UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

CIVIL ACTION NO. 3:94CV-634-H

JAMES CLARK and
BONNIE E. CLARK PLAINTIFFS

V.

DANEK MEDICAL, INC. DEFENDANT

MEMORANDUM OPINION

Over the past eight months the Court has had an opportunity to consider various claims arising from Plaintiff James Clark receiving a Texas Scottish Rite Hospital spinal system ("TSRH system") implant manufactured by Danek Medical, Inc. ("Danek").[1] In its Memorandum Opinion and Order dated March 26, 1999, the Court dismissed plaintiffs' claims for negligence per se, product liability (under both negligence and strict liability theories), and breach of warranty. A few months later the Court denied Plaintiffs' motion to alter or amend that dismissal. At that time, no other claims were pending. However, during that interim, Plaintiffs moved for leave to amend their complaint to include causes of action for fraud on the United States Food and Drug Administration (FDA) and for negligent misrepresentation to the FDA.[2] In this memorandum, the Court considers the motion to amend.

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[1] The specific facts alleged in this case are already established as detailed in the Court's earlier Memorandum Opinion. *See Clark v. Danek Medical, Inc.*, No. 3:94CV-634-H, slip op. at 2–4 (W.D. Ky. Mar. 26, 1999).

[2] Plaintiffs' counsel first mentioned the likelihood of an amendment during a conference earlier this year. Thus, it was no surprise to the Court that such a motion has been filed. However, Plaintiffs' proposed amended complaint also included causes of action for negligence per se, negligence, strict liability for defective design, failure

Pursuant to Rule 15 of the Federal Rules of Civil Procedure, plaintiffs may amend their pleading only by leave of the court; such leave "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Though freely given under the proper circumstances, leave to amend a complaint will be denied for valid reasons, including "futility of the amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Crawford v. Roane*, 53 F.3d 750, 753 (6th Cir. 1995).[3]

A proposed amendment to a complaint is futile if the amended pleading could not withstand a motion to dismiss for failure to state a claim upon which relief may be granted. *See United States v. Wood*, 877 F.2d 453, 456 (6th Cir. 1989). Therefore, the Court should grant plaintiffs leave to amend their complaints unless, construing all factual allegations in the proposed complaint as true and resolving all factual questions in their favor, their claim for fraud on the FDA fails as a matter of law. *See Roth Steel Prods. v. Sharon Steel Corp.*, 705 F.2d 134, 155 (6th Cir. 1983).

Essentially, Plaintiffs' new causes of action allege that Danek misrepresented, either intentionally or negligently, the proposed use of the TSRH system in its application for approval of the system by the FDA, and that, "[a]s a direct and proximate result of Danek's misrepresentations" or fraud, the FDA approved the TSRH system, Dr. Glassman implanted the system on Plaintiff James Clark during surgery, and the TSRH system injured Plaintiffs.

In January 1995, when this case was originally transferred to the Eastern District of

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to warn, and loss of consortium. Because these claims are substantially identical to those already dismissed, the Court need not entertain their reassertion in the proposed amended complaint.

[3] The circumstances which might explain why such a claim was neglected until this last moment are somewhat confused. It would serve no particular purpose to detail them here. The delay forms the basis of Danek's serious objections to Plaintiffs' proposed amended complaint based upon the likelihood of "undue prejudice to the opposing party by virtue of allowance of the amendment." *Foman*, 371 U.S. at 182. Though these objections may well have merit, due to the disposition of Danek's futility objection, the Court will not address prejudice in this Memorandum Opinion.

Pennsylvania for the multi-district litigation ("MDL") proceedings, many similar FDA fraud claims were present in other MDL cases. The MDL judge dismissed them in March 1995. In its November 17, 1998, opinion, the Third Circuit Court of Appeals reversed that dismissal, holding that the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938 ("MDA") do not preempt state common law fraud actions, and that whether a particular plaintiff's FDA fraud allegations meet the specific elements of fraud is a matter of state law. *See In re Orthopedic Bone Screw Prods. Liability Litig. (Buckman)*, 159 F.3d 817, 822–29 (3d Cir. 1998), *petition for cert. filed*, 67 U.S.L.W. 3684 (U.S. May 3, 1999) (No. 98-1768). Therefore, if Plaintiffs' new complaint states a valid claim, it must be under Kentucky's common law torts of fraudulent misrepresentation or negligent misrepresentation, not under any express or implied federal private right of action. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 & n.7 (1996).

Kentucky common law recognizes six elements for the tort of fraudulent misrepresentation: "(1) that defendant made a material representation; (2) that it was false; (3) that when he made it he knew it was false, or made it recklessly, without any knowledge of its truth and as a positive assertion; (4) that he made it with the intention of inducing plaintiff to act, or that it should be acted upon by the plaintiff; (5) that plaintiff acted in reliance upon it; and (6) that plaintiff thereby suffered injury." *Cresent Grocery Co. v. Vick*, 240 S.W. 388, 389 (Ky. 1922); *see also Progressive Specialty Ins. Co. v. Rosing*, 891 F. Supp. 378, 379 (W.D. Ky. 1995); *Keeneland Ass'n, Inc. v. Eamer*, 830 F. Supp. 974, 993 (E.D. Ky. 1993). If Plaintiffs' FDA fraud claim cannot meet each of these six elements, it cannot survive a motion to dismiss for failure to state a claim, and the motion to amend the complaint will be dismissed for futility. Defendant argues that Plaintiff has failed to allege a claim that satisfies the elements of material

representation, reliance, and causation.[4]

The Court has carefully considered the proposed claim in the context of the instant facts. More important than the claim's satisfaction of any of the individual six fraud elements is whether Plaintiffs' fraud allegations attempt to apply Kentucky's tort of fraud to the wrong victim or in an unprecedented manner. In substance, Plaintiffs are claiming that Danek defrauded the FDA, and that, but for such fraud, the TSRH system would not exist in the medical device market, and Plaintiffs would have suffered no injuries. Plaintiffs do not contend that Mr. Clark himself or his physician were "taken in" by the fraud, or that they labored under a belief in Danek's assertion to the FDA that the TSRH system was intended solely for sacral spine use. Their failure to allege such facts has significant consequences for the analysis which follows.

Kentucky is one of those states whose tort law does not require strict privity between the defendant and the ultimately defrauded party. In *Highland Motor Transfer Co. v. Heyburn Bldg. Co.*, 35 S.W.2d 521 (Ky. 1931), the Kentucky Court of Appeals held that the "right to recover

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[4] Since the Third Circuit's decision that FDA fraud claims might go forward under the laws of individual states, *see Buckman*, 159 F.3d at 822–29, many district courts have wrestled with the appropriateness of a fraud claim under applicable state law. Generally, they have concluded that the claims must fail for lack of proximate causation between the alleged fraud on the FDA and the resulting injury to a patient receiving the implanted device. *See, e.g., Murray v. Synthes (U.S.A.), Inc.*, No. Civ. A. 95-7796, 1999 WL 672937, at *3 (E.D. Pa. Aug. 23, 1999); *McCollin v. Synthes, Inc.*, No. 2:95CV1097C, 1999 WL 376090, at *9 (D. Utah May 27, 1999); *Burton v. Danek Medical, Inc.*, No. CIV. A. 95-5565, 1999 WL 118020, at *6 (E.D. Pa. Mar. 1, 1999); *West v. Danek Medical, Inc.*, No. CIV-97-575-T, 1998 WL 1041327, at *4 (W.D. Okla. Dec. 28, 1998). Though there is a strong argument that plaintiffs' injuries were not proximately caused by the alleged fraud, this Memorandum Opinion uses a different approach.

The Court is aware of only one post-*Buckman* decision allowing an FDA fraud claim to proceed under a state tort law. *See Price v. Danek Medical, Inc.*, No. CIV 95-1651-JO, 1999 WL 588171, at *2–*4 (D. Or. July 23, 1999). The *Price* court allowed an FDA fraud claim to go forward after holding that the Oregon tort laws do not require privity between the defrauded party and the defendant. Though Kentucky similarly excuses the need for privity of fraud, as the Court will discuss below, Kentucky tort law seems to allow the claims of plaintiffs who were not in privity to the original fraud only where they were within the sphere of people intended to be "taken in" by the fraud, believed the representation or concealment to be true, relied upon it, and suffered damage directly flowing from the fraud. Unlike Kentucky courts, "Oregon courts would dispense with the reliance element" in an FDA fraud claim. *Id.* at *2.

for deceit should not be restricted to the immediate parties making the contract. If a third party is injured by the deceit, he should be allowed to recover against the one who made possible the damages to him by practicing the deceit in the first place." *Id.* at 523–24. Taken literally, this language seems to allow recovery for any injury flowing from an original fraud. Nevertheless, Kentucky courts would not give a plaintiff *carte blanche* to assert any type of third party claim. The facts of *Highland Motor* and other Kentucky fraud cases sketch out some logical limitations of recovery for plaintiffs without privity to the fraud. In this Court's view, Kentucky state courts would certainly recognize these limitations.

In *Highland Motor*, the developer of an office building failed to disclose to its general contractor the existence of a marble and concrete swimming pool buried under the ground at the construction site. A subcontractor entered a fixed price agreement with the general contractor for the excavation work. The court held that the subcontractor could allege a claim for fraudulent or negligent concealment against the developer, since the "subcontractor did not bid as much as it would have if it had known the truth about the situation." *Id.* at 522. The court allowed the case to go forward even without privity. However, in that instance, the plaintiff was directly induced and "taken in" by the defendant's concealment.

Similarly, in *Graham v. John R. Watts & Son*, 36 S.W.2d 859 (Ky. 1931), a wholesaler sold fraudulently packaged alfalfa seed to a farm products retailer, who in turn sold the seed to a farmer. The ultimate consumer labored under the same misrepresentation that was the basis of the original fraud, so the Court of Appeals allowed his misrepresentation claim to proceed against the wholesaler in spite of a lack of privity. *See id.* at 860–62; *see also Cleveland Wrecking Co. v. Struck Constr. Co.*, 41 F. Supp. 70, 74–75 (W.D. Ky. 1941).

Danek's alleged fraud and the Clarks' injuries supposedly arising from it simply fall outside the logical and reasonable limits of a fraud claim without privity as described in *Highland Motor* and *Graham*. Those cases come "within the general rule and form[] no exception to it, i.e., that only the person to whom the representation is made may act upon it, and, if damaged thereby, he may maintain an action for deceit against the one who made it." *Graham*, 36 S.W.2d at 862. Danek made no representation to the Clarks. More important, no one else repeated the alleged misrepresentations to the Clarks. They could not be defrauded by Danek's alleged statements to the FDA since the Clarks never believed or relied upon those statements. Thus, their injuries have no direct relationship or nexus to the alleged original fraud. *See Loewy v. Stuart Drug & Surgical Supply, Inc.*, No. 91 CIV. 7148 LBS, 1999 WL 76939, at *4 (S.D.N.Y. Feb. 11, 1999) ("because Plaintiff has made no showing of any nexus between herself and [the manufacturer's] representations to the FDA, Plaintiff cannot succeed on a theory of fraud or misrepresentation arising from [the manufacturer's] statements to that agency"). The Kentucky courts, in allowing appropriate fraud claims to proceed absent privity, did not intend to make actionable any claim regardless of its tangential relationship to the alleged fraud. *See Snyder v. Rhinehart*, 118 S.W.2d 543, 547 (Ky. 1938) ("[b]efore a party can be defrauded the perpetrator of the fraud must make false statements or representations which the other party believes and acts upon"). That theoretically the device may not have come to market absent the alleged fraud is not sufficient to state a claim for injuries flowing from that fraud.

"The very essence of actionable fraud or deceit is the belief in and reliance upon the statements of the party who seeks to perpetrate the fraud. Where the plaintiff does not believe the statements or where he has knowledge to the contrary recovery is denied." *Wilson v. Henry*,

340 S.W.2d 449, 451 (Ky. 1960) (citations omitted); *see also Sita v. Danek Medical, Inc.*, 43 F.Supp.2d 245, 260 (E.D.N.Y. 1999) (New York FDA fraud claim fails for lack of reliance). The Plaintiffs have made no allegations of their belief in and reliance upon Danek's representations to the FDA. Dr. Glassman was not influenced by the alleged fraud. His legal use of the device is, therefore, quite disconnected from any fraud on the FDA. In the final analysis, the Court finds a fundamental disjunction between the purpose and definition of the Kentucky tort and the damages allegedly suffered by plaintiffs.

The tort of negligent misrepresentation differs from fraudulent misrepresentation only in that the former tort demands only that a false representation or concealment be made negligently, rather than recklessly or with knowledge of its falsity. *See Ingram Industries, Inc. v. Nowicki*, 527 F. Supp. 683, 684 (E.D. Ky. 1981); William S. Haynes, Ky. Jur. *Torts* § 10-5, at 274 (1987 & Supp. 1998). Under this standard, the requirements of a nexus to the misrepresentation are not met by the Clarks' proposed amended complaint. The Clarks were not misguided by Danek's allegedly negligent failure to disclose the TSRH system's intended use; they claim injury flowing only from the existence of the device in the market. Consequently, plaintiffs' cause of action for negligent misrepresentation suffers from the same deficiencies of nexus and reliance as does its fraud claim.

Accordingly, the Court finds that the proposed amended complaint fails to state any claim upon which relief may be granted, rendering it futile. The Court shall enter an Order consistent with this Memorandum Opinion.

JOHN G. HEYBURN II
JUDGE., U.S. DISTRICT COURT

cc: Counsel of Record

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ORDER

Plaintiffs have moved for leave to amend their complaint. Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Plaintiff's motion for leave to amend the complaint is DENIED.

IT IS FURTHER ORDERED that Plaintiffs' complaint is now stricken from the Court's docket.

This order and all previous orders in this case are now final and appealable.

This _____ day of September, 1999.

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JOHN G. HEYBURN II
JUDGE, U.S. DISTRICT COURT

cc: Counsel of Record