Vardouniotis v Pfizer, Inc.

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Supreme Court, New York County

Docket Number: Index No. 152029/2019

Judge: Nancy M. Bannon

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SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY

PRESENT: **HON. NANCY M. BANNON** **PART** **61M**

Justice

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VASILIKI VARDOUNIOTIS,

Plaintiff,

- v -

PFIZER, INC.,

Defendant.

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INDEX NO. 152029/2019

MOTION DATE 07/17/2023

MOTION SEQ. NO. 005 006 007

DECISION + ORDER ON MOTION

The following e-filed documents, listed by NYSCEF document number (Motion 005) 94, 95, 96, 146, 151, 184, 188, 191, 194, 197

were read on this motion to/for SEAL.

The following e-filed documents, listed by NYSCEF document number (Motion 006) 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 144, 147, 149, 152, 153, 156, 158, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 185, 189, 192, 195, 198

were read on this motion to/for PRECLUDE.

The following e-filed documents, listed by NYSCEF document number (Motion 007) 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 145, 148, 150, 154, 155, 157, 159, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 186, 187, 190, 193, 196, 199

were read on this motion to/for SUMMARY JUDGMENT.

I. INTRODUCTION

In this products liability action, the plaintiff seeks to recover for injuries allegedly resulting from her use of Chantix, a smoking cessation medication manufactured by the defendant and generically known as varenicline. The defendant now moves to exclude the opinions of the plaintiff's expert (MOT SEQ 006) and for summary judgment pursuant to CPLR 3212 dismissing the amended complaint (MOT SEQ 007). The plaintiff opposes these motions. The defendant also moves, unopposed, pursuant to 22 NYCRR 216.1(a), to seal certain exhibits and redact portions of the papers filed in support of its other two motions (MOT SEQ 005). The motion to exclude plaintiff's expert is granted and the motions for summary judgment and to seal are denied.

II. BACKGROUND

The plaintiff was prescribed Chantix for smoking cessation by her physician, Dr. Adrian Lombardi, on May 17, 2016. At the time, in addition to her expressed desire to quit smoking, the plaintiff complained of pre-existing back and neck pain, and had a documented history of anxiety and depression. She started Chantix the same day and took the drug for eleven days, through May 27, 2016. According to the plaintiff, on the night of May 27, 2016, she awoke with pain in her torso and back and felt as though her body was "frozen." When she saw Lombardi the next day, although he did not think her symptoms were related to Chantix, he instructed her to discontinue its use, which she did. At the time, the plaintiff was experiencing pain in her neck and back but was not experiencing any tics or other abnormal movements. Lombardi prescribed opioid medication for the pain. A few days later, after stopping Chantix, and while trying to gradually discontinue opioid use, the plaintiff claims that she began to experience abnormal movements of her torso and neck.

In July 2016, the plaintiff began treatment with a pain management specialist, Dr. Philippe Vaillancourt. She reported to Vaillancourt that her abnormal torso movements had started eight years prior. Vaillancourt prescribed the plaintiff an opioid medication for her pain, which, according to the plaintiff, also completely resolved her abnormal movements. The plaintiff continued to take opioid medications throughout the remainder of 2016, 2017, 2018, 2019, 2020 and 2021.

Between July 2016 and February 2019, the plaintiff saw ten neurologists, including two at Columbia University Medical Center's Movement Disorders Clinic, and underwent multiple diagnostic tests to determine the cause of her abnormal movements. None of the plaintiff's diagnostic tests, which included MRIs, EEGs, EMGs, and nerve conduction studies, demonstrated a neurological basis for the plaintiff's abnormal movements. One EMG study conducted in July 2017 did find "occasional patterns of EMG activity consistent with stereotypies or tic-like movements," but also noted that "[t]here were no findings of prolonged contractions characteristic of dystonia[,]" a type of movement disorder characterized by muscle contractions that are repetitive and may be stereotyped. The same EMG study also noted that the

plaintiff's "jerking movement and firing pattern were modulated by distraction," and concluded that, "[i]n their aggregate, the frequency range, EMG burst discharge variability, and modulation with distraction and other movement suggest that these findings were not indicative of a pathophysiological movement disorder[.]"

Similarly, with one exception, none of the plaintiff's treating neurologists determined that Chantix caused her abnormal movements, and several diagnosed her with a psychogenic or functional movement disorder—i.e., a physical manifestation of an underlying psychological condition, or possibly a purposeful performance for secondary gain (malingering), rather than an organic condition caused by a neurological abnormality or chemical imbalance. For example, in November 2016, neurologist Dr. Agha Raza noted that the plaintiff's abnormal movements went away with distraction and indicated his suspicion that they had a psychogenic basis. Also in November 2016, neurologist Dr. Sulada Kanchana noted that the plaintiff's trunk spasms were "likely psychogenic" and "unlikely to be from Chantix." In December 2016, neurologist Dr. Anthony Adamo noted that the plaintiff's abnormal movements were "intermittent" and "random" and suspected "a conversion disorder, i.e., psychogenic etiology." In January and March 2017, the plaintiff consulted neurologists at the Columbia University Medical Center's Movement Disorders Clinic, including Dr. Miriam Sklerov and Dr. Sheng-Hen Kuo, who offered a differential diagnosis of thoracic spinal myoclonus versus psychogenic movement disorder. In December 2018, neurologist Dr. Marcie Rabin posited a diagnosis of "[t]ics vs psychogenic vs tics + embellishment[.]" Also in December 2018, Dr. Marc Cohen, a pain specialist, suggested the plaintiff's abnormal movements were "psychogenic in nature[.]" And in February 2019, neurologist Dr. Ronald Kanner indicated "the most likely diagnosis" to be "a psychogenic movement disorder and possible borderline personality disorder[.]"

The sole exception was neurologist Dr. Roger Kurlan, whom the plaintiff sought out and began treating with in December 2017, who diagnosed the plaintiff with a Chantix-induced movement disorder. The plaintiff had indicated to prior treatment providers that she believed her abnormal movements were caused by her use Chantix, and she specifically sought treatment from Kurlan after reading an article he co-authored that reported the cases of two patients who developed a movement disorder following Chantix use.

During this period, multiple treatment providers also noted concerns of opioid use disorder and malingering. During an involuntary admission to Zucker Hillside Hospital in May 2018 for suspected psychosis, the plaintiff's abnormal movements were observed on camera only when she was communicating with physicians or other medical providers, but not when she was alone or socializing with peers, which contributed to diagnoses of "conversion disorder (i.e., psychogenic) versus factitious disorder versus malingering[.]" These same concerns were noted six months later during a voluntary admission to Zucker Hillside for depression and pain. Similarly, on January 2, 2019, the plaintiff presented to the emergency room at Long Island Jewish Medical Center with suicidal ideation after Dr. Vaillancourt refused to prescribe oxycodone. During this visit, the plaintiff's abnormal movements were observed on camera only when she was communicating with physicians but not when she was alone. The plaintiff was offered a psychiatric admission but requested to be discharged home after learning she would not receive oxycodone due to suspected opioid use disorder and malingering. The plaintiff returned to Long Island Jewish on January 5, 2019, again seeking oxycodone, which physicians refused to prescribe, having diagnosed her with "opioid abuse," "personality disorder," and "truncal myoclonus (high suspicion for malingering vs Chantix induced [reflecting Kurlan's diagnosis])." On January 7, 2019, the plaintiff returned to Zucker Hillside seeking oxycodone for her abnormal movements. Hospital staff once again noted that her abnormal movements were observed only when she was aware of being visible to staff, "raising concern for volitional movement vs. functional movement disorder." The plaintiff once again requested discharge after being denied oxycodone. On January 14, 2019, the plaintiff presented to NYU Langone Brooklyn and was discharged the same day with an impression of malingering. And in June 2019, Dr. Vladimir Salomon, a pain specialist, noted signs of opioid use disorder and malingering.

The plaintiff initiated this action in February 2019 with the filing of a summons and complaint. She alleges that her brief, eleven-day use of Chantix caused her to develop a movement disorder characterized as dystonia and persistent dystonic tics, as well as various other injuries, including: chronic pain in entire spine, abdomen, and hips; muscular spasms; spinal disk bulges; arthritic changes in neck, cervical spinal stenosis, and an abnormal straightening of

cervical spinal canal; limping upon ambulation; difficulty lifting items; persistent exhaustion; labored breathing; depression; anxiety; and hospitalization. She alleges that the defendant failed to properly disclose these risks, that her prescribing physician, Dr. Lombardi, was therefore not aware of them, and that, had Lombardi known of the risks of these side effects, he would not have prescribed Chantix.

The plaintiff's original complaint asserted the following causes of action: (1) negligence; (2) breach of express warranty; (3) breach of implied warranty; (4) fraudulent misrepresentation; (5) fraudulent concealment; (6) reckless and/or negligent misrepresentation and concealment; (7) gross negligence; (8) willful, wanton, and malicious conduct; and (9) unjust enrichment. The defendant moved to dismiss the complaint in its entirety (MOT SEQ 001).

By decision and order dated July 7, 2020, the court dismissed the first (negligence), seventh (gross negligence), and eighth (willful, wanton and malicious conduct) causes of action, insofar as those causes of action were based on failure to warn allegations. It also dismissed in their entirety the second (breach of express warranty), fourth (fraudulent misrepresentation), fifth (fraudulent concealment), and sixth (reckless and/or negligent misrepresentation and concealment) causes of action, as well as the plaintiff's request for punitive damages, and otherwise denied the motion.

In dismissing the first (negligence), seventh (gross negligence), and eighth (willful, wanton and malicious conduct) causes of action, to the extent they were based on a failure to warn, the court held that the plaintiff failed to sufficiently plead a failure to warn claim that is not preempted by the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), because "the complaint fail[ed] to allege facts indicating that [there was] 'published medical literature' [that] 'reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to FDA.'" Nonetheless, the court held the complaint adequately pleaded these three causes of action to the extent they were based on the defendant's alleged failures to properly test Chantix before releasing it to the market and to conduct adequate post-market surveillance and monitoring of the drug.

The court denied the motion as to the ninth cause of action (unjust enrichment), holding that the plaintiff "sufficiently allege[d] a relationship sufficient to create reliance or inducement," as she "allege[d] that Pfizer advertised Chantix as a safe product, and that it knew or should have known of the dangers of the drug," and "that Pfizer accepted payment from her, and that it would be unjust for Pfizer to retain this money because she did not receive the product that Pfizer represented Chantix to be." Moreover, the court held that the "claim [was] not duplicative of any other claim, given that [the plaintiff sought] disgorgement of Pfizer's profits and monetary benefits."

Following the issuance of the July 7, 2020, decision, the plaintiff filed the amended (operative) complaint, asserting causes of action sounding in: (1) negligence; (2) breach of express warranty; (3) breach of implied warranty; (4) gross negligence; (5) willful, wanton, and malicious conduct; and (6) unjust enrichment. Once again, the defendant moved to dismiss the amended complaint in its entirety (MOT SEQ 002).

By decision and order dated January 10, 2022, the court dismissed the second cause of action (breach of express warranty) in its entirety, as well as so much of the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action as were based on allegations of a failure to warn the plaintiff or the public of the alleged risks of Chantix, and otherwise denied the motion.

With respect to the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action, the court determined that the amended complaint corrected the pleading deficiency in the original complaint and now stated failure to warn claims that were not preempted. Specifically, the court found that allegations that the Chantix label was inadequate in failing to warn of the risks of "dystonia, muscular spasm, movement disorders and abnormal posture" were not preempted because the amended complaint "sufficiently allege[d] the existence of newly acquired information that could have permitted a change of the Chantix label under the CBE regulation" with respect to these risks. NYSCEF Doc. 81 at 6, 13-14. The court based this determination on a pair of medical case reports submitted by the plaintiff concerning three patients who developed movement disorders after

taking varenicline. The court held that these reports satisfied the definition of "newly acquired information" for purposes of the CBE regulation because they "draw a causal relationship between Chantix and the side effects plaintiff claims should have been included on its label." Id. In so ruling, the court necessarily determined that the *only* failure to warn claims that were not preempted were those based on allegations of a failure to warn of the risks of "dystonia, muscular spasm, movement disorders and abnormal posture"—in effect, the risk of a Chantix-induced movement disorder. The court further held that the informed intermediary doctrine did not preclude the failure to warn claims in their entirety, as, in addition to a failure to warn the plaintiff and the public, the amended complaint also alleged a failure to warn the plaintiff's physician.

The court found that the plaintiff had not amended its allegations with respect to the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action insofar as they were based on alleged failures to properly test Chantix and to conduct adequate post-market surveillance, nor had she amended her allegations with respect to the third (breach of implied warranty) and sixth (unjust enrichment) causes of action. Accordingly, the court held that the sufficiency of these allegations had already been fully litigated and denied the defendant's motion with respect to these claims based on the law of the case.

Thus, the claims presently remaining in the case are the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action to the extent they are based on an alleged failure to warn the plaintiff's prescribing physician of the risk of a Chantix-induced movement disorder, as well as a failure to properly test Chantix before releasing it to the market and a failure to conduct adequate post-market surveillance and monitoring of the drug; the third (breach of implied warranty) cause of action; and the sixth (unjust enrichment) cause of action.

Discovery thereafter commenced, during which the plaintiff produced her voluminous medical records, the plaintiff and certain of her treating physicians were deposed, and the parties' exchanged expert reports. The Note of Issue was filed on April 28, 2022.

The defendant now moves to exclude the opinions of the plaintiff's treating physician and expert, Roger Kurlan, MD, and for summary judgment dismissing the amended complaint in its entirety. In support of these motions the defendant submits, *inter alia*: two unsworn reports prepared by its experts; hundreds of pages of the plaintiff's medical records; a copy of the Chantix label in effect when the plaintiff was prescribed Chantix; excerpts from the deposition transcript of the plaintiff's prescribing physician, Dr. Lombardi; and Kurlan's expert report, together with copies of the medical literature cited therein.

With respect to the motion to exclude, the defendant argues that Kurlan's general causation opinion is inadmissible because it is based solely on case reports and adverse event reporting, which are not generally accepted in the scientific community as a reliable basis for establishing causation. The defendant further argues that Kurlan's specific causation opinion is fatally unreliable because it disregards material facts and medical evidence in the record and fails to address and rule out the adverse findings of the plaintiff's nine other treating neurologists.

With respect to the summary judgment motion, the defendant argues all causes of action should be dismissed because, if Kurlan's opinions are excluded, the plaintiff cannot establish causation as to any of her alleged injuries, and even if Kurlan's opinions are not excluded, he fails to opine that Chantix is defective with respect to its warning label, pre-market testing, or post-market surveillance and monitoring. The defendant further contends that the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action, insofar as they are premised on allegations of a failure to warn, should be dismissed for lack of proximate cause based on the deposition testimony of the plaintiff's treating physician, and because they are preempted by the FDCA. Additionally, despite the court's prior decisions having limited the failure to warn claims to the alleged absence of a warning regarding the risk of a movement disorder, the defendant argues that, to the extent these claims are based on an alleged failure to warn of the risks of anxiety and depression, they must be dismissed because the Chantix label adequately warned of those risks.

III. DISCUSSION

1. Plaintiff's Summary Judgment Motion (MOT SEQ 007)

The proponent of a motion for summary judgment pursuant to CPLR 3212 must establish prima facie entitlement to judgment as a matter of law by submitting proof in admissible form demonstrating the absence of triable issues of fact. See Winegrad v New York Univ. Med. Ctr., 64 NY2d 851 (1985); Zuckerman v City of New York, 49 NY2d 557 (1980). Should the movant meet that burden, it then becomes incumbent upon the party opposing the motion to come forward with proof in admissible form sufficient to raise a triable issue of fact. See Alvarez v Prospect Hosp., 68 NY2d 320 (1986); Winegrad v New York Univ. Med. Ctr., supra; Zuckerman v City of New York, supra; O'Halloran v City of New York, 78 AD3d 536 (1st Dept. 2010). If the movant fails to meet the burden and establish a claim or defense sufficiently to warrant a court's directing judgment in the movant's favor as a matter of law, the motion must be denied regardless of the sufficiency of the opposing papers. See Alvarez v Prospect Hosp., supra.

A. Causation

To prevail on any of her claims the plaintiff must tender evidence demonstrating "general causation," i.e., that Chantix can cause the particular movement disorder and other medical conditions she alleges, and also "specific causation," i.e., that her ingestion of Chantix at the prescribed dosage for only eleven days created or aggravated her movement disorder and other alleged conditions. See Parker v Mobil Oil Corp., 7 NY3d 434, 448 (2006); Heckstall v Pincus, 19 AD3d 203, 204 (1st Dept. 2005). Given that this is a complex products liability action against a pharmaceuticals manufacturer, expert testimony will likely be required for this purpose. See Parker v Mobil Oil Corp., supra; Heckstall v Pincus, supra; In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II), 387 F. Supp. 3d 323, 342-43 (SDNY 2019) ("[G]enerally in products liability cases involving complex causation issues, including cases involving pharmaceuticals or medical devices, to establish causation, plaintiffs must offer admissible expert testimony regarding both general causation and specific causation.").

The defendant contends it is entitled to summary judgment on all causes of action because the plaintiff requires Kurlan's expert opinions to establish causation, and Kurlan's opinions should be excluded as inadmissible. As discussed further below, the court finds that

Kurlan's causation opinions are speculative and fundamentally unreliable. However, although the defendant asserts in its moving papers that Kurlan is the plaintiff's only expert, this is neither admitted by the plaintiff nor established by any evidentiary submission. As such, summary judgment cannot be based on the exclusion of Kurlan's opinions alone, and it remains incumbent upon the defendant to submit proof in admissible form demonstrating the absence of triable issues of fact and its *prima facie* entitlement to judgment as a matter of law. The defendant fails to meet this burden.

The defendant relies on a pair of expert reports prepared by Dr. Drew Kiraly and Dr. James Morley, respectively, to demonstrate that Chantix did not cause the plaintiff's movement disorder, which is the principal injury alleged. However, the reports, which are annexed to the affirmation of defendant's counsel, are both unsworn, and the defendant does not submit an affidavit or affirmation from either expert. It is well-established that an unsworn expert report is inadmissible. See Fiuzzi v Paragon Sporting Goods Co. LLC, 212 AD3d 431, 433 (1st Dept. 2023); Ulm I Holding Corp. v Antell, 155 AD3d 585, 586 (1st Dept. 2017); Frees v Frank & Walter Eberhart L.P. No. 1, 71 AD3d 491, 492 (1st Dept. 2010). As such, the defendant fails to meet its initial burden of establishing a *prima facie* case with respect to lack of causation, rendering it unnecessary to consider the sufficiency of the plaintiff's opposition on this issue. See Alvarez v Prospect Hosp., supra; Winegrad v New York Univ. Med. Ctr., supra; Zuckerman v City of New York, supra; O'Halloran v City of New York, supra.

B. Product Defect

Similarly unavailing is the defendant's contention that it is entitled to summary judgment on all causes of action because Kurlan's report, even if not excluded, fails to opine that Chantix is defective with respect to its warning label, pre-market testing, or post-market surveillance and monitoring. Here, too, the defendant fails to meet its burden of submitting proof in admissible form to establish, *prima facie*, that Chantix was not defective in these respects, rendering the purported insufficiency of Kurlan's report irrelevant.

C. Failure to Warn Claims

The defendant contends that the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action, insofar as they are premised on allegations of a failure to warn, should be dismissed for lack of proximate cause based on the deposition testimony of the plaintiff's prescribing physician, and because they are preempted by the FDCA. As discussed above, the court's prior decisions on the defendant's two motions to dismiss have limited the failure to warn claims to the issue of the defendant's alleged failure to warn the plaintiff's prescribing physician of the risk of a Chantix-induced movement disorder.

1. Proximate Cause

Under New York law, a negligence claim based on a failure to warn requires proof that the product did not contain adequate warnings, directed to the plaintiff's prescribing physician, and that the inadequacy of those warnings was the proximate cause of the plaintiff's injuries. See Mulhall v Hannafin, 45 AD3d 55, 58 (1st Dept. 2007). The plaintiff has the burden to show that, had a different warning been given, she would not have used the product that caused her injury because her physician would have made a different prescribing decision. See id. at 60-61.

The defendant argues that the failure to warn claims fail for lack of proximate cause because the deposition testimony of the plaintiff's prescribing physician, Dr. Lombardi, purportedly demonstrates that he did not read the product label before prescribing Chantix for the plaintiff, nor did he rely on the label's warnings or on post-market adverse event reports in making his prescribing decision. As such, the defendant argues, the plaintiff cannot demonstrate that, had a different warning been given, Lombardi would have made a different prescribing decision. This argument is unavailing.

Lombardi's testimony is insufficient to establish lack of proximate cause with respect to the alleged failure to adequately warn of the risk of a Chantix-induced movement disorder. Lombardi did not state definitively whether he read the product label prior to prescribing Chantix for the plaintiff. While he stated that he did not have the label in front of him when prescribing Chantix for the plaintiff, he also allowed that he may have previously read it, though he could not specifically recall one way or the other. Moreover, while he testified that, in deciding to

prescribe Chantix for the plaintiff, he did not "specifically" rely on the label warnings or on post-market adverse event reports, he also stated that "the label mirrors the same concerns that I had at the time that the prescription was issued[,]" and that he generally familiarizes himself with the safety information for a new medication before prescribing it, using various online sources, some of which "may be from manufacturers[.]" At no point in the testimony submitted by the defendant did Lombardi state that a different safety warning would not have dissuaded him from prescribing Chantix for the plaintiff. In short, Lombardi's testimony does not definitively establish that he would have been unaware of any changes made to the safety warnings for Chantix, nor that he would have made the same prescribing decision had a different warning been given. As such, Lombardi's testimony does not establish, *prima facie*, lack of proximate cause with respect to the plaintiff's failure to warn claims.

2. Federal Preemption

The defendant argues the plaintiff's failure to warn claims are preempted by the FDCA. The court previously considered and rejected this same argument with respect to the surviving failure to warn claims when it was raised by the defendant in its motion to dismiss the amended complaint (MOT SEQ 002). See NYSCEF Doc. 81 at 6-14. Under the doctrine of law of the case, if the parties had a "a full and fair opportunity to litigate when the initial determination was made," they are precluded "from relitigating an issue that has already been decided." Chanice v Federal Express Corp., 118 AD3d 634, 635 (1st Dept. 2014).

The defendant contends that, while the court previously found that two case reports annexed to the amended complaint were sufficient to allege the existence of "newly acquired information that could have permitted a change of the Chantix label under the CBE regulation" to advise of the risk of developing a movement disorder, the court should now reverse itself and hold that the surviving failure to warn claims are preempted. The sole basis for this contention is the defendant's insistence that neither of the subject case reports provide "reasonable evidence of a causal association" between Chantix and the plaintiff's alleged movement disorder. However, the court specifically addressed precisely this issue in holding that the subject case reports satisfied the definition of "newly acquired information" because they "draw a causal relationship between Chantix and the side effects plaintiff claims should have been included on its label."

NYSCEF Doc. 81 at 13-14. The parties, having had a "a full and fair opportunity to litigate" the preemption issue, and the sufficiency of the subject case reports in particular, may not relitigate that issue now. See Chanice v Federal Express Corp., supra.

3. Anxiety and Depression

The defendant also contends that the plaintiff's failure to warn claims should be dismissed to the extent that they are based on an alleged failure to warn of the risks of anxiety and depression because the product label at the time the plaintiff was prescribed Chantix adequately warned of those risks. The defendant is correct. Indeed, that relief was previously granted. As already discussed, the failure to warn claims survived the defendant's motions to dismiss *only* insofar as they are based on an alleged failure to warn of the risk of a Chantix-induced movement disorder. Any claim based on an alleged failure to warn of the risk of anxiety and depression has already been held to be preempted. As such, to the extent the defendant seeks summary judgment dismissing such claims, its motion is denied as moot.

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The court has considered the defendant's remaining arguments and determined that they are without merit.

Therefore, the defendant's motion for summary judgment is denied.

2. Defendant s Motion to Exclude Kurlan's Opinions (MOT SEQ 006)

The defendant seeks to exclude the opinions of the plaintiff's expert, Roger Kurlan, MD, as to general and specific causation with respect to the plaintiff's alleged Chantix-induced movement disorder.

Kurlan obtained his MD from Washington University School of Medicine in 1978 and thereafter completed a residency in Neurology and a Fellowship in Movement Disorders at the University of Rochester Medical Center in 1984. He then joined the faculty of the University of Rochester Medical School, where he was a Professor of Neurology and headed the Movement Disorders and Cognitive Neurology Units for several years. In 2009, he entered private practice, starting a movement disorders program at Overlook Medical Center in Summit, New Jersey, and

opening his own practice in 2017. He has authored over 250 scientific publications, including a substantial number in the field of neurological movement disorders.

The defendant does not attack Kurlan's expert qualifications. Rather, it argues that: (1) Kurlan's general causation opinion is unsupported by any clinical or epidemiological data or peer reviewed studies, and is instead based solely on a handful of anecdotal case reports and post-market adverse event reports, which is not a generally accepted methodology in the scientific community for establishing causation; and (2) his specific causation opinion is also not founded on a generally accepted methodology because he disregarded facts and medical evidence in the record and failed to rule out alternative causes for the plaintiff's condition.

"[W]here [as here] a plaintiff's qualified experts offer no novel test or technique but intend to testify about a novel theory of causation . . . it is proper to proceed directly to the foundational inquiry of admissibility, which is whether the theory is properly founded on generally accepted scientific methods or principles." Ratner v McNeil-PPC, Inc., 91 AD3d 63, 73 (2nd Dept. 2011), citing Parker v Mobil Oil Corp., supra at 447 (inquiry focuses on the "reliability of the procedures followed to generate the evidence proffered and whether they establish a foundation for the reception of the evidence at trial"); see Marsh v Smyth, 12 AD3d 307, 312-13 (1st Dept. 2004) (Saxe, J., concurring) (where expert offers no novel test or process, but rather a novel theory of causation, the inquiry is "whether a reasonable quantum of legitimate support exists in the literature for the expert's views"). Additionally, "even though the expert is using reliable principles and methods and is extrapolating from reliable data, a court may exclude the expert's opinion if there is simply too great an analytical gap between the data and the opinion proffered." Cornell v 360 W. 51st St. Realty, LLC, 22 NY3d 762, 781 (2014); see Ratner v McNeil-PPC, Inc., supra at 74-75.

A. General Causation

With respect to general causation, Kurlan posits that Chantix can cause "excessive dopamine transmission" in the brain, which in turn "can result in an involuntary movement disorder." To demonstrate that Chantix can generally stimulate the release of dopamine in the brain, Kurlan cites three studies: (1) "Pharmacological profile of the alpha4beta2 nicotinic

acetylcholine receptor partial agonist varenicline, an effective smoking cessation aid," an animal study that found that varenicline stimulated increased dopamine release in the brains of rats; (2) "Nicotine exposure and tardive dyskinesia," another animal study, which not concern varenicline at all, but speculated that increased dopamine release from smoking "*may* contribute to the higher prevalence of [tardive dyskinesia, a type of movement disorder] in smokers" (emphasis added); and (3) "Varenicline-induced elevation of dopamine in smokers: a preliminary [11C]-(+)-PHNO PET study," which used PET scan brain imaging to show that varenicline can cause increased dopamine release in humans.

None of these studies draw a causal connection between varenicline use and any sort of movement disorder. The first and third studies do not concern movement disorders at all and are relied upon by Kurlan only to demonstrate that varenicline can cause increased dopamine release. The second study, which *is* addressed to movement disorders, does not discuss varenicline. And, while that study does suggest that increased dopamine release (caused by smoking, not by varenicline use) may contribute to a higher risk of developing a movement disorder, proof of a risk, even an increased risk, does not constitute proof of causation. See Cornell v 360 W. 51st St. Realty, LLC, supra at 782-83 (reports and studies that speak only in terms of "risk" and "linkage" and "association" do not establish causation). Indeed, "equat[ing] association with causation . . . depart[s] from the generally accepted methodology for evaluating epidemiologic evidence when determining whether exposure to an agent causes a harmful effect or disease." Id. at 783.

Kurlan cites no controlled clinical studies, epidemiological data, or peer reviewed studies demonstrating a causal link between the use of varenicline and any movement disorder. Instead, to (purportedly) demonstrate a causal connection between varenicline-induced excessive dopamine transmission and the development of a movement disorder, Kurlan cites five case reports, concerning a total of seven patients, who developed various movement disorders, or experienced a worsening of movement disorder symptoms, after taking varenicline. Specifically, Kurlan relies on the following: (1) "Withdrawal-Emergent Dyskinesias following Varenicline Therapy" (the "TD Report"), an article that Kurlan co-authored which reported the cases of two patients who developed tardive dyskinesia after discontinuing varenicline; (2) "Varenicline-

induced acute dystonic reaction: a case report" (the "Dystonia Report"), which reported on a single patient who developed acute dystonia after using varenicline; (3) "Acute worsening of tics on varenicline" (the "Tourette Report"), which reported the cases of two patients with Tourette syndrome whose symptoms worsened after taking varenicline; (4) "Possible varenicline withdrawal-induced akathisia: a case report" (the "Akathisia Report"), which reported on a single patient who developed akathisia after discontinuing varenicline; and (5) "Parkinsonism related to varenicline in a patient during smoking cessation" (the "Parkinsonism Report"), which reported on a single patient who developed Parkinsonism while taking varenicline.

However, "[c]ourts have recognized that . . . observational studies or case reports are not generally accepted in the scientific community on questions of causation." Heckstall v Pincus, supra at 205 (precluding expert's opinion where plaintiff presented "no clinical or epidemiological data or peer reviews" linking the drug to the disease, and supported claim of causation solely with case reports and adverse event reports); see Ratner v McNeil-PPC, Inc., supra at 76 (precluding expert's causation opinion supported only by a pair of case reports, "which are of a lesser caliber than controlled clinical studies from which results can be reviewed and verified"). As explained in In re Breast Implant Litigation, which has been cited approvingly on this point by the First Department, "[t]he generally accepted view in the scientific community is that . . . case reports and animal studies can be used to generate hypotheses about causation, but not causation conclusions[,]" for which "controlled clinical trials and epidemiological studies" are necessary. 11 F.Supp.2d 1217, 1230 (D. Colo. 1998) (internal quotation marks and brackets omitted); see Pauling v Orentreich Med. Group, 14 AD3d 357 (1st Dept. 2005) (citing In re Breast Implant Litigation for proposition that "the plaintiff's expert's own unpersuasive observational studies" were insufficient to demonstrate general acceptance in the medical community of the expert's novel theory of causation). "[C]ase reports are not reliable scientific evidence of causation, because they simply described reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." In re Breast Implant Litigation, supra at 1231. Indeed, the Court of Appeals has similarly rejected reliance on case reports as a generally accepted methodology for establishing causation, explaining that, "[a]lthough a causal

relationship is one possible explanation for an observed association between an exposure and a disease, an association does not necessarily mean that there is a cause-effect relationship." Cornell v 360 W. 51st St. Realty, LLC, supra at 783 (holding that studies showing an association between a moldy environment and the medical conditions attributed to plaintiff's exposure to mold "do not establish that the relevant scientific community generally accepts that molds *cause* these adverse health effects").

Moreover, even taken at face value, the case reports Kurlan cites by-in-large do not support his opinion. Three of the reports—the Tourette Report, the Akathisia Report, and the Parkinsonism Report—are circumspect regarding causation, speculating only that varenicline "may" have caused or exacerbated the movement disorders observed without unequivocally concluding that it did so. See Cornell v 360 W. 51st St. Realty, LLC, supra at 782-83 (expert departed from generally accepted epidemiological methodology for establishing causation by relying on reports and studies that "speak in terms of 'risk' and 'linkage' and 'association'—not causation"); Ratner v McNeil-PPC, Inc., supra at 76 ("[E]ven taking the two case studies at face value, they do not unequivocally state that acetaminophen caused the liver cirrhosis observed therein."). The Dystonia Report, too, though it states a more definite conclusion regarding causation, does not support Kurlan's general causation theory, as it attributes the patient's development of acute dystonia to the "dopaminergic deficiency" resulting from his varenicline-aided smoking cessation—i.e., the report attributes the cause of the patient's movement disorder to his smoking cessation, not the direct neurological effects of varenicline itself, and the mechanism proffered was *decreased* dopamine transmission, the exact inverse of the "excessive dopamine transmission" mechanism that Kurlan seeks to prove.

Other than the five case reports discussed above, the only other medical literature that Kurlan cites in support of his general causation theory is a study, "Strong Safety Seen for New Varenicline Risks," prepared by The Institute for Safe Medication Practices ("ISMP"), which summarizes post-market adverse event reports concerning Chantix, including 372 reports of a wide range of movement disorders, and an article, "Potential therapeutic application for nicotinic receptor drugs in movement disorders," which reviews the scientific evidence that varenicline and other similar drugs may be helpful in the treatment of movement disorders (the "Treatment

Article"). However, the ISMP study does not conclude that Chantix caused any of the movement disorders reported, and expressly states that "[a]dverse event reports in themselves do not establish a causal link to the drug." See Heckstall v Pincus, supra at 205 (case reports and adverse event reports not generally accepted basis for establishing causation). Similarly, the Treatment Article, at best, provides evidence that varenicline may affect neurological systems involved in certain movement disorders, but nowhere in the article is it suggested that varenicline can *cause* movement disorders.

In sum, Kurlan's general causation opinion, based principally on case reports and adverse event reports, is not founded on a generally accepted methodology for establishing causation (see Cornell v 360 W. 51st St. Realty, LLC, supra at 783; Heckstall v Pincus, supra at 205; Pauling v Orentreich Med. Group, supra; Ratner v McNeil-PPC, Inc., supra at 76), and, even accepting that he is extrapolating from case reports that reliably recount the association observed between varenicline use and the development or worsening of various movement disorders in the seven patients that were the subject of those reports, "there is simply too great an analytical gap between the data and the opinion proffered" (Cornell v 360 W. 51st St. Realty, LLC, supra at 781; see Ratner v McNeil-PPC, Inc., supra at 74-75).

In opposition, the plaintiff contends that the lack of epidemiological studies supporting Kurlan's conclusions is irrelevant, and that Kurlan's causation opinion *is* supported by generally accepted scientific methods because it is based upon reasonable extrapolations from legitimate empirical data. In this regard, the plaintiff principally relies upon Zito v Zabarsky, 28 AD3d 42 (2nd Dept. 2006), and Lugo v New York City Health and Hospitals Corp., 89 AD3d 42 (2nd Dept. 2011), which she cites for the propositions that "it is not necessary that the underlying support for the theory of causation consist of cases or studies considering circumstances exactly parallel to those under consideration in the litigation" (Zito v Zabarsky, supra at 44), and that "[i]t would be unreasonable to preclude a 45-year smoker from seeking recovery if the only available empirical data addressed 50-year smokers" (Lugo v New York City Health and Hospitals Corp., supra at 62). However, the issue with Kurlan's general causation opinion is not that he relies on empirical data that does not precisely match the plaintiff's circumstances, but rather, that his general causation opinion, at its core, is founded entirely on a handful of case reports and adverse

event reports, which "are not generally accepted in the scientific community on questions of causation." Heckstall v Pincus, supra at 205. Indeed, the plaintiff simply ignores the controlling and well-established caselaw cited above on this point. She does attempt to distinguish the Court of Appeals' decision in Cornell v 360 W. 51st St. Realty, LLC, but focuses entirely on the portion of that opinion addressed to specific causation, and not the portions cited above that relate to the general causation analysis.

B. Specific Causation

The court's determination regarding Kurlan's general causation opinion is dispositive of his specific causation opinion as well. However, even considered on its own, Kurlan's opinion as to specific causation is similarly unreliable. Kurlan states that, in opining that the plaintiff has a Chantix-induced movement disorder, he relied on his own treatment and examination of the plaintiff, as well as the medical records and deposition testimony of Dr. Lombardi, the plaintiff's primary physician, and Dr. Vaillancourt, the plaintiff's pain management physician. He does not, however, claim to have reviewed the medical records of the plaintiff's nine other treating neurologists, her multiple objective diagnostic tests to determine the cause of her movement disorder, her numerous emergency room visits and hospitalizations, or any of her other medical providers, nor does he address any of these records in his expert report.

As detailed above, these voluminous medical records, submitted by the defendant in support of its motion, include nearly a dozen objective diagnostic tests, such as MRIs, EEGs and EMGs, none of which demonstrated a neurological basis for the plaintiff's abnormal movements. These records also demonstrate that many, if not most, of the plaintiff's other treating neurologists diagnosed her movement disorder as psychogenic, and none of them shared in Kurlan's diagnosis of a Chantix-induced movement disorder. In this regard, the records notably include repeated findings that the plaintiff's abnormal movements lessened or disappeared when she was mentally distracted, a finding that directly contradicts Kurlan's assertion, based solely on his own examination of the plaintiff, that her abnormal movements did not display signs of "distractibility." These conflicting findings are notable because, according to Kurlan, "distractibility" is one of the "core" clinical signs of a psychogenic movement disorder, and he therefore cites its absence upon his own examination of the plaintiff as one of his principal

reasons for discounting the possibility that she suffers from a psychogenic movement disorder. Finally, the medical records that Kurlan disregarded further reflect numerous and repeated notations by various treatment providers linking the plaintiff's complaints of abnormal movements, and her efforts to obtain opioid medication as a treatment for her purported condition, to her suspected opioid use disorder and malingering. These notably include notes from her several hospitalizations reflecting that her abnormal movements disappeared entirely when she believed that she was not being observed by medical staff, suggesting that her symptoms were potentially fictitious, or at least embellished, and linked to her persistent efforts to obtain opioids.

Thus, Kurlan's specific causation opinion also departs from generally accepted methodologies by (i) failing to specifically address and rule out the findings of the plaintiff's other treating neurologists who diagnosed her with a psychogenic movement disorder, and, similarly, by (ii) disregarding the numerous facts and findings inconsistent with his opinion, such as the repeated findings that the plaintiff's abnormal movements lessened with distraction, the multiple objective diagnostic tests that found no neurological basis for her abnormal movements, and the numerous provider notes linking her abnormal movements to her suspected opioid abuse. See Cornell v 360 W. 51st St. Realty, LLC, supra at 784-85 (expert departed from accepted methodology for differential diagnosis by, *inter alia*, failing to address diagnostic findings inconsistent with his diagnosis); Akel v Gerardi, 200 AD3d 445, 446 (1st Dept. 2021) (expert's opinion was conclusory and speculative where it failed to specifically address opinions of opposing expert and disregarded facts and medical evidence in the record); Heckstall v Pincus, supra at 205 (expert failed to rule out alternative causes for plaintiff's illness).

In opposition, the plaintiff argues that the fact that many of her other treating physicians diagnosed her with a psychogenic movement disorder simply creates a question of fact for the jury. This is another red herring, as the issue is not that other doctors reached a different diagnosis, but that Kurlan ignores and fails to specifically address those inconsistent diagnoses and the findings upon which they were based. Indeed, the plaintiff submits an affidavit from Kurlan in which he still does not claim to have reviewed any of the medical records discussed above, but nevertheless asserts that, in reaching his specific causation opinion, he was right to

rely more-or-less exclusively on his own experience and treatment of the plaintiff, and to discount the inconsistent findings of her other doctors. Kurlan explains that, "I have seen many more patients with tic disorders, conducted many more research studies on tic disorders and published many more scientific articles and books on tic disorders than all of the [other] treating and expert neurologists combined[,]" and "it was clear to me that almost none of the other neurologists had the depth of knowledge or experience with psychogenic tics to make a valid diagnosis [and] I 'ruled out their findings' by my own findings and my realization that theirs were mostly invalid." In other words, Kurlan asserts that there was no need for him to consider and specifically address the inconsistent findings of the plaintiff's other doctors, or the considerable evidence on which those findings were based, because, in his opinion, those doctors are simply inferior physicians whose findings may be summarily discounted. Similarly, with respect to his failure to address the results of the plaintiff's numerous objective diagnostic tests, Kurlan states in his affidavit that none of those tests "is able to properly diagnose psychogenic tics," completely ignoring that the salience of those tests is not that they demonstrated a psychogenic basis for the plaintiff's movement disorder, but rather that they uniformly failed to demonstrate that her abnormal movements had any neurological basis. In short, even in his affidavit in opposition to the defendant's motion, Kurlan still simply refuses to engage with, and in many instances to even acknowledge, the considerable medical evidence that is inconsistent with his opinion.

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Accordingly, the defendant's motion to exclude the opinions of the plaintiff's expert, Roger Kurlan, MD, is granted. The exclusion of Kurlan's opinions does not necessitate summary judgment in favor of the defendant. As already noted above, while the defendant states in its moving papers that the plaintiff cannot prove its case with respect to any of its claims without Kurlan as an expert, the defendant submits no support for this conclusion.

3. Plaintiff's Motion to Seal (MOT SEQ 005)

Pursuant to 22 NYCRR 216.1(a), "a court shall not enter an order in any action or proceeding sealing the court records, whether in whole or in part, except upon a written finding of good cause, which shall specify the grounds thereof. In determining whether good cause has

been shown, the court shall consider the interests of the public as well as of the parties." The Appellate Division, First Department, has emphasized that "there is a broad presumption that the public is entitled to access to judicial proceedings and court records." Mosallem v Berenson, 76 AD3d 345, 348 (1st Dept. 2010). Because "confidentiality is clearly the exception, not the rule" (Matter of Hofmann, 284 AD2d 92, 93–94 [1st Dept. 2001]), that Court has authorized sealing "only in strictly limited circumstances." Gryphon Dom. VI, LLC v APP Intl. Fin. Co., 28 AD3d 322, 325 (1st Dept. 2006); see Mosallem v Berenson, supra.

The burden is on the party seeking to seal court records to establish "good cause." Maxim, Inc. v Feifer, 145 AD3d 516, 517 (1st Dept. 2017). "Since there is no absolute definition, a finding of good cause, in essence, 'boils down to … the prudent exercise of the court's discretion.'" Applehead Pictures, LLC v Perelman, 80 AD3d 181, 192 (1st Dept. 2010), quoting Mancheski v Gabelli Group Capital Partners, 39 AD3d 499, 502 (2nd Dept. 2007) (some internal quotation marks and citation omitted). "Conclusory claims of the need for confidentiality … [are] not … sufficient bas[es] for a sealing order" (Matter of Hofmann, supra at 93-94), and "the court will not approve wholesale sealing of [court] papers, even when both sides to the litigation request sealing." Applehead Pictures, LLC v Perelman, supra (citations omitted); see Gryphon Dom. VI, LLC v APP Intl. Fin. Co., supra; Liapakis v Sullivan, 290 AD2d 393 (1st Dept. 2002); Matter of Hofmann, supra. That is, a party's own "designation of the materials as confidential or highly confidential is not controlling on the court's determination whether there is good cause to seal the record pursuant to 22 NYCRR 216.1." Eusini v Pioneer Electronics (USA), Inc., 29 AD3d 623, 625 (2nd Dept. 2006); see Mosallem v Berenson, supra. Even where there is a proper basis for sealing, redaction is favored over sealing of an entire document or record. See Vergara v Mission Capital Advisors, LLC, 187 AD3d 495 (1st Dept. 2020); Danco Laboratories, Ltd. v Chemical Works of Gedeon Richter, Ltd., 274 AD2d 1 (1st Dept. 2000).

The defendant seeks the wholesale sealing of exhibits 1, 6, 7, 11-70, 73, and 80 to the Affirmation of Jessica Wilson (NYSCEF Docs. 100, 105, 109 and 119), filed in support of its own motion for summary judgment and to exclude Kurlan's expert opinions (NYSCEF Docs. 100, 105, 109, 112, 119, 124, 129, 133, 136, 143). These voluminous exhibits include all of the

plaintiff's medical records submitted on the other two motions, which number in the hundreds of pages, along with various other documents that refer to said medical records, such as deposition transcripts, the parties' expert reports, and the plaintiff's interrogatory responses. Notably, documents having nothing to do with the plaintiff are also included. The defendant seeks wholesale sealing of these documents but provides no specific ground for any particular document. The defendant also seeks to maintain redactions applied to portions of its papers filed in support of its other two motions, which likewise refer to and discuss the plaintiff's medical records (NYSCEF Docs. 98, 121-22).

The defendant does not meet its burden of demonstrating "good cause" for sealing/redacting the subject documents. The defendant asserts only a very general argument that sealing these documents is necessary to comply with the defendant's desire to protect the plaintiff's medical and mental health records from public disclosure. However, it offers no explanation for its conclusory assertion that these records are "sensitive" and "confidential," but instead simply invokes New York's public policy of protecting the privacy of personal medical records and all physicians' obligations to do so. See Chanko v Am. Broad. Companies Inc., 27 NY3d 46 (2016). The defendant pharmaceutical company, of course, is not a physician and no such privilege applies. Notably, the defendant wholly ignores the well settled rule that where a litigant affirmatively places his or her medical condition into issue, any such privilege is waived and the protection falls. See Arons v Jutkowitz, 9 NY3d 393 (2007); Hoenig v Westphal, 52 NY2d 605 (1982); DiLorenzo v Toledano, 190 AD3d 941 (2nd Dept. 2021); Ava v NYP Holdings, Inc. ,64 AD3d 407 (1st Dept. 2009). Moreover, courts have declined to seal medical and mental health records in such circumstances. See e.g. Jose V. v Smiley & Smiley LLP, 214 AD3d 523, 524 (1st Dept. 2023) (no good cause for sealing where guardian placed incapacitated individual's mental condition at issue in legal malpractice action arising from personal injury action). Further, in the instant case, which concerns a medication that had been widely prescribed, the interests of the public weighs in favor of disclosure. See In Re East 51st Street Crane Collapse Litigation, 106 AD3d 473 (1st Dept. 2013) (court denied sealing of settlement in wrongful death action arising from a tower crane collapse); Guardino v Graco Children's Products, Inc., 50 Misc 3d 646 (Sup Ct, Suffolk County 2015) (sealing denied in wrongful death action for product liability regarding defective baby stroller).

In support of this motion, the defendant also relies upon the parties' Stipulated Protective Order in this case, in which the parties agreed to maintain the confidentiality of medical records. However, the parties' agreement that these records should remain confidential between them does not, in itself, establish good cause to seal. See Applehead Pictures, LLC v Perelman, supra; Eusini v Pioneer Electronics (USA), Inc., supra.

Therefore, the defendant's motion to seal is denied, but without prejudice to renewal. The court is cognizant that the hundreds of pages of the plaintiff's medical records submitted as exhibits on the instant motions may well include sensitive and/or potentially embarrassing information that is not relevant to the matters at issue in this litigation. Such information, if identified, may properly be kept confidential, should the parties seek leave to do so, via narrowly tailored redactions.

IV. CONCLUSION

In light of the court's rulings herein and in its prior orders, the causes of action remaining for trial are as follows: the first (negligence), fourth (gross negligence) and fifth (willful, wanton, and malicious conduct) insofar as they are based upon allegations of a failure to warn of the risks of dystonia, muscular spasm, movement disorders and abnormal posture, as well as a failure to properly test Chantix before releasing it to the market, and a failure to conduct adequate post-market surveillance and monitoring of the drug; the third cause of action (breach of implied warranty); and the sixth cause of action (unjust enrichment).

Accordingly, upon the foregoing papers and after oral argument, it is

ORDERED that the defendant's motion for summary judgment dismissing the amended complaint (MOT SEQ 007) is denied; and it is further

ORDERED that the defendant's motion to exclude the opinions of the plaintiff's expert, Roger Kurlan, MD (MOT SEQ 006), is granted; and it is further

ORDERED that the defendant's motion to seal documents (MOT SEQ 005), is denied; and it is further

ORDERED that the Clerk shall mark the file accordingly.

This constitutes the Decision and Order of the court.

NANCY M. BANNON, J.S.C.
HON. NANCY M. BANNON

7/8/2024
DATE

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