IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: REGLAN/METOCLOPRAMIDE LITIGATION	:	JANUARY TERM, 2010 NO. 1997 CONTROL NO. 11060023

ORDER

AND NOW, this 21st day of December, 2011, upon consideration of the PEM Defendants' Preliminary Objections to Plaintiffs' Short Form Complaints, Plaintiffs' Response and Defendants' Reply thereto, and after oral argument, it is hereby **ORDERED** said Preliminary Objections are **OVERRULED** without prejudice to raise these issues in a motion for summary judgment.

BY THE COURT:

Sandra Mazer Moss, J.
Coordinating Judge
Complex Litigation Center

In Re: Reglan Litigatio-ORDOP

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IN RE:	:	JANUARY TERM, 2010
REGLAN/METOCLOPRAMIDE	:	NO. 1997
LITIGATION	:	CONTROL NO. 11060023

OPINION

Sandra Mazer Moss, J. December 21, 2011

Presently before this Court are the PEM[1] Defendants[2] ("PEMs") Preliminary Objections to Plaintiffs' Short Form Complaints[3] seeking dismissal. We have carefully considered counsel's arguments both written and oral and the preliminary objections are now ripe for disposition.

I. BACKGROUND

Plaintiffs allege they suffer from the neurological disorder, tardive dyskinesia, resulting from ingesting Reglan/Metoclopramide ("Reglan"). In addition to manufacturers, Plaintiffs sued Defendants herein for drafting and publishing medical and scientific information provided to doctors, hospitals and pharmacies. *See generally* N.T. 11/30/11; *see also* Defendants' Preliminary Objections, 5/31/11 and Plaintiffs Response, 8/1/11. Plaintiffs' PEM claims,

[1] PEM is short for Patient Education Monograph, described by Defendants as a short educational supplement that summarizes the use information and side effects associated with a drug (in this instance Reglan). *See* Defendants' Preliminary Objections, 5/31/11, p. 3. A PEM is most commonly found stapled to the prescription bag given by a pharmacy. *See* N.T. 11/30/11, p. 7.
[2] Defendants include Wolters Kluwer, Inc, Wolters Kluwer U.S. Corp., Wolters Kluwer United States Inc., First DataBank, Inc., Thomson Reuters (Healthcare), Inc., Elsevier Inc., Gold Standard, Inc., Cerner Corporation and Cerner Multum, Inc.
[3] Preliminary Objections were filed globally to apply to the Short Form Complaints for all Plaintiffs in the Reglan/Metoclopramide Litigation Program.

include, *inter alia,* strict liability-failure to warn, strict liability-design defect, negligence, negligence *per se*, fraud and intentional misrepresentation, constructive fraud, breach of implied warranty, unfair and deceptive trade practices and unjust enrichment. *See* Examples of Reglan Short Form Complaints, Defendants' POs, Exhibits A-C.

The PEMs argue they do not manufacture or distribute, but merely supply drug information to health care providers and pharmacies. *See* Defendants' POs, pp. 3-4, 8. Because there is no direct relationship, they do not owe Plaintiffs a duty. *Id.* Moreover, the First Amendment limits duties imposed on publishers and the U.S. Supreme Court has "never allowed a claim based on truthful speech on a matter of public concern." *Id.* at 14.

Plaintiffs contend the duty is voluntarily contracting with pharmacies and health care providers to supply, for profit, accurate, adequate and up to date information about Reglan. *See* Plaintiffs' Response, pp. 8-12, 19-22. This obligation to provide medical and scientific information in accord with the Keystone Guidelines[4] makes the Plaintiffs their beneficiaries. *Id.* at 23-24. Further, the PEMs' website advertising calls them experts in providing scientifically accurate drug information. *Id.* at 25-26. Additionally, they argue the First Amendment does not afford PEMs protection because they are not publishers but authors of false or misleading statements. *Id.* 29-33.

II. DISCUSSION

Pennsylvania law is well established on preliminary objections raising legal insufficiency. "We note initially that the standard for review for preliminary objections is a

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[4] The "Keystone Guidelines," more formally known as *Action Plan for the Provision of Useful Prescription Medicine Information*, were drafted and published in 1996 in response to a Congressional mandate (Public Law 104-180) to "develop a long-range, comprehensive action plan to improve oral and written communication to patients about their prescription medicines." *See* Defendants' POs, Exh. D, p. 3.

limited one." *Emplrs. Ins. of Wausau v. DOT*, 581 Pa. 381, 389 (Pa. 2005). "Preliminary objections to a complaint in the nature of a demurrer admit as true all well-pleaded material facts set forth in the complaint, as well as all inferences reasonably deducible therefrom, but not the pleader's conclusions of law." *Clevenstein v. Rizzuto*, 439 Pa. 397, 400 (Pa. 1970). "The question presented by the demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible." *Emplrs. Ins. of Wausau v. DOT*, 581 Pa. 381, 389, n.5 (Pa. 2005) (citing *Hoffman v. Misericordia Hospital of Philadelphia*, 439 Pa. 501, 267 A.2d 867 (1970)). "The test on preliminary objections is whether it is clear and free from doubt from all the facts pleaded that the pleader will be unable to prove facts legally sufficient to establish his right to relief." *Bourke v. Kazaras*, 746 A.2d 642, 643 (Pa. Super. Ct. 2000). "Where a doubt exists as to whether a demurrer should be sustained, this should be resolved in favor of overruling it." *Clevenstein,* 439 at 401, *citing Birl v. Philadelphia Electric Co.*, 402 Pa. 297 (1960).

All parties agree the FDA approved label changes in 2004 included warnings that Reglan therapy should not exceed 12 weeks. *See* N.T. 61. There is also no dispute the PEMs, for profit, license drug information to health care facilities and pharmacies counseling patients. *Id.* at 5-6. The PEM contracts prohibit recipients from changing information provided to them. *Id.* at 63. Plaintiffs argue PEMs, through advertising and licensing agreements, have promised to provide scientifically accurate, comprehensive and current drug information which they have failed to do. *See* N.T. 57-59, 62-65, 68. Although label changes were approved in 2004, Plaintiffs allege PEMs failed to include same in their materials until at least 2009. *See* N.T. 88. They further allege warnings about irreversible tardive dyskinesia were also not included timely. *Id.* at 62. The PEMs deny these allegations, making them disputed issues of material fact which will become more fully developed during discovery. However, we note voluntarily undertaking to

provide drug information to the public must be done accurately to avoid harming end users. *Id.* at 56-58; Restatement (2d) of Tort, §324A.

The PEMs continually reiterate as merely *publishers*, not manufacturers, they cannot and do not provide comprehensive drug warnings to the public. *See* N.T. 79; Defendants' POs. However, website advertising for at least one defendant, Cerner Multum, clearly states "Multum and its parent company, Cerner Corporation, are health care information companies, *not publishers*. *See* N.T. 73-74, Plaintiffs' Exhibit Binder, 11/30/11, Exh. 20 (emphasis supplied). Such evidence raises disputed issues of material fact about the PEMs legal duties. We find Defendants have failed to sustain their heavy burden at this early stage to show with certainty the law would not recognize any claims Plaintiffs now assert.

II. CONCLUSION

For the foregoing reasons, the PEM Defendants Preliminary Objections are OVERRULED without prejudice to raise these issues in a motion for summary judgment.

BY THE COURT:

Sandra Mazer Moss, J.