SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

PRESENT: **HON. JOHN J. KELLEY** **PART** **IAS MOTION 56EFM**

Justice

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DEBORAH BACON-ROTHCHILD,

Plaintiff,

- v -

CITY MD, CITY PRACTICE GROUP OF NEW YORK, LLC, MARCELLUS WALKER, M.D., DUANE READE, INC., and WALGREENS SPECIALTY PHARMACY, LLC,

Defendants.

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INDEX NO. 805254/2018

MOTION DATE 06/15/2021

MOTION SEQ. NO. 001

DECISION AND ORDER

The following e-filed documents, listed by NYSCEF document number 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, and 48 (Motion 001)

were read on this motion to/for SUMMARY JUDGMENT.

In this action to recover damages for medical malpractice, the defendants City MD, City Practice Group of New York, LLC, and Marcellus Walker, M.D. (collectively the movants), together move pursuant to CPLR 3212 for summary judgment dismissing the complaint insofar as asserted against them. In the alternative, the movants seek to preclude the plaintiff's expert from offering an opinion at trial that the plaintiff's atrial fibrillation was caused by the dosage of Levofloxacin (Levaquin) prescribed to her by the defendants City MD and Walker, contending that any such causation opinion is not generally accepted the medical community (*see Frye v United States*, 293 F 1013 [DC Cir 1923]). As a further alternative, the movants seek an immediate *Frye* hearing. The plaintiff opposes the motion. The motion is denied, albeit without prejudice to the movants' right to request, immediately prior to trial, a *Frye* hearing on the issue of whether the plaintiff's theory of causation is generally accepted in the medical community.

In her complaint, the plaintiff alleged that the movants departed from good and accepted medical practice by prescribing her an excessive dosage of the antibiotic Levofloxacin

(Levaquin) to treat a bacterial upper-respiratory infection, and in failing to warn her of the potential adverse effects of taking Levofloxacin at the dosage and in the amounts being prescribed. She asserted that the amounts of that drug that she took caused her to sustain atrial fibrillations, a type of heart arrhythmia. The plaintiff, in her bill of particulars, asserted that the movants departed from good and accepted medical practice in prescribing her a dosage of Levofloxacin 500 milligrams (mg), to be administered two times daily, for a total daily dosage of 1,000 mg, when the recognized safe dose is 500 mg one time daily. She further asserted that, as a consequence of the excessive dosage, she suffered from

> "[a]trial fibrillation; increased risk of sudden death due to cardiac failure; [i]ncreased risk of pulmonary embolism; [i]ncreased risk of myocardial infarction; [i]ncreased risk of cerebral vascular injury; [n]eed for daily anticoagulation medication, to wit, Coumadin; [n]eed to check I[nternational] N[ormalized] R[atio] levels [of prothrombin clotting time] test every three months by virtue of blood testing; [and a]s a result of living with daily dosage of Coumadin, plaintiff is additionally at increased risk for excessive bleeding and injuries associated thereto, including but not limited to death."

In support of their motion, the movants submit the pleadings, the plaintiff's bill of particulars, transcripts of the parties' depositions, relevant medical and pharmacy records, and the expert affirmation of Malcolm Phillips, M.D., a physician who is board certified in cardiology, adult echocardiography, and internal medicine. Dr. Phillips, among other things, relies upon the manufacturer's published dosage guidelines for Levofloxacin and the United States Food and Drug Administration's (FDA) approved-medication guidelines for Levofloxacin. He averred that

> "it is my opinion, with a reasonable degree of medical certainty, that the prescription and dosage of Levaquin plaintiff received for an upper respiratory infection is not causally related to plaintiff's atrial fibrillation. Atrial fibrillation is not a known complication or side-effect of Levaquin. It is not listed as a risk or side-effect of the drug by the drug manufacturer Janssen Pharmaceuticals, and there have not been any reported cases of onset of atrial fibrillation from the Levaquin dosage plaintiff received. Plaintiff's theory that her episode of atrial fibrillation and consequent anti-coagulant therapy was the result of a dosage of Levaquin is not supported by any evidence in clinical trials, drug manufacturer's warning and is contrary to medical science."

As Dr. Phillips noted, the plaintiff is a 78-year-old woman who had been suffering from seasonal bronchial infections over a period of several years. Her medical records reflected that,

in early January 2017, when she was 74 years old, she presented to City MD with what she asserted were her usual seasonal bronchial symptoms. Dr. Phillips further noted that Walker had testified at his deposition that the plaintiff had advised Walker, during her January 10, 2017 visit that "she had bronchitis and pneumonia in the past and that whenever this happens her doctors give her an antibiotic." Specifically, Walker had recalled that the plaintiff "was extremely anxious about the symptoms she had" and feared "it could turn into pneumonia." Walker thereupon reviewed the plaintiff's past visits to City MD, including March 9, 2016 visit with similar complaints, and prescribed her Levaquin at a dosage of 1,000 mg per day. Dr. Phillips further explained that, although the Levaquin improved the plaintiff's cough after she took it in January 2017, she nonetheless continued to feel unwell four days into the prescription regimen, after which she presented to her primary care physician, who performed an electrocardiogram and determined that she was suffering from atrial fibrillation.

Dr. Phillips opined, however, that the

> "plaintiff's episode of atrial fibrillation is not causally related the dosage of Levaquin she received at City MD. Atrial fibrillation is not a known or reported complication or side-effect of the prescription drug Levaquin. It is well-settled that . . . dosages of Levaquin equal to 1000 mg per day are not known to cause atrial fibrillation, nor is atrial fibrillation listed as a risk or side-effect in the drug manufacturer Janssen Pharmaceuticals."

As he further explained,

> "Levaquin has been an FDA approved antibiotic since 1996. Its effects have been studied extensively. As a practicing cardiologist, I have been aware of the uses, warnings and indications for Levaquin since its introduction. In all my years of practicing cardiology, I have never heard of patients suffering from atrial fibrillation as a result of any dosage of Levaquin. I know of no of no clinical trial or authoritative academic study warning that atrial fibrillation [is a] potential side-effect of a 1000 mg per day dosage of the drug Levaquin.
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> "It is my opinion, with a reasonable degree of medical certainty, that the Levaquin dosage plaintiff received did not cause atrial fibrillation and is not causally related to plaintiff's anti-coagulant treatment.
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> "There is no clinical or academic evidence in the medical profession that supports the theory that 1000 mg per day dosage of Levaquin can cause atrial

> fibrillation. Levaquin 1000 mg per day is the recommended dosage for treatment of Tuberculosis/Pneumonia (Global Tuberculosis Advisory Board: Dosage Guidelines . . .). Plaintiff's theory that this dosage caused atrial fibrillation has no academic or clinical trial support. Janssen Pharmaceuticals' reported side-effects from of clinical trials included dosages of 500 mg twice per day with no reported atrial fibrillation as an adverse reaction."

Phillips also quoted from the FDA-approved Levaquin Medication Guide, at Section 6.2 (Clinical Trial Experience):

> 'Patients received LEVAQUIN® doses of 750 mg once daily, 250 mg once daily, *or 500 mg once or twice daily.* Treatment duration was usually 3-14 days, and the mean number of days on therapy was 10 days. The overall incidence, type and distribution of adverse reactions was similar in patients receiving LEVAQUIN® doses of 750 mg once daily, 250 mg once daily, and 500 mg once or twice daily. Discontinuation of LEVAQUIN® due to adverse drug reactions occurred in 4.3% of patients overall, 3.8% of patients treated with the 250 mg and 500 mg doses and 5.4% of patients treated with the 750 mg dose. The most common adverse drug reactions leading to discontinuation with the 250 and 500 mg doses were gastrointestinal (1.4%), primarily nausea (0.6%); vomiting (0.4%); dizziness (0.3%); and headache (0.2%). The most common adverse drug reactions leading to discontinuation with the 750 mg dose were gastrointestinal (1.2%), primarily nausea (0.6%), vomiting (0.5%); dizziness (0.3%); and headache (0.3%).

(emphasis added).

As Dr. Phillips further noted, Janssen Pharmaceuticals had reported that cardiac side effects of Levaquin were "less common," affecting 0.1%-1% of patients, with cardiac conditions including cardiac arrest, palpitations, ventricular tachycardia, and ventricular arrhythmia in clinical trials. He stressed that, "[s]ignificantly, atrial fibrillation is not listed as a potential side effect," and he made the observation that "atrial fibrillation is an entirely different [condition] and unrelated to ventricular fibrillation," in that, "[i]n atrial fibrillation, the upper chambers of the heart (atria) do not contract properly," while "[i]n ventricular fibrillation it is the lower chambers heart (ventricles) that do not contract properly."

Dr. Phillips thus opined that "the Levaquin dosage had no effect whatsoever on plaintiff's episode of atrial fibrillation" and that the "plaintiff had a single non-recurring episode of atrial fibrillation that is more likely than not the result of her upper respiratory infection. . . . Neither the episode of atrial fibrillation or the subsequent treatment have any causal relation to the dosage

of Levaquin plaintiff received." He concluded that the plaintiff's claim to the contrary was itself "contrary to the prevailing view of medical science."

In opposition to the motion, the plaintiff submitted, among other things, an expert affirmation of a physician who is board certified in internal medicine and pulmonary medicine, who relied on, among other things, several peer-reviewed articles that had been published in medical journals. The plaintiff's expert asserted that,

> "[a]t the outset, it must be pointed out that the defendants do not move for summary judgment on the departure from good and accepted medical practice by Dr. Walker in prescribing Levaquin with a dosage of 1000 mg per day. Although they do not concede this was a departure, they only move on causation grounds claiming that Levaquin at that dosage does not cause atrial fibrillation. Regardless, the prescription of this dosage of Levaquin, as will be detailed in this Affirmation, was a clear departure from good and accepted medical practice as it is double the recommended dose for an upper respiratory infection, particularly a mild one as Ms. Bacon-Rothchild had. Additionally, it is my opinion that the prescription of Levaquin in this dosage was a substantial factor in causing Ms. Bacon-Rothchild to develop atrial fibrillation."

The expert noted that, prior to the onset of atrial fibrillation in January 2017, the plaintiff had had regular visits with a cardiologist over the preceding years, none of which reflected that she had any symptoms correlated with atrial fibrillation prior to 2017, but only hypertension and elevated cholesterol levels, with slight bradycardia, or low pulse rate. Based on the expert's review of the plaintiff's medical records and Walker's deposition testimony, he concluded that, in January 2017,

> "[e]ssentially, Ms. Bacon-Rothchild had a cough and maybe the beginning of a cold. Nonetheless, Dr. Walker prescribed a dose of Levaquin (1000 mg a day) which is above the recommended maximum dose by the manufacturer is 750 mg/day. He really should have prescribed 500 mg per day for Ms. Bacon-Rothchild. Instead, he prescribed double the proper amount. Dr. Walker admitted that he had never prescribed a dose that high in his 25-year medical career."
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> "It is my opinion, based upon a reasonable degree of medical probability, that Dr. Walker's prescription of Levaquin to Ms. Bacon-Rothchild in the dosage of 1000 mg per day was clearly excessive under the circumstances and a departure from good and accepted medical practice. This dose is beyond the manufactures recommendation and was, in fact, completely unwarranted given Ms. Bacon-

> Rothchild's presentation and Dr. Walker's diagnosis. Realistically, if Ms. Bacon-Rothchild was sick enough to require this level of antibiotics, Dr. Walker should have immediately admitted her into the hospital and given her antibiotics intravenously. Ms. Bacon-Rothchild required a 500mg dose of Levaquin daily – not 1000mg."

The plaintiff's expert went on to note that, at the time of the plaintiff's January 18, 2017 visit to her cardiologist, she had stopped taking the Levaquin in accordance with instructions given to her by her primary care physician, and that her heart rate had normalized. Approximately one month later, after she was placed on a Holter monitor to ascertain the regularity of her heartbeat and pulse rate, her cardiologist noted that the plaintiff's atrial fibrillation was possibly caused by the antibiotic regimen on which she had been placed by the movants. The expert asserted that, contrary to the movants' contention, and that of Dr. Phillips,

> "Atrial Fibrillation is a known side-effect of Levaquin and is not some unheard of side effect or unknown medical proposition, despite the lack of reference in the medical literature. Ms. Bacon-Rothchild had no prior history of atrial fibrillation as she was regularly seen by her cardiologist, Dr. Friedman. Dr. Shah was clearly aware of the possibility that the Levaquin was the cause of Ms. Bacon-Rothchild's atrial fibrillation. Instead of dismissing that notion or writing that it was unrelated, Dr. Shah – on two separate occasions – mentioned the antibiotic was a possible cause of the atrial fibrillation.
>
> "Defendant's assertion that Levaquin does not cause atrial fibrillation must be rejected. The recommended dose of Levaquin is 500 mg a day and on rare exceptions, and with certain limited conditions, a doctor may go as high as 750 mg. Levaquin is associated with serious arrythmias, especially ventricular arrythmias*. Atrial fibrillation is not common but it is a known risk of Levaquin. This risk is increased especially if there is an overdose of the medication such as prescribed by Dr. Walker the instant case*"

(emphasis added). The plaintiff's expert thus concluded that the prescription to the plaintiff of 1000 mg per day of Levaquin was a departure from good and accepted medical practice, and a proximate producing cause of her atrial fibrillation.

In one peer-reviewed study from a Nigerian medical journal, submitted by the plaintiff's expert, the authors referred to another such report finding that "cumulative incidence of serious cardiac dysrhythmias . . . for antibiotic type used over 10 days was worse for levofloxacin, and increased with duration of intake" and that, with respect to the one patient identified in their own

case study, "with discontinuation of levofloxacin, he started gradually to feel better." The report further noted that the FDA had issued public warnings that heart arrhythmias, particularly QT wave elongations, were known to be associated with fluoroquinolones such as Levofloxacin and macrolides such as Azithromycin. The Mayo Clinic issued a summary of side effects that might be expected from the intake of Levofloxacin, noting that

> "[i]f you have low blood potassium *or an abnormally slow heartbeat*, levofloxacin may increase your risk of having a fast, slow, or *irregular heartbeat*, loss of consciousness, or fainting spells. If these symptoms occur, tell your doctor right away."

(emphasis added).

Conversely, in a 2012 peer-reviewed article appearing in the journal Clinical Infectious Diseases, the authors came to a different conclusion. The authors posed the issue as follows:

> "Fluoroquinolones have been suspected to cause cardiac arrhythmia but data are lacking, particularly for the individual fluoroquinolones. We assessed the risk of serious arrhythmia, defined as ventricular arrhythmia or sudden/unattended death identified in hospital discharge diagnoses, related to fluoroquinolones as a class as well as for each individual molecule."

The authors concluded that

> "[t]he use fluoroquinolones is associated with an elevated risk of serious arrhythmia, with some differences among molecules. Given that the individual fluoroquinolones share various indications, the relative risks of serious arrhythmia could inform the choice of different molecules in high-risk patients."

The study, however, did not assess cardiac arrhythmias associated with atrial fibrillation, as opposed to ventricular arrhythmias, and noted that, although Levofloxacin was included in the study, "[a]mong individual fluoroquinolones, gatifloxacin was the only molecule to be *significantly* associated with a higher risk of serious arrhythmia," while "moxifloxacin and ciprofloxacin were also associated with a significantly increased risk of serious arrhythmia" (emphasis added). The study also concluded that, based on randomized clinical trials, which "reported on prolongation of the QT interval as a proxy for arrhythmia," "QT prolongation did not occur in the vast majority of subjects receiving levofloxacin or ciprofloxacin," although some QT elongation was noted among a few of those subjects.

In a 2017 article published in the journal Medicine, the authors concluded that fluoroquinolones did increase the rise of ventricular arrhythmias, but, contrary to the 2012 Clinical Infectious Diseases article, further conclude that the use of Moxifloxacin and Levofloxacin showed "a higher risk of serious arrhythmias" than other fluoroquinolones. As with the 2012 study, however, the 2017 article did not include arrhythmias attributable to atrial fibrillation.

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]).

"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).

Consequently, where the parties' conflicting expert opinions are adequately supported by the record, summary judgment must be denied (*see Frye v Montefiore Med. Ctr.*, 70 AD3d at 24 *Cruz v St. Barnabas Hospital,* 50 AD3d 382 [1st Dept 2008]).

As the plaintiff correctly notes, the movants premise their motion solely on the ground that any departure from good and accepted medical practice in prescribing 1000 mg per day of Levofloxacin to the plaintiff to treat an upper respiratory infection did not cause her to sustain atrial fibrillations. They did not explicitly argue that there was no departure. Hence, to defeat summary judgment, the plaintiff only needs to raise a triable issue of fact with respect to causation (*see Stukas v Streiter*, 83 AD3d at 24-25). The movants established their prima facie entitlement to judgment as a matter of law dismissing the complaint insofar as asserted against them, based on their contention that the prescription of 1000 mg per day of Levofloxacin did not cause or contribute to the plaintiff's atrial fibrillation. The court concludes that the plaintiff, through her expert's affirmation, and the peer-reviewed studies upon which he relied, submitted facts sufficient to raise a triable issue of fact as to whether the prescription of 1000 mg per day of Levofloxacin caused or contributed to the plaintiff's atrial fibrillation. Hence, the branch of the motion seeking summary judgment must be denied.

That does not end the inquiry, however. The movants alternatively sought to preclude the plaintiff's expert from testifying at trial on the ground that, in accordance with *Frye,* it is not accepted within the medical profession that that the daily prescription of 1000 mg of Levofloxacin to patient could cause or contribute to the onset of atrial fibrillation. At the very least, they seek a *Frye* hearing to determine whether such a conclusion is or is not accepted within the medical profession. The court concludes that the plaintiff submitted a sufficient number of peer-reviewed articles from medical journals and institutions to defeat summary judgment, but that, due to the small number of such articles and documentation submitted by both parties, the movants may request a *Frye* hearing through an in limine motion at the outset of the trial in this action, at which the extent of the acceptance of the plaintiff's theory by the medical profession may be assessed and determined.

In *Parker v Mobil Oil Corp*. (7 NY3d 434, 446-447 [2006]), the Court of Appeals explained that

> "[t]he introduction of novel scientific evidence calls for a determination of its reliability. Thus, the *Frye* test asks 'whether the accepted techniques, when properly performed, generate results accepted as reliable within the scientific community generally' (*People v Wesley*, 83 NY2d 417, 422 [1994]; *see also People v Wernick*, 89 NY2d 111, 115-116 [1996]). *Frye* holds that 'while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs' (*Frye,* 293 F at 1014). It 'emphasizes "counting scientists' votes, rather than on verifying the soundness of a scientific conclusion"' (*Wesley*, 83 NY2d at 439 [citation omitted] [Kaye, Ch.J., concurring]).
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> "The *Frye* inquiry is separate and distinct from the admissibility question applied to all evidence--whether there is a proper foundation--to determine whether the accepted methods were appropriately employed in a particular case (*Wesley*, 83 NY2d at 429). 'The focus moves from the general reliability concerns of *Frye* to the specific reliability of the procedures followed to generate the evidence proffered and whether they establish a foundation for the reception of the evidence at trial' (*Wesley*, 83 NY2d at 429).

A *Frye* inquiry need not be undertaken solely by means of a pre-trial hearing. Rather, the factors articulated in *Frye* may be assessed in the context of a summary judgment motion or a pre-trial motion to preclude expert testimony on which a request for summary judgment could thereafter be premised (*see Cornell v 360 W. 51st St. Realty, LLC*, 22 NY3d 762, 765 [2014]; *Parker v Mobil Oil Corp*., 7 NY3d at 442).

The type of inquiry envisioned by *Frye* is particularly apt in connection with disputed issues as to whether exposure to a specific substance or drug caused a particular disease or physical infirmity (*see Cornell v 360 W. 51st St. Realty, LLC*, 22 NY3d at 781-783 [issue of whether expert's opinion that plaintiff's respiratory symptoms were caused by exposure to mold and dampness had general support in the medical literature]; *Parker v Mobil Oil Corp*. 7 NY3d at 448 [issue of whether expert's opinion that plaintiff's acute myelogenous leukemia was caused by long-term exposure to benzene had general support in the medical literature]; *Fraser v 301-52 Townhouse Corp*., 57 AD3d 416, 418-419 [1st Dept 2008] [same as *Cornell*]; *Lewin v County of Suffolk*, 18 AD3d 621, 622 [2d Dept 2005] [issue of whether expert's opinion that plaintiff's

exposure to the pesticide Malathion while in utero caused birth defects had general support in the medical literature]).

> "It is well-established that an opinion on causation should set forth a plaintiff's exposure to a toxin, that the toxin is capable of causing the particular illness (general causation) and that plaintiff was exposed to sufficient levels of the toxin to cause the illness (specific causation) (*see e.g. McClain v Metabolife Intl., Inc*., 401 F3d 1233, 1241 [11th Cir 2005]; *Wright v Willamette Indus., Inc*., 91 F3d 1105, 1106 [8th Cir 1996]). . . . [I]t is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship, provided that whatever methods an expert uses to establish causation are generally accepted in the scientific community"

(*Parker v Mobil Oil Corp*., 7 NY3d at 448). As the courts have also frequently noted, however, mere "association" between an exposure to a substance and adverse physical effects is not the same as legal causation (*Cornell v 360 W. 51st St. Realty, LLC*, 22 NY3d at 783), and that a plaintiff must ultimately establish not only general causation, as accepted in the relevant medical or scientific community, but show that, in his or her own case, the exposure specifically caused the injuries or conditions complained of.

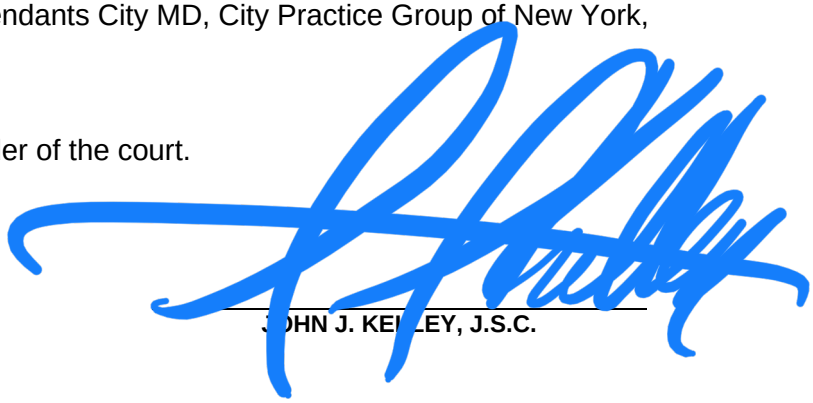
In the instant dispute, the movants submit only two documents to establish that it was not generally accepted in the medical community that the prescription of 1,000 mg per day of Levofloxacin increased the risk of or caused atrial fibrillation. Those documents---the manufacturer's own dosage guidelines and the FDA-approved medication guideline drafted by the manufacturer---are submitted in an attempt to establish the absence of the general acceptance of the plaintiff's theory of causation by the mere absence of the mention of atrial fibrillation. The plaintiff's submission of peer-reviewed articles, some of which support her theory that the prescription of 1,000 mg per day of Levofloxacin increases the risk of or causes atrial fibrillation, and others that either do not support her theory, or only generally support the notion that other fluoroquinolones cause other types of cardiac arrhythmias, suggest that the issue of "general acceptance with the medical community" has not fully been addressed. Nonetheless, the movants' submissions simply are insufficient, at this juncture, to establish that the testimony of the plaintiff's expert as to causation should be precluded. Even if they were

sufficient, the plaintiff's submissions were themselves sufficient to forestall the granting of a motion to preclude. Nonetheless, given the inconsistencies in the literature, the denial of the motion here is without prejudice to the movants application for a *Frye* hearing immediately prior to trial. This court expresses no opinion on whether such an application should or should not be granted by the trial justice ultimately assigned to this action.

In light of the foregoing, it is

ORDERED that the motion of the defendants City MD, City Practice Group of New York, LLC, and Marcellus Walker, M.D., is denied.

This constitutes the Decision and Order of the court.



10/22/2021
DATE

JOHN J. KELLEY, J.S.C.

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