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

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	MDL NO. 1871 07-MD-01871
THIS DOCUMENT APPLIES TO:	:	HON. CYNTHIA M. RUFE
SAMUEL MORGAN JR. *on behalf of himself and all others similarly situated*	:	CIVIL ACTION
v.	:	
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE	:	NO. 10-2401

MEMORANDUM OPINION AND ORDER

Rufe, J. **September 7 , 2011**

The plaintiff in this case is a former user of the prescription diabetes drug Avandia. Plaintiff does not allege that he has been physically injured as a result of taking Avandia; instead he seeks a refund of any monies he paid for Avandia (including insurance co-pays) and medical monitoring. Each type of relief is sought on behalf of a class of similarly-situated individuals (the "Refund Class" and the "Monitoring Class," respectively), but no classes have been certified. The defendant, GlaxoSmithKline LLC ("GSK"), has filed a motion to dismiss. The motion will be granted.

I. BACKGROUND

Plaintiff alleges that GSK promoted the use of Avandia to lower blood-sugar levels of patients with Type 2 diabetes. Plaintiff also alleges that taking Avandia significantly increases

the patient's chances of suffering a heart attack or susceptibility to other health risks, and that GSK concealed the risks of Avandia use while promoting the drug's safety, efficacy, and effectiveness through a fraudulent and deceptive marketing program.[1] According to Plaintiff, this resulted in Plaintiff and others purchasing Avandia instead of seeking alternative treatments.[2] Plaintiff alleges that his is a resident of Pennsylvania and that on or after May 25, 1999, he was prescribed Avandia for the treatment of Type 2 diabetes, that he purchased the drug and was "exposed" to Avandia for at least 12 weeks,[3] and having been exposed, he is at high risk for future myocardial ischemic events.[4] These are the only allegations in the complaint specific to Plaintiff.

II. LEGAL STANDARD

Dismissal of a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted is appropriate where a plaintiff's "plain statement" does not possess enough substance to show that plaintiff is entitled to relief.[5] In determining whether a motion to dismiss is appropriate the court must consider those facts alleged in the complaint, accepting the allegations as true and drawing all logical inferences in favor of the

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[1] Compl. ¶¶ 4, 8.

[2] Compl. ¶ 19.

[3] Compl. ¶ 31.

[4] Compl. ¶ 28.

[5] Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557 (2007).

non-moving party.[6] Courts are not bound to accept as true legal conclusions couched as factual allegations.[7] Something more than a mere possibility of a claim must be alleged; the plaintiff must allege "enough facts to state a claim for relief that is plausible on its face."[8] The complaint must set forth direct or inferential allegations with regard to all the material elements necessary to sustain recovery under some viable legal theory.[9] The court has no duty to "conjure up unpleaded facts that might turn a frivolous action . . . into a substantial one."[10]

III. DISCUSSION

A. *Unfair Trade Practices and Consumer Protection Law*

On behalf of the proposed Refund Class, Plaintiff alleges violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL").[11] The statute prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce,"[12] and in addition to listing specific prohibited practices, includes a "catch-all provision" that bars "[e]ngaging in any . . . fraudulent or deceptive conduct which creates a

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[6] ALA, Inc. v. CCAIR, Inc., 29 F.3d 855, 859 (3d Cir.1994); Fay v. Muhlenberg Coll., No. 07–4516, 2008 WL 205227, at *2 (E.D. Pa. Jan. 24, 2008).

[7] Twombly, 550 U.S. at 555, 564.

[8] Id. at 570.

[9] Id. at 562.

[10] Id. (citing McGregor v. Indus. Excess Landfill, Inc., 856 F.2d 39, 42–43 (6th Cir.1988)).

[11] 73 Pa. Stat. §§ 201-1 *et seq*.

[12] Id. § 201-2.

likelihood of confusion or of misunderstanding."[13]

GSK argues that the UTPCPL does not apply to prescription drugs because the learned intermediary doctrine interposes the prescribing physician between the patient and the pharmaceutical company, and that even if the statute did apply, Plaintiff has not alleged the elements of a UTPCPL claim.

"Under the learned intermediary doctrine, the drug manufacturer owes a duty of disclosure to the prescribing physician, but it is then the duty of the prescribing physician to communicate any risks or other information about the drug to the patient."[14] As courts have held, "the existence of the 'learned intermediary' doctrine in Pennsylvania makes it difficult, if not impossible, for plaintiffs to successfully bring a UTPCPL claim based on a prescription drug."[15] Plaintiff argues that the doctrine does not bar his claims because Defendant 1) subverted the learned intermediary doctrine by providing deceptive information to physicians, so that the prescribing physicians were not "learned"; and 2) provided deceptive information directly to consumers.

Plaintiff has failed to allege any facts that would permit him to surmount the hurdle of the learned intermediary rule. The complaint does not allege what information was provided to the (unidentified) prescribing physician, or upon what alleged misrepresentations the prescribing physician relied. "[A] patient in Pennsylvania cannot justifiably rely on the prescription drug manufacturer; instead, it is the prescribing physician who provides the grounds for justifiable

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[13] Id. § 201-2 xxi.

[14] Zafarana v. Pfizer, Inc., 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010).

[15] Id. at 557.

reliance."[16] No such reliance has been alleged.

Nor do Plaintiff's allegations that the drugs were directly marked to consumers overcome the learned intermediary rule. "Media dissemination of information concerning the existence of these drugs does not enhance the public's ability to acquire them, as the skill and knowledge of the physician still must be brought to bear in a determination of whether the pharmaceutical is appropriate for the patient."[17] Because Plaintiff could not obtain Avandia without a physician's prescription, and there are no allegations regarding the prescribing physician, the learned intermediary doctrine bars Plaintiff's claim.[18]

Even if the learned intermediary rule did not bar the claim, there are no allegations as to when Plaintiff took Avandia, for how long he took it (other than for at least 12 weeks), why or if he stopped taking it, what advertising materials or information Plaintiff relied upon (or even read), or how much Plaintiff paid for Avandia. In short, Plaintiff's complaint as currently pleaded is a form complaint, without any information about the individual claim, and is insufficient to state a claim as to Plaintiff. Plaintiff has not alleged justifiable reliance, causation, or injury.[19]

B. Medical Monitoring

On behalf of the proposed Medical Monitoring Class, Plaintiff alleges that "[a]s a direct and proximate result of Defendant's misrepresentations regarding Avandia's safety, Plaintiff and

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[16] Id.

[17] Albertson v. Wyeth, Inc., 63 Pa. D.&C. 4th 514 (Phila. Ct. Com. Pl. 2003) (citing Lennon ex rel. Lennon v. Wyeth–Ayerst Labs., Inc., No. 1793 EDA 2000, 2001 WL 755944, at *2 (Pa. Super Ct. June 14, 2001)).

[18] Smith v. Bristol-Myers Squibb Co., No. 3:06-cv-6053, 2009 WL 5216982, at *11 (D.N.J. Dec. 30, 2009).

[19] Hunt v. U.S. Tobacco Co., 538 F.3d 217 (3d Cir. 2008); Toy v. Metro. Life Ins. Co., 928 A.2d 186, 202 (Pa. 2007).

the Pennsylvania Medical Monitoring Class have an increased risk of contracting a serious latent disease and will incur (if they have not incurred already) the cost of medical monitoring."[20] GSK argues that Plaintiff has not alleged any facts to support a medical monitoring claim beyond the cardiovascular monitoring recommended for any patient with Type 2 diabetes.

Pennsylvania recognizes medical monitoring as a viable cause of action. It was first applied in the asbestos context,[21] and later extended by Pennsylvania trial courts to pharmaceutical cases.[22] To state a claim for medical monitoring, Plaintiff must allege:

> (1) exposure greater than normal background levels;
> (2) to a proven hazardous substance;
> (3) caused by the defendant's negligence;
> (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease;
> (5) a monitoring procedure exists that makes the early detection of the disease possible;
> (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and
> (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.[23]

Defendant argues that Plaintiff has not alleged the existence of a traditional tort cause of action, such as negligence, and that Plaintiff has not alleged the need for cardiovascular

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[20] Compl. ¶ 254.

[21] See Simmons v. Pacor, Inc., 674 A.2d 232 (Pa. 1996).

[22] See, e.g., Lewis v. Bayer AG, 66 Pa. D.&C.4th 470 (Phila. Ct. Com. Pl. 2004) (Baycol, a cholesterol-reducing drug); Albertson v. Wyeth, Inc., 63 Pa. D.&C.4th 514 (Phila. Ct. Com. Pl. 2003) (hormone replacement drugs). See also In re Diet Drugs Products Liability Litigation, 1999 WL 673066 (E.D. Pa. Aug. 26. 1999) (conditionally certifying a class seeking medical monitoring).

[23] Redland Soccer Club, Inc. v. Dep't of the Army & Dep't of Defense of the U.S., 696 A.2d 137, 145-46 (Pa. 1997).

monitoring for Avandia patients beyond that recommended for all patients with Type 2 diabetes.[24] As to the first point, the only apparent reference to negligence in the complaint is the allegation that "[d]espite having knowledge of the increased risk of heart problems related to use of its product, Defendant intentionally, negligently, and/or willfully misrepresented the safety and efficacy of Avandia and omitted relevant information showing adverse effects of Avandia . . . ."[25] The claim for medical monitoring essentially tracks the elements of the claim, but without any specific facts alleged (e.g., as to what medical monitoring procedure exists and how it differs from the monitoring for all patients with Type 2 diabetes).[26] These generalized allegations are legally insufficient to state a claim.

C. Unjust Enrichment Claim

This claim, asserted on behalf of the proposed Refund Class, alleges that "Defendant has been and continues to be enriched by their [*sic*] deceptive acts and omissions alleged herein for all states wherein the Refund Class' members reside."[27] Under Pennsylvania law, to state a claim for unjust enrichment, the plaintiff must allege that he conferred a benefit on the defendant, that the defendant knew of the benefit and accepted or retained it, and that it would be inequitable to allow the defendant to keep the benefit without paying for it.[28] "[U]njust enrichment is not a substitute for failed tort claims in Pennsylvania but, instead, will generally be used to imply quasi-contract

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[24] Def.'s Mem. 14.

[25] Compl. ¶ 179.

[26] Cf. In re Diet Drugs, 1999 WL 673066, at *4 (the plaintiffs alleged the monitoring sought, including performing state-of-the art echocardiograms and chest x-rays for each class member).

[27] Compl. ¶ 259.

[28] Mitchell v. Moore, 729 A.2d 1200, 1203 (Pa .Super. Ct.1999).

liability."[29] Plaintiff alleges that he was prescribed Avandia for the treatment of his diabetes and he received the product for which he paid. Plaintiff has not alleged that Avandia did not serve its intended purpose of reducing blood-sugar levels. The allegations that Avandia was not safe, and that GSK knew it was unsafe but promoted the drug anyway, do not give rise to a claim for unjust enrichment.[30]

IV. CONCLUSION

Plaintiff's complaint fails to state any claim upon which relief can be granted. Defendant's motion to dismiss will be granted without prejudice; Plaintiff may file an amended complaint.

An appropriate order will be entered.

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[29] Zafarana, 724 F. Supp. 2d at 560-61 (citations omitted).

[30] Albertson v. Wyeth, Inc., 63 Pa. D.&C.4th 514 (Phila. Ct. Com. Pl. 2003).