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

BRIAN KLINE,	:	
	:	CIVIL ACTION
Plaintiff,	:	
	:	
v.	:	No. 08-3238
	:	
PFIZER, INC.,	:	
	:	
Defendant.	:	
	:	

MEMORANDUM

ROBERT F. KELLY, Sr. J. **OCTOBER 31, 2008**

Presently before the Court is the Motion of Defendant Pfizer, Inc. ("Pfizer") to dismiss Plaintiff Brian Kline's ("Kline") Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, Pfizer's Motion to Dismiss is granted with respect to Counts II, III, IV, V, VI, VIII and IX of the Plaintiff's Complaint. Counts I and VII survive the Motion to Dismiss.

I. FACTS

Defendant Pfizer is a prescription drug manufacturer responsible for the manufacture and distribution of the prescription smoking cessation drug, Chantix. Kline was prescribed and began using Chantix in July 2007. Shortly thereafter, Kline asserts that he began experiencing "manic behavior, aggressive and violent behavior and diagnosis of psychotic disorder for which [he] was hospitalized in August 2007." (Compl. ¶¶ 11, 19.) On July 10, 2008, Kline filed a Complaint against Pfizer in this Court, alleging that his symptoms were caused by his use of Chantix and that Pfizer had failed to adequately warn Kline, Kline's physician and the public of

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the dangers of ingesting the drug. The Complaint asserts a host of claims against Pfizer, including: negligence (Count I); strict liability (Count II); breach of express warranty (Count III); breach of implied warranty (Count IV); fraudulent misrepresentation (Count V); fraudulent concealment (Count VI); reckless and/or negligent misrepresentation & concealment (Count VII); gross negligence (Count VIII); and unjust enrichment (Count IX). Pfizer moved to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) on September 9, 2008. Kline filed his Response in Opposition on October 7, 2008.

II. STANDARD OF REVIEW

When deciding whether to grant a Rule 12(b)(6) Motion to Dismiss, this Court must accept as true all well-pleaded allegations in the Complaint, and view them in a light most favorable to the Plaintiff. Doe v. Delie, 257 F.3d 309, 313 (3d Cir. 2001). Therefore, Defendant's Motion will be granted only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. Id. Nonetheless, a plaintiff must plead specific factual allegations. Neither "bald assertions" nor "vague and conclusory allegations" must be accepted as true. See Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997); Sterling v. Southeastern Pa. Transp. Auth., 897 F. Supp. 893 (E.D. Pa. 1995).

III. DISCUSSION

Pfizer moves to dismiss Kline's Complaint on several grounds. First, Pfizer argues that Kline's claim for strict liability (Count II), should be dismissed pursuant to the Pennsylvania Supreme Court's holding in Hahn v. Richter, which announced that prescription drugs are exempt from strict liability, and that failure to warn claims against drug manufacturers may be pursued under a negligence theory only. 673 A.2d 888, 891 (Pa. 1996). With regard to Kline's

claims for breach of implied warranty and gross negligence (Counts III and VIII), Pfizer argues that Pennsylvania law does not recognize such claims in the context of this case. Pfizer also asserts that Kline's fraud claims (Counts V and VI) fail under Rule 9(b) for failure to plead fraud with particularity, and that the facts alleged in the Complaint do not make out viable claims for breach of express warranty or unjust enrichment (Counts III and IX). Additionally, Pfizer asks this Court to dismiss the Complaint to the extent that it asserts liability against Pfizer for failure to warn Kline and/or the public.

In contrast, Kline argues that the allegations in the Complaint are sufficiently pled, and that he is entitled to relief on all counts. Specifically, he asserts that Pfizer attempts to dismiss his claims based on an overly-broad reading of Hahn and urges this Court to take a more narrow interpretation of the case. Additionally, Kline argues that each claim contains allegations specific enough to survive the Motion to Dismiss.

A. Non-negligence claims and Hahn v. Richter

Federal courts sitting in diversity must apply the substantive law of the forum state. Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938). Here, neither party disputes that Pennsylvania law controls the allegations set forth in Kline's Complaint. Pennsylvania has adopted the Restatement (Second) of Torts § 402A(1), which imposes strict liability upon sellers of unreasonably dangerous products. Restatement (Second) of Torts § 402A(1) (1965) ("Restatement"). Nonetheless, comment k to § 402A provides an exception to the rule of strict liability for the makers of "unavoidably unsafe products." Comment k reads:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the

> field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement § 402A(1) cmt. k. Pennsylvania courts have made clear that prescription drugs are "unavoidably unsafe products" within the meaning of comment k, and therefore, strict liability will not be imposed against manufacturers in suits for injuries relating to the use of prescription drugs. See Hahn, 672 A.2d at 889-90; Incollingo v. Ewing, 282 A.2d 206, 219-20 (Pa. 1971).

In Hahn, a suit against a prescription drug manufacturer based on failure to warn, the Pennsylvania Supreme Court explicitly stated that "[s]ince the strict liability rule of § 402A is not applicable, the standard of care required is that set forth in § 388 of the Restatement . . . . Under this section, the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." 673 A.2d at 890. As such,

the Hahn Court, relying on long line of Pennsylvania cases, held that where the adequacy of the warnings accompanying prescription drugs is at issue, negligence is the sole avenue of recovery. Id. (referencing Mazur v. Merck & Co., Inc., 964 F.2d 1348, 1353-55 (3d Cir. 1992); Baldino v. Castagna, 478 A.2d 807 (Pa. 1984); Incollingo, 282 A.2d at 220 n. 8).

Since Hahn, Pennsylvania courts, as well as federal courts applying Pennsylvania law, have consistently held that negligence is the only theory upon which a prescription drug manufacturer can be held liable for failure to warn. See Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006); Lineberger v. Wyeth, 894 A.2d 141, 145 (Pa. Super. Ct. 2006); Luke v. Am. Home Prod. Corp., No. 1998-01977, 1998 WL 1781624, at *7 (Pa. Commw. Ct. Nov. 18, 1998). In Colacicco, the Plaintiff brought suit against a prescription drug manufacturer for failure to warn, and asserted many of the same claims that Kline asserts in the present action.[1] 432 F. Supp. 2d at 518-20. There, the Court found that the Plaintiff's non-negligence claims must be dismissed under the rule of Hahn. Id. at 548. The Colacicco Court found that, after Hahn, it was clear that negligence was the sole cause of action that a Plaintiff may maintain against a prescription drug manufacturer for failure to warn under Pennsylvania law. Id. at 547-48. As such, Hahn requires that this Court dismiss those of Kline's claims that do not rest on a theory of negligence.

B. Claims Sounding in Negligence

With respect to Kline's negligence-based claims, the Complaint alleges three claims

[1]The Complaint in Colacicco asserted the following claims: breach of express warranty (Count I); breach of implied warranty (Count II); fraud by intentional misrepresentation and violation of New York consumer protection law (Count III); negligent misrepresentation (Count IV); intentional infliction of emotional distress (Count V); negligent infliction of emotional distress (Count VI); negligence (Count VII); negligence per se (Count VIII); and strict products liability (Count IX). 432 F. Supp. 2d at 518, 548. The Plaintiff later withdrew the claim for breach of express warranty. Id. at 518.

sounding in negligence: Count I asserts a claim for negligence; Count VII asserts a claim for reckless and/or negligent misrepresentation & concealment; and Count VIII asserts a claim for gross negligence.

With respect to Kline's claim for gross negligence (Count VIII), we find that this claim must be dismissed. Pennsylvania courts do not recognize degrees of negligence. Floyd v. Brown & Williamson Tobacco Corp., 159 F. Supp. 2d 823, 828 (E.D. Pa. 2001) (applying Pennsylvania law). Rather, Pennsylvania courts regard the term "gross negligence" as referring to a standard of care, rather than a separate, independent claim. Id. Thus, the claim for gross negligence must be dismissed.

To the extent that Kline's claims for negligence (Count I) and negligent misrepresentation & concealment (Count VII) rest on allegations that Pzifer failed to adequately warn Kline's physician concerning the dangers and possible side effects of using Chantix, these claims remain intact. It is well-settled that under Pennsylvania's "learned intermediary doctrine," the duty of a drug manufacturer to warn of the possible dangers and side effects of prescription drugs runs to the physician, and not to the patient or to the general public. Baldino, 478 A.2d at 812 (citing Incollingo, 282 A.2d at 220); Lineberger, 894 A.2d at 149-50; Makripodis v. Merrell-Dow Pharm. Co., 523 A.2d 374, 377-78 (Pa. Super. Ct. 1987). A prescription drug manufacturer has "'a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous . . . .' However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer." Makripodis, 523 A.2d at 378 (quoting Incollingo, 282 A.2d at 220 n. 8). This is so because the physician acts as a "learned intermediary" between the manufacturer and consumer,

and can use the information obtained from the manufacturer, as well as his independent medical knowledge and knowledge of the patient's medical history, in deciding whether or not to prescribe a certain prescription to a certain patient. Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449, 457 (Pa. Super. Ct. 1973). Kline's Complaint alleges that Pfizer failed to adequately warn Kline himself, Kline's physician, and the public concerning the dangers of Chantix. As noted above, Pfizer had no duty under Pennsylvania law to warn Kline or the public of the dangers potentially caused by the use of Chantix. However, Pfizer could be held liable if it is later proven that it failed to adequately warn Kline's healthcare providers as to the dangers of the drug. As such, to the extent that Kline's claims for negligence and negligent misrepresentation & concealment rest upon allegations that Pfizer failed to adequately warn Kline's physician, these claims survive the Motion to Dismiss.

Because we find that Kline's non-negligence claims are barred by the Pennsylvania's Supreme Court's holding in Hahn, we need not go into detail concerning Pfizer's additional arguments for dismissal. We find that Kline's claims for strict liability (Count II); breach of express warranty (Count III); breach of implied warranty (Count IV); fraudulent misrepresentation (Count V); fraudulent concealment (Count VI); and unjust enrichment (Count IX) are barred by the holding of Hahn and must be dismissed. Similarly, the claim for gross negligence (Count VIII) must be dismissed, as Pennsylvania law does not recognize gross negligence as an individual claim. Kline's claims for negligence (Count I) and negligent misrepresentation & concealment (Count VII) survive to the extent that they assert liability for failure to adequately warn Kline's physician.

An appropriate Order follows.

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PFIZER, INC.,	:	
Defendant.	:	

ORDER

AND NOW, this 31st day of October, 2008, upon consideration the Defendant's Motion to Dismiss Plaintiff's Complaint pursuant to Rule 12(b)(6) (Doc. No. 6), and the response thereto, it is hereby **ORDERED** as follows:

1) The Motion to Dismiss is **GRANTED** with respect to Counts II, III, IV, V, VI, VIII and IX of Plaintiff's Complaint;

2) The Motion to Dismiss is **DENIED** with respect to Counts I and VII.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
SENIOR JUDGE