SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: IAS PART 42

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VASILIKI VARDOUNIOTIS,

Plaintiff,

- against – Index No. 152029/2019

PFIZER, INC. Motion Sequence No. 002

Defendant.

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BANNON, J:

I. INTRODUCTION

Plaintiff Vasiliki Vardouniotis brings this product liability action to recover for injuries allegedly resulting from her use of Chantix, a smoking cessation medication manufactured by defendant Pfizer, Inc. ("Pfizer"), and generically know as varenicline. Plaintiff's amended complaint asserts 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.[1] Plaintiff also seeks punitive damages.

Pfizer moves to dismiss the amended complaint in its entirety, pursuant to CPLR 3013, 3211, and 3016 (b).

[1] The amended complaint withdraws the causes of action for fraudulent misrepresentation, fraudulent concealment and reckless and/or negligent misrepresentation and concealment. However, rather than omit them entirely, the amended complaint indicates that these claims have been withdrawn with a strikethrough. As a result, the causes of actions that follow the withdrawn claims are misnumbered. For example, gross negligence, which immediately follows the withdrawn claims, is incorrectly designated as the seventh cause of action, whereas it is the fourth one to be asserted. This decision takes no notice of the withdrawn claims and renumbers the remaining claims accordingly.

II. BACKGROUND

Plaintiff alleges that she was prescribed and began taking Chantix in May 2016 (NYSCEF Doc No. 24, amended complaint, ¶ 11), which caused various injuries, including: chronic pain in entire spine, abdomen, and hips; dystonia; muscular spasms; persistent dystonic tic; 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 (*id.*, ¶ 20). According to plaintiff, Pfizer failed to properly disclose these risks and, as such, her healthcare providers were not aware of them. Plaintiff alleges that had her healthcare providers known of these side effects, they would not have prescribed Chantix. (*Id.*, ¶¶ 15-19.)

The amended complaint alleges that Chantix "was approved for use and launched into the market for sale in the United States" in May 2006 (*id.*, ¶ 31) and that "Pfizer obtained at least two modifications to the label to CHANTIX by the FDA in March 9, 2015 . . . and December 16, 2016," but that "Pfizer never applied for nor sought inclusion in the label of [sic] that CHANTIX causes dystonia, muscular spasm, movement disorders, abnormal posture, serious injury, or death" (*id.*, ¶ 75).

According to Pfizer, the modifications to its label were in response to "reports of serious changes in mood and behavior in some patients taking the medication" (NYSCEF Doc No. 36, Pfizer's brief at 4). Pfizer explains that "in July 2009, FDA required Pfizer to add a boxed warning . . . to the Chantix label about the risk of changes in mood and behavior" (*id.*; *see* NYSCEF Doc No. 40 [Chantix label, dated October 2014, containing a boxed warning of "serious neuropsychiatric events"]). However, per an FDA communication issued on December 16, 2016, after a large clinical trial, the FDA determined that these risks were "lower than

previously suspected" and that "the benefits of stopping smoking outweigh the risks" (NYSCEF Doc No. 39 at 1). Accordingly, the FDA "remov[ed] the Boxed Warning, FDA's most prominent warning, for serious mental health side effects from the Chantix drug label" (*id.*).

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. Pfizer moved (in motion sequence no. 001) to dismiss the complaint.

By decision and order dated July 7, 2020 ("Decision"), this 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 "the second cause of action (breach of express warranty), the fourth cause of action (fraudulent misrepresentation), the fifth cause of action (fraudulent concealment), the sixth cause of action (reckless and/or negligent misrepresentation and concealment), and the plaintiff's request for punitive damages," and otherwise denied the motion. (NYSCEF Doc No. 20, Decision at 22-23.)

In dismissing the first cause of action (negligence), to the extent it was based on a failure to warn, this court found that plaintiff failed to sufficiently plead a failure to warn claim that is not preempted, 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'" (Decision at 8 [internal citations omitted]). Nonetheless, the court held that the complaint adequately pleaded the branch of the

claim that alleged that plaintiff "was injured as a result of Pfizer's failure to adequately test Chantix and failure to conduct post-marketing surveillance" (*id.* at 11-12).

Likewise, the court dismissed the seventh (gross negligence) and eighth (willful, wanton, and malicious conduct) causes of action to the extent they were based on Pfizer's alleged failure to warn, but "decline[d] to dismiss the seventh and eighth causes of action in their entirety," because "[t]he gravamen of these causes of action [was] that Pfizer failed to exercise due care, *i.e.*, failed to test Chantix, and failed to conduct adequate post-market surveillance of the drug, among other things" (*id.* at 19).

This court dismissed the second cause of action for breach of express warranty because "the complaint fail[ed] to allege any express warranties made by Pfizer" or "annex any express warranty to the complaint" (*id.* at 13, 14). However, it declined to dismiss the third cause of action for breach of implied warranties, finding that "plaintiff adequately allege[d] that Pfizer breached the implied warranties of merchantability and fitness by holding Chantix out as reasonably fit and suitable when it was allegedly unreasonably dangerous," as the complaint alleged that "Pfizer marketed, advertised, and promoted the sale of Chantix, while minimizing the serious risk of injury and death associated with the drug" (*id.* at 15).

The court dismissed the fourth (fraudulent misrepresentation), fifth (fraudulent concealment) and sixth (reckless, negligent misrepresentation and/or concealment) causes of action for failure to comply with CPLR 3016 (b), finding that the claims consisted of "bare assertions" that "fail[ed] to permit a reasonable inference of the alleged misconduct" (*id*. at 19).

The court denied the motion as to the ninth cause of action (unjust enrichment), finding that "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" (*id.* at 21). Moreover, the court held that the "claim [was] not duplicative of any other claim, given that [plaintiff sought] disgorgement of Pfizer's profits and monetary benefits" (*id.*).

Lastly, this court dismissed plaintiff's request for punitive damages, because "the complaint fail[ed] to allege that Pfizer engaged in any morally culpable conduct" (*id.* at 22).

Following the Decision, plaintiff filed the amended complaint and a notice of appeal from the Decision.

III. DISCUSSION

"[O]n a motion to dismiss a complaint for failure to state a cause of action, the complaint must be construed in the light most favorable to the plaintiff and all factual allegations must be accepted as true" (*Allianz Underwriters Ins. Co. v Landmark Ins. Co.*, 13 AD3d 172, 174 [1st Dept 2004]). The court is not permitted "to assess the merits of the complaint or any of its factual allegations, but only to determine if, assuming the truth of the facts alleged, the complaint states the elements of a legally cognizable cause of action" (*Skillgames, LLC v Brody*, 1 AD3d 247, 250 [1st Dept 2003]). "However, factual allegations that do not state a viable cause of action, that consist of bare legal conclusions, or that are inherently incredible or clearly contradicted by documentary evidence are not entitled to such consideration" (*id.*).

On a motion to dismiss based on documentary evidence, dismissal is appropriate where "the documentary evidence utterly refutes plaintiff's factual allegations, conclusively establishing a defense as a matter of law" (*Goshen v Mutual Life Ins. Co. of N.Y.*, 98 NY2d 314, 326 [2002] [internal citation omitted]).

A. Failure to Warn Claims

As part of its first (negligence), fourth (gross negligence) and fifth (willful, wanton, and malicious conduct) causes of action, the amended complaint alleges that Pfizer failed to adequately warn of Chantix's risks (*see* amended complaint, ¶¶ 110 [N], 193 [N], 201 [N]). Pfizer contends that the Food, Drug, and Cosmetic Act of 1938 ("FDCA") preempts plaintiff's failure to warn claims because, without newly acquired information concerning risks of a different type or greater severity or frequency than previously included in its submissions to the FDA, Pfizer could not amend the Chantix label without FDA approval. Pfizer argues that the publications included in the amended complaint do not constitute newly acquired information, because: (1) they do not relate to plaintiff's alleged injuries; or (2) the FDA was informed of them at the time it approved the Chantix label. In addition, Pfizer contends that the informed intermediary doctrine bars the failure to warn claims to the extent that they are premised on Pfizer's alleged failure to warn plaintiff or the general public rather than the medical community. Lastly, Pfizer contends that the negligence claim should be dismissed to the extent it is based on a failure to warn because the amended complaint's allegations of how the Chantix label was inadequate and how this proximately caused plaintiff's injuries are conclusory.

Plaintiff counters that the label for Chantix does not include warnings for dystonia, muscular spasm, movement disorders and abnormal posture. Plaintiff argues that the publications referenced in, and annexed to, the amended complaint demonstrate that Pfizer had actual knowledge of these side effects before plaintiff took Chantix. Plaintiff contends that the inclusion of these publications corrects the pleading deficiency identified in the Decision. Plaintiff also argues that Pfizer misapplies the informed intermediary doctrine, because while

Pfizer was required to warn plaintiff's physician, the duty to do so was nonetheless owed to plaintiff.

Under New York law, to state a negligence claim based on a failure to warn, plaintiff must allege that "the product did not contain adequate warnings and that the inadequacy of those warnings was the proximate cause of the injuries" (*Mulhall v Hannafin*, 45 AD3d 55, 58 [1st Dept 2007] [internal citation omitted]). A manufacturer of prescription drugs has a duty "to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist" (*Martin v Hacker*, 83 NY2d 1, 8 [1993] [internal citations omitted]). However, "[w]arnings for prescription drugs are intended for the physician, . . . [who] acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty . . . is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient" (*id.* at 9 [internal citations omitted]).

"Under the [FDCA] . . . the FDA closely controls the label for all FDA-approved drugs and therapies" *Gayle v Pfizer Inc.*, 452 F Supp 3d 78, 84 [SD NY 2020], *affd* 847 Fed Appx 79 [2d Cir 2021] [citation omitted]). "Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. A manufacturer may, however, make certain changes to its label without prior agency approval through the 'changes being effected' ('CBE') regulation" (*Utts v Bristol-Myers Squibb Co.*, 226 F Supp 3d 166, 177 [SD NY 2016]). Pursuant to the CBE regulation, a pharmaceutical company may makes "[c]hanges in the labeling to reflect newly acquired information . . . [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction" (21 CFR 314.70 [c] [6] [iii] [A]), where there is "reasonable evidence of a causal association" between "a clinically significant hazard" and a drug, although "a causal relationship need not have been definitely established" (21 CFR 201.57

[c] [6] [i]). Clinically significant hazards include "any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug" (*id.*). "Newly acquired information" is defined as:

> "data, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA" (21 CFR 314.3 [b]).

Under impossibility preemption, where it is impossible for a drug manufacturer to fulfil its state law requirements without violating federal requirements, the state law claim is preempted (*see Wyeth v Levine*, 555 US 555, 573 [2009]). "Since the FDCA and FDA regulations require that the FDA approve a drug's initial label and significantly limit manufacturers' ability to update that label, state law failure-to-warn claims can be preempted" (*Gayle*, 452 F Supp 3d at 87). However, because the CBE regulation permits a drug manufacturer to correct labeling deficiencies without prior FDA approval, a plaintiff states a failure to warn claim that is not preempted by pleading a labeling deficiency that could have been corrected based on newly acquired information (*see Gibbons v Bristol-Myers Squibb Co.*, 919 F 3d 699, 708 [2d Cir 2019]). "If the plaintiff meets that standard, the burden shifts to the party asserting a preemption defense to demonstrate that there is clear evidence that the FDA would not have approved a change to the [prescription drug's] label" (*id*. [internal quotation marks and citations omitted]; *see Merck Sharp & Dohme Corp. v Albrecht*, 139 S Ct 1668, 1679 [2019]).

In response to this court's previous determination—that the complaint failed to sufficiently plead a failure to warn claim that was not preempted because it "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'" (Decision at 8)—the amended complaint points to several examples of such published medical literature (*see* amended complaint, ¶ 53, exhibits A-D). While not all of the publications meet the definition of newly acquired information, two do.

As a preliminary matter, Pfizer's contention that two of these publications are not "newly acquired information" because the FDA was aware of them before it approved the Chantix label is unpersuasive. The first of these publications is a report prepared by the Institute for Safe Medication Practice, dated May 21, 2008, and titled "Strong Safety Signal Seen for New Varenicline Risks" (NYSCEF Doc No. 25, amended complaint, exhibit A). Because it is based on "adverse drug events reported to the [FDA]" (*id.* at 1), Pfizer contends that, on its face, it does not constitute newly acquired information. The second is a publication titled "Varenicline-induced acute dystonic reaction: a case report" (NYSCEF Doc No. 26, amended complaint, exhibit B). Pfizer contends that because it submitted this publication to the FDA in its "NDA Periodic Adverse Drug Report," dated July 2, 2014, (NYSCEF Doc No. 41) and in a MedWatch Form, dated September 18, 2020, (NYSCEF Doc No. 42) they have provided documentary evidence that the report is not "newly acquired information."

Pfizer provides no support, nor did the court's own research reveal any, for its contention that information reported to the FDA automatically disqualifies it from being newly acquired information, even when that information was not part of the drug manufacturer's submissions to the FDA as part of its new drug application, seeking authorization to market the drug (*see* 21 USC § 355; 21 CFR 314.50). Moreover, pharmaceutical companies are required to report to the FDA post-marketing life-threatening, serious, or unexpected adverse drug experiences, as well as

scientific literature and medical journals discussing such adverse drug experiences (21 CFR 314.80 [c] [d]). If all such reported information is automatically disqualified from being newly acquired information, it is difficult to see how anything could be grounds for a label change under the CBE regulation. Indeed, to adopt such a narrow view of what constitutes newly acquired information would shift to the FDA the responsibility of ensuring that warnings on drugs remain adequate. This would contravene the "central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times" (*Wyeth*, 555 US at 570-571).

Here, both publications were reported to the FDA after the initial approval of the label and launch of Chantix in 2006. There is no indication that either was part of Pfizer's submissions to the FDA in connection with the subsequent label changes. As such, Pfizer fails to demonstrate that either report was "plainly known to the FDA prior to approving the label" (*Utts*, 226 F Supp 3d at 182 [internal quotation marks and citation omitted]).

Turning to the substance of plaintiff's medical literature, the report titled "Strong Safety Signal Seen for New Varenicline Risks" (NYSCEF Doc No. 25) does not satisfy the definition of newly acquired information. In pertinent part, the report notes that "[s]erious reported events included 86 cases of convulsions (seizures) [and] 372 reports of a wide variety of movement disorders" (*id.* at 2). However, the report also notes that the data it relies on has its limitations, "among the most important . . .[being] that these reports do not establish causality," which is why the "overall findings [are described] as a signal that requires further investigation and confirmation" (*id.* at 11). "[W]ithout any analysis indicating causality, [the report] cannot constitute 'newly acquired information'" (*Gayle*, 452 F Supp 3d at 88; *see* 21 CFR 314.70 [c] [6] [iii] [A]; 21 CFR 201.57 [c] [6] [i]; *see also Sabol v Bayer Healthcare Pharm., Inc.*, 439 F Supp

3d 131, 149 [SD NY 2020] [stating that "[w]hile federal regulations define 'newly acquired information' to include items such as adverse event reports, the CBE regulation still requires causation"] [citation omitted]; *Utts v Bristol-Myers Squibb Co.*, 251 F Supp 3d 644, 669 [SD NY 2017], *affd sub nom. Gibbons v Bristol-Myers Squibb Co.*, 919 F3d 699 [2d Cir 2019] [finding that articles that "merely express[ed] a desire for further investigation" did not contain newly acquired information]).

Notably, the amended complaint also references a Wall Street Journal article, titled "Report Links Pfizer Drug to Accidents" (amended complaint, ¶ 56). This article merely discusses the above report and does not constitute "newly acquired information" any more than the report it discusses.[2]

The next publication that the amended complaint points to is titled "From the Director… FDA Fails to Protect Public Once Again" (*id.*, ¶ 53 [B]). This document is not annexed to the amended complaint or plaintiff's opposition to the instant motion. The amended complaint contains no allegations as to its contents and plaintiff does not argue that this article contains any newly acquired information. As such, it is not helpful to plaintiff in stating her failure to warn claim (s*ee In re Celexa and Lexapro Mktg. and Sales Practices Litig.*, 779 F3d 34, 42-43 [1st Cir 2015] [finding that a complaint failed to allege the existence of newly acquired information, where, among other things, it relied on an "opinion piece" that "simply argue(d) that the FDA should not have approved" a drug, without pointing to any "information (that) was unknown to the FDA prior to label approval"]).

[2] The article is not annexed to the amended complaint. However, the court was able to obtain a copy of the article, which is publicly available, online (*see* Avery Johnson and Alicia Mundy, *Report Links Pfizer Drug to Accidents, Heart Trouble*, Wall Street Journal, May 22, 2008 [https://www.wsj.com/articles/SB121140022590611635]).

The amended complaint also points to two news reports from 2008. The first was issued by the Federal Aviation Administration and concerns its response to "reports of psychiatric problems associated with [Chantix]" (NYSCEF Doc No. 29, amended complaint, exhibit E at 1). The other discusses the Federal Motor Carrier Safety Administration's advisory that Chantix "may adversely affect the driver's ability to safely operate a commercial motor vehicle," which was issued following the FDA's determination that the Chantix label should include a warning of severe changes in mood and behavior (NYSCEF Doc No. 30, amended complaint, exhibit F at 1). Both articles clearly deal with information that the FDA was aware of and acted upon to require the boxed warning on the Chantix label for serious mental health side effects (*see* NYSCEF Doc No. 39). Neither relates to plaintiff's failure to warn claims.

The amended complaint also relies on an article titled "Role for the nicotinic cholinergic system in movement disorders; therapeutic implications" (NYSCEF Doc No. 27, amended complaint, exhibit C). Neither the amended complaint nor plaintiff's opposition explains how this article constitutes newly acquired information. Instead, plaintiff merely states that that the article is cited for its "analysis of the known interaction of CHANTIX and nAChR agonists" (NYSCEF Doc No. 49, plaintiff's brief at 14). The article deals with nonhuman studies demonstrating that several drugs, including varenicline, "may be of therapeutic benefit in movement disorders" (NYSCEF Doc No. 27 at 1). Nothing in this article appears to draw a causal relationship between Chantix and a clinically significant hazard. Therefore, it does not constitute newly acquired information that would permit a change in the Chantix label under the CBE regulation (*see* 21 CFR 314.70 [c] [6] [iii] [A]; 21 CFR 201.57 [c] [6] [i]; *see also Gayle*, 452 F Supp 3d at 88; *Sabol*, 439 F Supp 3d at 149).

However, a case study titled "Varenicline-induced acute dystonic reaction: a case report" does meet the definition of newly acquired information (NYSCEF Doc No. 26, amended complaint, exhibit B). This report concerns "a 25-year-old patient who was admitted to an emergency department with acute dystonia following the use of varenicline" (*id.* at 1). It concludes that "[the] case demonstrates that the use of varenicline can lead to extrapyramidal side effects," but notes that the "[t]his adverse effect may be rare" and that "prospective studies are needed to determine the frequency of this side effect" (*id.* at 2). As this draws a causal connection between varenicline and a "serious even if infrequent" adverse reaction (21 CFR 201.57 [c] [6] [i]), it satisfies the definition of newly acquired information that may be used to change a label under the CBE regulation (*see* 21 CFR 314.70 [c] [6] [iii] [A]; 21 CFR 314.3 [b]).

Likewise, the article titled "Withdrawal-Emergent Dyskinesias following Varenicline Therapy" draws a causal connection between varenicline and an adverse reaction. It consists of two "case reports of involuntary movements occurring upon the withdrawal of varenicline therapy" (NYSCEF Doc No. 28, amended complaint, exhibit D). The parties dispute whether the article's reference to "tardive dyskinesias" is distinct from the plaintiff's alleged injuries, which include dystonia, muscular spasms and persistent dystonic tic (*see* amended complaint, ¶ 20), and, as such, whether this could have been used to alter the Chantix label in a manner that could have prevented plaintiff's alleged injuries. Whatever the distinction drawn between tardive dyskinesias and dystonia in the medical literature generally, the instant article makes no such distinction. First, the article describes symptoms similar to those complained of by plaintiff, with one patient suffering from "involuntary choreoathetotic movements of her hands, feet, neck, trunk, face, eyelids, mouth, and jaw" and the other from "involuntary movements of the jaw and head/neck that appeared to be dystonic tics" (NYSCEF Doc No. 28 at 1). Moreover, the article

defines the dyskinesias under discussion as including "dystonia, tics, and other abnormal movements" (*id.*). Therefore, the article's conclusion "that the nicotinic partial agonist varenicline is a newly recognized cause of tardive and withdrawal-emergent dyskinesias" (*id. at* 2) does draw a causal relationship between Chantix and the side effects plaintiff claims should have been included on its label.

Accordingly, the amended complaint sufficiently alleges the existence of newly acquired information that could have permitted a change of the Chantix label under the CBE regulation. As such, it states failure to warn claims that are not preempted.

In addition, the informed intermediary doctrine does not require the wholesale dismissal of the failure to warn claims. The amended complaint alleges that Pfizer failed to adequately warn plaintiff and the public (*see* amended complaint, ¶¶ 69, 79, 90). However, it also alleges that "[t]he CHANTIX label and package insert in use when Plaintiff's physician prescribed the drug did not provide Plaintiff's physician with an adequate warning about the increased risk of dystonia, serious injury and/or death from CHANTIX" (*id.*, ¶ 68). Therefore, to the extent the failure to warn claims are premised on a failure to warn plaintiff's physician, "[t]he learned intermediary doctrine does not compel dismissal . . . ." (*Wholey v Amgen, Inc.*, 165 AD3d 458, 459 [1st Dept 2018]; *see Bikowicz v Nedco Pharmacy* 130 AD2d 89, 92 [3d Dept 1987] ["(w)hile the drug manufacturer's duty under the doctrine is to warn the physician, the manufacturer is directly liable to the patient for a breach of such duty"]). However, to the extent the claims are premised on a failure to warn plaintiff or the public, the claims are dismissed.

Lastly, the amended complaint sufficiently alleges negligence based on a failure to warn. First, it alleges that "the product [does] not contain adequate warnings" (*Mulhall*, 45 AD3d at 58). The amended complaint specifically identifies what warning is missing from the label,

stating that "[t]he label for CHANTIX does not include warnings for the following: dystonia, muscular spasm, movement disorders and abnormal posture, typically due to neurological disease or a side effect of drug therapy" (amended complaint, ¶ 46). Second, the amended complaint adequately alleges causation. It states that plaintiff's healthcare providers were not aware of these risks (*id.*, ¶ 15) and that they would not have prescribed Chantix had they known of them (*id.*, ¶ 16; *see Skillgames, LLC*, 1 AD3d at 250). Accepting all allegations as true and according plaintiff the benefit of every favorable inference, as the court must on a motion to dismiss, the amended complaint states a negligence claim based on a failure to warn (*see Allianz Underwriters Ins. Co*. 13 AD3d at 174).

For the foregoing reasons, the branch of Pfizer's motion seeking dismissal of the failure to warn claims is denied, except to the extent that they are premised on a failure to warn plaintiff and the public.

B. Negligence, Breach of Implied Warranty and Unjust Enrichment Claims

Pfizer argues that the first (negligence), third (breach of implied warranty) and sixth (unjust enrichment) causes of action fail to state a claim. It argues that the negligence claim should be dismissed because: (1) there is no claim for failure to test in New York; and (2) the branch of the claim based on Pfizer's alleged failure to conduct adequate post-market monitoring of Chantix is conclusory and identical to the failure to warn branch of the claim. Pfizer argues that the breach of implied warranty claim should be dismissed because plaintiff fails to identify any specific inadequacy with the Chantix label or allege how such inadequacy was a proximate cause of her injury. Pfizer also argues that the unjust enrichment claim should be dismissed because plaintiff has not alleged any facts supporting reliance or inducement.

Plaintiff counters that the sufficiency of the complaint's allegations was fully litigated on the previous motion to dismiss and that the amended complaint merely corrects the deficiencies identified in the Decision, without altering the portions of the complaint that the court found to state a claim. Accordingly, plaintiff argues, this portion of Pfizer's motion to dismiss should be denied under the doctrine of law of the case.

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]]).

To the extent that the negligence claim is based on Pfizer's failure to adequately test Chantix and to conduct post-marketing surveillance, Pfizer acknowledges that this court "previously found these allegations adequate to give Pfizer notice of the occurrences to be proved" (Pfizer's brief at 15). Likewise, Pfizer acknowledges that plaintiff has not amended the breach of implied warranty allegations or the unjust enrichment allegations and that the Court previously found that plaintiff had adequately alleged these claims (*id.* at 17, 18). The parties, having had a "a full and fair opportunity to litigate" the sufficiency of these claims, may not relitigate them (*see Chanice*, 118 AD3d at 635 ; *cf MBF Clearing Corp. v JPMorgan Chase Bank., N.A.*, 189 AD3d 546, 546 [1st Dept 2020] [finding that "(t)he motion court properly applied the law of the case doctrine in dismissing the third amended complaint (TAC), as the claims in the TAC (were) essentially the same as those in the dismissed second amended complaint"]). Therefore, the branch of Pfizer's motion seeking dismissal of these claims is denied.

Notably, Pfizer's contention that New York does not recognize a failure to test claim is without merit (*see Enright v Eli Lilly & Co.*, 77 NY2d 377, 388 [1991] [stating that "drug manufacturers [do not] enjoy immunity from liability stemming from their failure to conduct adequate research and testing prior to the marketing of their products"]; *Bichler v Eli Lilly & Co.*, 55 NY2d 571, 587 [1982] [affirming judgment entered on a jury's verdict against a drug manufacturer in a "case pleaded and proved exclusively on a failure to test theory"]; *Babalola v Crystal Chems.*, 258 AD2d 367, 368 [1st Dept 1999] [finding that "a negligent testing claim against a manufacturer" of a janitorial product was not preempted]).

C. Breach of Express Warranty Claim

Pfizer contends that the second cause of action should be dismissed because the amended complaint fails to set forth the terms of the express warranty or plaintiff's reliance. Plaintiff counters that the amended complaint cures the defects identified by this court in the Decision and adequately pleads the specific warranties and the breaches thereof.

To state a claim for breach of express warranty, a plaintiff must "set forth the terms of the alleged warranty with sufficient particularity to give fair notice thereof" (*Hicksville Dry Cleaners, Inc. v Stanley Fastening Sys., L.P.*, 37 AD3d 218, 218 [1st Dept 2007] [internal citations omitted]) and allege "reliance on the express warranty as being a part of the bargain between the parties" (*CBS Inc. v Ziff-Davis Publ. Co.*, 75 NY2d 496, 503 [1990]; *see also* UCC § 2–313 [1] [a]).

Here, the amended complaint continues to suffer from the same defects as the original. While it alleges that Pfizer "expressly represented to Plaintiff (and to other consumers and the medical community) that CHANTIX was safe, efficacious, and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects,

and that it was adequately tested" (amended complaint, ¶ 115), it does not identify any representation that Pfizer made to that effect. The sole statement the amended complaint specifically identifies appears on the Chantix Label and states that "CHANTIX is a nicotmic receptor partial agonist indicated for use as an aid to smoking cessation treatment" (*id.*, ¶ 116). Contrary to plaintiff's insistence, this statement contain no *express* warranties as to whether Chantix is "is medically safe for use in treatments to stop smoking" (*id.*). Because plaintiff's "characterization of [Pfizer's] marketing material as generally implying that [Chantix] was 'safe and effective' does not identify any specific actionable conduct or statement on behalf of [Pfizer]," the amended complaint fails to state a claim for breach of express warranty (*Kennedy v Covidien, LP*, 2019 WL 1429979, *6, 2019 US Dist LEXIS 54450,*14 [SD NY, Mar. 29, 2019, No. 1:18-cv-01907-LTS-KNF]; *see also Bichler v Willing*, 58 AD2d 331, 333 [1st Dept 1977] [dismissing breach of express warranty claim that was based on conclusory allegation, without "specific factual reference to (the defendant pharmacist) having proffered any oral or written warranty regarding the safety or side effects of (the subject drug)"]). Therefore, the second cause of action for breach of express warranty is dismissed.

D. Punitive Damages

The parties dispute whether the amended complaint contains factual allegations of morally culpable conduct that would entitle plaintiff to punitive damages.

To sustain a claim for punitive damages in tort, "[t]he misconduct must be exceptional, as when the wrongdoer has acted maliciously, wantonly, or with a recklessness that betokens an improper motive or vindictiveness . . . or has engaged in outrageous or oppressive intentional misconduct or with reckless or wanton disregard of safety or rights" (*Ross v Louise Wise Servs, Inc.*, 8 NY3d 478, 489 [2007] [internal quotation marks and citations omitted]).

Here, the amended complaint's allegations of morally culpable conduct are largely identical to those of the original complaint (*compare* complaint, ¶¶ 58-87, *with* amended complaint, ¶¶ 76-105). The amended complaint adds two paragraphs, alleging that Pfizer determined not to update the Chantix label, despite knowledge that the drug causes the complained of side effects (*see* amended complaint, ¶¶ 74, 75). However, these additions merely paraphrase what has been alleged before, that despite knowledge of side effects (*see* complaint, ¶ 60), Pfizer "failed to properly warn the Plaintiff, patients, consumers, physicians, and the public of the serious risk of serious injury and/or death caused by CHANTIX" (*id.*, ¶ 61). As such, nothing in the amended complaint calls for a change from this court's previous determination that the allegations "fail to allege that Pfizer engaged in any morally culpable conduct" (Decision at 22). Therefore, plaintiff's request for punitive damages is denied.

IV. CONCLUSION

Accordingly, it is hereby

ORDERED that the motion of defendant Pfizer, Inc., to dismiss the amended complaint is granted to the extent of dismissing the first (negligence), fourth (gross negligence), and fifth (willful, wanton, and malicious conduct) causes of action, only insofar as they are based upon allegations of failure to warn plaintiff or the public, as well as the second cause of action (breach of express warranty) and plaintiff's request for punitive damages, and the motion is otherwise denied; and it is further

ORDERED that defendant is directed to serve an answer to the amended complaint within 20 days after service of a copy of this order with notice of entry; and it is further

ORDERED that counsel are directed to appear for a status conference to be held via Microsoft Teams, as previously scheduled on March 10, 2022, at 10:30 a.m.

This constitutes the Decision and Order of the court.

Dated: January 10, 2022

ENTER:

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