

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

VERONICA MARTINEZ, a minor,)
By APRIL MONTOYA, Guardian, and)
APRIL MONTOYA, Individually,)
)
Plaintiffs,)

vs.)

Civil Action No. 2-11-CV-07427

WOLTERS KLUWER HEALTH, INC.,)
WOLTERS KLUWER UNITED STATES)
INC., and PFIZER, INC.)
)
Defendants.)

**PLAINTIFFS’ COMBINED RESPONSE AND MEMORANDUM OF LAW IN
OPPOSITION TO DEFENDANTS WOLTERS KLUWER HEALTH INC.’S AND
WOLTERS KLUWER UNITED STATES INC.’S MOTION TO DISMISS**

TO THE HONORABLE UNITED STATES DISTRICT COURT:

Plaintiffs APRIL MONTOYA, individually and a guardian for her minor daughter, VERONICA MARTINEZ, (collectively "Plaintiffs") hereby submit this, their combined response and memorandum of law in opposition to the motion to dismiss filed by Defendants Wolters Kluwer Health Inc. ("WKH") and Wolters Kluwer United States Inc. ("WKUS")(collectively "WK"). In support of this response, and in opposition to Defendants' motion to dismiss, Plaintiffs would respectfully show the Court the following:

I. INTRODUCTION

The "big picture" question presented by Defendants' motion is this: Is a company that authors, creates and sells consumer-directed PEMs as a profit-making endeavor immune from all possibility of liability to its target consumers if its product causes them harm? The answer is "no."

Plaintiffs have alleged that WK undertook to profit by providing consumers with patient education monographs (“PEMs”)¹ –which are informational materials intended to educate and warn the consumer about the drug prescribed. WK promoted its PEMs as “comprehensive,” “up-to-date,” “scientifically accurate,” and inclusive of all “need to know” medical information. Once WK undertook to render such services, WK bore a duty to exercise reasonable care in its undertaking. Additionally, WK assumed duties with regard to its provision of PEMS by: (1) professing to comply with the Keystone Guidelines for useful prescription medicine information that apply to its industry, (2) promoting its PEMs as being “comprehensive” and “up-to-date,” and (3) contracting with pharmacies to provide drug information directly to consumers in the form of PEMs. For all of these reasons, every court to consider the issue under a similar fraudulent joinder standard has found that valid claims had been alleged against the PEM defendants. The same finding is warranted in the case at bar.

II. RELEVANT FACTS AND ALLEGATIONS

Zoloft is a prescription medication used to treat depression and other mental disorders. [Complaint ¶ 25]. Medical evidence and data has long indicated that Zoloft causes congenital birth defects when taken by women during their pregnancies. [Complaint ¶ 29, 30, 31, 40, 41].

WK is an author of PEMs. [Complaint ¶ 44]. WK began providing PEMs as a means to profit by purporting to assist pharmacies in complying with state requirements to counsel patients.² To that end, WK’s PEMs are intended to be provided by pharmacies directly to pharmacy customers. [Complaint ¶ 47]. Customers, like the Mother Plaintiff, receive the PEM

¹ Throughout this Response, Plaintiffs shall use the term “PEM” with the intent that it encompass all patient education monographs, patient inserts, warnings, labels, handouts, brochures, drug information, databases, software and/or literature (whatever its form and however described by WK) that was prepared by WK to educate, inform or warn consumers, patients, health care professionals and/or pharmacists about the prescription drug Zoloft.

² Plaintiffs allege that WK contracted with the Mother Plaintiff’s pharmacy, Walgreens pharmacy, to provide patient drug information in various forms – including written PEMs. [Complaint ¶ 47].

and other drug information, which is usually stapled to the prescription bag, at the time of purchase. [Complaint ¶ 47, 48]. WK represents that its PEMs are intended to provide "consumer-oriented information written to educate patients about their drug therapy..." [Complaint ¶ 54].

WK touts its PEMs as delivering "comprehensive" and "up-to-date" information to patients. [Complaint ¶ 54]. WK also proclaims that its PEMs increase patient safety and "provide critical 'need to know' information." [Complaint ¶ 54; *see also* Plaintiffs' Motion to Remand and Plaintiffs' Brief in Support of Motion to Remand (hereafter "Motion to Remand") at Exhibit "J"].

Although the Zoloft label³ is completely inadequate and fails to truthfully inform patients concerning the risk of birth defects, WK nevertheless deleted what little information Pfizer included in the product labeling about the risks associated with Zoloft during pregnancy. [Complaint ¶ 28-31, 50; *See* Motion to Remand at Exhibits "L" and Exhibit "M"].

ZOLOFT LABEL	WK MONOGRAPH
Pregnancy - Pregnancy Category C	DELETED
"When pregnant rats and rabbits were given sertraline during the period of organogenesis, delayed ossification was observed in fetuses..."	DELETED
"When female rats received sertraline...there was an increase in the number of stillborn pups..."	DELETED
"When female rats received sertraline...there was an increase in the number of pups dying during the first 4 days after birth..."	DELETED
"The decrease in pup survival was shown to be due to in utero exposure to sertraline." (emphasis added).	DELETED
"There are no adequate and well controlled studies in pregnant women."	DELETED

³Let there be no doubt that Pfizer's labeling has never adequately warned prescribing physicians about the association between Zoloft and birth defects. In fact, even though other SSRI manufacturers have updated their label to disclose the potential risk, Pfizer continues to take the position that its drug is not a teratogen.

"Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures... <u>These features are consistent with either direct toxic effect of SSRIs and SNRIs, or, possibly, a drug discontinuation syndrome.</u> " (emphasis added).	DELETED
"Infants exposed to SSRIs in late pregnancy may have increased risk for persistent pulmonary hypertension of the newborn (PPHN)."	DELETED
"Pup body weights were also decreased..."	DELETED
"Zoloft (sertraline hydrochloride) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus."	DELETED
The effects of Zoloft on labor and delivery in humans is unknown.	DELETED

Plaintiffs allege that WK breached its duty of care by negligently or defectively authoring, analyzing, editing, evaluating, and compiling the known information regarding Zoloft. [Complaint ¶ 50, 139]. More specifically, Plaintiffs have alleged that (1) WKH “failed to use reasonable care to modify the Zoloft prescription drug information and labels” and (2) that WKH “failed to properly assess, analyze and interpret the studies, research, adverse event reports, and other information available” when preparing the Zoloft PEM. [Complaint ¶ 139]. As demonstrated above, WK deleted from its monograph, among other things, that no adequate studies had been done on pregnant women taking Zoloft to determine the risk to a fetus during organogenesis . WK also intentionally deleted that during animal studies, it was determined that there **was** a cause and effect relationship between the death of rat pups and Zoloft exposure during pregnancy. Not only did WK delete this information from its monograph, it also failed to include key drug information, relevant studies and/or scientific literature showing an association between SSRIs (including Zoloft) and birth defects. [Complaint ¶ 54]. As alleged in the

Complaint, this information should have been disclosed and that failure was one of the producing causes of the Minor Plaintiff's injuries. [Complaint ¶ 44-55].

Plaintiffs allege that the Mother Plaintiff relied on the representations in the Zoloft PEM, and particularly the fact that congenital birth defects were not included and/or emphasized in the PEM, as a basis for believing that the drug was safe to ingest during her pregnancy. [Complaint ¶ 20]. After the Mother Plaintiff ingested Zoloft during her pregnancy, the Minor Plaintiff was born with congenital birth defects, heart defects and other conditions attributed to the Mother Plaintiff's ingestion of Zoloft. [Complaint ¶ 4, 19].

III. EVIDENCE

In support of their response in opposition to WK's motion to dismiss, Plaintiffs specifically rely upon the following documents which are attached hereto as exhibits:

- A. Memorandum, *Robinson v. Wolters Kluwer Health, Inc.*, et al., No. 11-5702 (E.D.Pa. Dec. 2, 2011);
- B. Order, *Slater v. Hoffman-La Roche, Inc.*, et al, Case No. 10-6956 (E.D.Pa. March 24, 2011);
- C. Memorandum Order, *Farmer v. Wyeth, et al.*, Case No. 4:11CV348 CDP, 2011 WL 2462066, (E.D.Missouri, Eastern Division, June 17, 2011);
- D. Memorandum Order, *Lyons v. Wyeth, et al.*, Case No. 4:11CV365 CDP, 2011 WL 2462071, (E.D.Missouri, Eastern Division, June 17, 2011);
- E. Memorandum Order, *Ferguson v. Wyeth, et al.*, Case No. 4:11-CV-00360-SNLJ, (E.D.Missouri, Southeastern Division, June 8, 2011);
- F. Memorandum Order, *Franzman v. Wyeth, et al.*, Case No. 4:11-CV-00362-CAS, 2011 WL 3847420 (E.D.Missouri, Eastern Division, Aug. 26, 2011);
- G. Memorandum Order, *Nicely v. Wyeth, et al.*, Case No. 4:11CV338 CDP, 2011 WL 2462060, (E.D.Missouri, Eastern Division, June 17, 2011);
- H. Memorandum and Order, *Lawson v. Wyeth, et al.*, Case No. 4:11CV364 RWS, (E.D.Missouri, Eastern Division, Aug. 16, 2011);

- I. *Newby v. Wyeth, Inc., et al.*, Case No. 4:11-cv-00339-AGF (E.D. Missouri, Eastern Division, October 21, 2011).

In addition, Plaintiffs rely upon all pleadings, discovery and evidence filed in this case and any admissions made by Defendants therein.

IV. GOVERNING LEGAL STANDARDS

A. WK'S MOTION TO DISMISS SHOULD NOT BE CONSIDERED BY THIS COURT UNTIL AFTER A DECISION HAS BEEN REACHED ON PLAINTIFFS' PENDING MOTION TO REMAND.

Plaintiffs' currently pending motion to remand should be addressed by this Court prior to any ruling on WK's motion to dismiss. Plaintiffs initially filed this action in the Court of Common Pleas for Philadelphia County, Pennsylvania. It is undisputed that Wolters Kluwer Health, Inc. has its principal place of business in Philadelphia, Pennsylvania. [Notice of Removal ¶ 8]. Accordingly, federal jurisdiction is lacking because Wolters Kluwer Health, Inc. is a citizen of the State in which the action has been brought. *See* 28 U.S.C. § 1332. Roche removed Plaintiffs' case to this Court alleging that Wolters Kluwer Health, Inc. was fraudulently joined and that complete diversity exists among the remaining parties. [*See* Notice of Removal]. Plaintiffs dispute that Wolters Kluwer Health, Inc. was fraudulently joined and have moved to have this case remanded to its proper Pennsylvania state court forum.

Confronted with the same procedural posture as the present case (a pending motion to remand and a motion to dismiss under Rule 12(b)(6)), this Court previously has held that the motion to remand should be adjudicated first. *Uon v. Tanabe Intern. Co., Ltd.*, 2010 WL 4946681 (E.D.Pa., Dec. 3, 2010). This process makes good sense. As this Court noted, "if [the court finds that] joinder was not fraudulent, then complete diversity does not exist, this court lacks subject-matter jurisdiction to consider [defendant's] 12(b)(6) motion, and the action must

be remanded.” *Id.* at *2. Conversely, if the defendant has satisfied the more onerous standard of establish fraudulent joinder for jurisdiction purposes, then that determination will necessarily satisfy the burden of establishing a motion to dismiss as well. *Id.* This rationale led Eastern District of Pennsylvania judges J. Dubois and Robert Kelly to both order the remand of cases against WK without reaching WK’s pending motions to dismiss. Memorandum, *Robinson v. Wolters Kluwer Health, Inc., et al.*, No. 11-5702 (E.D.Pa. Dec. 2, 2011)(Exhibit “A”); Order, *Slater v. Hoffman-La Roche, Inc., et al.*, No. 10-6956 (E.D.Pa. March 24, 2011)(Exhibit “B”).

Consequently, this Court should determine whether jurisdiction exists by resolving Plaintiffs’ motion to remand prior to taking up WK’s motion to dismiss.

B. UNDER THE APPLICABLE STANDARDS, WK’S MOTION TO DISMISS MUST BE DENIED BECAUSE PLAINTIFFS HAVE STATED A PLAUSIBLE FACTUAL BASIS FOR THEIR CLAIMS.

1. WK Has Not, And Cannot, Carry Its Burden To Prove That Plaintiffs Have Failed To Plead A Plausible Claim Against It.

In a Rule 12(b)(6) motion, the defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. FED.R.CIV.P. 12(b) (6); *see also Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005); *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991). When deciding a Rule 12(b)(6) motion, the court must accept all allegations in the complaint as true and indulge all inferences that may reasonably be drawn in favor of the plaintiffs. *Ordonez v. Yost*, 289 Fed. Appx. 553, 554 (3d Cir. 2008); *Halterman v. Tullytown Borough*, 2011 WL 2411020, *1 (E.D.Pa., June 14, 2011); *Gould Elec. Inc. v. United States*, 220 F.3d 169, 178 (3d Cir.2000); *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). In deciding such motions, courts may “consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim,” *Brown v. Daniels*, 128 Fed. Appx. 910, 913 (3d

Cir.2005); *Halterman*, 2011 WL 2411020 at *1. The court must “determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *Pinkerton v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n. 7 (3d Cir. 2002).

The United States Supreme Court has explained that the showing necessary to survive a motion to dismiss, requires only sufficient factual matter in the complaint, that, when accepted as true (as it must be), would suffice to “state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). In other words, a complaint adequately states a claim if its factual allegations are sufficient to “raise a right to relief above the speculative level.” *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008); *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). Importantly, this standard “does not impose a probability requirement at the pleading stage, ’but instead ‘simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element.’ ” *Phillips*, 515 F.3d at 234, *Twombly*, 550 U.S. at 556.

2. WK’s Motion To Dismiss Is Premature And Should Be Dismissed Because Plaintiffs Have Alleged Adequate Facts To Raise a Reasonable Expectation That Discovery Will Reveal Further Support For Their Claims.

It is entirely premature to dismiss Plaintiffs’ claims at the pleading stage. *See e.g. Romero v. Allstate Corp.*, 404 F.3d 212 (3d Cir. 2005)(finding Rule 12(b)(6) motion premature where it was possible facts would be developed in support of the challenged claim). It may be the case, that following discovery, summary judgment may lie as to some or all of Plaintiffs’ claims against WK. However, it cannot be said at this early stage that no set of provable facts consistent with the allegations of the complaint can emerge that would entitle Plaintiff to relief. This Court has held that a motion to dismiss must be denied if the plaintiffs have merely stated “ ‘enough facts to raise a reasonable expectation that discovery will reveal evidence of’ the

necessary element[s]” of the cause of action. *Sheet Metal Workers' Intern. Ass'n Local Union No. 19 v. Keating Bldg. Corp.*, 2009 WL 1362491 (E.D.Pa., May 13, 2009). Because it is, at least, possible that discovery will reveal evidence in support of Plaintiffs’ claims, dismissal at this early stage of the litigation is premature.

C. PENNSYLVANIA LAW APPLIES IN THIS MATTER BECAUSE THERE IS NO CONFLICT BETWEEN THE LAW OF PENNSYLVANIA AND THE LAW OF PLAINTIFFS’ HOME STATE OF NEW MEXICO.

When conducting a choice of law analysis, courts are to first determine whether “an actual or real conflict [exists] between the potentially applicable laws.” *Hammersmith v. TIG Ins. Co.*, 480 F.3d 220, 230 (3d Cir. 2007). WK has not raised any area of conflict between Pennsylvania and New Mexico law. *Bel-Ray Co., Inc. v. Chemrite (Pty) Ltd.*, 181 F.3d 435 (3rd Cir. June 28, 1999)(“[T]he party who claims that the foreign law is different from the local law of the forum has the burden of establishing the content of the foreign law”); *Payne v. Goodyear Tire & Rubber Co.*, 216 F.R.D. 21 (D.Mass.,2003). To the contrary, WK asserts that the law of both states will produce the same outcome. [Memorandum in Support of Motion to Dismiss, p. 7]. If the laws of the competing jurisdictions are not in conflict, then “no further analysis is necessary” and the Court will apply Pennsylvania law. *See, e.g., Teledyne Techs v. Freedom Forge Corp.*, 2002 WL 748898 (Pa.Com.Pl., April 19, 2002); *Rosen v. Tesoro Petro. Corp.*, 1990 WL 902403 (Pa.Com.Pl., March 7, 1990). Here, there is no material conflict between the laws of Pennsylvania and New Mexico with respect to the theories set forth against the PEM defendants. Under either state’s law, WK’s motion to dismiss should be denied.

V.

ARGUMENT AND AUTHORITIES

A. COURTS HAVE UNIFORMLY HELD, IN A REMAND CONTEXT, THAT IT IS POSSIBLE PEM PROVIDERS OWE A DUTY OF CARE TO THE CONSUMERS

THAT RECEIVE AND RELY UPON THEIR PEMS. *(In response to WK's argument at I.D. p. 14 and I.A, pp. 7-11).*

At least nine different opinions, originating out of four separate courts, have granted motions to remand in cases involving non-diverse PEM defendants. *See* Memorandum, *Robinson v. Wolters Kluwer Health, Inc., et al.*, No. 11-5702 (E.D.Pa. Dec. 2, 2011)(Exhibit "A"); Order, *Slater v. Hoffman-La Roche, Inc., et al.*, No. 10-6956 (E.D.Pa. March 24, 2011)(Exhibit "B"); Memorandum Order, *Farmer v. Wyeth, et al.*, Case No. 4:11CV348 CDP, 2011 WL 2462066, (E.D.Missouri, Eastern Division, June 17, 2011)(Exhibit "C"); Memorandum Order, *Lyons v. Wyeth, et al.*, Case No. 4:11CV365 CDP, 2011 WL 2462071, (E.D.Missouri, Eastern Division, June 17, 2011)(Exhibit "D"); Memorandum Order, *Ferguson v. Wyeth, et al.*, Case No. 4:11-CV-00360-SNLJ, (E.D.Missouri, Southeastern Division, June 8, 2011)(Exhibit "E"); Memorandum Order, *Franzman v. Wyeth, et al.*, Case No. 4:11-CV-00362-CAS, 2011 WL 3847420 (E.D.Missouri, Eastern Division, Aug. 26, 2011)(Exhibit "F"); Memorandum Order, *Nicely v. Wyeth, et al.*, Case No. 4:11CV338 CDP, 2011 WL 2462060, (E.D.Missouri, Eastern Division, June 17, 2011)(Exhibit "G"); Memorandum and Order, *Lawson v. Wyeth, et al.*, Case No. 4:11CV364 RWS, (E.D.Missouri, Eastern Division, Aug. 16, 2011)(Exhibit "H"); *Newby v. Wyeth, Inc., et al.*, Case No. 4:11-cv-00339-AGF (E.D.Missouri, Eastern Division, October 21, 2011)(attached hereto as Exhibit "I"). Plaintiffs know of no order from any court (and Defendant has cited none) finding that liability on the part of the PEM was an impossibility. To the contrary, every court presented this issue in a remand context has found it possible Plaintiffs will prevail against the PEM defendants and has ordered the case remanded to state court.

While Plaintiffs acknowledge that the fraudulent joinder standard is not identical to the Rule 12(b)(6) standard, numerous courts have described the fraudulent joinder and motion to dismiss standards as "similar" *Uon v. Tanabe Intern. Co., Ltd.*, 2010 WL 4861436, *2 (E.D.Pa.,

Nov. 30, 2010); *Ross v. Citifinancial, Inc.*, 344 F.3d 458 (5th Cir. 2003); *Garwood v. Indiana*, 2011 WL 4826998 (S.D.Ind., October 11, 2011); *Roland–Warren v. Sunrise Senior Living, Inc.*, 2009 WL 2406356 (S.D.Cal. Aug. 4, 2009)(recognizing that fraudulent joinder standard parallels the Rule 12(b)(6) standard). More specifically, both standards are focused on the allegations of the complaint. *Batoff*, 977 F.2d at 851-52; *Brown v. Daniels*, 128 Fed. Appx. 910, 913 (3d Cir. 2005). Both standards require that contested issues of law and fact be resolved in Plaintiffs’ favor. *West v. Marriott Hotel Services, Inc.*, 2010 WL 4343540 (E.D.Pa., 2010); *Ordonez v. Yost*, 289 Fed. Appx. 553, 554 (3d Cir. 2008). And both standards impose a heavy burden on defendants to establish the “impossibility” or “implausibility” of Plaintiffs’ claims. *Burnett v. Chesapeake Appalachia, LLC*, 2011 WL 387641 (M.D. Pa., Aug. 21, 2011); *Boyer v. Snap-On Tools Corp.*, 913 F.3d 108, 111 (3d Cir. 1990); *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). Consequently, the unanimous remand orders holding that it is “possible” Plaintiffs will prevail against the PEM defendants are persuasive authority as to the similar question of whether it is “plausible” Plaintiffs will succeed when presented via a motion to dismiss.

B. PLAINTIFFS HAVE SUFFICIENTLY ALLEGED A PLAUSIBLE BASIS FOR EACH OF THEIR CLAIMS AGAINST WK.

1. Plaintiffs Have Alleged A Plausible Basis for Finding That WK Owed A Duty To Plaintiffs Under the Facts of This Case. (*In response to WK’s Argument at I.A, pp. 7-9; I.F., pp. 14-15*).⁴

The cornerstone of WK’s motion to dismiss is the PEM provider’s belief that it owes no duty to Plaintiffs. [Memorandum In Support of Motion to Dismiss, pp. 7-9]. WK is mistaken. The United States District Court for the Eastern District of Pennsylvania expressly rejected the “no-duty” argument in a remand context. Memorandum, *Slater v. Hoffman-La Roche, Inc., et al.*,

⁴ References to sections in WK’s motion to dismiss are provided for the convenience of the Court and are not intended to limit Plaintiffs’ response. Any argument set forth herein should be viewed as responsive to all applicable matters in the motion to dismiss regardless of the primary section referenced herein.

No. 10-6956 (E.D. Pa. March 24, 2011)(Exhibit “A”), Instead, the federal court noted that a health care professional that undertook to provided detailed warnings to consumers may have a duty to provide complete warnings and information. *Id.*, citing, *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 823 (Mass. 2002).

Plaintiffs have repeatedly alleged that WK undertook to provide information and warnings to Zoloft users by supplying written materials that would accompany the prescription medication. [Complaint ¶ 45, 49, 50, 156]. In so doing, WK voluntarily assumed a duty to act with reasonable care in preparing such warnings. [Complaint ¶ 45]. Second, WK promoted its patient handouts as being in compliance with industry guidelines and as being comprehensive, accurate, up-to-date and an enhancement to patient-safety. [Complaint ¶ 54]. These assurances give rise to an additional duty on the part of WK to provide PEMs that comply with the standards WK itself professes to follow. Finally, by entering into a contractual agreement with Walgreens to provide information targeted at customers, WK assumed a duty to perform its contractual obligation with due care for those customers. [Complaint ¶ 47]. For each of these reasons, Plaintiffs have alleged a plausible basis for finding that WK owes Plaintiffs a duty.

a. WK has a general common law duty to exercise ordinary care in its business undertakings.

Both Pennsylvania and New Mexico law provide that WK is subject to a “social” or “universal” duty of care under which every person owes a duty to every other person to exercise ordinary care in his activities to prevent foreseeable injury. *Probst v. Caldwell Store, Inc.* 409 Pa. 421, 427 (Pa. 1963)(“It is a primary social duty of every person to take thought and have a care lest his action result in injuries to others”); *St. Clair v. B & L Paving Co.*, 270 Pa. Super. 277 (Pa. Super. Ct. 1979)(“Those who undertake an activity pursuant to a contract have both a self-imposed contractual duty and a ‘social’ duty imposed by the law to act without

negligence.”); *Baca v. Britt*, 385 P.2d 61 (N.M. 1963)(“one who assumes to act, even though gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all”); *St. Clair v. B & L Paving Co.*, 270 Pa. Super 277 (Pa. Super. Ct. 1979)(“Those who undertake an activity [have] a “societal’ duty . . . to act without negligence.”). Hence there is no material difference between Pennsylvania and New Mexico law regarding WK’s alleged liability for violating a common law duty of care.

The scope of the duty owed is defined by the foreseeability of the injury. *Russo v. Pittsburgh R.Co.*, 164 Pa. Super 396, 400 (Pa. Super Ct 1949)(“The reasonably foreseeable risk of harm defines the orbit of duty to be imposed”). In the case at bar, Plaintiffs have alleged that WK owed a common law duty of care. [Complaint ¶ 45]. Under that common law duty, when WK undertook to author and provide consumer drug information regarding Zoloft, it had a societal obligation to take care that consumer’s would not be harmed by their foreseeable reliance on the PEMs representations. WK failed in this obligation. Thus, a plausible basis has been alleged for finding that WK is liable under common law principles for its failure to exercise ordinary care in its provision of Zoloft warnings.

b. Having undertaken to warn consumers of Zoloft’s dangers, WK assumed a duty to exercise reasonable care in making those warnings.

It is “ancient learning that one who assumes to act, even though gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all.” *Brown v. Travelers Ins. Co.*, 434 Pa. 507, 529, 254 A.2d 27, 36 (1969); *Baca v. Britt*, 385 P.2d 61 (N.M. 1963)(“one who assumes to act, even though gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all”). To this end, one may assume a duty by a course of conduct. *Riddle Memorial Hospital v. Dohan*, 504 Pa. 571, 576-77, 475 A.2d 1314, 1316 (1984); *Glick v. Martin and*

Mohler Inc., 369 Pa. Super. 428, 433-34, 535 A.2d 626, 628 (1987). Indeed, Pennsylvania has adopted the Restatement (Second) of Torts § 324A which provides:

One who undertakes, ... for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if (a) his failure to exercise such care increases the risk of such harm, or (b) he has undertaken to perform a duty owed by another to a third person, or (c) the harm is suffered because of the other's reliance upon the undertaking.

Restatement (Second) of Torts § 324A (“Section 324A”); *Cantwell v. Allegheny County*, 506 Pa. 35, 483 A.2d 1350 (1984)(recognizing Section 32 as a basis for liability, and noting that “the essential provisions of [Section 324A] have been the law in Pennsylvania for many years.”); *Farabaugh v. Pa. Tpk. Comm’n*, 590 Pa. 46, 78-79, 911 A.2d 1264, 1283-1284 (2006)(recognizing Section 324A as a basis of liability); *DiMarco v. Lynch Homes-Chester County, Inc.*, 525 Pa. 558, 560 (Pa. 1990)(affirming Superior Court ruling finding a basis for liability under Section 324A); *Waddell v. Bowers*, 415 Pa. Super. 469, 474 (Pa. Super. Ct. 1992)(recognizing liability under Section 324A).⁵

⁵ Although Pennsylvania law governs this matter in the absence of any material conflict of laws, it is worth noting that, while New Mexico has not yet addressed whether to adopt Restatement Section 324A, existing precedent suggests that it is likely to adopt the provision in the future. *Blake v. Public Service Co. of New Mexico* 82 P.3d 960, 967 (N.M. App. 2003). That is, there are numerous indications that New Mexico would adopt the majority position reflected in Section 324A when given the opportunity. First, New Mexico has referred favorably to Section 324A in the past. *Davis v. Board of County Comm’rs*, 987 P.2d 1172, 1180 (N.M. Ct. App. 1999)(citing favorably to Section 324A and noting that, although the defendant could have “chosen to remain silent . . . once the County elected to offer a recommendation it had a duty to exercise reasonable care.”); *Knapp v. Fraternal Order of Eagles*, 106 N.M. 11, 738 P.2d 129 (N.M.App.,1987)(referring the parties to Section 324A as potentially applicable if the case proceeds to trial). In addition, New Mexico has applied Restatement (Second) of Torts Section 323 which is a substantively identical provision to Section 324A that applies to direct actors.⁵ *Couch v. Astec Industries, Inc.*, 132 N.M. 631, 53 P.3d 398 (N.M.App., 2002); *Knapp v. Fraternal Order of Eagles*, 106 N.M. 11, 738 P.2d 129 (N.M.App.,1987); *Baer v. Regents of University of California*, 126 N.M. 508, 972 P.2d 9 (N.M.App., 1998). Hence there is every reason to believe that New Mexico law is in accordance with Pennsylvania law regarding potential liability for negligently performed voluntary undertakings.

Restatement Section 324A creates a legal duty where none would otherwise exist. *See Boyanoski ex rel. Estate of Kane v. Gould, Inc.*, 1999 WL 33226460 (9 Pa.Com.Pl, September 27, 1999); *Henry v. First Federal Savings & Loan Association*, 313 Pa. Super. 128, 134 n.3, 459 A.2d 772, 775 n.3 (1983). Moreover, even industries otherwise shielded by the learned intermediary doctrine can assume a duty based on their voluntary undertakings. *Cottam v. CVS Pharmacy*, 436 Mass. 316, 323 (2002) (“A pharmacy, like any other person or entity, may voluntarily assume a duty that would not otherwise be imposed on it, and thus may voluntarily assume a duty to provide information, advice or warnings to its customers.”).

Here, Plaintiffs have alleged facts establishing a duty pursuant to Section 324A. Plaintiffs have alleged that WHK voluntarily undertook to profit by providing Zoloft warnings and drug information, including written PEMs, to consumers. [Complaint ¶ 45]. By so doing, WHK assumed a duty to exercise reasonable care in providing drug warnings and information regarding the risks and benefits of Zoloft. Having undertaken a duty of care to Plaintiffs, WHK had an obligation to discharge that duty in a non-negligent manner.

In addition to alleging a voluntary undertaking by WHK, Plaintiffs have alleged two separate bases for imposing a duty on WK pursuant to Section 324A. First, Plaintiffs have alleged that WK knew or should have known that accurate warnings were necessary for the protection of consumers and that the failure to exercise reasonable care in providing such warnings would increase the risk of harm to Zoloft users. [Complaint ¶ 51, 52]. Second, Plaintiffs allege that the Minor Plaintiff suffered harm due to reliance on the information contained in WK’s PEM. [Complaint ¶ 55]. Having alleged two separate bases for finding WK liable pursuant to Section 324A, it cannot be said that no plausible basis has been alleged for Plaintiffs’ claims against WK. *Koken v. Steinberg*, 825 A.2d 723, 726 (Pa. Cmwlth. 2003).

c. WK assumed a duty to comply with the Keystone Guidelines for its industry.

The Keystone Guidelines govern the drug information industry. WK as a drug information provider is subject to the Keystone Guidelines when providing drug information.⁶ Among other things, the Keystone Guidelines require that written prescription information be: 1) scientifically accurate, (2) unbiased, (3) sufficiently specific and comprehensive, and (4) timely and up-to-date. [*See* Motion to Remand at Exhibit “H”].

Under Pennsylvania and New Mexico law, established industry standards, such as the Keystone Guidelines, are evidence of both a duty and the relevant standard of care. *See, e.g. Dallas v. F.M. Oxford, Inc.*, 381 Pa. Super. 89, 96, 552 A.2d 1109, 1112 (Pa. Super. Ct. 1989)(noting that “our own Superior court has condoned the admission of standards, be it through expert testimony or the introduction of private and governmental regulations regarding a particular business or industry”); *citing Wood v. Smith*, 343 Pa. Super. Ct. 547, 495 A.2d 601 (1985)(instructions on government and industry standards were properly admitted); *Walker v. L.G. Everist, Inc.*, 102 N.M. 783, 788 (N.M. Ct. App. 1985)(noting compliance with industry practices can show an absence of negligence if the standards themselves meet the negligence standard). Thus, both states recognize the use of industry standards as evidence of the relevant standard of care and that a violation of such standards is evidence of negligence.

Pursuant to the Keystone Guidelines, WK assumed a duty of care to ensure that the PEMs and other drug information it provided to the Mother Plaintiff, the Mother Plaintiff’s physicians and the Mother Plaintiff’s pharmacists was scientifically accurate, comprehensive and up-to-date. WK should be held to a duty of reasonable skill in the exercise of its vocation given its

⁶ WK professes to comply with the “Keystone Guidelines” which govern the drug information industry. *See* Motion to Remand at Exhibits “I” and “K.”

claims of expertise and adherence to industry standards. It is at least possible that WK assumed a duty to comply with the FDA guidelines and industry standards that it professes to follow.

d. A duty upon WK arose as a result WK's contractual undertakings.

It is well-established that parties to a contract have a duty to perform their contractual undertakings in such a manner as to avoid injury to third parties. *Farabaugh v. Pa Tpk Comm'n*, 590 Pa.46, 78, 911 A.2d. 1264, 1283 (2006)(noting “[i]t has long been the law of this Commonwealth that a contracting party may owe a duty, imposed by law and society, to perform its contractual obligations in such a manner as to avoid injury to third parties.”), *citing*, *Evans v. Otis Elevator Co.*, 403 Pa. 13 (Pa. 1961). That is, a contract may create a duty which requires a party to the agreement to use due care in performing a contract for the benefit of the other party to the agreement, as well as for third parties who are strangers to the contract. *See e.g., Gilbert v. Korvette's Inc.*, 457 Pa. 602, 616-17, 327 A.2d 94, 102 (1974) (under an agreement with a building owner, an escalator company owed a duty of care to all persons using the escalator); *Heath v. Huth Engineers Inc.*, 279 Pa. Super. 90, 92, 420 A.2d 758, 759 (1980) (based upon its contract with a sewer authority to supervise and inspect work, an engineering company owed a duty to a contractor's employee who was killed as result of the collapse of a trench). The duty does not arise directly from the contract itself, but, rather, is imposed by law as a result of the nature of the undertaking in the contract. *Cantwell v. Allegheny County*, 506 Pa. 35, 40, 483 A.2d 1350, 1353 (1984); *Hawthorne v. Dravo Corp., Keystone Division*, 313 Pa. Super. 436, 442, 460 A.2d 266, 269 (1983).

Here, it is alleged that WK contracted with the Mother Plaintiff's pharmacy to provide patient drug information in various forms - including in a written form intended to be provided to customers at the time a filled prescription is picked-up. [Complaint ¶ 47]. By contracting

with the Mother Plaintiff's pharmacy to provide the last source of information regarding Zoloft likely to be considered by patients before ingesting the drug, WK assumed a duty to perform its contractual undertaking in such manner as to avoid causing injury to the patients receiving its PEM.⁷

Nor does the mere fact that WK does not have a relationship with Plaintiffs negate the possibility of a duty on the part of WK. In Pennsylvania, as elsewhere, privity of contract is not a prerequisite for tort action. *Farabaugh v. Pa Tpk Comm'n*, 590 Pa.46, 78, 911 A.2d. 1264, 1283 (2006)(privity not required to be found liable in tort action brought by third party), *citing*, *Evans v. Otis Elevator Co.*, 403 Pa. 13 (Pa. 1961)("The orbit of [Defendant's] duty to third persons is measured by the nature and scope of his contractual undertaking. . . regardless of any privity of contract."). The lack of a direct contractual relationship between WK and Plaintiff does not make it impossible for Plaintiffs to prevail on their tort claims against WK.

- e. **Having promoted its PEMs as being accurate, up-to-date, and inclusive of all information consumers needed to know about the safety of a prescription drug, WK assumed a duty to provide PEMs that complied with its own representations.**

It is well established that when someone holds himself out as having a particular expertise, the law will require him to perform with a standard of skill or care commensurate with the claim of expertise. *See, e.g., In re Scheidmantel*, 868 A.2d 464, 486 (Pa. Super. 2005); *Rodriquez v. Horton*, 622 P.3d 261, 264 (N.M. Ct. App. 1980). Thus, where a defendant advertises that it will perform specific functions, such as monitoring medicines and providing safety warnings about those medicines that are current and include critical information, courts have held that the defendant "voluntarily assumes a duty of care with respect to the advertised

⁷ If a duty to third persons arises from a contract, the defendant is not relieved of liability to those third parties merely because the defendant has satisfied its obligation to the original party with whom it had contracted, nor is the defendant exculpated by the fact that the other contracting party was also negligent toward the third person. *St. Clair v. B & L Paving Co.*, 270 Pa. Super. 277, 280, 411 A.2d 525, 527 (1979).

system.” *Cottam v. CVS Pharmacy*, 436 Mass. 316, 323 (2002); *Somerset Sav. Bank v. Chicago Title Ins. Co.*, 420 Mass. 422, 430-431 (1995)(denying motion for summary judgment where the defendant’s advertising professed knowledge of local laws and practices which could be fairly interpreted as an assurance that matters of local law would be brought to the plaintiff’s attention).

Pennsylvania courts have recognized that an actor may, through its own advertising, impose upon itself a duty to act in a manner consonant with the advertised traits and standards. *In re Scheidmantel*, 868 A.2d 464 (Pa.Super. 2005)(holding that company’s advertising pamphlet indicating that it had special expertise in managing trusts imposed a duty to perform trust management with superior skill).

In the case at bar, WK advertised its patient-directed drug information as being “comprehensive,” “up-to-date,” and “unbiased.” [Complaint ¶ 54]. Having assured the public that its PEMs were current, accurate and inclusive of the information they would “need to know” about a prescription drug, WK assumed a duty to provide PEMs that adhered to those standards.

2. The Three Non-Pennsylvania, Non-Pleading Based Cases Cited By Pfizer Do Not Prove That Plaintiffs Have Failed to State A Plausible Claim in the Case at Bar.

Defendants boldly assert that prior courts have found Plaintiffs cannot state a claim against PEM defendants. Not so. None of the three cases Defendants cite was decided at the pleading stage. *Cheatham* and *Wilkow* were summary judgment cases. *Rivera* was decided on a motion to strike under California’s Anti-SLAPP statute.⁸ Consequently, the *Cheatham*, *Wilkow*

⁸ WK also mistakenly cites a distinguishable order in *Lewis v. Kmart* for the proposition that PEM providers do not owe a duty to patients. Order, *Lewis v. Kmart Corp.*, No. 1:08-CV-1448-RLV, (N.D.Ga. July 21, 2011). In *Lewis*, the plaintiff brought claims against the Kmart pharmacy that the plaintiff alleged falsely represented in writing that a generic drug was “FDA approved.” Kmart filed a third-party claim for indemnification against the designer of the software that produced the written drug information. The software company, in turn, filed a fourth party complaint for indemnification against Wolters Kluwer Health, Inc. which provided the drug information. While Wolters Kluwer was dismissed from the case, the reason for the dismissal was that the underlying complaint attributed the false statements solely to Kmart. WKH was *not* dismissed because it was impossible that WKH could be liable to a plaintiff. To the contrary, the *Lewis* opinion notes that an indemnification claim would have been proper if

and *Rivera* courts were concerned, not merely with whether it was conceivably possible for the plaintiff to establish a duty on the basis of the pleading, but with determining whether the plaintiffs had offered sufficient proof to raise a question of fact regarding the PEM provider's duty. *Id.* at *3. A different conclusion would likely have been reached in those under the heavy burden of a motion to dismiss.

To establish their right to a Rule 12(b)(6) dismissal, Pfizer bears the heavy burden of proving that there is no possibility a duty on the part of WK will be imposed under Pennsylvania law. To carry this burden, Pfizer relies principally upon three non-Pennsylvania cases: *Cheatham v. TEVA Pharmaceuticals*, Civil Action No. 4:09-CV-00880, 2010 WL 2990115 (E.D. Ark. May 20, 2010); *Wilkow v. Drug Fair, Inc.*, No. L-2137-98, 1999 WL 33645139 (N.J. Super. Ct. Law Div. Oct. 22, 1999) and *Rivera v. First Databank, Inc.*, 115 Cal.Rptr.2d 1, 8, (Ct.App. 2010). These three opinions are distinguishable from the case at bar and do not support the dismissal of this action for several reasons.⁹

In *Cheatham*, the Plaintiff's wife had received a two-page informational printout from her pharmacy when she filled her prescription for the pain medicine, Tramadol. *Cheatham v. TEVA Pharmaceuticals*, Civil Action No. 4:09-CV-00880, 2010 WL 2990115 (E.D. Ark. May 20, 2010). WKH moved for summary judgment on the ground that it owed no duty to the deceased Plaintiff with whom it had no relationship. In granting WK's summary judgment motion, the Eastern District of Arkansas relied on a specific factual showings that does not exist at the pleading stage of this case: namely, that the evidence before the court showed WK merely

negligence in the collecting or reporting of data by WKH had been alleged. *Id.* p. 6. Because, Plaintiffs have alleged false statements attributed to WK and wrongdoing by WK in the preparation of the PEM, the holding in *Lewis* does not apply.

⁹ In *Rivera*, the PEM issue arose in connection with the defendant's anti-SLAPP motion. *Rivera v. First Databank, Inc.*, 115 Cal.Rptr.3d 1, 8, (Ct. App. 2010). Hence, the *Rivera* ruling turned on whether the asserted cause of action arose from protected speech.

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undertook to provide drug information to the pharmacy, USA Drug Express, and not the Plaintiff. The Court specifically noted that the Plaintiff *had offered no proof* in support of his allegation that WK had undertaken to provide extensive warnings to the patient herself. *Id.* at 1024. The obvious implication of the *Cheatham* opinion is that it is possible a duty could exist – if sufficiently proven. Thus, while summary judgment may have been warranted where no proof existed that the PEM was directed at the injured plaintiff, that holding is of no import at the pleading stage where proof that WK targeted its PEM at Plaintiff is yet to be developed and presented.¹⁰

Like *Cheatham*, *Wilkow* presented a twist on the usual PEM fact pattern that doesn't exist in the case at bar. Hearing on Defendant Medi-Span's Motion for Summary Judgment, *Wilkow v. Drug Fair, Inc.*, No. L-2137-98, 1999 WL 33645139 (N.J. Super. Ct. Law Div. Oct. 22, 1999). In *Wilkow*, the plaintiff's pharmacy incorrectly advised him to take his prescription medication on an empty stomach. In reality, the medication should have been taken with food. The plaintiff brought claims against the PEM defendant for failing to include language that would have alerted him to his pharmacy's error. The PEM defendant moved for summary judgment claiming that it bore no duty to correct the errors of the pharmacy. In an unreported bench ruling, the Court stated that it did not find a duty (presumably to correct errors of the pharmacy) and encouraged the Plaintiff to proceed against the pharmacy directly. Again, even assuming the unreported New Jersey bench ruling has precedential value in this action, the issue of correction of pharmacy errors which was a central factor in *Wilkow*, is not at issue in the case at bar.

¹⁰ By appearances, the *Cheatham* litigation was not directed substantively at the PEM defendant. The Amended Complaint referenced the PEM defendant only in its last paragraph and set forth only conclusory allegations that the warnings and instructions were negligently designed, created and published and tested. Complaint, *Cheatham v. TEVA Pharmaceuticals*, Civil Action No. 4:09-CV-00880, p. 8 (E.D. Ark. Nov. 20, 2009).

Finally, it is important to note that, unlike Plaintiffs' allegations in the present case, the rulings in *Cheatham*, *Wilkow* and *Rivera* did not address the significance of (1) Restatement Section 324A, (2) the Keystone guidelines for the provision of PEMs, (3) contractual obligations of the PEM provider, or (4) public assurances regarding the quality and characteristics of the drug warnings as a basis for imposing a duty on WH. Consequently, the failure to find a duty in *Cheatham*, *Wilkow* and *Rivera* cannot carry WKs burden to disprove all plausibility of a duty being imposed in the case at bar. *West v. Marriott Hotel Services, Inc.*, 2010 WL 4343540 (E.D.Pa., 2010)(any uncertainties regarding the governing law must be indulged in favor of the plaintiff).

3. The First Amendment Does Not Preclude A Finding Of Liability Against WK. (*In response to WK's argument at I.C. pp. 11-13*).

As an initial matter, Plaintiffs would point out that a motion to dismiss is an inappropriate means of evaluating allegedly false speech for First Amendment protection. *Virgin Enterprises Ltd. v. American Longevity*, 2001 WL 34142402 (S.D.N.Y., 2001); *Castrol, Inc. v. Pennzoil Company*, 987 F.2d 939, 949 (3d Cir.1993). *U.S. v. Bell*, 207 F.Supp.2d 940, 943 (S.D.Iowa, 2002); *Carvalho v. Town of Westport*, 140 F.Supp.2d 95, 99 (D.Mass., April 09, 2001); *United States v. Luros*, 243 F.Supp. 160, 166 (N.D.Iowa 1965), *cert. denied*, *Luros v. Hanson*, 382 U.S. 956, 86 S.Ct. 433, 15 L.Ed.2d 361 (1965).

If the Court were inclined to look to the merits of WK's First Amendment defense, it would find that WK's inaccurate PEM does not warrant First Amendment protection for several reasons: (1) WK is responsible for the content of the PEM and so is not merely a "publisher" entitled to First Amendment protection, *E.g. Smith v. Lin*, 48 Pa. D. & C. 3d 339 (Pa. Com. Pl. 1988); *Jones v. J.B. Lippincott Co.*, 694 F.Supp. 1216, 1217 (D.Md. 1988); *Lewin v. McCreight*, 655 F.Supp. 282, 283 (E.D. Mich. 1987); (2) false or misleading statements such as those

contained in the PEM are not protected speech, *Gorran v. Atkins Nutritionals, Inc.*, 464 F.Supp.2d 315, 326 (S.D.N.Y. 2006); (3) by this action, Plaintiffs are not seeking to enjoin speech; but, rather to recover damages, *Norwood v. Soldier of Fortune Magazine*, 651 F.Supp. 1397, 1402 (W.Dist. Ark. 1987) and (4) PEMS are akin to instruction manuals. Errors in instruction manuals accompanying products, the manuals being deemed a part of the products themselves, have led to recoveries for physical injuries on strict liability theory. *See, e.g., Jackson v. Baldwin-Lima-Hamilton Corp.*, 252 F.Supp. 529 (E.D. Pa. 1966); *Wichman v. Allis Chalmers Mfg. Co.*, 117 F.Supp. 857 (W.D. Mo. 1954).

a. WK is not merely a “publisher” of PEMS; it is also the author of the PEMS at issue.

WK’s argument that it should be extended First Amendment protection as a publisher of information fails for the most basic reason: WK is not a mere “publisher” of drug information. Plaintiffs have clearly alleged that WK is the *author* of the Zoloft PEM. [Complaint ¶ 44, 45, 139, 145]. As such, WK is alleged to have controlled the PEM’s content. This fact alone distinguishes WK from pure publishing companies that do not author the materials they publish. Unlike a publisher, that generally is not liable for the content of works they publish, an author’s liability for errors in the content of the materials the author creates depends on the facts of the case. *E.g. Jones v. J.B. Lippincott Co.*, 694 F.Supp. 1216, 1217 (D.Md. 1988). More specifically, author liability for errors in the content of its writings depend upon (1) the nature of the publication, (2) the intended audience for the information, (3) causation and foreseeability of damages. *Id* at 1216-17. Because WK controls the content of a mass-produced PEM product that would foreseeably be used (indeed, was intended by WK to be used) to guide consumers Zoloft use – it is, at least, possible that WK will be liable for to the intended users for foreseeable harm resulting from the negligently prepared PEM product.

b. False or misleading statements such as those contained in the PEM are not protected speech,

No less an authority than the United States Supreme Court has held that inaccurate statements are not protected by the First Amendment. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm. Of New York*, 447 U.S. 557, 562, 100 S.Ct. 2343 (U.S. 1980) (“There can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.”). Indeed, Defendants’ own cited authorities provide that “commercial speech that is false or misleading is afforded no First Amendment protection at all.” *Gorran v. Atkins Nutritionals, Inc.*, 464 F.Supp.2d 315, 326 (S.D.N.Y. 2006). Simply stated, there is no prohibition against restricting communications that are more likely to deceive the public than to inform it. *Id. citing Friedman v. Rogers*, 440 U.S. 1, 15-16, 99 S.Ct.887, 896-97, 59 L.Ed.2d 100 (1979).

The repeated theme of Plaintiff’s Complaint is that the commercial information WK licensed to pharmacies and provided to consumers was *not* truthful. [Complaint ¶ 54, 139]. This fact alone precludes dismissal at the pleading stage:

Because “it is well settled that false commercial speech is not protected by the First Amendment and may be banned entirely . . . the plaintiff’s allegations in their complaint . . . that the utterances in question are false and commercial in nature are sufficient to survive a Rule 12(b)(6) motion.

Virgin Enterprises Ltd. v. American Longevity, 2001 WL 34142402 (S.D.N.Y., 2001)(internal citations omitted), *citing, Castrol, Inc. v. Pennzoil Company*, 987 F.2d 939, 949 (3d Cir.1993).

Moreover, because it is essential to determine whether the statements at issue are false or misleading to determine whether a defendant’s speech is protected by the first amendment, First Amendment defenses are not properly resolved on the pleadings. Instead, fact issues regarding the truthfulness and accuracy of challenged speech is an issue of fact for resolution at trial.

South Carolina Ports, 676 F. Supp. at 350; *see also Schiff*, 379 F.3d at 623-24. At this juncture in the case at bar, WK's speech must be treated as false, deceptive or misleading with regard to objective factual data that WK was in a position to verify before they were disseminated. Thus, it is (at least) plausible that the First Amendment does not bar the claims asserted in Plaintiffs' complaint.

c. Plaintiffs are not seeking to enjoin speech; but, rather to recover damages.

Plaintiffs have not sought an injunction attempting to restrain or abridge Defendants' "speech" in this action. Instead, Plaintiffs' Complaint sets forth various theories of liability against WK and seeks compensation for WK's negligence and other wrongdoing. As explained in *Norwood v. Soldier of Fortune Magazine*, when a plaintiff is not seeking to enjoin speech but is instead requesting damages as a consequence of the "speech" at issue, the First Amendment is not implicated. 651 F.Supp. 1397, 1402 (W.Dist. Ark. 1987). The First Amendment is also not implicated because it is not an exemption from generally applicable common law. *See Cohen v. Cowles Media Co.*, 501 U.S. 663, 111 S.Ct. 2513, 115 L.Ed. 2d 586 (1991). Accordingly, WK cannot defeat adequately pled common law claims at the pleading stage merely by invoking the First Amendment. WK's motion to dismiss on the basis of the First Amendment should be denied.

d. The "speech" at issue is of a type that has been held not to warrant First Amendment protections.

While WK is correct in its assertion that book publishers generally are not liable for the content of the volumes they publish, WK omits to mention that the First Amendment does not shield (1) publishers of instructional charts and manuals, and (2) negligent preparers of reports based on objective data. The rationale for treating these two categories of informational

materials -- both of which are analogous to PEMS -- differently from books or periodicals is highly instructive in the present case.

Instruction manuals and aviation charts have been found to support a claim for strict products liability. *See, e.g., Jackson v. Baldwin-Lima-Hamilton Corp.*, 252 F.Supp. 529 (E.D. Pa. 1966)(holding that errors in instruction manuals accompanying products can support a claim under a strict liability theory); *Brocklesby v. United States*, 767 F.2d 1288, 1294-98 (9th Cir. 1985)(holding that defendant could be liable for defects in instrument approach procedure included on a flight chart); *Saloomey v. Jepperson & Co.* 707 F.3d 671, 676-77 (2nd Cir. 1983)(holding strict liability claim would like for defective aeronautical chart).

Courts have also recognized the possibility of liability for negligent misstatements involving compilations of factual data. In *South Carolina State Ports Authority v. Booz-Allen & Hamilton, Inc.*, a large management-consulting firm was sued for negligently preparing a report comparing the Ports of Savannah, Georgia and Charleston. 676 F. Supp. 346 (D.D.C. 1987). The report was alleged to contain misleading, false, and damaging information. The defendant firm asserted a First Amendment defense. In rejecting the First Amendment defense, the court observed that the defendant's report consisted of "objective factual data," which "because of the greater objectivity and hardiness of commercial speech" did not require the protection of the First Amendment. *Id.* at 350 ("When the speech at issue revolves around fact, not opinion, the first amendment concerns, though still existent, are diminished").

The holdings and rationales in *South Carolina*, *Jackson*, *Brocklesby*, and *Saloomey* are easily transferable to the context of PEMs. First, Like the *South Carolina* report or the aeronautical charts, the data which forms the content base of the PEM consists of objective, verifiable facts, drawn from FDA approved labeling and the existing body of medical

knowledge. Such data is objective in nature, and so, less in need of First Amendment protection. Second, the concerns that normally drive First Amendment protections – namely the practical inability of publishers to guarantee the accuracy of wide-ranging publications – does not apply where the defendant controls the informational content. Third, unlike a newspaper article, for example, which adds to the overall store of knowledge and encourages discussion and the dissemination of new ideas, a PEM merely takes existing expert knowledge and drug information and makes it more widely available and more easily accessible. While inhibiting the development PEMs by raising the specter of liability may be undesirable, *this undesirability does not arise from First Amendment concerns*. If a newspaper article is suppressed, society will be deprived of a principle medium for the dissemination of information, and thus will be worse off for its suppression. If an expert system is suppressed, by contrast, the knowledge would still be available through the study results and on the product label. Indeed, if a PEM providing only inaccurate and incomplete information supplants the more extensive label, society is arguably worse off than if the negligently produced PEM was never offered.

In sum, while First Amendment concerns may be important in the area of publisher liability generally, the special nature and function of PEMs makes First Amendment concerns in that area unwarranted.

4. Plaintiffs Have Adequately Alleged The Elements of Their Claims Against WK for Fraud, Breach of Warranty and Strict Liability.

- a. Plaintiffs have alleged a plausible claim for strict products liability.** (*In response to WK's argument at II.A, pp. 16-18*).

WK correctly asserts that Plaintiffs have not alleged WK to be a “seller” of Zoloft. Yet, that fact is not fatal to Plaintiffs’ strict liability claim for two reasons. First, while WK does not actually sell Zoloft, it does sell PEMs that are a part or component of the Zoloft product as

provided to consumers by their pharmacy. Second, to the extent (if any) that the PEM is considered a wholly separate and independent product from the Zoloft medication, WK is liable for the defects in the PEM product.

The term ‘seller’ is used generically to include all sellers or suppliers of a product who may be said to have undertaken and assumed a responsibility toward the consuming public and who are in a position to spread the risk of defective products. Under Pennsylvania law, the definition of “seller” liable for physical harm caused by use of a defective product includes all suppliers in chain of distribution, whether retailers, *part-makers*, assemblers, owners, sellers, lessors, or any other relevant category. *Balczon v. Machinery Wholesalers Corp.*, 993 F.Supp. 900 (W.D.Pa., February 13, 1998); RESTATEMENT (SECOND) OF TORTS § 402A. Plaintiffs have alleged that the PEM was a component of the Zoloft product. [Complaint ¶ 145]. A manufacturer of a component part can be liable under Section 402A if the component is defective.” *Brenda Miller v. Franklin Institute Research Laboratory, Inc., a/k/a Franklin Research Center*, 1990 WL 902435 (Pa.Com.Pl. Aug. 24, 1990). Here, Plaintiff’s strict liability claim against WK is premised on the fact that WK prepared and placed into the stream of commerce a drug monograph which was a component of the Accutane product. [Complaint ¶ 99]. Hence, it is at least plausible that a strict liability claim against WK will lie.

Additionally, and alternatively, to the extent (if any) that the PEM is considered a separate and independent product rather than a part or component of the Zoloft prescription, then it is not necessary that WK be a “seller” of Zoloft because WK is a “seller” of PEMs.¹¹ Plaintiffs acknowledge that information in the format of book content generally has not been considered a product. The rationale for excluding book content from the “product” definition is that book

¹¹ Plaintiffs repeatedly allege that WKH undertook to author, market and supply PEMs to patients for profit. [Complaint ¶ 45, 49, 145]. The obvious inference, which must be indulged in Plaintiffs’ favor when considering a motion to dismiss, is that WKH was in the business of selling PEMs.

manufacturers (1) do not produce the content of the books they publish and (2) would have a nearly impossible task if required to confirm the accuracy of countless, wide-ranging publications. Those rationales do not apply in the case at bar. WK does not merely publish a Zoloft PEM. WK authors and determines the content of the PEM. Moreover, PEMs are more akin to instruction manuals or aviation charts – both of which have been found to support a claim under a strict products liability theory. *See, e.g., Jackson v. Baldwin-Lima-Hamilton Corp.*, 252 F.Supp. 529 (E.D. Pa. 1966)(holding that errors in instruction manuals accompanying products can support a claim under a strict liability theory); *Brocklesby v. United States*, 767 F.2d 1288, 1294-98 (9th Cir. 1985)(holding that defendant could be liable for defects in instrument approach procedure included on a flight chart); *Saloomey v. Jepperson & Co.* 707 F.3d 671, 676-77 (2nd Cir. 1983)(holding strict liability claim would like for defective aeronautical chart). Because WK controls the content of a mass-produced PEM product that would foreseeably be used (indeed, was intended by WK to be used) to guide consumers Zoloft use – WK should be liable under a strict liability theory for defects in its PEM product.

b. Plaintiffs have alleged a plausible claim for fraud. (*In response to WK's argument at II.B, pp. 18-20*).

Each of the elements claimed by WK to be missing from Plaintiffs' fraud cause of action has been alleged. For example, WK claims that Plaintiffs have not identified any false representations in the monograph. In actuality, Plaintiffs have alleged that WK misrepresented the safety of Zoloft, [Complaint ¶ 160], concealed, suppressed or omitted adverse information regarding Zoloft's safety, [Complaint ¶ 160], misrepresented that Zoloft had minimal side effects [Complaint ¶ 161], concealed the inadequacy of Zoloft testing [Complaint ¶ 164], and concealed or omitted that prior studies, research reports and testing had linked the use of Zoloft to serious adverse reactions including congenital birth defects [Complaint ¶ 164]. Although

these allegations are more than sufficient to provide WK with notice of the claims alleged against it, Plaintiffs have also set forth specific information from the PEM label that was fraudulently omitted from WK's Zoloft PEM.¹² [*See Chart supra* at II.].

Similarly, Plaintiffs have alleged each of the other elements of its fraud claim that WK says is lacking. First, Plaintiff has alleged that the omission of any IBD warning was knowing and intentional. [Complaint ¶ 160, 163, 165]. Although WK's knowledge and intent are matters uniquely within the drug-maker's control and will require discovery to establish fully, at the very least it can be inferred that WK had knowledge of the information publicly available on the Zoloft product label and that, as the author of the Zoloft PEM, the decision to omit statements from the label regarding the risks of Zoloft use during pregnancy was an intentional one.

Second, Plaintiffs have alleged reliance upon WK's omission. [Complaint ¶ 169, 170]. Specifically, Plaintiffs have alleged that they would not have used Zoloft if they had known of the drug's risk of causing congenital birth defects. [Complain ¶ 169]. Although WK desires more specificity in Plaintiffs' allegations, Plaintiffs have indicated the nature, the general substance, and the form of WK's misrepresentations. Dismissal at the pleading stage should be denied where the allegations are sufficient to define the parameters of the statements to be examined in discovery. *Foster v. Northwestern Mut. Life*, 2002 WL 31991114 (E.D.Pa., July 26, 2002). Plaintiffs' allegations are sufficient to meet that standard.

c. Plaintiffs have alleged a plausible claim for breach of warranty. (*In response to WK's argument at II.C, pp. 20-21*).

WK makes three arguments against Plaintiffs' breach of warranty allegations, the first (that the PEM is not "goods") and the third (that WK is not a "seller" of goods) fail for the same

¹² In the event that the Court is inclined to find that the allegations of Plaintiffs' fraud count require additional information to survive a motion to dismiss (which they do not), Plaintiffs respectfully request leave to amend their Complaint to include the allegations of specific statements omitted from the Zoloft PEM as set forth herein.

reasons that WK's attack on Plaintiffs' product liability claims fail. [*See* Argument *supra* at V.B.5.a]. By representing to consumers through its PEMs that Zolofit was safe and did not cause congenital birth defects, WHK, as the manufacturer and seller of the drug information component of the product, expressly warranted that the product was safe. For the reasons set forth above, it is plausible that WHK will be treated as a "seller" and/or that the Zolofit PEM will be considered a "product" for purposes of Plaintiffs' breach of express warranty claim.

The remaining allegation, that Plaintiffs have not alleged a basis for a warranty is simply wrong. Plaintiffs have alleged that WK expressly and impliedly warranted that the PEM it was providing was truthful, accurate, up-to-date, and complete. [Complaint ¶ 173]. Plaintiffs have also alleged that WK overstated Zolofit's safety and understated its risks – including the risk of congenital birth defects. [Complaint ¶ 175]. WK is alleged to have known that its warranties regarding Zolofit's safety and the PEM's truthfulness and accuracy would impact the prescribing practices of Plaintiff's physicians and Plaintiff's use of the medication – purposes of which WK was aware. [Complaint ¶ 175]. Thus, the knowledge and purpose that WK claims is lacking has been adequately alleged. Dismissal of Plaintiff's breach of warranty claim must be denied.

d. Plaintiffs have adequately alleged a basis for the loss of consortium and punitive damage claims. (*In response to WK's argument at II.D, pp. 21-22 and II.E, p. 22*).

WK makes no attack on Plaintiffs' loss of consortium allegations other than their dependence upon a viable underlying action. Because Plaintiffs have adequately alleged a legal and factual basis for their negligence, product liability, fraud, and breach of warranty claims, WK's attack on their loss of consortium claims necessarily fails.

Similarly, WK does not seriously challenge the sufficiency of Plaintiffs' allegations that punitive damages are warranted. Rather, WK urges only that Pennsylvania law does not require

a separate claim for punitive damages. Whether enumerated as a separate count or recoverable as an element of damages arising from Plaintiffs' other claims, Plaintiffs have stated intentional, reckless conduct by WK including removing safety information included in the Zolofit product label from the PEM with knowledge that doing so put the health and safety of consumers, such as Plaintiffs, at risk. [Complaint ¶ 186]. Thus, a plausible basis has been alleged for Plaintiffs' recovery of punitive damages.

C. PLAINTIFFS HAVE ALLEGED PLAUSIBLE CLAIMS AGAINST WKUS. (*In response to WK's argument at III., pp. 23-24*).

Defendants assert, without evidence or support, that WKUS is not engaged in the business of publishing drug information and that WKH "is the only Wolters Kluwer entity that publishes the patient education monographs at issue in this matter." [Memoranda in Support of Motion to Dismiss, p. 23]. Defendants also assert that WKUS is not owned by WKH and has no ownership interest in WKH. [Memoranda in Support of Motion to Dismiss, p. 23]. Plaintiffs acknowledge that such assertions, *if* established by proof and borne out through discovery, may be the basis of a future summary judgment motion by WKUS. But, at this preliminary stage of the litigation, dismissal is governed by the allegations of the Complaint. Because the Complaint alleges conduct sufficient to state a claim by WKH and WKUS alike, unproven assertions contrary to the allegations of the Complaint cannot secure the dismissal of WKUS.

D. IT IS NOT OBVIOUS FROM THE FACE OF PLAINTIFFS' COMPLAINT THAT PLAINTIFFS' CLAIMS ARE BARRED BY THE STATUTE OF LIMITATIONS. (*In response to WK's argument at IV, pp. 24-26*).

WK's pursuit of dismissal at the pleadings stage on statute of limitations grounds violates virtually every standard for a Rule 12(b)(6) motion. First, the Third Circuit Court of Appeals joins with numerous other courts in holding that a statute of limitation defense generally should not be raised by way of a 12(b)(6) motion. *E.g., Muma v. High Spec. Inc.*, 2010 WL 4386718

(3d. Cir. Nov. 12, 2010)(“a statute of limitations defense generally cannot be raised by way of a 12(b)(6) motion”), *Mackin Engineering Co. v. American Exp. Co.*, 2011 WL 2728446, n. 2 (3rd Cir., July 14, 2011); *Barefoot Architect, Inc. v. Bunge*, 632 F.3d 822, 835 (3rd Cir. 2011); *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n. 1 (3rd Cir. 1994). *accord*, *Williams-Jones v. LaHood*, 656 F.Supp.2d 63 (D.D.C. 2009)(noting courts should hesitate to grant a motion to dismiss on the basis of a statute of limitations defense because limitations issues commonly depend on contested questions of fact).

Second, WK’s motion to dismiss must be denied because the Complaint both expressly alleges and reasonably infers application of the discovery rule. Under Pennsylvania law, to survive a motion to dismiss asserting that a claim is barred by the statute of limitations, a plaintiff asserting the discovery rule exception, need only allege facts tending to show that they were unable to identify their claims through the exercise of reasonable diligence. *Brandow Chrysler Jeep. Co., v. DataScan Technologies*, 511 F.Supp.2d 529 (E.D.Pa. 2007). Here, Plaintiffs have directly alleged that both their injuries, and the role of Zolof in causing those injuries, was not discoverable through reasonable care and diligence until within the limitations period. [Complaint ¶ 63].

WK acknowledges that Plaintiffs have pled the discovery rule. Nevertheless, WK asserts that the claim should be dismissed as time-barred for failure to plead diligence. WK is mistaken. Plaintiffs have clearly alleged that they diligently investigated the cause of their injuries “including consultations with Plaintiff’s medical providers” [Complaint ¶ 64]. More specifically, the Mother Plaintiff alleges that, despite inquiring of her health care providers as to the cause of the injuries, she was not told [by the physicians] that Zolof could have caused the Infant Plaintiff’s injuries.” [Complain ¶ 21]. Nor did the Mother Plaintiff see or read any

information suggesting Zoloft caused her daughter's injuries. [Complaint ¶ 21]. These undertakings by the Mother Plaintiff state a plausible factual basis for finding that she was diligent in investigating the cause of Plaintiffs' injuries.

Moreover, Plaintiffs have alleged that the statute of limitations should be tolled due to the Defendant's fraudulent concealment. [Complaint ¶ 65]. Specifically, the Mother Plaintiff has alleged (1) that she relied on the PEM provided to her by WK, [Complaint ¶ 154, 170], (2) that her reliance was justified because WK was in a better position to know the true facts concerning Zoloft [Complaint ¶ 55, 155, 170], (3) that WK and Pfizer concealed adverse information about Zoloft while misrepresenting the safety of the drug. [Complaint ¶ 160-168]. These allegations, and the reasonable inferences therefrom, state a plausible claim that Plaintiff could not have discovered the defective nature of Zoloft more than two years prior to filing his claim. *Brandow*, 511 F.Supp.2d at 535 (finding the plaintiffs' allegation of reliance on information the defendant corporation was hired to provide itself can be interpreted to show that plaintiffs were unable to discover their injury). WK's motion to dismiss on statute of limitations grounds must be denied.¹³

E. SHOULD THIS COURT BE INCLINED TO GRANT WK'S MOTION TO DISMISS ON ANY CLAIM, PLAINTIFFS REQUESTS LEAVE TO AMEND THEIR COMPLAINT PRIOR TO DISMISSAL.

The Third Circuit recognizes that leave to amend a complaint shall be extended prior to dismissal of a claim pursuant to Rule 12(b)(6). *See Abulkhair v. PPI/Time Zero, Inc.*, 2010 WL 4230752 (3d. Cir. Oct. 27, 2010) ("District Courts are required to grant leave to amend

¹³ The primary case cited by WHK in support of granting dismissal on statute of limitations grounds presents extreme and unusual factual allegations. In *Meehan*, the plaintiffs alleged incidents of sexual abuse by identified priests that pre-dated the filing of the complaint by as much as 47 years. *Meehan v. Archdiocese of Philadelphia*, 870 A.3d 912, 919 (Pa.Super.Ct. 2005). The Superior Court of Pennsylvania specifically contrasted the facts of that case – where the plaintiffs knew of their injury, knew the identities of their abuser and knew that their abuser was employed by the Catholic Church – to cases (such as this one) where an injury did not emerge until a later date from the act that caused it. *Id.* at 920. Hence, the very case cited by WHK as precedent for granting a rare motion to dismiss on limitations grounds suggests that such dismissal would not be proper under the facts of the case at bar.

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CERTIFICATE OF SERVICE

I hereby certify that on January 20, 2012, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

/s/

Rosemary Pinto, Esq.