UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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JESSE MCDOWELL,

Plaintiff,

-against-

13 Civ. 3786

ELI LILLY AND COMPANY,

OPINION

Defendant.

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A P P E A R A N C E S:

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Sweet, D.J.

Defendant Eli Lilly and Company ("Eli Lilly" or the "Defendant") has moved pursuant to Federal Rule of Civil Procedure 56 for summary judgment dismissing the failure-to-warn diversity action brought by the plaintiff Jesse McDowell ("McDowell" or the "Plaintiff"). Based upon the facts and conclusions set forth below, the Defendant's motion is granted and the action is dismissed.

Prior Proceedings

The Plaintiff filed his complaint on June 4, 2013 alleging that the Defendant's labelling for its anti-depression drug Cymbalta failed to warn adequately about the risk of withdrawal upon continuance and that the Defendant designed the drug defectively, was negligent, breached an implied warranty, made a negligent misrepresentation, committed fraud, and violated state consumer fraud laws.

Discovery proceeded and the instant motion was heard and marked fully submitted on September 17, 2014.

The Facts

The facts have been set forth in the Defendant's Rule 56.1 Statement, the Plaintiff's Response to Defendant's Rule 56.1 Statement and Statement of Facts, and Defendant's Response to Plaintiff's Statement of Facts. The facts are not in dispute except as noted below.

Defendant's Rule 56.1 Statement

On August 3, 2004, the United States Food and Drug Administration ("FDA") approved Cymbalta (duloxetine), a serotonin norepinephrine reuptake inhibitor ("SNRI"), for the treatment of major depressive disorder. At the same time, the FDA approved the contents of the U.S. Physician Package Insert, or label, for Cymbalta.

The Cymbalta Physician Package Insert in effect in September 2008 cited the risk of potential discontinuation-emergent adverse events in three sections of the label: Highlights of Prescribing Information, Dosage and Administration, and Warnings and Precautions.

The Cymbalta Physician Package Insert included the following language on the risk of potential discontinuation symptoms in the Highlights of Prescribing Information section:

HIGHLIGHTS OF PRESCRIBING INFORMATION

. . . .

DOSAGE AND ADMINISTRATION

. . . .

Discontinuing Cymbalta: A gradual dose reduction is recommended.

WARNINGS AND PRECAUTIONS

. . . .

Discontinuation: May result in symptoms, including dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis, and vertigo (5.6).

The Cymbalta Physician Package Insert included the following language on the risk of potential discontinuation symptoms in the Dosage and Administration section:

2 DOSAGE AND ADMINISTRATION

. . . .

2.4 Discontinuing Cymbalta

Symptoms associated with discontinuation of Cymbalta and other SSRIs and SNRIs have been reported. A gradual reduction in the dose rather

than abrupt cessation is recommended whenever possible [see Warnings and Precautions (5.6)]

The Cymbalta Physician Package Insert included the following language in the Warnings and Precautions section:

5 WARNINGS AND PRECAUTIONS

5.1 Clinical Worsening and Suicide Risk

. . . .

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

. . . .

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that discontinuation can be associated with certain symptoms [see Dosage and Administration (2.4) and Warnings and Precautions (5.6) for descriptions of the risks of discontinuation of Cymbalta].

The Cymbalta Physician Package Insert included the following language in the Warnings and Precautions section:

5.6 Discontinuation of Treatment with Cymbalta

Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate greater than or equal

> to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo.
>
> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional instability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe. Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

According to the Plaintiff, the following language contained in Section 5.6 of the Package Insert is deliberately misleading and inaccurate: "Following abrupt or tapered discontinuation in placebo-controlled clinic trials, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo . . . ."

and Defendant has been aware since 2005 at the very latest that approximately 44% of patients who abruptly discontinued Cymbalta after having used the medication for 9 weeks or less experienced withdrawal symptoms, as well as 50% of patients who had used the medication for "longer term" trials.

The American Psychiatry Association's Practice Guidelines For the Treatment of Patients With Major Depressive Disorder ("APA Guidelines") state that "[a]s with the S[elective] S[erotonin] R[euptake] I[nhibitors]s, abrupt discontinuation of SNRIs should be avoided whenever possible." AMERICAN PSYCHIATRIC ASSOCIATION, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH MAJOR DEPRESSIVE DISORDER 40 (2010), available at http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. According to the Plaintiff, it does not appear that these "guidelines" are tailored to Cymbalta or its specific risks and these guidelines were approved in May 2010 and published in October 2010 while Plaintiff began his Cymbalta treatment in September 2009.

The APA Guidelines further recommend that "[w]hen pharmacotherapy is being discontinued, it is best to taper the medication over the course of at least several weeks," and that

discontinuation symptoms may occur. PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH MAJOR DEPRESSIVE DISORDER 20.

In 2005, an article entitled "Symptoms following abrupt discontinuation of duloxetine treatment in patients with major depressive disorder" was published in the Journal of Affective Disorders ("2005 JAD Article"). David G. Perahia et al., Symptoms Following Abrupt Discontinuation of Duloxetine Treatment In Patients with Major Depressive Disorder, 89 J. AFFECTIVE DISORDERS 207 (2005). Two of the named authors David G. Perahia, and Durisala Desaiah, were employees of the Lilly Research Centre and Lilly Research Laboratories, respectively, at the time of the publication of the 2005 JAD Article.

According to the Plaintiff, there were three authors who contributed to the article who were Lilly employees: Daniel Kajdasz is also affiliated with the Lilly Research Laboratories. Further, the fourth author had been "paid by Eli Lilly" for lecturing and consultancy work. Additionally, the article was never circulated to Nurse Practitioner Joan Caruana ("Caruana") nor other prescribing practitioners, and the Defendant has produced no evidence that in 2008 the information contained in

the 2005 article appeared anywhere other than the Journal of Affective Disorders.

The 2005 JAD Article reported data arising from nine clinical trials assessing the efficacy and safety of Cymbalta in the treatment of major depressive disorder. All of the studies in the article "were funded, designed and conducted by Eli Lilly and Company." The 2005 JAD Article noted that discontinuation symptoms are "common following antidepressant treatment." Perahia et al., supra, at 207.

The 2005 JAD Article reported that in the short-term placebo-controlled study "[s]ignificantly more duloxetine-treated patients (44.3%) reported at least 1 DEAE than placebo-treated patients (22.9%), with dizziness being the most common symptom." Perahia et al., supra, at 208.

The 2005 JAD Article reported that "[o]f the 510 events reported, 203 (39.8%) were mild, 258 (50.6%) were moderate and 49 (9.6%) were severe." Perahia et al., supra, at 208-09. According to the Plaintiff, the "510 events reported" only account for the events reported in six of the nine studies

and therefore do not represent the total number of events reported for the entirety of the studies.

The 2005 JAD Article reported that in the long-term placebo-controlled study "[s]ignificantly more duloxetine-treated patients reported at least one discontinuation-emergent adverse event ("DEAE") (9.1%) than did placebo-treated patients (2.0%) with dizziness being the most common symptoms." Perahia et al., supra, at 210. The 2005 JAD Article reported that "[o]f the 34 DEAEs reported, 24 (70.6%) were mild, 9 (26.5%) were moderate, and 1 (2.9%) was severe." Id. According to the Plaintiff, it is significant to point out that the "34 DEAEs" referenced only reflect the reportable DEAEs for the two long-term trials.

The 2005 JAD Article reported that in the uncontrolled 52-week open-label study, "half of the patients reported at least one DEAE with dizziness being the most common symptom." Id.

The 2005 JAD Article reported that "[a]mong the 281 patients reporting at least one DEAE, there were a total of 793 DEAEs reported of which 290 (36.6%) were reported as being of

mild severity, 367 (46.3%) moderate, and 136 (17.2%) severe." Id. According to the Plaintiff, the figures of "281" patients and "793 DEAEs" are only representative of the findings of one of the nine studies: the 52-week open-label study.

The Plaintiff began experiencing symptoms of depression and anxiety at the age of 18. At that time, he experienced a "lack of motivation or desire to really do anything" or "participate in any activities at all." (Pl.'s Dep. 106:21-107:25.) As a consequence of his depression, the Plaintiff would experience periods of one to two months where he "would feel really down." (Id. at 108:17-109:5.)

The Plaintiff also experienced periods in which he had trouble with his sleep, including both "times that I really slept too much, and then there were times that it was -- that I just didn't get a lot of sleep at all." (Id. at 109:23-110:20.) The Plaintiff denies that sleep issues began at age 18.

The Plaintiff also suffered migraines, which he reported in his October 30, 2008 visit to neurologist Dr. Josh Torgovnick. (Id. at 113:22-22; 171:5-7.)

Handwritten notes drafted by the Plaintiff prior to his first visit with Caruana in September 2008 indicate that he had previously taken Remeron, Zoloft, Lexapro, Wellbutrin, Effexor, and Prozac, alone and in combination, in an effort to manage his depression. (Caruana Med. R. 4.) After treatment with those medications, the Plaintiff "had not yet been able to get [his] depression under control." (Pl.'s Dep. 140:15-18.)

The Plaintiff's handwritten notes of the antidepressants he had taken prior to commencing Cymbalta therapy indicate that he experienced side effects with all of those therapies, including insomnia, "feeling over-medicated," "tranquilized feeling[s]," "no energy," a "tight heavy feeling in [the] head," feeling "physically tired," feeling "down" even after increased dosages, and "feelings of paranoia." (Caruana Med. R. 4.)

Caruana first prescribed Cymbalta to the Plaintiff in September 2008. (Caruana Dep. 11:13-15; 18:22-24.)

Because the Plaintiff had tried various medications in the past, Caruana agreed that she had been "looking for perhaps a different option from something he had used before

unsuccessfully," and that it was her "best medical judgment at the time that Cymbalta was the best treatment to consider that given moment." (Id. at 145:8-25.)

As a consequence of her experience as a nurse practitioner treating patients with affective disorders, Caruana understood that when discontinuing an antidepressant "[t]here are symptoms that are going to occur if you . . . discontinue abruptly." (Id. at 33:18-25.)

Caruana further indicated that she understood that "most patients who stop abruptly are going to get . . . symptoms of stopping abruptly," because "[p]atients report[ed] it to [her]." (Id. at 33:4-17.) According to the Plaintiff, Caruana's testimony is unclear as to whether she was referring to antidepressants in general or Cymbalta.

Caruana knew from her clinical practice that a gradual dose reduction was the recommended course of action for discontinuing Cymbalta treatment. (See id. at 38:2-23.) Caruana was generally aware of the potential discontinuation symptoms described in the Cymbalta Physician Package Insert, including dizziness, nausea, headache, fatigue, paresthesia,

vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis, and vertigo. (See id. at 39:13-40:2.) According to the Plaintiff, this is a presumption about Caruana's general testimony.

Caruana knew that paresthesias occur "very frequently" upon discontinuation of antidepressants from her clinical experience. (See id. at 40:22-24.)

From her own personal experience, Caruana understood that at least half of her patients who discontinued an SNRI or SSRI abruptly experienced some type of discontinuation symptom. (See id. at 41:5-23; 57:16-58:11.) According to the Plaintiff, her testimony was unclear as to whether she was referring to Effexor or to SSRIs and SNRIs in general.

In Caruana's clinical experience, she had seen that "many people" experience discontinuation symptoms. (See id. at 58:10-11.)

With respect to discontinuation of antidepressants, Caruana agreed that "you'd want to wean or taper someone off a medicine to minimize the chance of those symptoms." (See id. at

34:2-8.) Caruana did not understand the Cymbalta label's reference to discontinuation symptoms occurring "at a rate greater than or equal to 1%" to mean that there was only a 1% chance of the listed symptoms occurring. (See id. at 47:14-18.)

Had Cymbalta's Physician Package Insert stated that discontinuation events occurred in at least one patient in the Cymbalta clinical trials 44.3% of the time while they occur in placebo discontinuation 22.9% of the time, it would not have impacted Caruana's decision to prescribe Cymbalta because "in actual practice . . . [she had] seen that many people . . . have those problems." (Id. at 58:08-11.) Plaintiff denies this statement citing later testimony from Caruana that had she been aware in 2008 of the results from the clinical trials that 44% of patients on Cymbalta for 9 weeks and 50% percent of patients on longer trials were experiencing withdrawal symptoms, she would have opted to "choose another drug" for the Plaintiff. (Id. at 137:18-138:16.)

Caruana continued to prescribe Cymbalta to the Plaintiff during the period in which he was under her care, from September 2008 to April 2009. (See id. at 22:20-25:10; 25:19-26:11; 28:12-29:5.) After initiating Cymbalta treatment in

September 2008, the Plaintiff continued to fill prescriptions for Cymbalta until May 2012. (Thriftway Pharmacy R. 6.)

The Plaintiff stopped taking Cymbalta in or around June 2012. (See id.; see also Pl.'s Dep. 162:7-11.)

Upon discontinuing Cymbalta, the Plaintiff claims that he experienced "brain zaps," "suicidal thoughts," "insomnia," "headaches," and "dizziness" (Pl.'s Resp. to Def.'s Interr. No. 5) and in addition the Plaintiff's "brain zaps" ended by the spring of 2013. (See Pl.'s Dep. 165:25-166:14.)

The Plaintiff's dizziness ended within four months of discontinuing Cymbalta. (See id. at 171:12-14.)

The Plaintiff's headaches existed "over a week" after discontinuing Cymbalta. (See id. at 170:22-24.)

The Plaintiff no longer suffers any of the discontinuation symptoms he has alleged. (See id. at 178:7-10.) According to the Plaintiff, while most of the withdrawal symptoms he experienced post-discontinuation have since

subsided, he continues to live with the memory and fear of a return of his suicidal thoughts. (See id. at 184:21-185:7.)

Plaintiff's Statement of Facts

In the early 2000s, Lilly conducted clinical trials for their new drug, Cymbalta, to analyze the occurrence rate of withdrawal symptoms following discontinuation of the medication. The studies revealed that 44% of patients discontinuing after eight to nine weeks and 50% of longer-term trial patients reported withdrawal symptoms similar to those that Plaintiff would eventually come to suffer. (See Perahia et al., supra; see also INSTITUTE FOR SAFE MEDICATION PRACTICES, WHY REPORTS OF SERIOUS ADVERSE EVENTS CONTINUE TO GROW (2012), available at www.ismp.org/quarterwatch/pdfs/2012Q1.pdf. The Defendant denies this statement in part stating, as described in the 2005 JAD Article, Eli Lilly funded, designed, and conducted nine multi-center clinical trials to examine the efficacy and safety of Cymbalta in treating major depressive disorder. See Perahia et al., supra.

The description of the Plaintiff's alleged symptoms as similar to those experienced by trial participants is without

citation to specific admissible evidence and is therefore denied.

These results were published in the 2005 JAD Article. See Perahia et al., supra. The results were not released nor published elsewhere as of September 2008, the time at which Plaintiff was initially prescribed Cymbalta by his treating nurse practitioner, Caruana. The Defendant denies this statement in part as without citation to specific admissible evidence. Defendant further notes that these data were disseminated by and cited to in other sources, including government publications and internet fora. See, e.g., GARTLEHENER ET AL., U.S. DEP'T OF HEALTH AND HUMAN SERVS. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, COMPARATIVE EFFECTIVENESS OF SECOND-GENERATION ANTIDEPRESSANTS IN THE PHARMACOLOGIC TREATMENT OF ADULT DEPRESSION, 7 COMPARATIVE EFFECTIVENESS REVIEW 1, 99, APP'X D-193 (Jan. 2007) (summarizing results of the 2005 JAD Article and analyzing its quality), available at http://www.ncbi.nlm.nih.gov/books/NBK43023/pdf/TOC.pdf. In addition, as required by regulation, Eli Lilly also provided the study to the FDA. See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY E2C CLINICAL SAFETY DATA MANAGEMENT: PERIODIC SAFETY UPDATE REPORTS FOR MARKETED DRUGS 15-16 (1996), available at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073102.pdf.

Despite having an uncontested knowledge of the 44-50% withdrawal occurrence rates in Cymbalta patients, Eli Lilly designed and endorsed a Cymbalta label that omitted that information and instead assured physicians and patients that the risk of withdrawal symptoms was only "1% or greater;" a lower occurrence rate than which Eli Lilly knew to be true. Defendant denies this statement in part and states that the warnings in the Cymbalta label relevant to discontinuation-emergent adverse events are directed at physicians as required by FDA regulation. Plaintiff's additional statements are argument and without citation to specific admissible evidence, and are therefore denied.

The "1% or greater" language was on the Cymbalta label on September 29, 2008 when Caruana first saw Plaintiff to treat him for his depressive disorder. (See Caruana Dep. Ex. 2.)

Caruana testified that she had reviewed the product label and Physician's Desk Reference ("PDR") entry for Cymbalta prior to prescribing the antidepressant to Plaintiff. (See

Caruana Dep. 96:12-24, 104:23-105:8.) Defendant denies this statement and states that Caruana testified that she had the Cymbalta product labeling in her office at the time that she prescribed Cymbalta to Plaintiff and that it was a "source of information that [she] was aware of and familiar with" at that time (Caruana Dep. at 104:18-105:8) and also testified that she thought that "[a]t some point in time" she had "avail[ed her]self of the product labeling contained in the PDR for Cymbalta." (Id. at 96:12-15.)

Caruana had significant experience prescribing antidepressant medications by September 2008, although Cymbalta had only been on the market for approximately three to four years by this time. The Defendant denies this statement as being without citation to specific admissible evidence and states that Cymbalta was first approved for use in the United States on August 3, 2004 (see Jones Decl. Ex. 3 (Letter from Robert Temple to Eli Lilly & Co., Inc. (Aug. 3, 2004)) and that Caruana was familiar in September 2008 "with the various psychiatric medicines that could be used to treat someone in Mr. McDowell's condition" and that at any point in her over twenty years of experience, approximately 90% of her patients were

taking either an antidepressant or antianxiety medication. (Caruana Dep. 20:8-13, 70:12-71:2.)

In September 2008, Caruana had no knowledge of the clinical studies conducted by Eli Lilly or that withdrawal symptoms were occurring in 44-50% of Cymbalta patients. Until the time of her deposition on June 6, 2014, Caruana had never seen the 2005 JAD article which explained Cymbalta's 44-50% occurrence rate for withdrawal symptoms:

> Q. So this is the journal article that Mr. Imbroscio made reference to. It's cited in the - the document that I marked as Exhibit 3 . . . And the title is "Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder" . . . It's published in the Journal of Affective Disorders, correct?
>
> A. Yes.
>
> Q. Okay. Did anyone from Lilly ever give you that article prior to your prescribing Jesse McDowell Cymbalta in 2008?
>
> A. I do not believe so.
>
> Q. Do you have any idea or recollection as we sit here today as to whether or not you ever read that article?
>
> A. No, I never have.

(See Caruana Dep. 153:7-154:11.)

Defendant denies this statement in part and admits that the excerpt from Caruana's testimony is correctly reproduced and that Caruana had not read the 2005 JAD Article prior to prescribing Cymbalta for the Plaintiff but understood from her clinical practice that "most patients who stop [Cymbalta] abruptly are going to get . . . symptoms of stopping abruptly," because "[p]atients report[ed] it to [her]" (Caruana Dep. at 33:4-14) and that at least half of her patients who discontinued an SNRI or SSRI abruptly experienced some type of discontinuation symptom. (See id. at 41:5-23; 57:16-58:11.)

The statement that "Nurse Caruana had no knowledge . . . that withdrawal symptoms were occurring in 44-50% of Cymbalta patients" is therefore denied.

Caruana did not possess a separate independent knowledge of Cymbalta's 44-50% withdrawal occurrence rate among its users:

> Q. Okay. And then "Lilly reported symptoms in 44 percent of patients discontinuing after nine weeks or less and 50 percent longer-term trials. About 10 percent of withdrawal events and short-term trial were related as 'severe' and 53.7 had not yet resolved after one or two weeks of observation"; have I read that correctly?

A. Yes.

Q. Is this information that had been provided to you by September of 2008 by Eli Lilly?

A. I don't believe so.

(Caruana Dep. 134:5-135:16.) The Defendant denies this statement in part and admits that Caruana's testimony is correctly reproduced here, with the exception of the third sentence in counsel's question, which should correctly be written as "About 10 percent of withdrawal events and short-term trials were rated as 'severe' . . . ." but denies the statement about Caruana's knowledge regarding rates of discontinuation-emergent adverse events among Cymbalta users who abruptly discontinue the drug.

Once provided with accurate risk information for the first time, Caruana's testimony was that had that risk information been provided to her in 2008, she would have treated Plaintiff with a drug other than Cymbalta:

Q. If the information that I read to you, flipping back again to Exhibit 3, if that - if the information in the data that we just looked over relating to the 44 percent after nine weeks and 50 percent long-term trials, if that had appeared in a black box warning in September of 2008, how would you have weighed that information in the black box?

. . . .

A. I would - I would look at that very carefully

Q. And can you elaborate a little bit by what you mean look at it very carefully and put that in context of Jesse McDowell if you could?

A. If I knew that it could be potentially as severe as the withdrawal from Effexor, then I would choose something else.

Q. I'm sorry?

A. I would choose another drug.

(Caruana Dep. 137:18-138:16.) The Defendant denies this statement in part and admits that Caruana's testimony is correctly reproduced.

Plaintiff eventually discontinued Cymbalta around June of 2012. In a matter of days following his last pill, he immediately began to suffer symptoms of withdrawal such as "brain zaps," insomnia, vertigo, nausea, constant dizziness, numbness and burning in his right hand, and, perhaps most severe of all, suicidal thoughts. (See Pl.'s Dep. 164:2-25.)

The Defendant denies this statement in part and admits that the Plaintiff discontinued Cymbalta in mid-June 2012 and that he has testified that he experienced, over a period of time

ranging from "within a few days" from when he last took a Cymbalta pill to spring of 2013, "brain zaps," headaches, dizziness, insomnia, and suicidal thoughts. (Id. at 163:24-166:17.) Defendant denies the contention that the Plaintiff suffered from vertigo, nausea, or numbness and burning in his right hand in the absence of admissible evidence and states when asked to describe his injuries at his deposition, the Plaintiff did not describe any of those three symptoms and denied that he had experienced additional symptoms. (Id. at 164:19-20 ("Q. Anything else? A. Not that I can -- not that I -- that I remember.").)

These symptoms were continuous and led to being temporarily bedridden and the insolvency of his young and growing business. Plaintiff testified that while most of the withdrawal symptoms he experienced post-discontinuation have since subsided, he continues to live with the memory and fear of a return of his suicidal thoughts. (Id. at 184:21-185:7.) The Defendant denies the statement in part in the absence of specific admissible evidence in support of Plaintiff's contention that his symptoms were continuous or led to him being temporarily bedridden and to the insolvency of his business and note that the Plaintiff has made no claim for lost wages. (Id.

at 190:21-191:2.) The Defendant admits that Plaintiff's brain zaps, dizziness, and headaches have subsided since his earlier experience of them and that Plaintiff testified that the "memory and experience that [he] had with that, with quitting Cymbalta, will affect [him] negatively" because it was "scary" that he had in the past experienced suicidal thoughts (Id. at 184:21-185:3) and states that the Plaintiff has not had a suicidal thought since 2012, and no medical professional or mental health professional has told him that those thoughts are likely to recur. (Id. at 185:8-16.)

The Applicable Standard

Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L.Ed.2d 202 (1986). The relevant inquiry on application for summary judgment is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail

as a matter of law." Id. at 251-52. A court is not charged with weighing the evidence and determining its truth, but with determining whether there is a genuine issue for trial. Westinghouse Elec. Corp. v. N.Y. City Transit Auth., 735 F. Supp. 1205, 1212 (S.D.N.Y. 1990) (quoting Anderson, 477 U.S. at 249).

A fact is "material" only if it will affect the outcome of the suit under applicable law, and such facts "properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248. Disputes over irrelevant facts will not preclude summary judgment. Id. The goal is to "isolate and dispose of factually unsupported claims." Celotex Corp. v. Catrett, 477 U.S. 317, 323-24, 106 S. Ct. 2548, 91 L.Ed.2d 265 (1986). "[I]t ordinarily is sufficient for the movant to point to a lack of evidence . . . on an essential element of the non-movant's claim . . . . [T]he nonmoving party must [then] come forward with admissible evidence sufficient to raise a genuine issue of fact for trial . . . ." Jaramillo v. Weyerhaeuser Co., 536 F.3d 140, 145 (2d Cir. 2008) (internal citations omitted); see also Goenaga v. March of Dimes Birth Defects Found., 51 F.3d 14, 18 (2d Cir. 1995) ("Once the moving party has made a properly supported showing sufficient to suggest the absence of

any genuine issue as to a material fact, the nonmoving party . . . must come forward with evidence that would be sufficient to support a jury verdict in his favor."). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson, 477 U.S. at 255.

The Discontinuance Warning is Adequate

Under New York law, a manufacturer's duty to warn of the risks of a prescription medicine runs to the prescribing medical professional, not an individual patient. See Martin v. Hacker, 628 N.E.2d 1308, 1311 (N.Y. 1993) ("Warnings for prescription drugs are intended for the physician . . . . [T]he manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient."). The Defendant has a duty to warn prescribing medical professionals of "potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." Martin, 628 N.E.2d at 1311. This duty applies to failure to warn claims based both in strict liability and negligence. See Mulhall v. Hannafin, 841 N.Y.S.2d 282, 285 (N.Y. App. Div. 2007).

Under the "informed intermediary" doctrine, "the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." Martin, 628 N.E.2d at 1311 (emphasis added); see also Spensieri v. Lasky, 723 N.E.2d 544, 549 (N.Y. 1999). The prescriber, "whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects," is thus the "informed intermediary" between the manufacturer and the individual patient. Martin, 628 N.E.2d at 1311; see also Wolfgruber v. Upjohn Co., 423 N.Y.S.2d 95, 96 (N.Y. App. Div. 1979) aff'd, 52 N.Y.2d 768 (N.Y. 1980); Ames v. Apothecon, Inc., 431 F. Supp. 2d 566, 573 (D. Md. 2006) (physicians "are presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information"). The adequacy of the warning provided to a prescriber may be determined as a matter of law. See, e.g., Martin, 628 N.E.2d at 1312.

A warning is adequate as a matter of law "if it provides specific detailed information on the risks of the drug." Martin, 628 N.E.2d at 1312. Specifically, "[i]t has

long been the law in New York that prescription medicine warnings are adequate when . . . information regarding 'the precise malady incurred' was communicated in the prescribing information." Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (quoting Wolfgruber, 423 N.Y.S.2d at 96-97). In making this determination, the Court should consider factors including "whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug." Id. A warning is clear if it is "direct, unequivocal and sufficiently forceful to convey the risk." Id. at 1313. The warning should also be evaluated as a whole and not through the nitpicking prism of an interested legal advocate after the fact:

> While a meticulous examination and parsing of individual sentences in the insert may arguably reveal differing nuances in meaning or variations in emphasis as to the seriousness of a side effect, any resulting vagueness may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable.

Id.

Federal courts applying New York law apply this standard. See, e.g., Yates v. Ortho-McNeil-Janssen Pharm., Inc., No. 3:09-oe-40023, 2014 WL 1369466, at *5 (N.D. Ohio Apr.

7, 2014) (applying New York law) ("Because the document explicitly warned that the product could cause strokes, the Court finds that the warning is sufficient to meet the Defendants' duty to provide adequate warnings to treating physicians regarding a possible risk of the product."); In Re Accutane Prods. Liab., MDL No. 1626, 2012 WL 3194954, at *1, *4-5 (M.D. Fla. July 24, 2012) (applying New York law) ("The Physician Package Insert plainly and prominently identified inflammatory bowel disease by name as a possible consequence of taking Accutane. This risk information appeared in the 'WARNINGS' and 'ADVERSE REACTIONS' sections of the insert. It also identified the common symptoms of IBD and instructed what should be done if those symptoms appeared.") (emphasis in the original). In sum, "[w]here the warning given to the prescribing physician by the manufacturer through the Physician's Desk Reference (PDR), package inserts and other literature gives specific detailed information on the risks of the drug, the manufacturer has been held absolved from liability as a matter of law." Wolfgruber, 423 N.Y.S. 2d at 97.

Since Cymbalta's initial 2004 approval for the treatment of major depressive disorder, the FDA-approved label for the medicine has included a three-paragraph warning on the

risk of symptoms upon discontinuation of Cymbalta therapy. That warning has included a statement about the occurrence of discontinuation symptoms in the Cymbalta clinical trial experience, including the important fact that the rate was significantly higher in Cymbalta patients than patients on placebo; a recitation of the specific symptoms possible upon Cymbalta discontinuation (including the symptoms alleged by the Plaintiff); and guidance on the appropriate protocol for safe discontinuation of the medicine.

The elements of the Cymbalta discontinuation warning "portray[] with sufficient intensity the risk involved in taking the drug." Martin, 628 N.E.2d at 1312. The Highlights of Prescribing Information section of the Cymbalta label in effect at the time of the Plaintiff's initial prescription warns that discontinuation "[m]ay result in symptoms, including dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis, and vertigo."

The Dosage and Administration section of the Cymbalta label warns that "[s]ymptoms associated with discontinuation of Cymbalta and other SSRIs and SNRIs have been reported. A gradual

reduction in the dose rather than abrupt cessation is recommended whenever possible" and directs prescribers to the more detailed warning provided in the label's Warnings and Precautions section.

The Warnings and Precautions section of the Cymbalta label additionally provides the risks of discontinuation symptoms.

The Cymbalta label sets out the risk of symptoms arising from "abrupt or tapered discontinuation" and warns that, in placebo-controlled clinical trials, discontinuation symptoms occurred "at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo." See Gurski v. Wyeth-Ayerst Div. of Amer. Home Prods. Corp., 986 F. Supp. 654, 654 (D. Mass. 1997) (granting summary judgment where warning "cautioned the plaintiff specifically regarding the probability, nature, and gravity of the precise condition that she sufficiently suffered").

The Cymbalta label includes a detailed catalog of symptoms possible upon discontinuation. Indeed, the symptoms the Plaintiff alleges that he experienced after stopping his

Cymbalta treatment are identified in the discontinuation warning. See Alston, 670 F. Supp. 2d at 284 ("[P]rescription medicine warnings are adequate when, as here, information regarding 'the precise malady incurred' was communicated in the prescribing information.") (quoting Wolfgruber, 423 N.Y.S.2d at 96-97).

During the period relevant here, the label included approximately a dozen symptoms occurring "at a rate greater than or equal to 1%" in placebo-controlled clinical trials for Cymbalta: "dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo."

This method of communicating information on individual symptoms appearing in clinical trials is consistent with the accepted practice of identifying such individual adverse events observed at or above a specified threshold and in accord with FDA regulations and guidance directing that the label "list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database." 21 C.F.R. § 201.57(c)(7); see also U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: ADVERSE REACTIONS SECTION OF LABELING FOR HUMAN

PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS-CONTENT AND FORMAT (2006), available at www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm075057.pdf. In addition, the label included an additional subset of potential symptoms reported upon discontinuation of products within the SNRI class to which Cymbalta belongs and warns that "patients should be monitored" for all of the symptoms identified in the warning.

Section 5.1 of the Warnings and Precautions in the Cymbalta label additionally provides an account of the clinical worsening and suicide risks attendant to taking antidepressants, including in the case of downward adjustments in the dosage of an antidepressant. The label warns:

> All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

These suicidality warnings are well-known in the medical community. See U.S. FOOD AND DRUG ADMIN., PUBLIC HEALTH ADVISORY: SUICIDALITY IN ADULTS BEING TREATED WITH ANTIDEPRESSANT MEDICATIONS (2005),

www.fda.gov/Drug/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053169.htm.

The discontinuation warning speaks to the "severity" and "duration" of potential discontinuation symptoms within the SNRI class: "Although these events are generally self-limiting, some have been reported to be severe." The label identifies symptoms that, by their nature, have the capacity to be severe and that are not, by definition, self-limiting, which appear in the label's WARNINGS and PRECAUTIONS section and which, by law, must include all "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent)." 21 C.F.R. § 201.57(c)(6); see also Ames, 431 F. Supp. 2d at 569 n. 9 (recounting opinion of plaintiffs' expert that "most 'serious' adverse reactions are listed in the Warnings section"); Martin, 628 N.E.2d at 1312 (noting that Warnings section "deals with side effects of graver consequences than the Adverse Reactions section").

The Cymbalta discontinuation warning devotes a paragraph to advising prescribers of the appropriate means of taking a patient off the medicine. Section 5.1 of Warnings and Precautions advises in connection with the suicidality warning,

"If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that discontinuation can be associated with certain symptoms." Section 5.6 states: "Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered."

The Plaintiff contends that the Cymbalta discontinuation warning was both inadequate because it did not include the frequency of patients with discontinuation symptoms in the 2005 JAD Article, and misleading, because it utilized a threshold of "greater than or equal to 1%" to identify individual discontinuation events. (Pl.'s Mem. at 6-8.)

However, courts have refused to graft onto the adequacy standard a requirement that a package insert must include specific adverse event frequencies. See Hurley v. Lederle Labs., Div. of Am. Cyanamid Co., 651 F. Supp. 993, 1002 (E.D. Tex. 1986) ("The plaintiff cites no authority for the

proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions. As a practical matter, this would be extremely difficult, perhaps impossible, with respect to a drug like the DPT vaccine, which has many possible harmful side effects.") (quoting Smith v. Wyeth Labs., Inc., No. 84-2002, slip op. (S.D. W.Va. Aug. 21, 1986)), rev'd on other grounds 863 F.2d 1173 (5th Cir. 1988); see also Percival v. Am. Cyanamid Co., 689 F. Supp. 1060, 1064 (W.D. Okla. 1987).

The Cymbalta warning closely parallels the warning that was found adequate as a matter of law in Alston. 670 F. Supp. 2d 279. The Alston warning stated in part that "[w]ithdrawal symptoms may occur if ULTRAM is discontinued abruptly. . . . These symptoms may include: anxiety, sweating, insomnia. . . and rarely hallucinations." Id. at 282. It was held that the warning warned about the injuries sustained by the plaintiff, despite lacking precise frequencies for each withdrawal event or for withdrawal symptoms as a category. See id. at 284-85. As a result, the manufacturer discharged its duty to warn. Id. The Cymbalta discontinuation warning likewise specifically identifies potential discontinuation symptoms. The warning also articulates the seriousness of the

risk, as required by Martin: it states that a number of these symptoms occurred "at a significantly higher rate" in patients taking the drug than in those taking a placebo and that some symptoms had been reported to be "severe."

The Plaintiff has contended that the Cymbalta label misleadingly suggests that discontinuation symptoms "occurred in only 1% of patients." (Pl.'s Mem. at 8.) Caruana, an experienced medical professional, expressly rejected that interpretation. (Caruana Dep. 47:12-18 ("Q. And then it goes on -- it lists all these events, and it says 'occurred at a rate greater than or equal to 1 percent.' Does that mean to you that there's only a 1 percent chance of any of this thing -- any of these things happening? A. No.").)

Using a numerical threshold for the inclusion of adverse events in a label is an appropriate, standard methodology for identifying adverse events arising with sufficient frequency to warrant inclusion in the product label. Pursuant to FDA regulations and guidance, manufacturers are to identify the "frequency cutoff" — the equivalent of the "greater than or equal to 1%" language — for potential adverse reactions in the product label. See 21 C.F.R. 201.57(c)(7)(ii)(A); see

also GUIDANCE FOR INDUSTRY: ADVERSE REACTIONS SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS 10 ("The frequency cutoff should be noted in the listing or table header, in the text accompanying the listing or table, or in a footnote.").

Taken together, the Cymbalta warning is adequate as a matter of law because it is "accurate, clear, consistent on its face" and "portrays with sufficient intensity the risk involved in taking the drug." See Martin, 628 N.E.2d at 1312.

The Discontinuance Warning Was Not the Proximate Cause of Plaintiff's Injuries

Under New York law, "where the treating physician is independently aware" of potential adverse events, that knowledge is "an intervening event relieving the manufacturer of any liability to a patient under the failure to warn theory." Banker v. Hoehn, 718 N.Y.S.2d 438, 440-41 (N.Y. App. Div. 2000); see also Alston, 670 F. Supp. 2d at 286 ("The Plaintiff has not shown that a failure to warn . . . was the proximate cause of his injuries, as his physicians were aware of the risks . . ."); Figueroa v. Boston Scientific Corp., 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003). A physician's existing awareness of a potential risk or side effect thus "sever[s] the causal [chain]"

between an allegedly inadequate warning and a plaintiff's injury. Glucksman v. Halsey Drug Co., 553 N.Y.S.2d 724, 726 (N.Y. App. Div. 1990).

Caruana testified that, based on her clinical experience and training, she was aware of the risk of discontinuation symptoms with abrupt cessation of Cymbalta treatment. (Caruana Dep. 33:04-34:08, 38:02-23.)

Upon reviewing the discontinuation symptoms listed on Cymbalta's label during her deposition, Caruana testified that she was independently aware of the specific symptoms described in the label. (Caruana Dep. 39:13-40:24.)

In describing her clinical experience with SSRIs and SNRIs, Caruana testified that "at least half" of her patients experience some discontinuation symptom upon an abrupt cessation of treatment. (Caruana Dep. 41:05-19.) With respect to paresthesia, the "electric shock" sensation, Caruana testified that they occur "very frequently" upon discontinuation. (Caruana Dep. 40:22-24.) When confronted with the specific data on discontinuation symptoms reflected in the 2005 JAD Article on the rate of patients with discontinuation symptoms upon abrupt

discontinuation in the reported studies – 44.3% on Cymbalta and 22.9% on placebo – Caruana volunteered that she had "seen that . . . many people have those problems." (Caruana Dep. 58:10-11.)

The Plaintiff's central claim is that the Defendant misled medical professionals about the rate of discontinuation symptoms by listing the events seen in the clinical trials "at a rate greater than or equal to 1%," consistent with the Federal Regulations. See 21 C.F.R. § 201.57(c)(7)(ii)(A). However, Caruana expressly testified that she was not misled in the way Plaintiffs suggest:

> Q. . . . Does that mean to you that there's only a 1 percent chance of any of this thing – any of these things happening?
>
> A. No.

(Caruana Dep. 47:14-18.)

A prescriber's independent knowledge of the risks of a drug or medical device breaks the chain of proximate causation. In Ohuche v. Merck & Co., 903 F. Supp. 2d 143 (S.D.N.Y. 2012), the physician who had prescribed the plaintiff a vaccine for shingles "testified at deposition that she was aware of the adverse reactions associated with ZOSTAVAX." Id. at 151. The

manufacturer's alleged failure to adequately disclose the risks of the drug, therefore, was not the proximate cause of the plaintiff's injuries. Id. at 151-52. Similarly, in Banker v. Hoehn, "there [was] no question" that the treating physician "was fully cognizant of the potential of hypertrophic scarring" from the use of an argon laser to treat a facial birthmark. 718 N.Y.S.2d at 441. That knowledge was an "intervening event" in the causal chain which "reliev[ed] the manufacturer of any liability to a patient under the failure to warn theory." Id. at 440-41. See also Figueroa, 254 F. Supp. 2d at 370 (holding that no proximate causation existed where "a treating physician is well aware of the risks of a medical device, independent of any warning by the manufacturer"); Glucksman, 553 N.Y.S.2d at 726-27 (holding that plaintiff could not show proximate cause where treating physician had independent knowledge of the risks posed by treatment, because "physician's decision not to inform the plaintiff of the risk . . . was an intervening cause.").

Another federal court has recently held that a prescribing physician's independent knowledge of potential Cymbalta discontinuation symptoms made it impossible for the plaintiffs to establish proximate cause. See Carnes v. Eli Lilly and Co., C/A No. 0:13-591, 2013 WL 6622915, at *7 (D.S.C.

Dec. 16, 2013). There, the plaintiffs, represented by the same lawyers as in this case, made allegations that the "1%" figure in the Cymbalta label was misleading. Because the prescribing doctor in Carnes had "independent knowledge of the risk of withdrawal symptoms through his training and experience" and independent of the Cymbalta label, the court ruled that plaintiffs could not prove proximate cause. Id. at *5-6.

The Plaintiff seeks to distinguish Carnes by noting that the South Carolina District Court found that the prescribing physician in Carnes had independent knowledge of the extent of Cymbalta's 44-50% withdrawal symptom occurrence rate and that the physician would still have prescribed Cymbalta to his patient had there been a warning on the label of the sort the Plaintiffs argue for in the case at bar. See Carnes, 2013 WL 6622915, *7 ("Dr. Knight also testified that 'more than half' of his patients experienced some type of withdrawal symptom following abrupt discontinuation of Cymbalta."). See also id. at *5 ("Dr. Knight testified that, had he been provided the warning Plaintiffs allege would have been adequate, he still would have prescribed Cymbalta to Mr. Carnes in the summer of 2011.").

Here Caruana testified that she had knowledge of the risks of abrupt discontinuation independent of the information provided by Eli Lilly and that she was not misled by the discontinuance warning claim. Thus, even under Plaintiff's theory, the Defendant did not proximately cause the Plaintiff's injuries and is relieved of liability. See Banker, 718 N.Y.S.2d at 441. See also Porterfield v. Ethicon, Inc., 183 F.3d 464, 468 (5th Cir. 1999) (no proximate cause where physician was independently aware of possible risks of using medical device through experience and review of literature); Odom v. G.D. Searle & Co., 979 F.2d 1001, 1003 (4th Cir. 1992) ("[T]he manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk."); Kirsch v. Picker, Int'l, Inc., 753 F.2d 670, 671 (8th Cir. 1985) ("Picker's failure to warn Dr. Murphy could not have been the proximate cause of Kirsch's injury if Murphy was already aware of the cancer risks associated with radiation therapy."); Ames, 431 F. Supp. 2d at 573 ("[T]he warnings are intended to be read by learned intermediaries who are presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information.").

Furthermore, under New York's proximate cause standard, "a plaintiff must demonstrate that had a different, more accurate warning[] been given, his physician would not have prescribed the drug in the same manner." Alston, 670 F. Supp. 2d at 285; see also Mulhall, 841 N.Y.S. 2d at 287 ("[P]laintiffs had to show that had the warning been different, Dr. Hannafin would have departed from her normal practice and used another device."). Summary judgment is appropriate where a plaintiff fails to establish that a prescribing physician's decision to prescribe a particular medication would have changed had a different warning been given. Id.; see also Erony v. Alza Corp., 913 F. Supp. 195, 200 (S.D.N.Y. 1995) ("An act cannot be the 'substantial cause' if the injury would have occurred regardless of the content of defendant's warning.").

In her deposition, Caruana testified that a different warning containing the information Plaintiff alleges was missing from the Cymbalta labeling would not have changed her decision to prescribe Cymbalta to the Plaintiff:

> Q. If the physician package insert, the prescribing information[,] had said not that the following symptoms occur[ ]at a rate equal to . . . or greater than . . . one percent, but it said that these events occur in at least one patient in the clinical trials 44.3 percent of the time

while they occur in placebo discontinuation 22.9 percent of the time, would that have [had] any impact on your decision to use Cymbalta?

A. No[.] [B]ecause in actual practice, we're talking about discontinuation and I've seen that many people have those problems.

(Caruana Dep. 57:20-58:11.)

Under examination by the Plaintiff's attorney, when asked whether information that discontinuation symptoms occurred in "40 to 50 percent" of patients in clinical studies would impact her decision to prescribe Cymbalta, Caruana testified that "it would affect not the prescribing so much." (Caruana Dep. 129:02-03.) Caruana did also testify that if the rate were indeed so high (in contrast to her own experience), she might have decided to emphasize to patients the importance of tapering off of Cymbalta (Id. at 129:04-12), but she did not say that it would have impacted her prescribing decision. Caruana explained that she relies on her clinical experience more than labeling language:

Q. And that's why I'm asking … if you had been provided this information in 2008, what would that have done in your mind in comparing [the effects of] Cymbalta [to other drugs,] with respect to withdrawals specifically?

. . .

A. I'd still have to go with my experience with patients[,] [s]o that would temper what I'm reading here [about discontinuation risk] . . . [b]ecause my experience with patients doesn't lead me to believe that it is in the same league [as Effexor's high rate of discontinuation symptoms].

(Caruana Dep. 132:13-25.)

Caruana also testified that "if [she] knew that [withdrawal from Cymbalta] could be potentially as severe as the withdrawal from Effexor, [another antidepressant therapy,] then [she] would choose something else." (Caruana Dep. 138:12-14.) Caruana distinguished Effexor as "the one drug [she] really dislike[s] because of the discontinuation syndrome that happens almost on a daily basis if you don't take it on time . . . ," (Caruana Dep. 76:21-24), and testified that in her experience with Cymbalta (which she estimated she has prescribed to over 100 patients), Cymbalta "is [not] in the same league" as Effexor on discontinuation symptoms. (Caruana Dep. 29:14-17; 132:13-25.)

Caruana's testimony that she had not read the 2005 JAD Article and that it "may have" been relevant to her decision-

making process (see Pl's. Mem. 10; Caruana Dep. 134:18-23) does not bar summary judgment. None of the cases that the Plaintiff has cited demand that a physician be independently aware of the precise frequency of an adverse event. In Ohuche v. Merck & Co., the product information provided to physicians about the shingles vaccine noted specific numbers of patients who suffered from the adverse event in question. 903 F. Supp. 2d at 146. The prescribing physician had never reviewed that product information, the PDR entry for the vaccine, or any publications about the vaccine by the FDA or in medical journals. See id. at 146-47. Nonetheless, the court concluded that there was no proximate cause because the physician had independent, general knowledge about the possibility of side effects. Id. at 147, 151-52; see also Glucksman, 553 N.Y.S.2d at 725-26 (finding prescriber's independent awareness that particular adverse event was a "possible adverse reaction associated with" the medication prevented plaintiff from demonstrating proximate cause).

The Plaintiff seeks to defeat summary judgment for lack of proximate cause by relying on Caruana's testimony that she might have prescribed a different medicine to the Plaintiff if Cymbalta discontinuation "could be potentially as severe as the withdrawal from Effexor," a different antidepressant. (Id.

at 138:12-16.) Under questioning by counsel for the Plaintiff, Caruana testified about her experience with the drug Effexor, which she characterized based on her clinical experience and discussions with other physicians as "remarkable in causing severe [withdrawal] reactions almost on a daily basis," even though she did not think she had seen any empirical data on that point. (See id. at 76:21-79:11.) Counsel then asked Caruana to assume that she had been provided with "information or material or data that showed that Cymbalta was worse" than Effexor with regard to withdrawal and asked what impact that would have on her prescribing decision, to which she agreed only that she would give such information attention. (See id. at 122:7-24.) Caruana testified that if she knew that Cymbalta was as severe as Effexor she would have chosen another drug for the Plaintiff. (Caruana Dep. 137:18, 138:16.)

However, there is no evidence in this record that Cymbalta and Effexor have equivalent discontinuation profiles. Caruana's clinical experience, having prescribed antidepressants to thousands of patients was that Cymbalta's discontinuation effects were not as severe as those experienced upon abrupt withdrawal from Effexor. (Id. at 68:10-13, 70:18-71:2.)

Counsel for the Defendant properly objected to the line of questioning that resulted in Caruana's testimony as lacking foundation and calling for speculation due to the absence in the record of any support for the claim that Cymbalta and Effexor have equivalent discontinuation profiles and Caruana's testimony contradicting that suggestion. (See Caruana Dep. 138:3-5.) The inadmissibility of Caruana's testimony is a separate, stand-alone ground for rejecting it as a basis for denying summary judgment. See Presbyterian Church of Sudan v. Talisman Energy, Inc., 582 F.3d 244, 264 (2d Cir. 2009) ("[O]nly admissible evidence need be considered by the trial court in ruling on a motion for summary judgment." (quoting Raskin v. Wyatt Co., 125 F.3d 55, 66 (2d Cir. 1997)).

Because the discontinuance warning was not the proximate cause of any injuries suffered by the Plaintiff, summary judgment in favor of the Defendant is appropriate.

The Adequacy of the Discontinuance Warning Bars the Remaining Claims

The remaining claims, Compl. ¶¶ 48-64 (defective design); ¶¶ 41-47 (negligence); ¶¶ 81-91 (breach of implied warranty); ¶¶ 92-103 (negligent misrepresentation); ¶¶ 104-114

(fraud); ¶¶ 115-130 (violation of consumer fraud laws) are barred by the adequacy of the discontinuance warning as concluded above. See In Re Accutane, 2012 WL 3194954 at *6 ("[U]nder New York law, the adequacy of the warnings, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud."). In addition, New York does not recognize a design defect theory of liability for prescription medicines. See Martin, 628 N.E.2d at 1311 ("[A] prescribed drug, accompanied by adequate warnings, is 'not defective, nor is it unreasonably dangerous.'") (internal quotation marks and citation omitted).

Relating a warning theory in terms of "warranty" or "fraud" does not avoid the implications of an adequate warning. See, e.g., In re Norplant Contraceptive Prods. Liab. Litig., 955 F. Supp. 700, 709 (E.D. Tex. 1997) (granting summary judgment on all claims because "[t]he gravamen of all of Plaintiffs' causes of action . . . is that Wyeth failed to adequately warn of or disclose the severity of Norplant's side effects"), aff'd 165 F.3d 374 (5th Cir. 1999); Ames, 431 F. Supp. 2d at 567-68 (D. Md. 2006) (granting summary judgment based on proximate cause and stating defective design, marketing defect, breach of implied warranty, and negligence claims can be "reduce[d] down"

to failure to warn claims); Jack v. Glaxo Wellcome Inc., 239 F. Supp. 2d 1308, 1320-22 (N.D. Ga. 2002) (holding the learned intermediary doctrine, as adopted by Georgia courts, insulated a defendant from liability for negligence, strict liability, and breach of implied warranty claims). In addition, all of Plaintiffs' additional claims require that he show proximate cause, and, as set forth above, that has not been established.

Conclusion

Based on the facts and conclusions set forth above, the Defendant's motion for summary judgment is granted, and judgment will entered in its favor dismissing of Plaintiff's claims.

It is so ordered.

Dated: **New York, New York**
November 6, 2014

Robert W. Sweet
U.S.D.J.