon ruptures. Dr. Andrews asserted that enough significant adverse events had been reported to the FDA regarding Levaquin use, including more reports of tendonitis and tendon rupture, that the FDA required the manufacturer of Levaquin to add a "Boxed Warning," formerly known as a "Black Box Warning," to its dispensing information sheet in 2008, which provided the following:

> "WARNING:
>
> Fluoroquinolones, including LEVAQUIN, are associated with an increased risk of tendinitis and tendon rupture in all ages. *This 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"

(emphasis added). As she interpreted it, the Boxed Warning explained that all patients are at an increased risk of tendonitis and tendon rupture associated with the use of Levaquin, and that the warning specifically provided that the risk is further increased in several patient populations, particularly older patients, usually over the age of 60, as well as those taking corticosteroid medications.

Inasmuch as the plaintiff was 73 years of age in 2016, and was on a maintenance regimen of the corticosteroid Prednisone, Dr. Andrews concluded that she was not a candidate for the administration of Levaquin, and was at a greatly increased risk of developing tendonitis or a tendon rupture by taking Levaquin and Prednisone simultaneously. Dr. Andrews asserted that Resnick failed to take the plaintiff's age, past medical history, and medication history into account before prescribing Levaquin to ensure that Levaquin was the best choice for the plaintiff, and that this failure posed serious risks to the plaintiff, thus constituting a departure

from the good and accepted standards of medical care and practice. She opined that the potential risks to the plaintiff presented by the use of Levaquin outweighed any potential benefits. In this regard, she asserted that, in 2016, there were viable, alternative antibiotics available that were equally effective as Levaquin in treating community acquired pneumonia that were and are considered safer, did not and do not present a risk of tendon rupture, and had and have a lesser propensity for collateral damage. Specifically, Dr. Andrews asserted that Resnick could and should have prescribed a combination of beta-lactam, which include penicillins, cephalosporins, monobactams, and carbapenems, and a macrolide antibiotic, rather than an antibiotic from the fluoroquinolone class. As she phrased it,

> "[t]he combination of these two alternative classes of antibiotics were available and well known in 2016 as a first line option for community acquired pneumonia. The combination was (and still is) as effective as Levaquin in treating community acquired pneumonia that requires hospitalization (additional non-fluoroquinolone options exist for patients with community acquired pneumonia treated out of the hospital)."

Dr. Andrews expressly disagreed with Dr. Charap's opinion that Levaquin was the appropriate and proper choice of antibiotic or that it was considered the best, first-line antibiotic of choice to treat community acquired pneumonia in 2016. She stated that, although Levaquin was one of several first-line antibiotic choices in 2016, "there were other, less dangerous, equally effective antibiotics available to treat the community acquired pneumonia," and that Resnick departed from accepted medical standards in prescribing Levaquin because of the ready availability of a first-line antibiotic choice that was safter for an elderly patient such as the plaintiff with a history of long-term corticosteroid use. As she explained it, "[t]herapeutic choice by a treating physician should be tailored to the individual patient with a goal to reduce any known risks to a patient---including assessing their personal risk of adverse effects of a medication," and that a physician must choose the medication that did not pose a risk to the plaintiff for development of a tendon rupture. Relying on a peer-reviewed article, Dr. Andrews concluded that

> "by 2016, the combination of beta-lactam and macrolide antibiotics had won favor over fluoroquinolones, as the first line of antibiotic choice to treat infections because of the many risks associated with use of the latter class. Additionally, fluoroquinolones had been linked to a growing list of serious adverse events including peripheral neuropathy, effects on the central nervous system, glucose homeostasis disturbances and a risk of aortic aneurysm and aortic dissection."

She further reported that, as a consequence of the numerous serious adverse reactions known to be associated with or caused by Levaquin, its manufacturer, Johnson & Johnson's Janssen Pharmaceuticals, voluntarily ceased production of the brand-name version of levofloxacin, Levaquin, in 2018. As Dr. Andrews described it, according to articles written on this topic, Janssen ceased production of Levaquin because additions needed to be included in the dispensing information sheet required by the FDA to explain that the risk of potential mental health side effects were linked to this "controversial" antibiotic. She stated that, although generic levofloxacin produced by other companies remained available, Janssen officials explained in the article that the discontinuation was due to the availability of other alternatives for patients. Dr. Andrews also adverted to a 2018 recommendation by the European Medicines Agency that fluoroquinolone antibiotics should be suspended and that restrictions be placed on the remaining cache of pills, due to disabling and potentially permanent side effects of usage, a recommendation that was formally endorsed and adopted by the Committee for Human Medicinal Products and its agency, the Pharmacovigilance Risk Assessment Committee, and was binding on all European Union nations.

Dr. Andrews explained that, although the discontinuation of production and suspension of use occurred in 2018, and thus after the plaintiff took Levaquin, "[t]he disabling and potentially permanent side effects of Levaquin and other Fluoroquinolone antibiotics were widely known well before 2018." Dr. Andrews averred that

> "[i]n an article entitled Relative and Absolute Risk of Tendon Rupture with Fluoroquinolone and Concomitant Fluoroquinolone/Corticosteroid Therapy: Population Based Nested Case - Control Study, published November 21, 2018 one of their findings was 'absolute risk of tendon rupture from fluoroquinolone exposure was greater than currently highlighted by product information and varied markedly according to age and concomitant exposure to oral

> corticosteroids.' . . . Even though this article was published in 2018, the study covered the time period of January 1, 1999 through December 31, 2015 demonstrating that it was well known in the medical community by 2016 that Levaquin caused tendon ruptures."

She reiterated that the first reported tendon rupture occurred in 1983 and, after numerous additional reports were submitted to the FDA over the ensuing years, the FDA ultimately was compelled to require the issuance of the above-mentioned Boxed Warning on the dispensing information sheet for Levaquin in 2008, "a full eight years before the malpractice complained of herein." Dr. Andrews concluded that Resnick should have been familiar with this warning, that it was "not evident" from Resnick's records that he considered the warning, and that there was no mention of any discussions or considerations of antibiotic choice for the plaintiff. Dr. Andrews thus opined that Resnick deviated and departed from good and accepted standards of medical care and practice in failing to familiarize himself with the adverse effects of Levaquin and the potential risks associated with Levaquin use, as well as in failing to realize that Levaquin was an inappropriate medication for the plaintiff.

Dr. Andrews asserted that she believed that occurrences of tendon rupture caused by Levaquin have been underreported because patients typically were unaware of the relationship between the two and, therefore, did not report Levaquin use to a doctor whom they were seeing for treatment of a tendon rupture. As she framed it, "[s]imilarly, a physician treating a tendon rupture will often times not think to ask the patient if they had taken Levaquin in the recent past." Dr. Andrews explained that the FDA had issued statements regarding preferential use of alternative therapies for many common diseases that otherwise could have been treated by fluoroquinolones because the risks of adverse effects of fluoroquinolones outweighed the potential benefits. She referred to a peer-reviewed article that concluded that many adverse effects of fluoroquinolone usage were reported to have occurred early in treatment, thus indicating that even short courses of Levaquin may be harmful.

According to Dr. Andrews, Resnick's failure timely to recognize the harm and greatly

enhanced risk to which he subjected the plaintiff by continuing her on a regimen of Levaquin and Prednisone constituted a departure from good and accepted standards of medical care. As she explained it, Levaquin should have been discontinued after the plaintiff's positive response in the hospital, and should not have been continued after her discharge, particularly since she had been administered the highest recommended dosage of Levaquin. Dr. Andrews expressly disagreed that this initial positive result was an acceptable reason to keep the plaintiff on Levaquin. She disagreed with Dr. Charap's statement that "an internist would not change a patient to a new antibiotic in light of a prior positive response to the medication." Rather, she opined that, once the plaintiff evinced this good response to the initial dose of Levaquin, that drug "should have been immediately discontinued and changed to a different, equally effective antibiotic which did not carry the risk of tendon rupture so as to minimize the potential risks." She also faulted Renick for continuing Levaquin after the plaintiff's Prednisone dosage had been increased from 5 mg per day to 60 mg per day, but decreased only to 40 mg per day by the time of her discharge, as well as for his determination to give the plaintiff another prescription for 750 mg tablets of Levaquin after she been discharged from the hospital with no fever after a five-day regimen of Levaquin.

Based on Resnick's deposition testimony that he was unfamiliar with Levaquin, its dosing, or any risks associated with its use, Dr. Andrews concluded that he departed from good and accepted standards of medical practice for failing to know that, by continuing to prescribe Levaquin to the plaintiff, he was "continuing the greatly increased risk for" the plaintiff to develop tendon ruptures. In this respect, she noted that, although Resnick testified that he "may have" looked up Levaquin on a subscription web site known as UTDOL (Up to Date online) to check the dosing recommendations, he also testified that he more likely chose to prescribe 750 mg of Levaquin because that was the dose that the plaintiff had been receiving in the hospital, but that, either way, he was unaware of the risks associated with that drug. In any event, Dr. Andrews explained that the UTDOL site listed both the FDA Boxed Warning with

respect to Levaquin, as well as information regarding tendon rupture and the increased risk in patients over age 60 or those who were also taking corticosteroids, along with the enhanced warning issued in April 2016 by the Infectious Disease Society of America (IDSA). She noted that, in May 2016, IDSA issued additional guidelines recommending that treatment with Levaquin be terminated 48 hours after the last fever, a period of time considerably less than prior guidelines, that was based on the known risks associated with Levaquin use.

Dr. Andrews rejected Dr. Charap's legal conclusion that a claim to recover for lack of informed consent only applies where an invasive procedure has been conducted. She asserted that "lack of informed consent is defined as a process in which patients are given important information, including possible risks and benefits, about a medical procedure, treatment, testing, or a clinical trial." She stated that, here, Resnick failed to inform the plaintiff about the serious risks associated with the use of Levaquin, that she, in particular, was at a greatly increased risk to develop tendon rupture, and that she had an absolute right to be fully informed of any alternative options, given her "46 fold increased risk." Since, according to Dr. Andrews, there was no evidence in the medical records that this was ever explained to, or discussed with the plaintiff, either during her hospitalization or during the first week after her discharge, Resnick did not obtain the plaintiff's fully informed consent to continued treatment with Levaquin. She also opined that a reasonable patient in the plaintiff's position would not have acquiesced to the continued administration of Levaquin had such a patient been provided with all relevant information as to risks, benefits, and alternatives.

With respect to the issue of whether Resnick's departure from good practice and failure to obtain informed consent proximately caused the plaintiff's injuries, Dr. Andrews asserted that it was well known in the medical community that 85% of people will develop tendon rupture within one month of taking the Levaquin, the very situation that occurred with respect to the plaintiff. She further stated that tendon rupture in a person with the plaintiff's profile was not a rare occurrence. She asserted that the plaintiff began to experience excruciating pain below her

hips in December 2016 and that, upon her evaluation by Dr. Meed on December 27, 2016, he noted in his records that the plaintiff sustained "*acute dramatic deterioration* and pain of left hip especially on weightbearing; onset *without trauma* approximately 3 weeks ago" (emphasis added). She further referred to Dr. Meed's chart, in which an MRI report dated December 28, 2016 found, in pertinent part, an "*acute/subacute* tearing of the gluteus medius tendon at its insertion, with soft tissue thickening and edema in the defect, but no gluteus medius muscle atrophy or edema." Dr. Andrews thus opined that "the timing of this injury is too coincidental to be anything other than causally related to the Levaquin use," and that there "was no evidence that this gluteal tendon rupture was caused traumatically," as there were subsequent medical records that similarly referred to the gluteal tendon ruptures as having been "non-traumatic" in nature and related to levofloxacin use.

Dr. Andrews explained that, although the plaintiff complained of left hip pain spreading down to her groin prior to her hospitalization, this complaint was not likely related to the gluteal tendon because (a) this earlier complaint referred to an area "more along the inguinal area as confirmed by Dr. Resnick's notes and she was checked at that time for a DVT (which she did not have)," and (b) inguinal pain would more commonly be associated with the hip joint than with a gluteal tendon pathology. She averred that the complaints of lower hip pain after the hospitalization were in the gluteal region, a completely different location from the earlier complaints along the inguinal area. Dr. Andrews thus reiterated her opinion that Levaquin administration caused the tendon rupture, a conclusion that she asserted was corroborated by the plaintiff's treating nephrologist, Dr. Joel Mittleman, in early 2017. She further referred to Dr. Mittleman's office notes, in which he stated that the plaintiff had sustained an acute, likely Levaquin-induced, kidney injury, another known potential side effect of Levaquin. Dr. Andrews thus expressly rejected Dr. Charap's opinion that the tendon ruptures occurred due to pre-existing medical conditions, including rheumatoid arthritis, pre-existing hip pain, or prior falls. She noted that, in direct contradiction to Resnick's allegations, the plaintiff denied having had

any falls, both in her deposition testimony and in the affidavit that she submitted in opposition to Resnick's motion.

Inasmuch as Dr. Mittleman characterized the tendon tear as "acute/subacute," Dr. Andrews rejected any claim that the tear was purely subacute, or that Dr. Mittlleman's characterization supported Dr. Charap's conclusion that the tear was caused by something other than Levaquin usage.

The plaintiff, in her own affidavit, asserted that she was an active, independent, energetic woman who engaged in multiple sports, including swimming and snow-skiing, and had Participated in a 1½-mile charity swim in Massachusetts only a few months before her hospitalization. Dr. Andrews asserted that, after the plaintiff sustained the tendon ruptures, her only option was surgical intervention to attempt to re-attach the tendons, and that, had she not undergone surgical intervention, she immediately would have been confined to a wheelchair. The expert nonetheless opined that gluteal tendon re-attachment surgery is "notoriously difficult and rarely successful," and that the surgeries were not successful in the plaintiff's case. As such, Dr. Andrews asserted that the plaintiff has been left unable to ambulate without the use of a walker while inside her apartment, or a wheelchair if she is going out, is permanently disabled, and in excruciating pain on a daily basis, requiring daily help with activities of everyday life.

Ultimately, Dr. Andrews concluded that the injuries that the plaintiff sustained "clearly and unequivocally meet all of the definitions of Levaquin induced injuries," and that "the gluteal tendon ruptures were caused by the Levaquin treatment."

In reply, Resnick asserted that Dr. Andrews's affidavit was not in admissible form because it did not include a certificate of conformity, as required by CPLR 2309. He also argued that Dr. Andrews's conclusions were speculative and conclusory, as she failed to cite to peer-reviewed articles published prior to 2016.

A. SUMMARY JUDGMENT STANDARDS

It is well settled that the movant on a summary judgment motion "must make a prima facie showing of entitlement to judgment as a matter of law, tendering sufficient evidence to eliminate any material issues of fact from the case" (*Winegrad v New York Univ. Med. Ctr.*, 64 NY2d 851, 853 [1985] [citations omitted]). The motion must be supported by evidence in admissible form (*see Zuckerman v City of New York*, 49 NY2d 557, 562 [1980]), as well as the pleadings and other proof such as affidavits, depositions, and written admissions (*see* CPLR 3212). The facts must be viewed in the light most favorable to the non-moving party (*see Vega v Restani Constr. Corp.*, 18 NY3d 499, 503 [2012]). In other words, "[i]n determining whether summary judgment is appropriate, the motion court should draw all reasonable inferences in favor of the nonmoving party and should not pass on issues of credibility" (*Garcia v J.C. Duggan, Inc.*, 180 AD2d 579, 580 [1st Dept 1992]). Once the movant meets his or her burden, it is incumbent upon the non-moving party to establish the existence of material issues of fact (*see Vega v Restani Constr. Corp.*, 18 NY3d at 503). A movant's failure to make a prima facie showing requires denial of the motion, regardless of the sufficiency of the opposing papers (*see id.; Medina v Fischer Mills Condo Assn.*, 181 AD3d 448, 449 [1st Dept 2020]).

"The drastic remedy of summary judgment, which deprives a party of his [or her] day in court, should not be granted where there is any doubt as to the existence of triable issues or the issue is even 'arguable'" (*De Paris v Women's Natl. Republican Club, Inc.,* 148 AD3d 401, 403-404 [1st Dept 2017]; *see Bronx-Lebanon Hosp. Ctr. v Mount Eden Ctr.*, 161 AD2d 480, 480 [1st Dept 1990]). Thus, a moving defendant does not meet his or her burden of affirmatively establishing entitlement to judgment as a matter of law merely by pointing to gaps in the plaintiff's case. He or she must affirmatively demonstrate the merit of his or her defense (*see Koulermos v A.O. Smith Water Prods.*, 137 AD3d 575, 576 [1st Dept 2016]; *Katz v United Synagogue of Conservative Judaism*, 135 AD3d 458, 462 [1st Dept 2016]).

Although the plaintiff's affidavit was executed in California, and Dr. Andrews's affidavit was executed in Connecticut, neither, as noted by Resnick, was accompanied by the certificate of conformity required by CPLR 2309. A certificate of conformity is a written instrument, pursuant to which a person qualified by the laws of the country or state in which an affidavit or affirmation is executed and notarized, or by the laws of New York, certifies that the out-of-state affidavit or affirmation has indeed been drafted, executed, and notarized in conformity with the laws of that country or state. Contrary to Resnick's contention, however, the absence of the certificates of conformity does not require the court to disregard the affidavits or reject the plaintiff's papers, as the failure to include a certificate of conformity is a mere irregularity that may be cured by the submission of the proper certificate nunc pro tunc (*see Parra v Cardenas,* 183 AD3d 462, 463 [1st Dept 2020]; *Bank of New York v Singh*, 139 AD3d 486, 487 [1st Dept 2016]; *DaSilva v KS Realty, L.P.,* 138 AD3d 619, 620 [1st Dept 2016]; *Diggs v Karen Manor Assoc., LLC*, 117 AD3d 401, 402-403 [1st Dept 2014]; *Matapos Tech. Ltd. v Compania Andina de Comercio Ltda*, 68 AD3d 672, 673 [1st Dept 2009]).

B. MEDICAL MALPRACTICE BASED ON DEPARTURE FROM ACCEPTED PRACTICE

"To sustain a cause of action for medical malpractice, a plaintiff must prove two essential elements: (1) a deviation or departure from accepted practice, and (2) evidence that such departure was a proximate cause of plaintiff's injury" (*Frye v Montefiore Med. Ctr.*, 70 AD3d 15, 24 [1st Dept 2009]; *see Roques v Noble*, 73 AD3d 204, 206 [1st Dept 2010]; *Elias v Bash*, 54 AD3d 354, 357 [2d Dept 2008]; *DeFilippo v New York Downtown Hosp.*, 10 AD3d 521, 522 [1st Dept 2004]).

A defendant physician moving for summary judgment must make a prima facie showing of entitlement to judgment as a matter of law by establishing the absence of a triable issue of fact as to his or her alleged departure from accepted standards of medical practice (*Alvarez v Prospect Hosp.*, 68 NY2d 320, 324 [1986]; *Frye v Montefiore Med. Ctr.*, 70 AD3d at 24) or by

establishing that the plaintiff was not injured by such treatment (*see McGuigan v Centereach Mgt. Group, Inc.*, 94 AD3d 955 [2d Dept 2012]; *Sharp v Weber*, 77 AD3d 812 [2d Dept 2010]; *see generally Stukas v Streiter*, 83 AD3d 18 [2d Dept 2011]). To satisfy the burden, a defendant must present expert opinion testimony that is supported by the facts in the record, addresses the essential allegations in the complaint or the bill of particulars, and is detailed, specific, and factual in nature (*see Roques v Noble*, 73 AD3d at 206; *Joyner-Pack v. Sykes*, 54 AD3d 727, 729 [2d Dept 2008]; *Koi Hou Chan v Yeung*, 66 AD3d 642 [2d Dept 2009]; *Jones v Ricciardelli*, 40 AD3d 935 [2d Dept 2007]). If the expert's opinion is not based on facts in the record, the facts must be personally known to the expert and, in any event, the opinion of a defendant's expert should specify "in what way" the patient's treatment was proper and "elucidate the standard of care" (*Ocasio-Gary v Lawrence Hospital,* 69 AD3d 403, 404 [1st Dept 2010]). Stated another way, the defendant's expert's opinion must "explain 'what defendant did and why'" (*id*., quoting *Wasserman v Carella*, 307 AD2d 225, 226, [1st Dept 2003]). Furthermore, to satisfy his or her burden on a motion for summary judgment, a defendant must address and rebut specific allegations of malpractice set forth in the plaintiff's bill of particulars (*see Wall v Flushing Hosp. Med. Ctr*., 78 AD3d 1043 [2d Dept 2010]; *Grant v Hudson Val. Hosp. Ctr.*, 55 AD3d 874 [2d Dept 2008]; *Terranova v Finklea*, 45 AD3d 572 [2d Dept 2007]).

Once satisfied by the defendant, the burden shifts to the plaintiff to demonstrate the existence of a triable issue of fact by submitting an expert's affidavit or affirmation attesting to a departure from accepted medical practice and opining that the defendant's acts or omissions were a competent producing cause of the plaintiff's injuries (*see Roques v Noble*, 73 AD3d at 207; *Landry v Jakubowitz*, 68 AD3d 728 [2d Dept 2009]; *Luu v Paskowski*, 57 AD3d 856 [2d Dept 2008]). Thus, to defeat a defendant's prima facie showing of entitlement to judgment as a matter of law, a plaintiff must produce expert testimony regarding specific acts of malpractice, and not just testimony that contains "[g]eneral allegations of medical malpractice, merely conclusory and unsupported by competent evidence tending to establish the essential elements

of medical malpractice" (*Alvarez v Prospect Hosp.,* 68 NY2d at 325; *see Frye v Montefiore Med. Ctr.*, 70 AD3d at 24). In most instances, the opinion of a qualified expert that the plaintiff's injuries resulted from a deviation from relevant industry or medical standards is sufficient to preclude an award of summary judgment in a defendant's favor (*see Murphy v Conner*, 84 NY2d 969, 972 [1994]; *Frye v Montefiore Med. Ctr*., 70 AD3d at 24).

Where the expert's "ultimate assertions are speculative or unsupported by any evidentiary foundation, however, the opinion should be given no probative force and is insufficient to withstand summary judgment" (*Diaz v New York Downtown Hosp*., 99 NY2d 542, 544 [2002]; *see Frye v Montefiore Med. Ctr*., 70 AD3d at 24). Thus, the affirmation of a plaintiff's expert should not be credited where it completely "is contradicted by the record" (*Mulroe v New York-Presbyt. Hosp*., 203 AD3d 665, 665 [1st Dept 2022]). The term "record," in this context, refers to medical records, charts, test results, and notes, or party admissions by the plaintiff (*see Wong v Goldbaum*, 23 AD3d 277, 280 [1st Dept 2005] [plaintiff's expert's opinion contradicted by defendant's notes and plaintiff's own testimony]).

Where the FDA has issued a Black Box Warning in connection with the use of a drug, a plaintiff may raise a triable issue of fact as to whether a physician departed from accepted practice by prescribing the drug where, as here, he or she adduces expert testimony that the medical community has adopted, in practice, the restrictions suggested by the warning (*see Waschitz v. Zupnick*, 2021 NY Slip Op 33338[U], 2021 NY Misc LEXIS 10220 [Sup Ct, Nassau County, Sep. 21, 2021] [denying summary judgment motion of physician who prescribed levofloxacin to an elderly patient on corticosteroids, despite FDA warnings of increased risk of tendon rupture in such patients, where plaintiff's expert physician opined that the administration of the drug to the plaintiff constituted departure from accepted care due, in part, to the medical community's general refusal to administer drug to such patients in light of the warning]).

Resnick established, with relevant medical records, his own testimony, and Dr. Charap's expert affirmation, that he did not depart from good and accepted practice in treating the plaintiff

with Levaquin and Prednisone between November 29, 2016 and December 6, 2016, and that nothing that he did or failed to do caused or contributed to the plaintiff's tendon ruptures. The plaintiff, however, raised triable issues of fact with other records, her own affidavit, and her expert's affidavit as to whether Resnick departed from good and accepted practice in prescribing 750 mg of Levaquin every 48 hours for six days while she was still on 40 mg per day of Prednisone and had a history of Prednisone usage, in failing to recognize or be aware of existing FDA warnings that described the significant risk of tendon rupture associated with Levaquin usage in elderly patients and patients who were on a maintenance dosage of corticosteroids, and in continuing the plaintiff on Levaquin despite his knowledge that she was elderly and was on a maintenance regimen of Prednisone. The expert affidavit also was sufficient to raise a triable issue of fact as to whether Resnick's continuation of the plaintiff on Levaquin caused or contributed to her tendon ruptures, the concomitant surgeries, and the adverse effects of those surgeries, as, contrary to Resnick's contention, Andrews's opinion was neither conclusory nor speculative. Rather, she explained why the administration of Levaquin, and not other purported factors or events, directly caused the plaintiff's tendons to rupture.

Hence, that branch of Resnick's motion seeking summary judgment dismissing the medical malpractice cause of action insofar as asserted against him must be denied.

C. LACK OF INFORMED CONSENT

The elements of a cause of action for lack of informed consent are

> "(1) that the person providing the professional treatment failed to disclose alternatives thereto and failed to inform the patient of reasonably foreseeable risks associated with the treatment, and the alternatives, that a reasonable medical practitioner would have disclosed in the same circumstances, (2) that a reasonably prudent patient in the same position would not have undergone the treatment if he or she had been fully informed, and (3) that the lack of informed consent is a proximate cause of the injury"

(*Spano v Bertocci*, 299 AD2d 335, 337-338 [2d Dept 2002]; *see Zapata v Buitriago*, 107 AD3d 977, 979 [2d Dept 2013]; *Balzola v Giese*, 107 AD3d 587, 588 [1st Dept 2013]; *Shkolnik v Hospital for Joint Diseases Orthopaedic Inst.*, 211 AD2d 347, 350 [1st Dept 1995]). For a

statutory claim of lack of informed consent to be actionable, a defendant must have engaged in a "non-emergency treatment, procedure or surgery" or "a diagnostic procedure which involved invasion or disruption of the integrity of the body" (Public Health Law § 2805-d[2]). Contrary to Resnick's contentions, the Appellate Division, First Department, has recognized that a lack of informed consent cause of action may be predicated on a physician's failure to obtain a patient's fully informed consent to the administration of drugs or medications where the physician failed to reveal all of the anticipated adverse side effects of such administration (*see Halloran v Kiri*, 173 AD3d 509, 510 [1st Dept 2019]; *Farkas v Saary*, 191 AD2d 178, 178-179, 181 [1st Dept 1993] ["No basis exists to dismiss plaintiffs' lack of informed consent claim against defendant (physician) given his conceded failure to issue any warning whatsoever concerning possible birth defects potentially caused by the hormone."]; *Oley-Trojanowska v Kelley*, 2022 NY Slip Op 34049[U], *26-27, 2022 NY Misc LEXIS 7404, *46-47 [Sup Ct, N.Y. County, Nov. 23, 2022 [Kelley, J.]).

Inasmuch as Resnick's expert did not address the qualitative sufficiency of the consent that Resnick obtained, but instead relied solely on an incorrect legal conclusion as to the nature and extent of a lack of informed consent cause of action, Resnick failed to establish his prima facie entitlement to judgment as a matter of law in connection with that cause of action. Hence, that branch of his motion seeking summary judgment dismissing that cause of action insofar as asserted against him must be denied, regardless of the sufficiency of the plaintiff's opposition papers. Even if he had made the necessary showing, however, the plaintiff's opposition papers, including her own affidavit and her expert's affidavit, raised a triable issue of fact as to the qualitative sufficiency of the consent that Resnick obtained, and whether that insufficiency caused or contributed to her injuries.

V. CONCLUSION

In light of the foregoing, it is

ORDERED that the motion of the defendant Jack Resnick, M.D., for summary judgment dismissing the complaint insofar as asserted against him is denied.

This constitutes the Decision and Order of the court.

1/11/2023
DATE

JOHN J. KELLEY, J.S.C.

CHECK ONE:		CASE DISPOSED			X	NON-FINAL DISPOSITION	
		GRANTED	X	DENIED		GRANTED IN PART	OTHER
APPLICATION:		SETTLE ORDER				SUBMIT ORDER	
CHECK IF APPROPRIATE:		INCLUDES TRANSFER/REASSIGN				FIDUCIARY APPOINTMENT	REFERENCE