UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

COLLEEN AND STEVE LYMAN Plaintiffs, v. PFIZER, INC., WYETH, INC., SCHWARZ PHARMA, INC., PLIVA USA, INC., ACTAVIS-ELIZABETH, L.L.C. Individually and as a subsidiary of ACTAVIS, INC. and as successor to PUREPAC PHARMACEUTICAL, INC, Defendants.	:	Case no. 2:09-cv-262

OPINION and ORDER

Plaintiffs Colleen and Steve Lyman have sued several manufacturers of the drug metoclopramide, alleging that they are liable for Colleen Lyman's overexposure to the drug, which caused her to develop tardive dyskinesia, a neurological movement disorder. Before the Court are Defendants Actavis Elizabeth LLC ("Actavis") and PLIVA, Inc. ("PLIVA")'s Motion to Dismiss Plaintiffs' Amended Complaint, ECF No. 211; Defendants Pfizer Inc.,[1] Wyeth LLC (collectively "Wyeth") and Schwarz Pharma, Inc. n/k/a UCB, Inc. ("Schwarz")'s Motion for Partial Judgment on the Pleadings, ECF No. 229; Actavis's Motion for Summary Judgment,

[1] Pfizer Inc. is joined as a party solely in its capacity as Wyeth's parent corporation, and not for any role in the design, marketing, manufacture or distribution of the brand name Reglan® or generic metoclopramide.

ECF No. 216; PLIVA's Motion for Summary Judgment, ECF No. 231; Wyeth's Motion for Summary Judgment, ECF No. 222; and Schwarz's Motion for Summary Judgment, ECF NO. 233.

Background[2]

I. Colleen Lyman's Medical History and Use of Metoclopramide

Colleen Lyman, born in 1954, began having migraine headaches when she was a child. When she was a senior in high school she suffered a serious head injury in the first of several motor vehicle accidents, and remained in a coma for two weeks. The effects of that accident persisted for years. Over the years, she has suffered from and been treated for numerous medical problems, including chronic severe migraine headaches, depression, anxiety, asthma, fibromyalgia and hypertension. The frequency and severity of her migraine headaches have fluctuated.

Mrs. Lyman has received a variety of medications to treat her headaches and their symptoms, which include debilitating pain, nausea and vomiting. The medications have included Compazine (prochlorperazine), Thorazine (chlorpromazine), Phenergan (promethazine), and Reglan (metoclopramide). The

[2] The following facts are taken in the light most favorable to the Lymans, as the nonmoving party. Well-pleaded facts derived from the amended complaint are taken as true for purposes of resolving the motions to dismiss and for judgment on the pleadings. Only those facts necessary to the disposition of the pending dispositive motions are recounted; familiarity with the Court's earlier decision dated February 3, 2012, ECF No. 192, is presumed.

medical records suggest that over the course of several years Mrs. Lyman was taking Thorazine rarely to control vomiting when other remedies weren't working, and Compazine or Phenergan more frequently to control nausea. She was taking none of these drugs daily.

Nurse practitioner Alice Roberge first prescribed Reglan® tablets for Colleen Lyman on September 11, 2003. At the time Mrs. Lyman was 49 years old. The prescription was for 10 mg. Reglan® tablets, to be taken three times a day as needed for relief of headache-induced nausea. Roberge believes that she issued the prescription based on advice from Dr. Thomas Ward, her superior and head of the Dartmouth-Hitchcock Headache Center. To obtain information about drugs that she might prescribe for a patient, Roberge would rely on a service called Clinical Pharmacology Online, the Physicians Desk Reference, information from Dartmouth-Hitchcock Medical Center ("DHMC") itself, and alerts from pharmaceutical companies. She understood that tardive dyskinesia was an uncommon side effect of metoclopramide, and she assumed that Mrs. Lyman would not need to take the drug daily.

After the initial prescription, Roberge continued to prescribe the drug intermittently until the end of 2005. Mrs. Lyman also received prescriptions for Reglan® from a resident physician in the DHMC Emergency Department in August and October

2003.

Dr. Elaine Fleming, Mrs. Lyman's primary care provider, began writing prescriptions for Reglan® in January 2006. She did not prescribe the drug as part of her treatment plan for Mrs. Lyman, but authorized refills of the prescription that originated from the Dartmouth-Hitchcock Headache Center. Dr. Fleming gained her knowledge of the drug as a resident in the mid-1980s, from The Medical Letter, a newsletter devoted to evaluations of prescription drugs, and from other sources. She was aware that metoclopramide could cause tardive dyskinesia, and thought it was a rare side effect. Had Dr. Fleming known that there was a higher risk of developing tardive dyskinesia with use beyond twelve weeks she would have discussed discontinuing the drug with the medical personnel at the Headache Center.

Neither Dr. Fleming nor Nurse Roberge recall speaking with Mrs. Lyman about the risks of using metoclopramide. Mrs. Lyman does not recall any specific discussion with them about the possible side effects of metoclopramide.

Beginning in late October 2005, Mrs. Lyman was refilling a metoclopramide prescription for ninety pills approximately monthly, suggesting that she was taking the medication daily. Her last prescription refill for metoclopramide was January 21, 2007. Although Mrs. Lyman does not recall precisely how often or for how long she took metoclopramide, she believes, based on the

pharmacy records, that she took metoclopramide nearly every day for at least a year. At a deposition she testified that when she was having a migraine once a month, she would take metoclopramide three times a day for the duration of the migraine, which might be three days. Medical records reveal that at times Mrs. Lyman reported that she was having severe migraines once a week, with less severe migraines or headaches once or twice a week. In October 2004, for example, Mrs. Lyman reported that she suffered from one severe headache a week and milder headaches three times a week. DHMC Office Notes 11/08/2004, ECF No. 233-23. By March 2005 this had evolved to chronic daily headaches, with three to four severe headaches per week. DHMC Office Notes 3/28/05. In late 2005, Mrs. Lyman described her migraines as typically lasting five days. DHMC Emergency Department Note 11/1/2005, ECF No. 233-24. In early 2006 Mrs. Lyman mentioned that she was having a headache every day. DHMC Office Notes 4/10/2006, ECF No. 233-24. In August 2006 Mrs. Lyman described a typical migraine headache as lasting seven days. DHMC Emergency Department Notes 8/26/2006.

Mrs. Lyman's pharmacy, in compliance with state law, filled the prescriptions for Reglan® with generic metoclopramide. *See* Vt. Stat. Ann. tit. 18, § 4605. Defendant Actavis supplied the metoclopramide that Mrs. Lyman received on July 12, 2005 and October 24, 2005; Defendant PLIVA and Teva Pharmaceuticals USA

("Teva")[3] supplied the metoclopramide that Mrs. Lyman received from December 2005 through January 2007.

On August 30, 2006, Dr. Stephen Lee, a neurologist at DHMC, evaluated Colleen Lyman and determined that she had involuntary head movements that most likely represent tardive dyskinesia. He added that he observed torticollis as well, a contraction of the neck muscles that causes the neck to rotate and tilt. He believed that raised the possibility of cervical dystonia, an involuntary contraction of the neck muscles that may be a feature of tardive dyskinesia. Based on her history of metoclopramide use, he concluded that her tardive dyskinesia, or tardive dystonia, was caused by the drug.

II. Regulatory Framework

The Food and Drug Administration ("FDA") is the federal agency charged with "protect[ing] the public health by ensuring that human . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). To that end, the FDA regulates the introduction into interstate commerce of all new drugs. *Id.* § 355. In 1938, the Food, Drug, and Cosmetic Act ("FDCA") established a system of premarket approval for drugs. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612 (1973); *see* Pub. L. No. 75-717, 52 Stat. 1040 (1938). Under the FDCA, a new drug could not be

[3] Teva was originally named as a defendant, but was dismissed from the suit on September 13, 2011.

marketed unless it was shown to be safe for its intended use. *See Weinberger*, 412 U.S. at 612-13. The Drug Amendments of 1962 amended the FDCA to require that new drugs be both safe and effective for their intended use. *See id.*; Pub. L. No. 87-781, sec. 102(a)(1), 76 Stat. 780, 781 (1962).

In order to market a new drug one must file a New Drug Application ("NDA") with the FDA, which must include full reports of investigations into the drug's safety and effectiveness; a list of the drug's components; a full statement of the drug's composition; a description of the manufacturing methods, processing and packing; and "specimens of the labeling proposed to be used for such drug," among other things. 21 U.S.C. § 355(b)(1). The FDA must refuse to approve the NDA if it finds, among other things, that the reports of testing show that the drug is unsafe, fail to show that the drug is safe or are inadequate to show that the drug is safe; that the manufacturing methods are inadequate; that it has insufficient information to determine whether the drug is safe; that there is a lack of substantial evidence that the drug will have its intended effect; or "based on a fair evaluation of all material facts, [the] labeling is false or misleading in any particular." *Id.* § 355(d). It must withdraw approval of a new drug if it finds that the drug is unsafe, or there is a lack of substantial evidence that the drug is effective. *Id.* § 355(e).

The FDA requires prescription drug labeling to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," 21 C.F.R. § 201.56(a). For older prescription drugs (those approved before June 30, 2001), it must include information under the following headings (in this order): description, clinical pharmacology, indications and usage, contraindications, warnings, precautions, adverse reactions, drug abuse and dependence, overdosage, dosage and administration, and how supplied. *Id.* §§ 201.56(e); 201.80. The FDA defines the contraindications section of the label as

> Contraindications. Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include . . . use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities shall be listed . . . .

Id. § 201.80(d). A manufacturer is required to revise the labeling to include a warning "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." *Id.* § 201.80(e).

The FDA maintains a public list of drugs which have been approved for safety and effectiveness under 21 U.S.C. § 355(c). *See* 21 U.S.C. § 355(j)(7). Drugs on this list are known as "listed drugs." *See id.* § 355(j)(2)(A)(I). Once a listed drug

loses patent protection, a company may seek permission from the FDA to market a generic version of the drug. *See id.* § 355(j).

The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments") amended the FDCA to authorize an abbreviated new drug application ("ANDA") process for generic drugs that are bioequivalent to approved new drugs. *See* Pub. L. No. 98-417, sec. 101, 98 Stat. 1585 (codified at 21 U.S.C. § 355(j)). An ANDA must include "information to show that the new drug is bioequivalent to the listed drug," 21 U.S.C. § 355(j)(2)(A)(iv), and "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug," with limited exceptions. *Id.* § 355(j)(2)(A)(v). The ANDA applicant is not required to conduct its own safety and effectiveness testing, but is permitted to rely upon the safety and effectiveness evidence presented in the NDA for the listed drug. *See SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 211 F.3d 21, 26 (2d Cir. 2000). Regulations provide that the FDA may withdraw approval of an ANDA for a generic drug if it finds that the labeling for the generic drug "is no longer consistent with that for the listed drug." 21 C.F.R. § 314.150(b)(10). Only the current NDA holder of a brand-name drug may change a drug's labeling; a generic drug manufacturer must ensure that its labeling remains the same as the labeling for the listed drug. *See PLIVA, Inc. v. Mensing*,

131 S. Ct. 2567, 2575-76 (2011).

III. Development and Approval of Metoclopramide

Metoclopramide, a dopamine receptor antagonist, was approved in tablet form by the FDA for the short-term (four to twelve weeks) treatment of heartburn associated with gastroesophageal reflux disease ("GERD") and for the treatment of nausea, vomiting and heartburn associated with diabetic gastroparesis, or delayed gastric emptying. Metoclopramide works by increasing the contractions of the stomach and intestines to facilitate the passage of food. Although not included as an indication in product labeling, metoclopramide has also been prescribed for the treatment of nausea associated with migraine headaches, a so-called "off-label" use.

The A.H. Robins Company ("AHR") obtained FDA approval for metoclopramide tablets under the brand name Reglan® in December 1980. At that time officials in the FDA were concerned about the potential for wide-spread non-approved use of metoclopramide for patients with relatively minor gastrointestinal complaints. During the course of several meetings between AHR representatives and FDA officials in connection with the approval, marketing and labeling of metoclopramide, AHR representatives downplayed, concealed and misrepresented information about the occurrence of tardive dyskinesia as a result of metoclopramide use, including the length of exposure, the dosage, and the persistence of the

symptoms. Numerous marketing materials were directed toward providers of treatment for upper gastrointestinal problems, touting the drug's low incidence of side effects.

AHR's label for Reglan® included warnings concerning tardive dyskinesia in the "Warnings" and "Adverse Reactions" sections. In both places it indicated that acute dystonic reactions were the most common type of extrapyramidal symptoms ("EPS")[4], occurring in one in five hundred patients, suggesting that such symptoms were a rare side effect. The AHR label advised in its "Dosage and Administration" section that "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." Physicians' Desk Reference ("PDR") 2937 (56th ed. 2002), ECF No. 233-9. This language indicates to prescribers that no clinical trials had examined administration of the drug for longer than twelve weeks. Nevertheless, the "Warnings" section of the label makes reference to "Parkinsonian-like" symptoms that may occur within the first six months of beginning treatment with metoclopramide, or occasionally after longer periods, suggesting

[4] "Extrapyramidal reaction" is defined as "a response to a treatment or a drug characterized by the signs of extrapyramidal disease." The C.V. Mosby Company, Mosby's Medical Dictionary 456 (Walter D. Glanze, et al. eds., 3rd ed. 1990). "Extrapyramidal disease" is defined as "any of a large group of conditions characterized by involuntary movement, changes in muscle tone, and abnormal posture, as in tardive dyskinesia . . . ." *Id.* "Extrapyramidal" side effects are those caused by drugs that block dopamine receptor sites in the extrapyramidal system tract. *Id.*

the manufacturer's expectation that the drug would be prescribed for longer than twelve weeks. The label did not address the risks associated with chronic use of metoclopramide, or the risks to certain populations such as women and the elderly, or that tardive dyskinesia could develop as a result of long-term use.

In 1985, the FDA required the Reglan® label to include additional information about the risks of tardive dyskinesia, including the increased risk from cumulative dose and chronic use, and the increased risk to women and the elderly. An AHR "Dear Doctor" letter introducing the revised labeling stated only that the change had been required to "be added to the official labeling of all drugs capable of producing tardive dyskinesia." Parisian Report ¶ 363, ECF No. 212-6.

Since the mid-1980s, metoclopramide has been available in generic form from several companies, including the defendant generic drug manufacturers Actavis and PLIVA. Wyeth obtained the rights to Reglan® tablets in 1989. From 1989 through 2001, Wyeth through its subsidiaries manufactured and distributed Reglan® and generic metoclopramide tablets. In late December 2001, Wyeth sold the rights to Reglan® tablets to Schwarz. Wyeth ceased distribution of Reglan® and generic metoclopramide tablets at the time of the sale. Pursuant to a supply agreement with Schwarz, Wyeth continued the manufacture of Reglan® tablets through late 2002.

Schwarz sold Reglan® tablets from late December 2001 until February 2008, when it sold the rights to Reglan® tablets to Alaven Pharmaceutical LLC.

In the course of acquiring the rights to manufacture and distribute Reglan®, Schwarz reviewed and evaluated the drug's safety and its labeling, and became aware that there were problems with EPS reactions to the drug and that long-term use of metoclopramide was common. Schwarz changed Reglan®'s labeling in 2003 and 2004, with the approval of the FDA. In 2003 the Reglan® label was updated to supply, among other things, information related to use in elderly patients, defined as aged 65 and older, under a single section entitled "**Geriatric Use.**" The label advised that "[T]he elderly may be at greater risk for tardive dyskinesia . . . ." Schwarz Label, ECF No. 233-8.

In 2004 the Reglan® label was changed to add a sentence in bold type in the "Indications and Usage" section that "**Therapy should not exceed 12 weeks in duration.**" *Id.* A similar sentence was added in the "Dosage and Administration" section: "**Therapy with Reglan® tablets should not exceed 12 weeks in duration.**" *Id.* After the FDA approved Schwarz's labeling change in 2004, the revised labeling accompanied Reglan® tablets manufactured or distributed by Schwarz, and appeared on the Schwarz website and the FDA's website. Schwarz has never published a copy of its label for Reglan® tablets in the PDR, a widely used source of

prescription drug information.

On November 12, 2004, Actavis's predecessor, Purepac Pharmaceutical Company, submitted a supplement to its ANDA to conform its metoclopramide labeling to the labeling for Reglan®, and advised the FDA that the new labeling would be implemented on January 4, 2005. The FDA approved the changes on May 5, 2005. PLIVA did not change its label to conform to the FDA-approved labeling changes of 2003 and 2004. Other than Schwarz's publication of its label on its website, there is no evidence that any defendant sought to communicate this revised labeling with its specific warning against therapy for longer than twelve weeks either to prescribers or to patients.

Studies conducted after the labeling change revealed that prescribers continued to prescribe metoclopramide for substantially longer than twelve weeks, and rarely advised patients of the risk of tardive dyskinesia.

In 2008 the FDA performed a medical review of metoclopramide "to re-examine the prescribing patterns with metoclopramide oral formulation, to assess the risk of metoclopramide induced movement disorders, and to recommend agency action in order to minimize this risk." Kate Gelperin et al., FDA Center for Drug Evaluation and Research, Risk of Metoclopramide-induced Movement Disorders 2 (June 2008), ECF No. 257-10. The agency concluded that heightened public awareness of the risk of movement

disorders from metoclopramide use was urgently needed. In 2009 it mandated adding a "black box warning" to the metoclopramide label concerning the risk of tardive dyskinesia from long term use and cumulative dose, informing the reader that the symptoms may be irreversible, there is no known treatment, women and the elderly are most susceptible, and treatment for longer than twelve weeks should be avoided in all but rare cases in which therapeutic benefit is thought to outweigh the risk of developing the condition. *See* Reglan Tablets Boxed Warning (June 2009), *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm170934.htm.

During the time Mrs. Lyman was prescribed Reglan®, the FDA-approved label for the drug included the following information:

> Like the phenothiazines and related drugs, which are also dopamine antagonists, metoclopramide produces sedation and may produce extrapyramidal reactions, although these are comparatively rare (see **WARNINGS**).
>
> * * *
>
> **INDICATIONS AND USAGE**
> **The use of Reglan® tablets is recommended for adults only. Therapy should not exceed 12 weeks in duration.**
>
> * * *
>
> **CONTRAINDICATIONS**
>
> * * *
>
> Metoclopramide should not be used in epileptics or patients receiving other drugs which are likely to cause extrapyramidal reactions, since the frequency and severity of seizures or extrapyramidal reactions may be increased.

Schwarz Label for Reglan® tablets, ECF No. 233-8; NDA 17-854/S-047, ECF No. 216-14. The "Warnings" section of the label

included the following:

> **WARNINGS**
>
> * * *
>
> Extrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages of 30 to 40 mg/day of metoclopramide. These usually are seen during the first 24 to 48 hours of treatment with metoclopramide, occur more frequently in pediatric patients and adult patients less than 30 years of age . . . .
>
> * * *
>
> **Tardive Dyskinesia**
>
> Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose. . . .

Id. There is no evidence that Mrs. Lyman or her prescribing healthcare providers ever read this label, or read any information about the risks associated with metoclopramide provided by any defendant in this lawsuit. The labels for both Compazine and Thorazine, used primarily to treat schizophrenia, include warnings concerning the risk of developing tardive dyskinesia from use of the drug, and both labels state the "the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase." Compazine Label 3, ECF

No. 233-18; Thorazine Label 2, ECF No. 233-19. Phenergan's label advises that the user may suffer extrapyramidal symptoms. Phenergan Label 7, ECF No. 233-25.

IV. Procedural History

The Lymans filed suit against brand name and generic manufacturers of metoclopramide on November 25, 2009. The case was stayed pending a decision from the United States Supreme Court resolving the issue of whether failure-to-warn claims against generic drug manufacturers were preempted. Following the Supreme Court's decision in *Mensing*, the generic drug manufacturing defendants moved for judgment on the pleadings. *See* Actavis & PLIVA's Mot. for J. on the Pleadings, ECF No. 182. On February 3, 2012, this Court granted in part and denied in part the motion, and gave leave to Plaintiffs to move to file an amended complaint within ten days. The Lymans filed their motion to amend along with a proposed First Amended Complaint on February 13, 2012. The motion was granted as unopposed on March 7, 2012, and the First Amended Complaint ("FAC") was docketed on March 22, 2012.[5]

Discussion

I. Standing

[5] Actavis and PLIVA take the position that Plaintiffs did not timely file their amended complaint, but they mistake the Court's order. Plaintiffs were given leave to move to amend their complaint within ten days, which they did.

Defendant PLIVA asserts that Plaintiffs lack constitutional standing to bring a claim based on changes to the metoclopramide labeling approved by the FDA in 2003 and 2004, because there is no causal connection between their injuries and its wrongful conduct. PLIVA has confused lack of standing with a challenge to the merits of the claim. *See Carver v. City of New York*, 621 F.3d 221, 226 (2d Cir. 2010) ("The standing question is distinct from whether [a plaintiff] has a cause of action.").

"In essence the question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). This question "involves constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise." *Id.* "[T]he irreducible constitutional minimum of standing" requires a plaintiff to show (1) injury in fact; (2) causation; and (3) redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). PLIVA challenges the second element, arguing that failure to incorporate and communicate the label changes—which added a subsection related to geriatric patients and included a statement that metoclopramide use should not exceed twelve weeks—could not have caused Mrs. Lyman's injury because she is not geriatric and did not use metoclopramide for longer than twelve weeks.

For purposes of showing Article III standing, a plaintiff

need only demonstrate "a causal connection between the injury and the conduct complained of—the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Bennett v. Spear*, 520 U.S. 154, 167 (1997) (citing *Defenders of Wildlife*, 504 U.S. at 560-61). The Lymans' amended complaint alleges that Colleen Lyman's long-term ingestion of metoclopramide caused her to develop tardive dyskinesia. FAC ¶ 3.22. It alleges that she and her prescribing physicians were unaware of the risks of long-term ingestion of metoclopramide, and relied upon the defendants to inform them of information that might affect the decision to prescribe or take the drug. *Id.* ¶¶ 3.19-3.20. It alleges that PLIVA, among the other defendants, "made no effort to communicate or disseminate the new label warnings added in 2003 and 2004, despite the fact that the manufacturers had numerous means at their disposal to communicate the fact that therapy with metoclopramide should not exceed twelve weeks in duration." *Id.* ¶ 3.49.

"When a party challenges the court's subject matter jurisdiction based upon the merits of the case, that party is merely arguing that the adversary has failed to state a claim." *Sarhank Grp. v. Oracle Corp.*, 404 F.3d 657, 660 (2d Cir. 2005); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 89 (1998) ("It is firmly established in our cases that the

absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, *i.e.*, the courts' statutory or constitutional *power* to adjudicate the case."). Without question, the Lymans have pleaded diversity jurisdiction over a colorable claim for relief. They have standing; whether their claim withstands summary judgment on the merits is addressed later in this opinion.

II. Motion to Dismiss; Motion for Partial Judgment on the Pleadings

Defendants Actavis and PLIVA have moved to dismiss the amended complaint, arguing that the additional allegations against them are either preempted, inadequately pled or fail to state a claim. Defendants Pfizer, Wyeth and Schwarz Pharma seek partial judgment on the pleadings on the claims for strict liability, breach of warranties, negligence in product manufacturing and negligence in product design.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff[s] plead[] factual content that allows the court to draw the reasonable inference that the defendant[s are] liable for the misconduct alleged." *Id.* Although detailed factual allegations are not required, "labels and conclusions or a

formulaic recitation of the elements of a cause of action will not do." *Id.* The same standard applies to a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 429 (2d Cir. 2011).

A. Allegations Related to Failure to Update and Communicate FDA-Approved Warnings

The amended complaint alleges that Actavis and PLIVA, among the other defendants, failed to "communicate warnings to Colleen Lyman, or her prescribing physicians, indicating that therapy with Reglan/metoclopramide should not be used in certain individuals, or in therapy that exceeds twelve weeks in duration—warnings approved by the FDA for inclusion in the Reglan/metoclopramide label in 2003 and 2004." FAC ¶ 3.28. Actavis and PLIVA argue that a claim against generic manufacturers for failure to inform physicians or consumers is preempted by federal law, according to *Mensing*, 131 S. Ct. at 2581.

In its Opinion and Order dated February 3, 2012, this Court ruled that it was not only possible, but required by federal law, to provide updated labeling upon approval by the FDA, and that the *Mensing* decision did not require preemption of such a claim. Op. & Order 13-14, ECF No. 192. The Plaintiffs were given leave to amend their complaint to allege such a claim, which they have done. Actavis and PLIVA have not offered grounds for

reconsideration of the Court's ruling, and to the extent that Actavis and PLIVA seek to relitigate the issue, the Court declines the opportunity.[6]

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[6] The Court acknowledges that other district courts have refused to allow amendment to allege the failure of a generic manufacturer to provide FDA-approved warnings. Aside from the fact that amendment has been allowed in this case, the Court does not find the treatment of the issue in these cases persuasive. *See Brinkley v. Pfizer*, No. 10-0274-CV-W-SOW, 2012 WL 1564945 at *5 (W.D. Mo. Apr. 12, 2012) (finding amended allegations indistinguishable from the claims in *Mensing*); *Fulgenzi v. PLIVA, Inc.*, No. 5:09CV1767, ___ F. Supp. 2d ___, 2012 WL 1110009 at *7 (N.D. Ohio Mar. 31, 2012) (finding no state-law requirement that a generic manufacturer's label match that of the brand name); *Bell v. Pliva, Inc.*, No. 5:10CV00101 BSM, ___ F. Supp. 2d ___, 2012 WL 640742, at *4 (E.D. Ark. Feb. 16, 2012) (holding that impossibility preemption applied because federal regulations did not require generic manufacturers to disseminate warnings to physicians); *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 2012 WL 123986, at *12 n.11 (N.D. Ga. 2012) (declining in a footnote to allow amendment, on preemption grounds, without explanation); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 660 (D. Md. 2011) (suggesting that failure to address the issue in the Sixth and Eighth Circuits, and the Supreme Court, warranted refusal to allow amendment on preemption grounds, and explicitly holding, upon denying reconsideration, that its decision did not rest on preemption); *Guarino v. Wyeth LLC*, 823 F. Supp. 2d 1289, 1292 (M.D. Fla. 2011) (holding that no state-law failure-to-warn claims against generic manufacturers survive *Mensing*); *Fullington v. PLIVA*, 2011 WL 6153608 at *4 (E.D. Ark. Dec. 12, 2011) (same). Additional cited district court decisions do not address the issue. *See, e.g.*, *Phelps v. Wyeth, Inc.*, No. 6:09-cv-06168-TC, ___ F. Supp. 2d ___, 2012 WL 1499343, at *10 (D. Or. Apr. 24, 2012) (declining to address whether failure to update claims against a generic manufacturer are preempted); *Bowman v. Wyeth, LLC*, No. 10-1946 (JNE/SER), 2012 WL 684116, at *7 (D. Minn. Mar. 2, 2012) (same); *Moretti v. Mut. Pharm. Co.*, No. 10-896, ___ F. Supp. 2d ___, 2012 WL 465867, at *5 (D. Minn. Feb. 13, 2012) (finding all asserted claims conflict preempted; no discussion of failure to provide FDA-approved warnings); *Morris v. Wyeth, Inc.*, No. 09-0854, 2012 WL 601455, at *4 (W.D. La. Feb. 23, 2012) ("Even if PLIVA's noncompliance with the duty of sameness escapes the preemption identified in *Mensing*, . . . amendment in this case would be futile because any claim based on the 2004 label

Actavis-Elizabeth and PLIVA speculate that the Plaintiffs may offer to prove a failure to communicate updated warnings by suggesting that generic manufacturers could and should have sent prescribing physicians a Dear Doctor letter with a copy of the updated label, which they contend generic drug manufacturers are not permitted to do under federal law. *See* Actavis-Elizabeth & PLIVA's Mem. in Supp. of Mot. to Dismiss 8-11, ECF NO. 211-1. If and or when Plaintiffs offer such evidence, the Court will address the Defendants' argument; the possibility that the Lymans *may* seek to prove their claim of failure to provide federally-approved warnings by means that *may* have been legally unavailable to generic drug manufacturers is not grounds for finding impossibility preemption based on the pleadings.

Actavis and PLIVA also argue that the Lymans' new allegations create an "irreconcilable inconsistency" with other allegations in the amended complaint. The amended complaint both alleges that the Lymans relied on inadequate Reglan®/metoclopramide labeling (without specifying whether the labeling included the 2003 and 2004 changes), and that the generic manufacturer defendants failed to communicate the updated

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would be inconsistent with Plaintiffs' assertion that all pre-2009 labeling failed to adequately warn."); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, No. 08-008 (GEB-LHG), 2011 WL 5903623, at *8 (D.N.J. Nov. 21, 2011) (refusing to consider a failure-to-communicate theory because it had not been pled in the complaint).

labeling. Actavis and PLIVA also read the amended complaint as alleging that the metoclopramide labeling continued to be inadequate until the FDA required the issuance of a "black box warning" for metoclopramide in 2009.

The allegations are not necessarily inconsistent, however. The amended complaint alleges that Colleen Lyman's prescribing physicians relied upon information published in the package inserts and/or the PDR that was "inaccurate, misleading, materially incomplete, false and/or otherwise inadequate." FAC ¶¶ 3.10, 3.15. No dates are mentioned in those paragraphs, although a subsequent paragraph specifies that Colleen Lyman and her prescribing physicians relied upon the defendants to alert them to information that might affect the decision to prescribe or take metoclopramide, such as the addition of warnings regarding safe use of the drug approved by the FDA in 2003 and 2004. *Id.* ¶ 3.20. The amended complaint alleges further that the defendants failed to warn Mrs. Lyman or her prescribing physicians about the warnings approved by the FDA in 2003 and 2004. *Id.* ¶¶ 3.18, 3.28. It states that the FDA, "[r]ecognizing the inadequate nature of the information and warnings provided to consumers and the medical community pertaining to long-term use of Reglan/metoclopramide," required the addition of a black box warning in 2009. *Id.* ¶ 3.26. And it concludes that "[T]he addition of the Boxed Warning . . . in 2009 was necessary as a

result of Drug Company Defendants' failure to communicate and disseminate the warnings added to the label for Reglan/metoclopramide in 2004 . . . ." *Id.* § 3.27.

To the extent that the amended complaint can be read as continuing to pursue liability against the generic manufacturing defendants for failure to provide warnings that were not required by the FDA, the claim is preempted, as the Court has stated and the plaintiffs have conceded. If Plaintiffs were attempting to assert that Defendants had a duty to provide updated warnings that were inadequate, the Court would agree that this theory would not provide a basis for recovery. But the amended complaint states that the FDA required the addition of the black box warning as a result of the inadequate warnings *provided* to consumers and the medical community, indicating that it is the failure to communicate the updated warnings adequately or at all, rather than the inadequacy of the updated warnings themselves, that is at the heart of this failure-to-warn claim against the generic manufacturing defendants. This claim survives *Mensing* impossibility preemption scrutiny, as discussed in the Court's previous opinion, and has now been adequately pled.[7]

[7] The Lymans' claim is thus framed distinctly differently from the claim dismissed as inconsistent in *Fullington*, 2012 WL 1893749 at *7 (dismissing as inconsistent pleading a failure-to-warn claim that alleged "Recognizing the inadequate nature of the . . . label and warnings, . . . [the FDA required] the addition of a Boxed Warning . . . .").

B. Allegations of Failure to Comply with the FDCA and Federal Regulations

Actavis and PLIVA point out that the amended complaint contains a new paragraph in its fact section asserting that the defendants violated various provisions of federal law pertaining to drug safety, and they argue that the provisions cannot form the basis of a state-law claim against them. The Lymans have not asserted any cause of action against the generic manufacturers based on violation of federal law, however. Under Vermont law, a plaintiff may seek to show that violation of a statutory duty is evidence of negligence. *See, e.g.*, *Dervin v. Frenier*, 100 A. 760, 761 (Vt. 1917) (noting that violation of a statute may be evidence of negligence or negligence per se "when there is a proximate, causal connection between the violation of the statute and the injury complained of"); *accord Collins v. Thomas*, 2007 VT 92, ¶¶ 7-9, 938 A.2d 1208, 1211-12. There is no indication that their recitation of alleged violations of federal law in the fact section of their amended complaint is intended to shoehorn an additional cause of action based on violation of federal law into the Lymans' claims for relief.

C. Allegations of Defective Design in Packaging[8]

The Lymans allege that Actavis and PLIVA failed to incorporate safety measures that would have reduced the risk associated with metoclopramide, including package designs that would discourage long-term use. Actavis and PLIVA argue that this is a thinly-disguised warning claim preempted by *Mensing*, and that it moreover fails to state a claim. In essence the Lymans are alleging that metoclopramide was unreasonably dangerous in part because its packaging did not indicate to the physician or the user that the product should not be prescribed for long-term use. This nonverbal failure-to-warn claim, assuming for the moment that it escapes preemption under *Mensing*, fails to allege a plausible claim for relief under *Iqbal* and *Twombly*. *See Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555.

The Court must be able to draw a reasonable inference from well-pleaded facts that Actavis and PLIVA are responsible for causing Colleen Lyman's tardive dyskinesia because they failed to package metoclopramide in a fashion that would discourage long-term use. The amended complaint, however, contains at best a

[8] To the extent that the amended complaint continues to pursue a design defect claim against the generic drug manufacturer defendants concerning the drug itself, the Court adheres to its previous ruling that *Mensing* bars such claims. *See* Op. & Order 9, ECF No. 192.

sketchy theory of liability.[9] Subtracting the legal conclusions, it amounts to a suggestion that certain unspecified types of packaging designs might have discouraged long-term use of the drug, which might have prevented the harm to Mrs. Lyman. This is an example of an allegation that "do[es] not permit the court to infer more than the mere possibility of misconduct," and thus the Lymans have not "'show[n]'" that they are "'entitled to relief.'" *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

In their opposition to the generic Defendants' motions for summary judgment, the Lymans spelled out that they referred to the possibility that a manufacturer could ensure that its label with its warnings reaches the consumer by employing "unit of use" packaging. Were the Court to consider this unpled information in assessing the viability of this claim, dismissal would still be the outcome. The essence of the claim is failure to warn. Any

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[9] In its entirety the claim of defective packaging alleges:

> Manufacturing Defendants failed to incorporate safety measures that would have reduced the risks associated with their metoclopramide, and likely prevented the harm to Plaintiffs. These safety measures included packaging designs useful in discouraging long-term use. . . . The failure of Manufacturing Defendants to undertake any effort whatsoever to discourage long-term use of Reglan/metoclopramide rendered their metoclopramide products dangerously and [sic] defective as designed and marketed. The defective and unreasonably dangerous design and marketing of Reglan/metoclopramide was a direct, proximate and producing cause of Plaintiffs' injuries and damages.

FAC ¶¶ 4.09, 4.11.

claim against a generic drug manufacturer that the label on unit-of-use packaging should have included a stronger warning is preempted under *Mensing*. 131 S. Ct. at 2577-78. For pleading purposes, the Lymans have already adequately stated a claim against Actavis and PLIVA for failure to provide FDA-approved warnings; changing the method of communication does not give rise to an additional cause of action.

For the reasons stated in the foregoing three sections, Actavis and PLIVA's motion to dismiss the amended complaint, ECF No. 211, is **granted in part and denied in part.**

D. Claims Against Wyeth and Schwarz for Strict Liability, Breach of Warranties, Manufacturing Defect and Design Defect

The Lymans do not pursue claims for strict liability, breach of warranties or negligence in manufacturing against Wyeth and Schwarz, and therefore do not oppose the motion to that extent. They contend, however, that they have a viable claim against them for negligent design of metoclopramide.

The amended complaint alleges that all defendants failed to exercise reasonable care in the design of metoclopramide. FAC ¶¶ 4.02, 4.03a. As this Court previously stated with respect to the same claim against the generic drug manufacturer defendants, the claim is inadequately pled. *See* Op. & Order 9-10 n.4, ECF No. 192. The Lymans have not alleged facts that give rise to a plausible claim that either Wyeth or Schwarz designed

metoclopramide or the design defect of which they complain. The only "defect" that arguably can be gleaned from the pleading is that the drug is unsafe for long-term use. This is simply another way of presenting a failure-to-warn claim.

The Motion for Partial Judgment on the Pleadings, ECF No. 229, is therefore **granted in part and granted in part as unopposed.**

III. Motions for Summary Judgment

Defendants Wyeth, Schwarz, Actavis and PLIVA have moved for summary judgment on all claims remaining against them. To justify an award of summary judgment, a moving party must show an absence of a genuine dispute as to any material fact and entitlement to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Emslie v. Borg-Warner Auto., Inc.*, 655 F.3d 123, 125 (2d Cir. 2011). "An issue of fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. A fact is material if it might affect the outcome of the suit under the governing law." *Fincher v. Depository Trust & Clearing Corp.*, 604 F.3d 712,720 (2d Cir. 2010) (quotation marks and citations omitted). "[A]ll ambiguities must be resolved and all inferences drawn in favor of the party against whom summary judgment is sought." *Gallo v. Prudential Residential Servs., Ltd.*, 22 F.3d 1219, 1223 (2d Cir. 1994). "[U]pon being confronted with a motion for summary judgment the party opposing

it must set forth arguments or facts to indicate that a genuine issue—not merely one that is colorable—of material fact is present." *Gibson v. Am. Broadcasting Cos.*, 892 F.2d 1128, 1132 (2d Cir. 1989). "When no rational jury could find in favor of the nonmoving party because the evidence to support its case is so slight, there is no genuine issue of material fact and a grant of summary judgment is proper." *Gallo*, 22 F.3d at 1224.

A. The Strict Product Liability Claims

The Lymans have asserted strict product liability claims against Defendants Actavis and PLIVA for defective design and marketing; and failure to incorporate safety measures including packaging design, incorporation and dissemination of FDA-approved warnings, and suspension of sales. *See* FAC ¶4.09. As previously discussed, the Lymans do not have viable claims against the generic drug defendants for defective design, marketing, failure to change the packaging design or failure to suspend sales of metoclopramide. *See* Op. & Order 9-10, ECF No. 192; *supra* II.C. The Lymans' remaining product liability claim involves the allegation that Actavis and PLIVA failed to incorporate and disseminate the labeling changes made by the brand name manufacturer, Schwarz, and approved by the FDA in April 2003 and July 2004, a failure-to-warn claim that survives impossibility preemption under *Mensing*. *See* Op. & Order 12-15; *supra* II.A.

"To establish strict liability for an inadequate warning, a

plaintiff must prove that the inadequate warning made the product unreasonably dangerous and was the proximate cause of the injury." *Needham v. Coordinated Apparel Grp., Inc.*, 811 A.2d 124, 129 (Vt. 2002) (quoting *Webb v. Navistar Int'l Transp. Corp.*, 692 A.2d 343, 347 (Vt. 1996)).

PLIVA argues that the Lymans do not have evidence of general or specific causation, specifically that they cannot show that metoclopramide causes tardive dyskinesia, and they cannot show that metoclopramide caused Mrs. Lyman's tardive dyskinesia. Notwithstanding the Defendants' motions to exclude Plaintiffs' experts from testifying about causation, addressed in the Court's Memorandum Opinion and Order Re: *Daubert* Motions issued today, the Plaintiffs have admissible expert testimony that, if believed, will permit a jury to conclude that Mrs. Lyman has tardive dyskinesia, caused by metoclopramide. The medical records document the escalating frequency and severity of Mrs. Lyman's headaches, and the pharmacy records document the quantity and frequency of her prescription refills. Although the evidence is not conclusive, a reasonable juror could believe that Mrs. Lyman was taking metoclopramide nearly every day during most of 2006. Plaintiffs' expert Dr. Tarsy will testify that Mrs. Lyman has tardive "dystonia," which he defines as a variant of tardive dyskinesia, caused by chronic ingestion of metoclopramide. Dr. Lee will testify that his diagnosis of tardive dyskinesia caused

by metoclopramide is based upon Mrs. Lyman's medication history and symptoms.

PLIVA also argues that the Lymans are unable to establish that its failure to update its metoclopramide label in 2004 to warn against therapy for longer than twelve weeks[10] was a proximate cause of Mrs. Lyman's injury. It contends that Mrs. Lyman was not prescribed the drug for continuous daily use, and therefore the label change did not apply to her. Mrs. Lyman was prescribed metoclopramide to be taken three times a day as needed. Dr. Fleming was authorizing a thirty-day supply of the drug on a monthly basis for approximately one year.

Dr. Fleming has testified that she tries to keep abreast of current drug information by reading information from drug companies about warnings or changes, or by going to conferences. She thought tardive dyskinesia was a rare side effect, and had she known that there was a higher risk of developing tardive dyskinesia with use beyond twelve weeks she would have discussed discontinuing the drug. Mrs. Lyman has stated that had she been informed of an appreciable risk of developing a movement disorder from taking metoclopramide she would not have continued to take the medication.

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[10] The Plaintiffs do not pursue their claim that PLIVA's failure to update the label in 2003 to warn of the risk of tardive dyskinesia in the geriatric population and to add a warning for neuroleptic malignant syndrome was a proximate cause of Mrs. Lyman's injury.

Whether Mrs. Lyman had daily migraine headaches with nausea, and whether she took metoclopramide on a daily basis for a significant period of time, will be for a jury to decide. There is evidence of these facts. Thus a reasonable jury could find that the 2004 warning would have applied and, if heeded, could have prevented the injury. PLIVA's motion for summary judgment on the product liability claim is therefore **denied.**

Actavis contends that nevertheless its metoclopramide did not cause and could not have caused Mrs. Lyman's tardive dyskinesia. According to Dr. Tarsy, tardive dyskinesia does not appear in patients who are subjected to intermittent exposure to metoclopramide. To bring about the symptoms of tardive dyskinesia, or tardive dystonia, usually requires continuous exposure to metoclopramide for several months, meaning virtually daily administration of the drug. Tarsy Dep. 76:1-77:22, Oct. 25, 2010, ECF No. 216-10.

It is undisputed that Mrs. Lyman took Actavis's metoclopramide only during a time when she was taking the drug intermittently. The medical and pharmacy records show that Mrs. Lyman used metoclopramide intermittently between October 2003 and October 2005. In 2003 Mrs. Lyman received IV administration of metoclopramide in the Dartmouth-Hitchcock Emergency Department on February 14, March 3, March 16 and August 21. DHMC Emergency Department notes dated 2/14/2003, 3/3/2003, 3/16/2003, 8/21/2003,

ECF No. 233-22. She obtained prescriptions for ten-day supplies of metoclopramide (thirty tablets) on September 21, 2003, November 6, 2003, January 23, 2004, March 18, 2004, April 11, 2004, May 16, 2004, August 6, 2004, October 1, 2004, December 6, 2004 and February 23, 2005. *See* Rite Aid Customer History Report, ECF 233-11. Beginning in March 2005, Mrs. Lyman obtained prescriptions for thirty-day supplies of metoclopramide (ninety tablets) on March 10, 2005, July 12, 2005, and October 24, 2005. *See id.* Mrs. Lyman last obtained metoclopramide manufactured by Actavis on October 24, 2005. *See* Pl.'s Master Statement of Disputed Facts ¶ 10, ECF No. 257.

Beginning with her prescription refill of December 6, 2005, and throughout 2006, the pharmacy records show that Mrs. Lyman was obtaining a thirty-day supply of metoclopramide (ninety tablets) virtually every month. *See id.* The tablets were manufactured either by PLIVA or by Teva. *See id.*[11]

[11] As part of its argument that Mrs. Lyman lacks constitutional standing to bring her claims because she did not take metoclopramide continuously for longer than twelve weeks, PLIVA noted that Mrs. Lyman's prescriptions were infrequently filled with PLIVA's product. During the period in which continuous use is alleged, PLIVA-produced metoclopramide was dispensed on May 10, 2006, August 2, 2006, October 31, 2006 and January 21, 2007. *See* Pl.'s Master Statement of Disputed Facts ¶ 10. Whether or not Mrs. Lyman took metoclopramide continuously for longer than twelve weeks is disputed; if a jury finds this to be established, it may conclude that PLIVA is liable, even though it did not provide all of the drug that she consumed during that period. *See Levine v. Wyeth*, 2006 VT 107 ¶ 36, 944 A.2d 179, 194 (reciting Vermont's "traditional rule . . . that multiple tortfeasors are jointly and severally liable.").

Throughout the period that Mrs. Lyman took Actavis's metoclopramide, the medical and pharmacy records indicate substantial gaps in her use of the drug, inconsistent with the continuous use required to produce symptoms of tardive dyskinesia, according to Plaintiffs' expert. This usage is consistent with her prescribers' instructions to take the drug three times a day only as needed to alleviate nausea. The Plaintiffs have provided no support for their assertion that metoclopramide produced by Actavis was a proximate cause of Mrs. Lyman's injury. No reasonable jury could find that Actavis's product caused Mrs. Lyman's injury; consequently, Actavis is entitled to summary judgment on the Plaintiffs' product liability claims.[12]

B. The Breach of Warranty Claims

The Lymans have asserted breach of warranty claims against the generic manufacturing defendants Actavis and PLIVA. Specifically they claim that Actavis and PLIVA have breached an implied warranty of merchantability that metoclopramide was merchantable and fit for safe use for chronic gastrointestinal conditions. They also claim that Actavis and PLIVA have breached

[12] Because Actavis is entitled to summary judgment, and PLIVA did not update its label, it is unnecessary at this point to address the extensively briefed and argued issue of whether a generic drug manufacturer has a duty under Vermont law to communicate its revised label to prescribers and/or patients, or the scope of that duty, if it exists.

an implied warranty of fitness for a particular purpose because metoclopramide was not reasonably safe for long-term treatment of chronic conditions, and that consumers and physicians were relying on these defendants' skill and judgment in selecting a suitable medication for that purpose. Actavis and PLIVA are entitled to summary judgment on these claims.

1. Implied Warranty of Merchantability

"The implied warranty of merchantability, like that of fitness, is primarily directed at the operative essentials of a product." *Tracy v. Vinton Motors, Inc.*, 296 A.2d 269, 272 (Vt. 1972). A party seeking to recover for a breach of an implied warranty of fitness or merchantability must establish that the product "was harmful or deleterious in some way; and the defect existed as of the time that the product was in the possession or under the control of the seller." *Rogers v. W.T. Grant Co.*, 321 A.2d 54, 57 (Vt. 1974); *see also Moffitt v. Icynene, Inc.*, 407 F. Supp. 2d 591, 598-99 (D. Vt. 2005) (Under the Uniform Commercial Code, goods are merchantable if, among other things, they "are fit for the ordinary purposes for which such goods are used."); Vt. Stat. Ann. tit. 9A, § 2—314(2)(c).

The Lymans contend that "there can be no doubt that use of metoclopramide for longer than twelve weeks was an 'ordinary purpose' for which metoclopramide was used." Pls.' Resp. in Opp'n to Generic Defs.' Dispositive Mots. for Summ. J. 15, ECF

No. 256. The Lymans have not alleged, however, that the metoclopramide Mrs. Lyman took was anything other than what it purported to be, ten milligrams of metoclopramide. Actavis and PLIVA counter that there is no dispute that generic metoclopramide was FDA-approved at the time Mrs. Lyman purchased and ingested it, . . . [and] that it was fit for the ordinary purpose for which it was used." Mem. in Support of PLIVA's Mot. for Summ. J. 20, ECF No. 231.[13] If the ordinary purposes of a prescription drug are determined by its FDA-approved indications, then there is no evidence in this case that the metoclopramide Mrs. Lyman ingested was not fit for the short-term treatment of certain gastric disorders.

It is not necessary however to conclude that the ordinary purposes of a prescription drug are restricted to its FDA-approved indications in order to determine whether the Lymans have a viable claim for breach of an implied warranty of merchantability, however. In their amended complaint the Lymans allege that Actavis and PLIVA's implied warranty of merchantability for metoclopramide was that it was fit for "use in chronic gastrointestinal conditions, the purpose for which [they] marketed [the drug]." FAC ¶ 4.13. Regardless of the truth or accuracy of that statement, it is undisputed that Mrs.

[13] The Defendants appear to accept, for purposes of their motion, that implied warranties of merchantability and fitness for a particular purpose apply to the sale of prescription drugs.

Lyman did not receive metoclopramide for a gastrointestinal condition. If the ordinary purpose of metoclopramide, as alleged in the amended complaint, were to treat chronic gastrointestinal conditions, the plaintiffs have offered no rationale for the inference that this gives rise to a further implied warranty that metoclopramide is fit for the treatment of chronic conditions in general. Granting even that Actavis and PLIVA were aware that physicians were prescribing metoclopramide for the long-term treatment of other conditions—such as Mrs. Lyman's headache-induced nausea—the Plaintiffs have not shown that this knowledge alone renders this usage an ordinary purpose for the drug.

Accordingly, summary judgment is **granted** on the claim for breach of an implied warranty of merchantability.

2. Implied Warranty of Fitness for a Particular Purpose

An implied warranty of fitness for a particular purpose arises when the buyer makes known to the seller the "circumstances and conditions which necessitate[] [the] purchase of a certain character of article or material and le[aves] it to the seller to select the particular kind and quality of article suitable for the buyer's use." *Green Mountain Mushroom Co. v. Brown*, 95 A.2d 679, 681-82 (Vt. 1953); *see also Moffitt*, 407 F. Supp. 2d at 599 (Under the Uniform Commercial Code, "the implied warranty of fitness for a particular purpose arises 'where the seller at the time of contracting has reason to know any

particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods . . . .'" (quoting Vt. Stat. Ann. tit. 9A, § 2–315)).

The Lymans allege that Actavis and PLIVA "knew that consumers such as Colleen Lyman commonly used Reglan/metoclopramide for periods in excess of twelve weeks for the treatment of chronic conditions, and that these consumers and their physicians were relying on [their] skill and judgment in deciding to select a suitable medication." FAC ¶ 4.16. Knowledge that consumers in general have a particular purpose for a product will not give rise to the implied warranty: under Vermont law the seller must know the particular buyer's particular purpose. *See Moffitt*, 407 F. Supp. 2d at 599. The Lymans have proffered no evidence that Actavis or PLIVA knew that Mrs. Lyman was seeking long-term treatment for the symptoms of chronic migraine headaches. Nor have they proffered evidence that Actavis or PLIVA knew that Mrs. Lyman's healthcare providers intended to prescribe metoclopramide for her for longer than twelve weeks. Absent any evidence of communication of some sort between the generic manufacturing defendants and the Lymans or the prescribers, no warranty of fitness for a particular purpose is implied. *See id.*

Accordingly, summary judgment is **granted** on the claim for

breach of an implied warranty of fitness for a particular purpose.

C. The Negligence Claims

The Lymans have asserted negligence claims for failure to exercise reasonable care in the design and marketing of metoclopramide and failure to warn of the risk of tardive dyskinesia.

1. The Claims Against Wyeth

The Lymans "allege that Wyeth was negligent in its initial design of Reglan® as a drug used to treat chronic conditions, and incorporating false information into the drug's label." Pls.' Resp. 4, ECF No. 255. As they must concede, by 2001 when Wyeth transferred to Schwarz all of its rights and responsibilities regarding Reglan® tablets, Wyeth lost any ability to change the design of Reglan® or its label. *See* 21 C.F.R. § 314.71(a). Long before Colleen Lyman received her first dose of metoclopramide, Wyeth could not have delivered a stronger warning regarding the drug, or have changed its design in any way.

Although the Lymans present the argument that Wyeth or AHR was negligent in its development of the drug and its label, along with facts that may support that argument, they cannot establish that this allegedly negligent conduct is the proximate cause of Mrs. Lyman's injury. To support a common-law negligence claim, a plaintiff must show that the defendant owed her a legal duty,

that the defendant breached that duty, that the breach was the proximate cause of the plaintiff's harm, and that she suffered actual loss or damage. *O'Connell v. Killington, Ltd.*, 665 A.2d 39, 42 (Vt. 1995). Assuming that Wyeth owed a legal duty to users of metoclopramide for some time after it ceased producing it, and breached that duty by having failed to conduct adequate testing, by having overpromoted the drug as a treatment for chronic gastrointestinal conditions, and by having failed to produce an accurate label, there is no evidence that could enable a jury to find that this conduct was a proximate cause of Colleen Lyman's injury.

For one reason, Mrs. Lyman received metoclopramide for the off-label use of controlling migraine-related nausea. The Lymans' facts show that AHR and Wyeth's development, testing and promotional efforts were directed toward treatment of gastrointestinal conditions, not Mrs. Lyman's condition. There must be a causal connection between the allegedly negligent acts "and the resulting flow of injurious consequences." *Lavoie v. Pac. Press & Shear Co.*, 975 F.2d 48, 57 (2d Cir. 1992) (construing Vermont law). Under these circumstances the negligent conduct alleged bears no causal connection to the injury suffered by Mrs. Lyman.

For another reason, Wyeth's alleged negligent actions are too remote to constitute a proximate cause of Mrs. Lyman's

injury. AHR and Wyeth's development, testing, labeling and promotional activity had ceased entirely by the end of 2001, long before Mrs. Lyman's first consumption of a dose of metoclopramide. In fact, much of the misconduct attributed to AHR occurred in the 1980s. Schwarz assumed regulatory responsibility for Reglan® in December 2001. It changed the label to warn against use of metoclopramide for longer than twelve weeks in 2004, substantially after Wyeth ceased to have any involvement with the drug, and substantially before Mrs. Lyman's alleged period of continuous long-term use. By the time Mrs. Lyman began taking metoclopramide on a regular basis, any negligence on the part of AHR or Wyeth "ha[d] so far spent itself as to be too small for the law's notice." *Woodcock's Adm'r v. Hallock*, 127 A.380, 382 (Vt. 1925).

"Ordinarily proximate cause is a jury issue, 'unless reasonable minds cannot draw different conclusions or where all reasonable minds would construe the facts and circumstances one way.'" *Estate of Sumner v. Dep't of Soc. & Rehabilitative Servs.*, 649 A.2d 1034, 1036 (Vt. 1994) (entry order) (quoting *Roberts v. State*, 514 A.2d 694, 695 (Vt. 1986)). As a matter of law, Wyeth's alleged negligence in the development, promotion and labeling of metoclopramide is not the proximate cause of Colleen Lyman's tardive dyskinesia.

2. The Claims Against Schwarz

Although the Lymans assert similar negligence claims against Schwarz, they have not submitted opposition to its motion for summary judgment on proximate causation. Because they have failed to point to any evidence that Schwarz's conduct in developing, testing, marketing or labeling Reglan® caused Colleen Lyman's injury, Schwarz is entitled to summary judgment on these claims.[14]

D. The Fraud, Fraudulent and Negligent Concealment and Constructive Fraud Claims

The Lymans assert claims of fraud, fraudulent or negligent concealment and constructive fraud against all Defendants.[15] The

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[14] Because the Lymans have not demonstrated a triable issue on proximate cause, it is unnecessary to address Schwarz's argument that Mrs. Lyman's prescribers' actions constituted an intervening cause, in that Mrs. Lyman's use of metoclopramide was expressly contraindicated by the Reglan label. The contraindication provided that "[m]etoclopramide should not be used in patients receiving other drugs which are likely to cause extrapyramidal reactions . . . ." It is undisputed that at times between 2003 and 2007 Colleen Lyman received Compazine and Thorazine, and that these drugs are capable of causing extrapyramidal reactions. The frequency and timing of the use of these drugs is disputed, however, and the significance of the contraindication, if relevant at trial, will require expert testimony.

[15] The Lymans have not clearly identified their constructive fraud theory. Their amended complaint asserts that the Defendants "committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiffs relating to the Reglan/metoclopramide at issue in this lawsuit . . . ." FAC ¶ 4.21. Although a constructive fraud may develop out of wrongdoing without bad faith, *see Miller v. Roseberry*, 144 A.2d 836, 838 (Vt. 1958), "[c]onstructive fraud is an equitable claim that typically has not afforded relief in the form of monetary

Defendants seek dismissal of these claims on a variety of grounds, including the Plaintiffs' inability to show actual or justifiable reliance. An essential element of any fraud claim is actual and justifiable reliance. *See Sugarline Assocs. v. Alpen Assocs.*, 586 A.2d 1115, 1120 & n.* (Vt. 1990) (holding that a party claiming fraud must show justifiable reliance, citing Restatement (Second) of Torts §§ 525, 537 (1977)); *accord Fuller v. Banknorth Mortg. Co.*, 788 A.2d 14, 16 (Vt. 2001) (stating that a claim for fraudulent concealment requires detrimental reliance by the defrauded party); *Silva v. Stevens*, 589 A.2d 852, 857 (Vt. 1991) (reciting the elements of fraud or intentional representation as including a misrepresentation that was relied on by the defrauded party).

As evidence of reliance in their fraud claims against Wyeth, the Lymans contend that Colleen Lyman's "physicians relied upon information disseminated by Wyeth in forming their understanding of metoclopramide's benefits and risks, and that her prescribing physicians relied upon this information in deciding to prescribe [Reglan® for her]." Pls.' Resp. to Brand Defs.' Dispositive Mots. 5, ECF No. 255. They cite to portions of the depositions of Mrs. Lyman's physicians and nurse practitioners that stated

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damages." *Hardwick-Morrison Co. v. Albertsson*, 605 A.2d 529, 532 (Vt. 1992); *see also Union Bank v. Jones*, 411 A.2d 1338, 1342 (Vt. 1980) (commenting that constructive fraud may provide grounds for rescission). Plaintiffs have not requested equitable relief in this lawsuit.

generally that they rely on pharmaceutical companies to provide accurate information; that they rely on a variety of sources for their information about prescription drugs; that they understood that the risk of movement disorders was low; that had they known that metoclopramide should not be prescribed for longer than twelve weeks they would not have continued to prescribe the drug; and that Dr. Ward believed he had obtained a suggestion from somewhere that metoclopramide was an effective treatment for certain effects of migraine headaches. Setting aside the fact that the Lymans utterly fail to identify the communication of a specific misrepresentation to either the Lymans or the medical personnel, and assuming that they could establish that the physicians and nurse practitioners did in fact rely upon false statements about Reglan® made by Wyeth, any reliance on such statements was not justified under the circumstances presented here.

There is no evidence that any of Mrs. Lyman's medical providers sought to obtain current information about the indications, contraindications, or risks and benefits of metoclopramide, either when she received her first prescription in September 2003, or when she began obtaining monthly refills of a month's supply of tablets in 2006. Mrs. Lyman's medical providers could not identify specific statements that informed their beliefs that the drug was generally safe and effective.

They derived their impressions from a variety of sources. Those sources could conceivably be traceable back to statements made by Wyeth or AHR, or to Wyeth's label, but from a time well before Mrs. Lyman began taking metoclopramide. Wyeth stopped manufacturing Reglan and ceased having responsibility for its label in December 2001, and there is no evidence that it made any statements regarding Reglan® after that time. By 2006, when Mrs. Lyman allegedly began long-term continuous use of the drug, the new NDA holder, Schwarz, had revised the label three times, and an inquiry into the current information for metoclopramide would have revealed the Schwarz warning that therapy should not exceed twelve weeks. Between September 2003 and January 2007, any prescriber's reliance on statements made by Wyeth before 2002 on the Reglan® label or elsewhere was not justifiable.

Concerning a claim of fraudulent or negligent concealment against Wyeth, the Lymans argue that there is "evidence that [it] purposely withheld negative information regarding metoclopramide when specifically inquired, and that [it] transferred the application to market Reglan instead of responding to these inquiries." *Id.* The evidence to which they allude, however, is evidence that in 2001 the FDA inquired about the incidence of tardive dyskinesia, and that Wyeth transferred the NDA rather than respond. Regardless of the blameworthiness of this conduct, the Lymans have no evidence that they or their healthcare

providers knew about the FDA inquiry and Wyeth's failure to respond, must less that they justifiably relied on Wyeth's silence as indicating that the drug did not pose a risk of tardive dyskinesia.

Accordingly, Wyeth is entitled to summary judgment on the fraud claims.

With respect to the other three defendants, the Lymans have proffered no evidence whatsoever to suggest that they or their physicians relied upon any material misstatements or omissions on the part of Schwarz, Actavis or PLIVA. At best, the evidence indicates that Mrs. Lyman's physicians and nurse practitioners relied on the pharmaceutical industry in general to provide them with accurate information. None of the medical personnel indicated any knowledge of Schwarz, Actavis or PLIVA in connection with metoclopramide. Moreover, Mrs. Lyman avers that had she been informed that metoclopramide should not be used for longer than twelve weeks, she would not have continued using the drug. By July 2004, Schwarz's label for Reglan® provided that warning in two places. Assuming that the Lymans could establish the other essential elements of fraud, fraudulent or negligent concealment, or constructive fraud against these three defendants, they have not established actual justifiable reliance. Therefore summary judgment is warranted on their behalf on the fraud claims.

E. The Gross Negligence Claim

Because the elements of a negligence claim have not been established, the Lymans cannot establish the elements of a claim for gross negligence. *See Powers v. Office of Child Support*, 795 A.2d 1259, 1266 (Vt. 2002); *Shaw v. Moore*, 162 A. 373, 374 (Vt. 1932) ("Gross negligence is equivalent to the failure to exercise even a slight degree of care. . . . The element of culpability which characterizes all negligence is, in gross negligence, magnified to a high degree as compared with that present in ordinary negligence.").

CONCLUSION

For the above-stated reasons, Actavis and PLIVA's Motion to Dismiss Plaintiffs' Amended Complaint, ECF No. 211, is **granted in part and denied in part.** Wyeth and Schwarz's Motion for Partial Judgment on the Pleadings, ECF No. 229, is **granted in part and granted in part as unopposed.** Actavis's Motion for Summary Judgment, ECF No. 216, is **granted.** Wyeth's Motion for Summary Judgment, ECF No. 222, is **granted.** PLIVA's Motion for Summary Judgment, ECF No. 231, is **granted in part and denied in part**. Schwarz's Motion for Summary Judgment, ECF No. 233, is **granted**. Summary judgment is granted to Defendants on Plaintiffs' claims for negligence; breach of warranties; fraud, fraudulent or negligent concealment and constructive fraud; and gross negligence.

Dated at Burlington, in the District of Vermont, this 20th day of July, 2012.

/s/William K. Sessions III
William K. Sessions III
U.S. District Court Judge