

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

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| DAVID K. BIFULCO, | : | CIVIL ACTION |
| Plaintiff, | : | |
| | : | |
| v. | : | NO. 06-3567 |
| | : | |
| SMITHKLINE BEECHAM, et al., | : | |
| Defendant. | : | |

MEMORANDUM

BUCKWALTER, S. J.

September 18, 2007

Presently before the Court are: Defendant Glaxo Smith Kline’s (“GSK”) Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 15); Defendant Donald B. Levin’s (“Dr. Levin”) Motion to Dismiss Plaintiff’s claims against Dr. Levin (Docket No. 17); Defendant Aetna’s Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 18); Plaintiff David Bifulco’s (“Bifulco”) Answer to Motion to Dismiss of GSK (Docket No. 20); Bifulco’s Answer to Motion to Dismiss of Dr. Levin, Magellan Health Services, Inc., Aetna, Rite Aid, and Tina Bazalekos (Docket No. 21); Defendant Magellan Health Services, Inc.’s (“Magellan”) Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 24); Dr. Levin’s Motion to Dismiss (Docket No. 25); GSK’s Motion to Strike Plaintiff’s Amended Complaint (Docket No. 26); Aetna’s Motion to Strike Plaintiff’s Second and Third Amended Complaints (Docket No. 28); Magellan’s Joinder with GSK’s Motion to Strike (Docket No. 29); and Bifulco’s Motions for

Enlargement of Time (Docket Nos. 30, 34)¹. For the reasons set forth below, Plaintiff's Second and Third Amended Complaints are stricken; Plaintiff's claims against Magellan and Aetna are dismissed with prejudice; and Plaintiff's claims against Dr. Levin and GSK are dismissed without prejudice.

I. FACTUAL AND PROCEDURAL BACKGROUND

On July 7, 2006, Plaintiff filed a *pro se* complaint in Philadelphia Court of Common Pleas² against GSK, Dr. Levin, Magellan, Aetna and Rite Aid Corporation alleging negligence in connection with his prescribed use of the drug, Lamictal. Plaintiff claims that he suffered a severe reaction to Lamictal, causing his alcoholism to resurface. As a result, Plaintiff was in a car accident that wrecked his Dodge Durango and inflicted personal injury and property damage to other individuals for which Plaintiff has been held financially responsible.

The remaining defendants in this matter are GSK, Dr. Levin, Aetna and Magellan.³ Lamictal is manufactured by GSK. As treatment for Plaintiff's bi-polar disorder, Dr. Levin prescribed Lamictal, which Plaintiff was instructed to take in addition to other drugs he was already taking.⁴ Aetna was Plaintiff's health insurance provider, and Magellan was the manager for mental health services under Plaintiff's plan with Aetna.

1. Pursuant to the Court's Order dated December 27, 2006, the Plaintiff's request for an extension of time was denied. (Docket No. 37). However, the Court has considered the arguments that Plaintiff made in his letters in ruling on the pending motions of defendants. In essence, the Court has treated Docket Numbers 30 and 34 as Plaintiff's response to defendants' motions.

2. The case was removed to this Court pursuant to Defendant Aetna's Notice of Removal on August 10, 2006. (Docket No. 1).

3. Plaintiff later added a claim for professional liability against Tina Bazalekos, a Pharmacy Manager at Rite Aid. The claims against Bazalekos and Rite Aid were dismissed with prejudice by stipulation of all parties. (Docket No. 39).

4. These drugs included Alprazolam (Xanax), Diazepam (Valium), Lithium and Trazodone.

Rather than recite the entire procedural history of the case, the Court highlights the relevant portions below. Following the removal of this action to federal court, Plaintiff filed an amended complaint on August 30, 2006 (“First Amended Complaint” or “Amended Complaint”). (Docket No. 11). The Amended Complaint contains the following claims: Product Liability against GSK (Count I), Medical Malpractice against Dr. Levin (Count II), General Negligence against Magellan (Count III), and General Negligence against Aetna (Count IV).

Defendants GSK, Dr. Levin, Aetna and Magellan each filed timely Motions to Dismiss Plaintiff’s Amended Complaint (Docket Nos. 15, 17, 18, and 24 respectively). On September 26, 2006, Plaintiff filed an Answer to GSK’s Motion to Dismiss. (Docket No. 20). As part of his Answer, Plaintiff attached another Amended Complaint (“Second Amended Complaint”). On October 2, 2006, Plaintiff filed an Answer to the Motions to Dismiss of Dr. Levin, Magellan and Aetna, to which he attached yet another Amended Complaint (“Third Amended Complaint”) (Docket No. 21).

On October 24, 2006, Dr. Levin filed a second Motion to Dismiss (Docket No. 25). On October 27, 2006, GSK filed a Motion to Dismiss or in the alternative to Strike Plaintiff’s Amended Complaint (Docket No. 26). On November 6, 2006, Aetna file a Motion to Strike Plaintiff’s Second and Third Amended Complaints, or in the alternative, Motion to Dismiss (Docket No. 28). Magellan joined GSK’s Motion to Strike Plaintiff’s Amended Complaint (Docket No. 29).

Plaintiff filed Motions for Enlargement of Time on December 5, 2006 and December 19, 2006 (Dockets No. 30, 34). The Court denied Plaintiff’s Motion for an Enlargement of Time on December 27, 2006. The instant action followed.

II. LEGAL STANDARD

A motion to dismiss pursuant to Rule 12(b)(6) is granted where the plaintiff fails to state a claim upon which relief can be granted. Fed.R.Civ.P. 12(b)(6). When determining a motion to dismiss pursuant to Rule 12(b)(6), the court must accept as true all well pleaded allegations in the complaint and view them in the light most favorable to the Plaintiff. Angelastro v. Prudential-Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir.1985). A Rule 12(b)(6) motion will be granted when a Plaintiff cannot prove any set of facts, consistent with the complaint, which would entitle him or her to relief. Ransom v. Marrazzo, 848 F.2d 398, 401 (3d Cir.1988).

An additional consideration is that the Plaintiff in this case is *pro se*. Allegations in a *pro se* complaint are held to less stringent standards than formal pleadings drafted by lawyers. Henderson v. Fisher, 631 F.2d 1115, 1117 (3d Cir.1980) (citing Haines v. Kerner, 404 U.S. 519 (1972)). Although *pro se* litigants are generally held to less stringent standards, “a *pro se* plaintiff is not excused from complying with the rules of procedural and substantive law.” Hatcher v. Potter, 2005 WL 3348864, at *2 (E.D. Pa. Dec. 7, 2005) (citing Faretta v. California, 422 U.S. 806, 835 n. 46 (1975)). Thus, “if a *pro se* plaintiff has been provided adequate information regarding what is expected of him and has ample opportunity to present opposing affidavits, but has nevertheless continually disregarded his obligations as a litigant, it would not be beyond the discretion of the court to dismiss his claims.” Gay v. Wright, 1990 WL 145553, at * 2 (E.D. Pa. Sep. 27, 1990).

III. DISCUSSION

A. Plaintiff's Second and Third Amended Complaints are Stricken

After a plaintiff has amended his complaint once as a matter of course, he must obtain leave of the court or written consent of the other parties before amending it again. Federal Rule of Civil Procedure 15 ("Rule 15") entitled "Amended and Supplemental Pleadings" in relevant part provides:

A party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served or, if the pleading is one to which no responsive pleading is permitted and the action has not been placed upon the trial calendar, the party may so amend it any within 20 days after it is served. **Otherwise a party may amend the party's pleading only by leave of court or by written consent of the adverse party and leave shall be freely given when the justice so requires.** A party shall plead in response to an amended pleading within the time remaining for the response to the original pleading or within 10 days after service of the amended pleading, whichever period may be the longer, unless the court otherwise orders.

Fed.R.Civ.P. 15(a) (emphasis added). Here, Plaintiff filed his First Amended Complaint on August 30, 2006. Any subsequent amendments required leave of court or consent of the parties. Plaintiff failed to secure either. Because Plaintiff is completely out of compliance with Rule 15, Plaintiff's Second and Third Amended Complaints are stricken.

B. Motions to Dismiss First Amended Complaint

Because Plaintiff's Second and Third Amended Complaints have been stricken, the Court's analysis deals with the Plaintiff's claims in his First Amended Complaint (Docket No. 11). The Court addresses the claims against each of the remaining defendants below.

1. Count II - Dr. Levin

Count II is a Medical Malpractice Claim against Dr. Levin. Plaintiff alleges that Dr. Levin “failed to provide the plaintiff the standard of care required by over prescribing medication and failing to treat the cause of his illness.” Pl. Amended Complaint (Docket No. 11) at ¶ 18. Dr. Levin seeks dismissal of this claim because Plaintiff failed to properly file a Certificate of Merit as required for claims of professional malpractice in Pennsylvania. Pennsylvania Rule of Civil Procedure 1042.3 (“Rule 1042.3”) in relevant part provides:

(a) In any action based upon an allegation that a licensed professional deviated from an acceptable professional standard, the attorney for the plaintiff, or the plaintiff if not represented, shall file with the complaint or within sixty days after the filing of the complaint, a certificate of merit signed by the attorney or party that either

(1) an appropriate licensed professional has supplied a written statement that there exists a reasonable probability that the care, skill or knowledge exercised or exhibited in the treatment, practice or work that is the subject of the complaint, fell outside acceptable professional standards and that such conduct was a cause in bringing about the harm[.]

Pa.R.C.P. 1042.3. Failure to submit the certificate is a possible ground for dismissal when properly presented to the court in a motion to dismiss. McElwee Group v. Municipal Auth. of Borough of Elverson, 476 F.Supp.2d. 472, 475 (E.D. Pa. 2007); Scaramuza v. Sciolla, 476 F.Supp.2d 508, 511 (E.D. Pa. 2004).

Despite Plaintiff’s *pro se* status, Plaintiff was aware of Rule 1042.3 because he attached a document he referred to as a certificate of merit as Exhibit A to his Amended Complaint. In Exhibit A, Plaintiff states:

Based upon the history of the Patient Mr. Bifulco and Dr. Pragna P. Patel’s refusal to treat the patient by prescribing a combination of Xanax, Valium, Trazadone, Lithium and Lamictal, (see attached), creates the existence of a reasonable

probability that the care, skill or knowledge exercised or exhibited in the treatment, practice or work that is the subject of the complaint, fell outside acceptable professional standards and that such conduct was a cause in bringing about harm to the patient.

Pl. Amended Complaint (Docket No. 11), Ex. A. However, Exhibit A, on its face, fails to comply with Rule 1042.3 because nowhere in the statement does Plaintiff aver that an “appropriate licensed professional has supplied a written statement that there exists a reasonable probability that the care, skill or knowledge exhibited or exercised in the treatment, practice or work which is the subject of the Complaint, fell outside the acceptable standards and that such conduct was the cause in bringing about the harm.” See Pa.R.C.P. 1042.3(a)(1).

The sixty day time period for filing a certificate of merit has long since expired – Plaintiff filed his First Amended Complaint on August 30, 2006. Moreover, Plaintiff concedes that he possesses no written statement by a licensed medical professional verifying the merits of his malpractice claim. Plaintiff attributes his failure to be in compliance with Rule 1042.3 due to the fact that “after repeated requests counsel for Defendants Levin and Rite Aid have failed to turn over the records necessary for a medical professional to render and [sic] opinion[.]” Pl. Mot. For Enlargement of Time (Docket No. 30). However, it appears that any deficiency in documentation is attributable to Plaintiff’s failure to provide Dr. Levin’s office with the appropriate HIPAA authorization for the release of Plaintiff’s chart. Levin’s Resp. in Opp’n to Pl.’s Req. for Additional Time (Docket No. 32) at ¶¶ 10, 19. On October 26, 2006, Dr. Levin informed Plaintiff that a HIPAA Authorization was necessary before Dr. Levin could release Plaintiff’s medical records. Id. at Exhibit A. Despite Plaintiff’s repeated assertions that defendants are using unfair tactics, including that opposing counsel is playing “hide the ball,” (Pl.

Ans. to Resp. of Defs. (Docket No. 35)), as of December 14, 2006, Plaintiff has failed to take the simple steps necessary to obtain access to Dr. Levin's file.⁵

Thus, because Plaintiff has failed to fully comply with the requirements of Rule 1042.3, Dr. Levin's Motion to Dismiss the medical malpractice claim against him is granted without prejudice. Despite the fact that the Court does not find Plaintiff's excuse for failing to secure a valid certificate of merit legitimate, because the Plaintiff is *pro se*, the Court will give him one last opportunity to cure the deficiency.⁶ Should Plaintiff independently obtain a medical expert who is willing to supply the written statement required under Rule 1042.3(a)(1), Plaintiff may file a motion for leave to reinstate his medical malpractice claim against Dr. Levin within thirty (30) days of the date of the Order accompanying this Memorandum. A certificate of merit that fully complies with the requirements of Rule 1042.3 must be attached to Plaintiff's motion.

2. Counts III and IV - Aetna and Magellan

Count IV of Plaintiff's First Amended Complaint (Docket No. 11) is a general negligence claim against Aetna and Count III is a general negligence claim against Magellan.

Plaintiff was insured under a policy of health insurance provided by Aetna ("the Plan"). Pl.

Amended Complaint (Docket No. 11) at ¶38; Aetna's Notice of Removal (Docket No. 1) Ex. 2.⁷

5. Apparently, Plaintiff did provide Rite Aid with the appropriate HIPAA Authorization for the release of his pharmacy records. Levin's Resp. in Opp'n to Pl.'s Req. for Additional Time (Docket No. 32), Exhibit B (November 9, 2006 letter from counsel for Rite Aid acknowledging receipt of Plaintiff's HIPAA Authorization and enclosing medical files).

6. See Rodriguez v. Smith 2005 WL 1484591, *7 (E.D.Pa. 2005) (granting medical defendants' Motion to Dismiss without prejudice for plaintiff's failure to fully comply with Rule 1042.3).

7. As Aetna's obligations to the plaintiff stem from the Plan, the court is permitted to consider this document in ruling on the pending motion. In re Burlington Coat Factory Securities Litigation, 114 F.3d 1410, 1426 (3d Cir. 1997) (permitting consideration of extrinsic document that is "integral to or explicitly relied upon in" the complaint). The Court may also consider Magellan's Behavioral Health Agreement with Aetna, which Magellan attached as
(continued...)

The Plan constitutes an employee welfare benefit plan governed by the Employee Retirement Income Security Act (“ERISA”) 29 U.S.C. § 1001, *et seq.* Magellan provided administrative services for Aetna on the mental health and substance abuse benefits of the Plan pursuant to the terms of Magellan’s agreement with Aetna. Def. Magellan’s Mot. to Dismiss (Docket No. 24) at ¶8.

Plaintiff’s claims against Aetna and Magellan are virtually identical. For the sake of simplicity, the Court directly addresses the claim against Aetna, but the analysis applies with equal force to Magellan.

Plaintiff alleges that Aetna was negligent because it knew or should have known that an inappropriate course of treatment and medications were being provided to Plaintiff. Plaintiff claims that Aetna’s “policies and protocols directly contributed to Plaintiff receiving substandard care,” which resulted in personal and financial injuries. Similarly, Plaintiff alleges that Magellan, as the “gatekeeper for mental health services” provided by Plaintiff’s plan with Aetna, was negligent because it should have known that the course of treatment being provided to Plaintiff was wrong and the medications were being over prescribed in inappropriate combinations. Both Magellan and Aetna argue for dismissal on the grounds that Plaintiff’s claim is preempted by ERISA.

Congress enacted ERISA to “protect ... the interests of participants in employee benefit plans and their beneficiaries” by setting out substantive regulatory requirements for employee benefit plans and to “provid[e] for appropriate remedies, sanctions, and ready access to

7. (...continued)
Exhibit C to its Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 24).

the Federal courts.” 29 U.S.C. § 1001(b). ERISA includes expansive pre-emption provisions, see 29 U.S.C. § 1114,⁸ which are intended to ensure that employee benefit plan regulation would be “exclusively a federal concern.” Aetna Health Inc. v. Davila, 542 U.S. 200, 208 (2004) (citation omitted). Any state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted. Id. at 209.

While at the same time recognizing the imprecise nature of its inquiry, the Third Circuit has consistently held that a plaintiff’s state law claims are pre-empted by ERISA if “the claim ‘could have been the subject of a civil enforcement action under § 502(a).’” DiFelice v. Aetna U.S. Healthcare, 346 F.3d 442, 446, 447 (3d Cir. 2003); Pryzbowski v. U.S. Healthcare Inc., 245 F.3d 266, 273 (3d Cir. 2001); Lazorko, 237 F.3d at 250. Section 502(a)(1)(B) allows for civil actions to be brought “by a participant or beneficiary...to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.” 29 U.S.C. § 1132(a)(1)(B). **Thus, the precise issue is whether Plaintiff’s claim of negligence on the part of Aetna falls within the scope of the federal causes of action provided in § 502(a) of ERISA. If so, the existence of the federal claim, while providing the basis for federal jurisdiction, would require dismissal based on complete preemption under § 502(a). DiFelice, 346 F.3d at 446.**

8. ERISA § 514(a) broadly provides “[e]xcept as provided in subsection (b) of this section, the provisions of this title ... shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. § 1144(a). This provision does not provide federal jurisdiction, but merely governs the law that will apply to state law claims, regardless of whether brought in state or federal court. Lazorko v. Pennsylvania Hosp., 237 F.3d 242, 248 (3d Cir. 2000).

As additional guidance on the issue, the Third Circuit has instructed that whether a claim is preempted depends upon whether the claim is challenging the administration of benefits or the quality of medical treatment performed. Pryzbowski, 245 F.3d at 273. ERISA preemption does not apply to the treatment decisions of medical care providers. Id. However, cases that challenge the administration of or eligibility for benefits fall within the scope of § 502(a) and are preempted. Id. Policy decisions “fall within the realm of the administration of benefits.” DiFelice, 346 F.3d at 447 (quoting Pryzbowski, 245 F.3d at 273). In its inquiry, a federal court may “look beyond the face of the complaint to determine whether a plaintiff has artfully pleaded his suit so as to couch a federal claim in terms of state law[.]” Pryzbowski, 245 F.3d at 274.

In the present matter, Plaintiff attempts to couch his claim against Aetna as a mixed eligibility and treatment decision by alleging that “it is the monetary constraints that Aetna’s policies place on health care providers that forces them to provide substandard care.” Pl. Amended Complaint (Docket No. 11) ¶ 42. However, by Plaintiff’s own characterization, his claim against Aetna does not stem from medical treatment decisions by Aetna. In fact, Plaintiff has not alleged that Aetna or its employees engaged in any medical treatment with regard to him. The sole factual basis for Plaintiff’s negligence claim is that when the Plaintiff asked Dr. Levin for longer sessions, “Dr. Levin advised the Plaintiff that the insurance carrier (Aetna) and the mental health provider gatekeeper (Magellan) did not provide for that.” Pl. Amended Complaint (Docket No. 11) ¶ 23. This allegation requires an inquiry into the mental health benefits covered under the Plan, which necessarily concerns the administration of benefits – Aetna’s only role in this case.

There is some Third Circuit precedent for finding no ERISA preemption where the plaintiff alleged that an HMO's policy or financial disincentive structure unduly interfered with a physician's independent medical judgment. See DiFelice, 346 F.3d at 452-53 (finding claim not preempted by § 502(a) where plaintiff alleged that insurance company interfered with his medical treatment by insisting on discharge from hospital); Lazorko, 237 F.3d at 250 (finding claim not subject to preemption where plaintiff alleged that an HMO's financial disincentives discouraged medical providers from hospitalizing a mentally ill woman); In re U.S. Healthcare, Inc., 193 F.3d 151, 162-63 (3d Cir. 1999) (finding that HMO's policy of discharging newborns within 24 hours of delivery was essentially a medical decision and thus not preempted).

However, in 2004, the Supreme Court once again reiterated the broad preemptive force of ERISA § 502(a) in Aetna Health Inc. v. Davila. In that case, the plaintiffs brought suit under THCLA,⁹ a Texas statute, alleging that the defendant healthcare plan administrators' refusals to cover requested services¹⁰ violated their "duty to exercise ordinary care when making health care treatment decisions[.]" Aetna Health, 542 U.S. at 205. The Supreme Court held that the plaintiffs' claims were completely preempted by § 502(a)(1)(B). Id. at 213. The Court rejected the Court of Appeals reasoning that because the Texas statute created an external

9. Texas Health Care Liability Act ("THCLA"), Tex. Civ. Prac. & Rem. Code Ann. §§ 88.011-88.003. Specifically, the plaintiffs brought suit under THCLA § 88.002(a) which provides, "A health insurance carrier, health maintenance organization, or other managed care entity for a health care plan has the duty to exercise ordinary care when making health care treatment decisions and is liable for damages for harm to an insured or enrollee proximately caused by its failure to exercise such ordinary care."

10. Plaintiff Davila complained regarding Defendant Aetna's refusal to pay for his Vioxx prescription, and Plaintiff Calad challenged Defendant CIGNA's decision to refuse coverage for her hospital stay. Aetna Health Inc. v. Davila, 542 U.S. at 211.

statutorily imposed duty of ordinary care, the terms of the plaintiffs' plans were immaterial to their claims. Id. at 215. The Court explained that "interpretation of [plaintiffs'] benefit plans forms an essential part of their THCLA claim, and THCLA liability would exist here only because of [defendants'] administration of ERISA-regulated benefit plans. [Defendants'] potential liability under the THCLA in these cases, then derives entirely from the particular rights and obligations established by the benefit plans." Id. at 213. In other words, any duty which could potentially give rise to liability was inextricably linked to the ERISA governed plan which formed the basis of the parties' relationship.

Due to Plaintiff's *pro se* status, the Court has carefully examined the relevant case law in determining whether Plaintiff's negligence cause of action is preempted by ERISA. While the Plaintiff's claim certainly bears some factual similarities to the Third Circuit cases mentioned above, in light of the Supreme Court's Decision in Aetna Health Inc. v. Davila, the Court finds that Plaintiff's claim is preempted by ERISA. Like the plaintiffs in Aetna Health Inc. v. Davila, Bifulco complains that Aetna violated a duty of care that arose independently of both ERISA and the terms of his benefit plan. From the sparse factual allegations in Plaintiff's Amended Complaint, it is not clear whether he ever sought and/or was denied longer psychiatric sessions, which would make this case more factually similar to the plaintiffs' situation in Aetna Health Inc. v. Davila. Despite this relatively minor factual difference, the Court's reasoning fully applies to the Plaintiff's claims here. The substance of Plaintiff's Plan is certainly material to his state cause of action - in fact, his negligence claim cannot be resolved without an analysis of the Plan. As a result, his claims are not entirely independent of the Plan, which is subject to federal regulation under ERISA. Thus, Counts III and IV fall within the scope of § 502(a) and are

preempted by ERISA. Plaintiff's negligence claims against Aetna and Magellan are dismissed with prejudice.

3. GSK

Count I of Plaintiff's Amended Complaint is a product liability claim against GSK. Plaintiff asserts that GSK "marketed Lamictal as a mood stabilizing drug to mental health professionals as a treatment for bi-polar disorder an[d] are liable under strict liability in tort for products liability under section 402a of Restatement of Torts." Pl. Amended Complaint (Docket No. 11), ¶ 14. GSK responds that, under Pennsylvania law, pharmaceutical companies are not subject to strict liability for injuries arising out of ingestion of prescription drugs.

Section 402A of the Restatement (Second) of Torts allows a plaintiff to recover in strict liability for unreasonably dangerous products. Phillips v. A-Best Products Co., 665 A.2d 1167, 1170-71 (Pa. 1995). However, Pennsylvania courts have repeatedly refused to impose strict liability on manufacturers of prescription drugs. Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996); Incollingo v. Ewing, 282 A.2d 206, 219-20 (Pa. 1971) (abrogated on other grounds). In Hahn, the Pennsylvania Supreme Court cited with approval to comment K of § 402A which "denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." 673 A.2d at 889-90. Accordingly, the court barred the strict liability claim against the pharmaceutical manufacturer and held that "where the adequacy of warnings associated with the prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e. the manufacturer's negligence,

is the only basis of liability. *Id.* at 891. Because 402A strict liability does not apply to prescription drugs, Count I of Plaintiff's Amended Complaint is dismissed.

In light of the leniency that courts must afford to *pro se* litigants, the Court will permit the Plaintiff to file an amended complaint with respect to defendant GSK.¹¹ If the Plaintiff chooses to file an amended complaint, it must be filed in accordance with all applicable rules within thirty (30) days of the date of the accompanying order and shall include any and all actions the Plaintiff has against GSK given the Court's dismissal of Plaintiff's strict liability claim. If filed, this amended complaint shall supersede all previous complaints in this matter.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's Second and Third Amended Complaints are stricken, the Motions to Dismiss of defendants Aetna and Magellan are granted, the Motions to Dismiss of defendants Dr. Levin and GSK are granted without prejudice.

An appropriate order follows.

11. The decision to grant or deny a party the opportunity to amend is within the discretion of the Court and "leave shall be freely given when justice so requires." Fed.R.Civ.P 15(a). "In the absence of any apparent or declared reason ... the leave sought should, as the rules require, be 'freely given.'" *Forman v. Davis*, 371 U.S. 178, 182 (1962). Reasons for a refusal to grant leave to amend include such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of amendment. *Id.*

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

| | | |
|-----------------------------|---|--------------|
| DAVID K. BIFULCO, | : | CIVIL ACTION |
| Plaintiff, | : | |
| | : | |
| v. | : | NO. 06-3567 |
| | : | |
| SMITHKLINE BEECHAM, et al., | : | |
| Defendant. | : | |

ORDER

AND NOW, this 18th day of September, 2007, upon consideration of Defendant Glaxo Smith Kline’s (“GSK”) Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 15); Defendant Donald B. Levin’s (“Dr. Levin”) Motion to Dismiss Plaintiff’s claims against Dr. Levin (Docket No. 17); Defendant Aetna’s Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 18); Plaintiff David Bifulco’s (“Bifulco”) Answer to Motion to Dismiss of GSK (Docket No. 20); Bifulco’s Answer to Motion to Dismiss of Dr. Levin, Magellan Health Services, Inc., Aetna, Rite Aid, and Tina Bazalekos (Docket No. 21); Defendant Magellan Health Services, Inc.’s (“Magellan”) Motion to Dismiss Plaintiff’s Amended Complaint (Docket No. 24); Dr. Levin’s Motion to Dismiss (Docket No. 25); GSK’s Motion to Strike Plaintiff’s Amended Complaint (Docket No. 26); Aetna’s Motion to Strike Plaintiff’s Second and Third Amended Complaints (Docket No. 28); Magellan’s Joinder with GSK’s Motion to Strike (Docket No. 29); and Bifulco’s Motions for Enlargement of Time (Docket Nos. 30, 34), it is hereby **ORDERED** as follows:

(1) Plaintiff's Second and Third Amended Complaints are stricken;

(2) Defendant Aetna's Motion to Dismiss Plaintiff's general negligence claim against it is **GRANTED** and Count IV of Plaintiff's Amended Complaint (Docket No. 11) is **DISMISSED with prejudice**;

(3) Defendant Magellan's Motion to Dismiss Plaintiff's general negligence claim against it is **GRANTED** and Count III of Plaintiff's Amended Complaint (Docket No. 11) is **DISMISSED with prejudice**;

(4) Defendant Dr. Levin's Motion to Dismiss Plaintiff's medical malpractice claim against him is **GRANTED** and Count II of Plaintiff's Amended Complaint (Docket No. 11) is **DISMISSED without prejudice**; and

(5) Defendant GSK's Motion to Dismiss Plaintiff's product liability claim against it is **GRANTED** and Count I of Plaintiff's Amended Complaint (Docket No. 11) is **DISMISSED without prejudice**.

Plaintiff is further instructed as follows. Should he obtain a medical expert who is willing to supply the written statement required under Rule 1042.3(a)(1), Plaintiff may file a motion for leave to reinstate his medical malpractice claim against Dr. Levin within thirty (30) days of the date of the Order accompanying this Memorandum. A certificate of merit that fully complies with the requirements of Rule 1042.3 must be attached to Plaintiff's motion. In addition, the Court will permit the Plaintiff to file an amended complaint with respect to defendant GSK. If the Plaintiff chooses to do so, the complaint must be filed in accordance with all applicable rules within thirty (30) days of the date of the accompanying Order and shall include any and all actions the Plaintiff has against GSK given the Court's dismissal of

Plaintiff's strict liability claim. If filed, this amended complaint shall supersede all previous complaints in this matter.

Judgement is entered in favor of Defendants Aetna and Magellan and against Plaintiff David K. Bifulco.

IT IS SO ORDERED.

BY THE COURT:

s/ Ronald L. Buckwalter

RONALD L. BUCKWALTER, S. J.