

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY  
SOUTHERN DIVISION  
PIKEVILLE

WHITNEY SMITH, et al.,	)	
	)	
Plaintiffs,	)	Civil Action No. 10-73-ART
	)	
v.	)	
	)	<b>MEMORANDUM OPINION &amp;</b>
SMITHKLINE BEECHAM CORP., et al.,	)	<b>ORDER</b>
	)	
Defendants.	)	

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The plaintiff alleges that a first trimester prescription for Paxil caused her son’s birth defects. She is suing Paxil’s manufacturers along with her physician. The physician, like the plaintiff, is a Kentucky citizen. The defendants removed to federal court on the theory that the physician was fraudulently joined, and thus his presence in the case does not defeat removal. R. 1 at 4-5. But the plaintiff states a colorable claim that her physician prescribed Paxil during her first trimester—despite generally available information that doing so is dangerous—and therefore proximately caused her son’s injuries. As a result, the motion to remand, R. 17, is granted.

### BACKGROUND

Several of the defendants—the “GSK defendants”—manufacture and/or market Paxil. R. 1, Attach. 1 at 7. As early as September 2005, third-party research allegedly revealed that taking Paxil while pregnant causes birth defects. *Id.* at 14. In December 2005, the FDA issued a Public Health Advisory bulletin reporting that the use of Paxil in a woman’s first trimester increased the risk of “congenital malformations, including cardiac malformations.” *Id.* at 15.

The bulletin warned physicians caring for women on Paxil to alert them to these risks should they become pregnant. *Id.* The FDA issued additional warnings in July 2006. *Id.* at 16. Accordingly, from September 2005 through October 2008, Paxil’s label described the risk of taking Paxil during the first trimester. *Id.* at 14-15, 16-17.

The GSK defendants allegedly were aware of the dangers of Paxil but nonetheless continued to promote it to pregnant women. *Id.* at 14. They assertedly failed to reclassify the drug as one which poses a risk of fetal abnormalities, *id.* at 17, or issue adequate warnings, *id.* at 18. And they reportedly misrepresented the risks to physicians who depend upon accurate information to decide whether to prescribe the drug. *Id.* at 33-36.

In October 2008, Dr. Tom McGuire of Kentucky allegedly prescribed Paxil to the plaintiff in the first trimester of her pregnancy without an appropriate warning. *Id.* at 14, 38. The plaintiff contends that Dr. McGuire therefore deviated from the appropriate standard of care and caused her son’s birth defects. *Id.* at 35-37. The question here is whether this is at least a colorable claim.

## **DISCUSSION**

The defendants bear the burden of justifying removal, *Alexander v. Elec. Data Sys. Corp.*, 13 F.3d 940, 948-49 (6th Cir. 1994), and their burden is particularly heavy here. The physician defendant<sup>1</sup> is a Kentucky resident and therefore, if properly joined, would prevent removal. R. 1, Attach. 1 at 12-13; *see also* 28 U.S.C. § 1441(b) (“Any other such action shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the

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<sup>1</sup> Dr. McGuire’s practice is also a defendant, but both will be referred to as “Dr. McGuire.”

state in which such action is brought.”); 28 U.S.C. § 1332. The defendants insist that Dr. McGuire was fraudulently joined. But this claim is a tough sell. There can be no fraudulent joinder of a defendant unless the plaintiff fails to state even a “colorable” claim against him. *Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999). In other words, “the question is whether there is arguably a reasonable basis for predicting that the state law might impose liability on the facts involved.” *Alexander*, 13 F.3d at 949 (internal quotation marks and citation omitted). “Several courts have noted that the standard for a defendant to show fraudulent joinder is even higher than the standard for succeeding on a motion to dismiss[.]” *Cordle v. Merck & Co.*, 405 F. Supp. 2d 800, 803 (E.D. Ky. 2005) (citations omitted).<sup>2</sup>

### **I. Inconsistent pleadings**

The defendants first argue that the negligence claim against Dr. McGuire represents fraudulent joinder because it is inconsistent with the claims against the GSK defendants. R. 1 at 8-13. Those defendants allegedly concealed the risks of Paxil for pregnant women from the medical community. In the face of such opacity, the plaintiffs allege, “physicians, including Ms. Smith’s doctor(s) and healthcare providers, cannot act in accordance with the professional and fiduciary obligations owed to the patient[.]” R. 1, Attach. 1 at 33-34; *see also id.* at 34

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<sup>2</sup> The *Cordle* court continued: “Any ambiguities in the relevant state law must be taken in the light most favorable to Plaintiff. . . . Thus, the question before the Court is not whether Plaintiff will prevail at trial on his claim against the physician. The question is not even whether the Court believes that the physician was in fact joined to defeat diversity. . . . The question is whether, resolving all ambiguities in favor of Plaintiff, Merck has shown that there is no colorable basis for predicting that Plaintiff could prevail in state court.” 405 F. Supp. 2d at 802-03.

(“Concealing adverse information and providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician’s professional judgment, as was the case with Ms. Smith and her doctor(s) and healthcare providers.”). These allegations, argue the defendants, “fundamentally preclude” the negligence claim against the doctor because that claim assumes he had knowledge of Paxil’s risks. R. 1 at 9-10.

To begin, this argument cannot be squared with the applicable pleading rules. Both the Kentucky and Federal Rules of Civil Procedure<sup>3</sup> allow plaintiffs to enter alternative or inconsistent pleadings. *Cordle v. Merck & Co.*, 405 F. Supp. 2d 800, 805-06 (E.D. Ky. 2005).

And, as another member of this Court has recognized, a plaintiff in Ms. Smith’s shoes can still state a colorable claim against her prescribing physician—at least where the complaint alleges that information about the drug’s risks was otherwise available. In *Cordle v. Merck & Co.*, 405 F. Supp. 2d at 800, the plaintiff patient sued Merck for concealing the cardiovascular risks of Vioxx. The plaintiff also sued his doctor for prescribing the drug because he knew or should have known of its dangers. *Id.* at 802. The defendants removed, arguing that the doctor was fraudulently joined because the claims were fundamentally inconsistent. *Id.* at 803. But because “the risks of Vioxx were publicly known at various times notwithstanding Merck’s concealment,” the claim against Merck was not “necessarily inconsistent with the allegations against the physician.” *Id.* at 805; *see also Melton v. Merck & Co.*, No. 06-45, 2006 WL

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<sup>3</sup> That court applied the Kentucky rule, but the Federal Rules more likely apply. *See Jessen v. Aetna Life Ins. Co.*, 209 F.2d 453, 458 (7th Cir. 1954) (holding that Fed. R. Civ. P. 8’s allowance of alternative pleading is a procedural rule and therefore applies in diversity cases).

1543036, at \*3 (E.D. Ky. June 1, 2006) (same); *Hedges v. Pfizer, Inc.*, No. 05-442, 2006 WL 197054, at \*6 (E.D. Ky. Jan. 20, 2006) (same).

Here, the plaintiff alleges that information about Paxil's dangers was independently available, and so she states a colorable claim. She alleges that a third-party group and the FDA revealed the risks in 2005 and 2006, before her 2008 prescription. R. 1, Attach. 1 at 15-16. In fact, the product itself purportedly included a warning label. *Id.* at 14, 16-17. Because physicians' duty of care requires that they stay abreast of medical developments, the availability of this information provides a reasonable basis for the plaintiff's claim. *Stacy v. Williams*, 69 S.W.2d 697, 704 (Ky. 1934) (“[A physician] is bound to keep abreast of the times, and a departure from approved methods in general use, if it injures the patient, will render him liable[.]”); 61 Am. Jur. 2d, Physicians, Surgeons, Etc. § 197 (“Physicians have a duty to keep reasonably abreast of current advances in their field.”).

None of the defendants' responses is convincing. First, the defendants cite to a series of cases in other districts which purportedly reached the opposite result. R. 1 at 10. But, in those cases, it is not clear that the plaintiffs alleged that risk information was independently available. In *Baisden v. Bayer Corp.*, to take one example, the court disregarded the only allegation that information about the dangers of the drug was independently available because the documents and claims supporting that allegation were not attached to the amended complaint at the time of removal. 275 F. Supp. 2d 759, 763 (S.D. W.Va. 2003). What's more, even if the complaints in those cases did allege that information was independently available, the conclusion that the resultant inconsistency invalidates the claims against the physicians cannot be squared with Fed.

R. Civ. P. 8(d)'s authorization of alternative pleading. *See City of Kingsport v. Steel & Roof Structure, Inc.*, 500 F.2d 617, 617 (6th Cir. 1974) (noting that Rule 8 "allows the pleading of inconsistent claims and defenses").

Second, the defendants argue that the complaint specifically alleges that Dr. McGuire himself was misled by the GSK defendants' misrepresentations, and so he could not possibly have had an understanding of the "full extent of Paxil's risks" sufficient to trigger his duty of care. R. 1 at 12-13; R. 22 at 23-24. But even if Dr. McGuire was specifically misled by the GSK defendants' misrepresentations and therefore unable to fully "assess the crucial risk/benefit balance for the patient or exercise professional judgment," R. 1, Attach. 1 at 31, the plaintiff could still present a colorable claim that the doctor breached his duty of care. Perhaps he was not *completely* informed about the full extent of the risks but nonetheless had enough warning from independent sources that his duty of care required a different course. And, again, even if the two claims were irreconcilable, the Federal Rules specifically authorize alternative pleading.

Finally, the defendants argue that the information available from independent sources merely duplicated what was already on Paxil's warning label. R. 22 at 22-23. The inference seems to be that doctors can have no duty to independently weigh the risks of prescribing a drug with a warning label or warn the patient of information listed on a product's label. Yet, the defendants offer no authority for this proposition, and it is unclear from the complaint that the warning label would even have been included on the package ultimately distributed to patients. R. 1, Attach. 1 at 14-17. Further, Kentucky law presupposes that warnings from manufacturers are directed to physicians, not patients. Under the so called "learned intermediary doctrine," drug

manufacturers have a duty to warn physicians about a drug's dangers because "the prescribing physician is in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient." *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763 (Ky. 2004). This is because "only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy." *Id.* The implication is that, because of his superior knowledge, the onus is on the physician to exercise his professional judgment as to whether to write a prescription on the basis of manufacturer warnings and also to translate those warnings to the patient.

## **II. Proximate cause**

Next, the defendants argue that the plaintiff failed to adequately plead that Dr. McGuire's negligence "proximately caused" her injuries and therefore has not presented a colorable claim. R. 1 at 13. In the complaint, the defendants note, the plaintiff concludes the section outlining the allegations against Dr. McGuire with a (clearly inadvertent) contention that the *GSK defendants* "proximately" caused the plaintiff's injuries. R. 1, Attach. 1 at 38-39. And the plaintiff's motion to amend the complaint to correct this error, R. 16, is not timely, the defendants elaborate, because the Court must consider the complaint at the time of removal. R. 22 at 11-12.

This assertion cannot be squared with the liberal pleading standard adopted by the Federal Rules.<sup>4</sup> Under the federal standard, a "complaint must contain either direct or *inferential*

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<sup>4</sup> The plaintiff assumes that the Kentucky pleading rule applies. R. 17, Attach. 1 at 16. Ultimately, it is immaterial which applies. "Kentucky Civil Rules, like the Federal Rules of Civil Procedure, require only that a plaintiff state a claim with sufficient specificity so that defendants

allegations respecting all the material elements to sustain a recovery under some viable legal theory.” *First Am. Title Co. v. Devaugh*, 480 F.3d 438, 444 (6th Cir. 2007) (emphasis added). Though it does not connect the words “proximate cause” with the name “Dr. McGuire,” the complaint certainly states an inferential allegation that Dr. McGuire’s negligence proximately caused the plaintiff’s injuries. In Kentucky, a “proximate cause” is a “substantial cause.” *Deutsch v. Shein*, 597 S.W.2d 141, 144 (Ky. 1980). That is, a cause is proximate if it “has such an effect in producing the harm as to lead reasonable men to regard it as a cause, using that word in a popular sense, in which there always lurks the idea of responsibility.” *Id.* Here, the complaint alleges that Dr. McGuire should have known about the dangers of Paxil but nonetheless prescribed it during the plaintiff’s first trimester without warning. R. 1, Attach. 1 at 38. “This deviation from that standard of care,” she alleges, “caused [her son and co-plaintiff] to suffer the aforesaid personal injuries and birth defects, including cardiac defects and pulmonary hypertension.” *Id.* at 39 (emphasis added). Even without the magic words “proximate cause,” this language “give[s] the defendant fair notice” of her allegation that Dr. McGuire substantially caused her injuries. *EEOC v. J.H. Routh Packing Co.*, 246 F.3d 850, 851 (6th Cir. 2001).

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receive fair notice of the claims against them.” *Cordle v. Merck & Co.*, 405 F. Supp. 2d 800, 804 (E.D. Ky. 2005) (citing *Pierson Trapp Co. v. Peak*, 340 S.W.2d 456, 460 (Ky. 1960)). But the federal rules apply. *See, e.g., Muick v. Glenayre Elecs.*, 280 F.3d 741, 743 (7th Cir. 2002) (“Although federal pleading requirements (which of course are applicable even when the claim pleaded arises under state rather than federal law) are lax, a claim of promissory estoppel requires the allegation of a promise[.]”); *Garvin v. S. States Ins. Exch. Co.*, 329 F. Supp. 2d 756, 760 (N.D. W.Va. 2004) (“Pleading requirements represent an area of procedural law, however, and are therefore governed by federal law.”).



### III. Record evidence

Finally, the defendants argue that the record amply demonstrates that Dr. McGuire did not prescribe Paxil in the plaintiff's first trimester. First, they contend that Dr. McGuire has entered a sworn statement that he never prescribed Paxil to the plaintiff. R. 1 at 6, R. 1, Attach. 10. Second, they argue that pharmacy records reflect that the plaintiff had a prescription for the generic form of Paxil *after* her first trimester—contradicting the claim that Dr. McGuire prescribed the drug during that period. *Id.* at 3.

These arguments ignore that, when considering whether there has been fraudulent joinder, the Court must resolve factual disputes in favor of the non-removing party. *Cordle*, 405 F. Supp. 2d at 802. And there are still factual disputes here. Neither piece of evidence—McGuire's affidavit or the pharmacy records—succeeds in completely vanquishing the possibility that Dr. McGuire did prescribe Paxil in the plaintiff's first trimester. A solitary self-serving affidavit cannot eliminate the prospect of any dispute, particularly where the complaint is in direct disagreement.<sup>5</sup> And it is not even clear that the Court can appropriately consider the pharmacy records at this stage. When considering a notice of removal, courts typically review the record as it exists at the time of removal. 14B CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 3723 (4th ed. 2010) (“The usual rule is that removability is

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<sup>5</sup> Though they were filed into the record after removal and therefore might not be appropriately considered at this stage, two contrary pieces of evidence illustrate why it would be a mistake to rely on a solitary affidavit. First, the plaintiff filed a contrary affidavit contending that Dr. McGuire did prescribe Paxil “in the early part of [her] pregnancy.” R. 25, Attach. 1. And despite McGuire's belief that he did not prescribe Paxil to Smith “at any point during her pregnancy,” pharmaceutical records reflect that she did have a prescription for generic Paxil later in her term. R. 17, Exs. A and B.

determined from the record before the court at the time the notice of removal . . . is filed in federal court.”); *but see Ohio Nat’l Life Ins. Co. v. United States*, 922 F.2d 320, 327 (6th Cir. 1990) (holding that district court has discretion to hold an evidentiary hearing to resolve a 12(b)(1) motion). These pharmaceuticals records were attached to the motion to remand. R. 17, Exs. A and B. Regardless, they show only that the plaintiff did have a prescription for generic Paxil after her first trimester. R. 17, Exs. A and B. It is still possible that she had an earlier prescription at another pharmacy, and the plaintiff is still searching for those records. R. 25 at 7-8.

It is true that the plaintiff’s counsel was equivocal about whether he could maintain this precise claim at a hearing on August 19, 2010. He seemed to say that he is unsure whether the plaintiff can prove a first trimester prescription with the currently available evidence, but he and his client continue to search for first-trimester records. Yet in response to a Court order, the plaintiff filed a notice in the record specifically stating that she does not concede that Dr. McGuire did not prescribe Paxil in her first trimester. R. 36. Thus, the timing of the plaintiff’s prescription is an issue of fact to be resolved in her favor. Her claim against Dr. McGuire remains colorable.

#### **IV. Attorney’s fees**

The plaintiff’s request for attorney’s fees under 28 U.S.C. § 1447(c) is denied. That provision authorizes an award of costs and fees when the removing party lacks an “objectively reasonable basis for removal.” *Martin v. Franklin Capital Corp.*, 546 U.S. 132, 136 (2005). Though incorrect, these defendants’ argument for removal was reasonable. They cited to several

courts in other districts which have held that a plaintiff cannot both claim that drug manufacturers misled physicians as to a drug's dangers and that the prescribing physician violated his standard of care by prescribing that drug. Therefore, awarding the plaintiff attorney's fees would be inappropriate.

### CONCLUSION

For the foregoing reasons, the motion, R. 17, is **GRANTED** as to the motion to remand and **DENIED** as to the motion for attorney's fees and costs. Additionally, all outstanding motions are **DENIED AS MOOT**.

This the 30th day of August, 2010.



Signed By:

Amul R. Thapar AT

United States District Judge