UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ELEANOR FULGENZI	)	CASE NO. 5:09CV1767
	)	
PLAINTIFF,	)	JUDGE SARA LIOI
	)	
vs.	)	
	)	MEMORANDUM OPINION
	)	
	)	
	)	
	)	
WYETH, INC., et al.	)	
DEFENDANTS.	)	

This matter is before the Court on a motion filed by Defendants Actavis-Elizabeth LLC and Actavis Inc. (Actavis or generic manufacturer). By its motion, Actavis seeks dismissal of all claims against it on the basis of federal preemption. (Doc. No. 13.) The motion is fully briefed. Based upon the parties' submissions, as well as a review of the ever evolving law relating to the manufacture and sale of prescription medication, the Court makes its determinations.

I. Background

Plaintiff brought suit against the manufacturers of the name-brand drug Reglan (name-brand manufacturers),[1] as well as the manufacturers[2] of Reglan's generic equivalent "Metoclopramide" (generic manufacturer). Reglan/metoclopramide is most

[1] On January 21, 2010, the parties filed a joint notice dismissing the name-brand manufacturers. (Doc. No. 26.)

[2] In addition to name-brand manufacturers and Actavis, two defendants are named in the Complaint: Pliva, Inc. and Teva Pharmaceuticals, USA, Inc. It does not appear from the record, however, that Pliva or Teva have been served. Plaintiff shall, therefore, show cause by March 5, 2010 as to why Pliva and Teva should not be dismissed, under Fed. R. Civ. P. 4(m), for want of service.

often prescribed to treat symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis. (Doc. No. 1, Compl. at ¶ 25.) According to Plaintiff, patients who use Reglan/metoclopramide for periods of time that exceed 12 weeks are at a significantly greater risk of developing a severe and permanent neurological movement disorder known as "tardive dyskinesia."[3] (*Id*. at ¶ 28.)

Plaintiff seeks damages for personal injuries she alleges she suffered as a result of long-term ingestion of Reglan/metoclopramide. (*Id*. at ¶ 2.) Plaintiff brings state-law tort claims against the generic manufacturers.[4] At the core of all of Plaintiff's claims is the basic assertion that the manufacturers of Reglan/metoclopramide should have provided warnings alerting doctors and patients to the heightened risk of developing neurological complications from long-term use of Reglan/metoclopramide.

Actavis has moved for dismissal on federal preemption grounds. In support of its motion, the generic manufacturer maintains that Plaintiff's claims are conflict-preempted under 21 U.S.C. § 335(j) of the Food, Drug & Cosmetic Act, 21 C.F.R. § 314.50, and various FDA rules and regulations and agency interpretations. Specifically, Actavis argues that it cannot comply with FDA regulations requiring generic drugs to conform to the warnings provided by the name-band drug and simultaneously comply with state law requirements to provide heightened warnings to protect the public

[3] Symptoms of tardive dyskinesia include involuntary and uncontrollable movements of the head, neck, and face, as well as grotesque facial grimacing and tongue movements, and tongue thrusting and chewing. (*Id.* at ¶ 30.) Presently, there is no cure for Tardive Dyskinesia. (*Id*.)

[4] Specifically, Plaintiff raises claims for strict product liability, manufacturing defect, design defect, breach of express warranty, breach of implied warranties, negligence, negligent misrepresentation, breach of undertaking special duty, fraud and misrepresentation, constructive fraud, fraud by concealment, violation of the Ohio Consumer Sales Practices Act, Ohio Rev. Code § 1345.01 *et seq*., and intentional infliction of emotional distress.

from risks attendant with taking certain medications. It also insists that Plaintiff's claims impermissibly pose an obstacle to the Congressional objective to provide the public with low cost generic drugs.

II. Motion to Dismiss Standard

When reviewing a motion to dismiss for failure to state a claim, the Court must construe the complaint in the light most favorable to the plaintiff, accept all well-pleaded factual allegations as true, and determine whether the moving party is entitled to judgment as a matter of law. *Commer. Money Ctr., Inc. v. Ill. Union Ins. Co.*, 508 F.3d 327, 336 (6th Cir. 2007) (citing *United States v. Moriarty*, 8 F.3d 329, 332 (6th Cir. 1993)). To survive a motion to dismiss under Rule 12(b)(6), the complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Although this is a liberal pleading standard, it requires more than the bare assertion of legal conclusions. Rather, the complaint must contain either direct or inferential 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) (quoting *Se. Tex. Inns, Inc. v. Prime Hospitality Corp.*, 462 F.3d 666, 671-72 (6th Cir. 2006)).

III. Law and Analysis

A. Generic Manufacturers' Motion to Dismiss

Federal Preemption

The federal preemption doctrine is based upon the Supremacy Clause of the United States Constitution. *State Farm Bank v. Reardon*, 539 F.3d 336, 341 (6th Cir. 2008). The Supremacy Clause provides that the Constitution, federal law, and all treaties

"shall be the supreme law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, Cl. 2. Federal law may preempt state law either expressly or impliedly. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152-53 (1988). Express preemption exists where either a federal statute or regulation contains explicit language indicating that a specific type of state law is preempted. *See id*. at 153.

Implied preemption is further divided into two categories: "field preemption" and "conflict preemption." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992). Field preemption exists "where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.* Conflict preemption occurs "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.*

Any preemption analysis is guided by two important considerations. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 418 U.S. 470, 485 (1996) (internal quotation marks omitted). Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated … in a field which the States have traditionally occupied,' … we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless there was [a] clear and manifest purpose of Congress.'" *Lohr*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)).

Federal Drug Regulation

Pursuant to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et. seq*., the Food and Drug Administration (FDA) is charged with the responsibility of approving new drugs on the market. *See* 21 U.S.C. § 355. *Riegel v. Medtronic Inc*., 128 S. Ct. 999, 1002 (2008). A manufacturer seeking to market a new drug must file a New Drug Application (NDA) with the FDA. 21 U.S.C. § 355(b). As part of its application, the manufacturer must demonstrate through pre-market trials and other relevant evidence that the drug is safe, and that the proposed labeling properly sets forth the correct dosage and possible risks. The NDA requires, among other things, that the manufacturer supply the agency with "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" and "specimens of the labeling proposed to be used for such drug." § 355(b)(1).

In contrast, drug manufacturers seeking to market a generic drug must file an Abbreviated New Drug Application (ANDA). The ANDA procedure, codified in the Hatch-Waxman Act, sets forth an expedited review process. To obtain approval, the manufacturer must demonstrate that the generic drug it seeks to market is approved as a listed drug, meaning that the new drug is the functional equivalent of a name-brand drug already approved by the FDA. 21 U.S.C. § 355(j)(2). "One of the benefits to manufacturers who opt for the ANDA procedure is that they are required only to conduct 'bioequivalency' studies that establish that the generic and the reference-listed drug are pharmaceutically equivalent […]." *Stacel v. Teva Pharmaceuticals*, USA, 620 F. Supp. 2d 899, 905 (N.D. Ill. 2009) (citing 21 U.S.C. § 355(j)(2)(ii)-(iv)). So long as the manufacturer can demonstrate that the generic drug is the pharmaceutical equivalent of

its name-brand counterpart, the generic manufacturer need not duplicate the pre-market trials conducted by the name-brand manufacturer. This advantage serves the purpose of the Hatch-Waxman Act to increase the availability of low cost generic drugs. *See id*. at 907.

Federal regulations further require that a generic drug's "labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers." 21 C.F.R. § 314.94(a)(8)(iv). The FDA can reject an ANDA application if the information submitted by the generic manufacturer is "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug. […]" 21 C.F.R. § 314.127(a)(7).

Post-approval, a manufacturer has the ability to submit additional information to the FDA to, among other things, change the drug's label "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction." 21 C.F.R. § 314.70. This regulation is known as the "changes being effected," or "CBE" regulation. Under this provision, a manufacturer may immediately implement any proposed change in the warning label while it awaits a ruling from the FDA on the change.

Federal Preemption and the ANDA Procedure

Prior to March, 2009, only a handful of district courts had addressed the issue of whether federal preemption applies to state failure-to-warn claims involving generic drugs approved under the ANDA procedure. *See Morris v. Wyeth*, 582 F. Supp.

2d 861, 867 (W.D. Ky. 2008) (collecting cases). The majority of these cases found in favor of federal preemption.[5] *But cf. Laisure-Radke v. Par Pharmaceutical, Inc.*, 2006 U.S. Dist. LEXIS 57158 (W.D. Wash. March 29, 2006) (denying motion for summary judgment based on preemption).

Courts adhering to the majority position focused on the duty of the generic manufacturer to conform its label to that of the listed drug. In *Mensing v. Wyeth, Inc*., 562 F. Supp. 2d 1056 (D. Minn. 2008), rev'd, 588 F.3d 603 (8th Cir. 2009), the court relied heavily upon the FDA's comments in implementing the Hatch-Waxman Amendment stating that the exceptions to the requirement that a generic label be "the same as" the listed drug label are limited, *id*. at 1062 (citing 54 Fed. Reg. 28872, 28884), the FDA's negative responses to comments to proposed ANDA regulations asking that ANDA applicants be allowed to deviate from the listed drug labeling to add contraindications, warnings, precautions, adverse reactions, and other safety-related

[5] In 2008 and early 2009, three district courts within the Sixth Circuit issued decisions ruling that state law failure-to-warn actions brought against generic drug manufacturers were preempted by federal law. *See Morris*, 582 F. Supp. at 868-69; *Wilson v. Wyeth*, 2008 WL 4696995, at *6 (W.D. Ky. Oct. 24, 2008); *Smith v. Wyeth*, 2008 U.S. Dist. LEXIS 87684, at *20 (W.D. Ky. Oct. 24, 2008). All three decisions are on appeal in the Sixth Circuit. *See Morris*, Case No. 09-5509 (6th Cir.); *Smith*, Case No. 09-5460 (6th Cir.); *Wilson*, Case No. 09-5466 (6th Cir.).

information,[6] and the statutory scheme allowing the FDA to withdraw an ANDA if the generic drug label is "no longer consistent with that for the listed drug," *id*. (citing 21 C.F.R. § 314.150(b)).

In support of their finding of federal preemption, courts in the majority determined that the CBE process, which allows for immediate revisions to warning labels, was not available to generic manufacturers. *Wilson v. Wyeth, Inc*., 2008 WL 4696995, at *5 (W.D. Ky. Oct. 24, 2008) (quoting Supplemental Applications Proposing Labeling changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848 (Jan. 16, 2008) stating that: "CBE changes are not available for generic drugs approved under an [ANDA] application under 21 U.S.C. § 335(j). To the contrary, a generic drugs manufacturer is required to conform to the approved labeling for the listed drug.") *See Morris*, 582 F. Supp. 2d at 866-67 (citing Abbreviated New Drug Applications, 57 Fed. Reg. 17950-01 (Apr. 28, 1992)). These courts also relied, in part, on the FDA's own interpretation that its reporting procedures preempt state law failure-to-warn claims. *See Gaeta v. Perrigo Pharmaceuticals Co*., 562 F. Supp. 3d 1091, 1097 (N.D. Cal. 2008) (citing 71 Fed. Reg. 3992, 3934)). The theme echoing through these cases is the notion that the generic manufacturers are bound by the labeling of the listed

[6] Specifically, in rejecting a comment proposing that ANDA labeling provisions be revised to permit ANDA applicants to deviate from the labeling, the FDA stated: "Except for labeling differences due to exclusivity of a patent and differences under section 505(j)((2)(v) of the act, the ANDA's product labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval. Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart. (*See* 54 FR 28872.) If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drug should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed. Reg. 17961.

drug, and that any deviation would prevent the FDA from ensuring that the generic drugs that the public was consuming were the same as the listed drug. *See Mensing*, 562 F. Supp. 2d at 1062 (citing 57 Fed. Reg. 17961).

The United States Supreme Court has recently spoken on the issue of whether the FDA's regulations provide a manufacturer with a complete defense to state law tort claims based upon a failure to warn, and has concluded that they do not. In *Wyeth v. Levine*, 129 S. Ct. 1187 (Mar. 4, 2009), the Court specifically rejected a manufacturer's arguments that it would be impossible to comply with both FDA regulations and state failure-to-warn laws, and that the state tort action created an unacceptable obstacle to the fulfillment of congressional objectives. 129 S. Ct. at 1193-94. While the generic manufacturers attempt to distinguish *Levine* on the ground that it concerned claims against a brand name manufacturer, the "decision carries implications for [the present] situation as well." *Mensing v. Wyeth*, 588 F.3d 603, 607 (8th Cir. 2009) (applying *Levine* to state law claims against generic drug manufacturers).

The Court in *Levine* began its analysis by exploring the history of the FDCA, and noted that Congress originally placed the burden on the FDA to prove that a potential drug was harmful. In 1962, Congress amended the FDCA to shift the burden to the manufacturers, requiring manufacturers to demonstrate that its drug was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." *Levine*, 129 S. Ct. at 1195 (citing 21 U.S.C. §§ 102(d) 104(b)). The Court further noted that, as the FDA's powers to ensure the safety of prescription medications expanded, "Congress took care to preserve state law." *Id.* at 1196. Specifically, the Court

underscored the fact that while Congress had the opportunity to expressly preempt state law governing the labeling of prescription medication, it declined to do so. *Id*.

Against this backdrop, the Court in *Levine* reasoned that Congress had made clear that manufacturers, and not the FDA, remain responsible for updating their labels. Further, it found that congressional "silence on the issue [of preemption], coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."[7] *Id.* at 1200.

In so ruling, the *Levine* Court chose not to afford weight to the FDA's interpretation of its regulations on drug labeling as creating both a ceiling and floor for drug labeling and preempting state law failure-to-warn cases. *Id*. at 1201. The Court found that the FDA's preamble to the 2006 regulation governing labeling (71 Fed. Reg. 3922) did not "merit deference" because it was filed without offering an opportunity for public comment and it was at odds with congressional purposes in legislating in the area of drug regulation. *Id*. at 1201.

Following the Supreme Court ruling in *Levine*, courts which have considered the issue have almost uniformly ruled that state failure-to-warn claims against generic manufacturers are not preempted. *See, e.g., Schrock v. Wyeth*, 601 F. Supp. 2d 1262, 1265-66 (W.D. Ok. 2009); *Stacel v. Teva Pharmaceuticals*, 620 F. Supp. 2d 899, 906-07 (N.D. Ill. 2009). In fact, the Fourth Circuit reached the same conclusion fifteen

[7]Instead of hindering congressional objectives, the Supreme Court concluded that state law claims promote Congressional objectives in regulating drugs by serving as an additional oversight on safety and effectiveness. *Levine*, 129 S. Ct. at 1200.

years earlier. *Foster v. American Home Products Corp*., 29 F.3d 165, 170 (4th Cir. 1994) ("The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law.")

The Eighth Circuit's analysis in *Mensing* is instructive. There, the court started with the assumption that generic labels must be substantially identical to the name brand labels even after they enter the market. *See*, *e.g*., 21 C.F.R. § 314.150(b)(10). Because of this requirement, the generic drug manufacturers, like generic manufacturers in the present case, argued that they were prohibited from implementing a unilateral change without FDA approval. The court rejected the argument, finding that 21 C.F.R. § 314.97 compels generic manufacturers to "comply with the requirements of [§ 314.70]," which includes the CBE process and the prior approval supplemental process.[8] *Mensing*, 588 F.3d at 608. *See Stacel*, 620 F. Supp. 2d at 905 (finding that generic manufacturers had access to, and were subject to, the CBE process).[9]

[8] The Eighth Circuit also relied upon the fact that generic manufacturers are required to follow the same record keeping and reporting of adverse drug experiences post marketing that name brand manufacturers must undertake. *Id*. at 609 (citing 21 C.F.R. § 314.98). It further drew from the FDA's own comment noting that "ANDA applicants [must] submit a periodic report of adverse drug experiences even if the ANDA applicant has not received any adverse drug experience reports or initiated any labeling changes." 57 Fed. Reg. 17950, 17965 cmt 53.

[9] In concluding that generic manufacturers were covered by the CBE, the court observed:

> The CBE regulations appear at 21 C.F.R. § 314.70(c)(6)(iii), which is located in Subpart B of Part 134. Subpart B is generally applicable to *new* applications, whereas, Subpart C is applicable to *generic* (or, "abbreviated") applications. Compare 314 C.F.R. Subpart B (titled "Applications") with Subpart C (titled "Abbreviated Applications"). However, section 314.97, which is located within Subpart C, states that "The applicant shall comply with the requirements of §§ 314.70 and 314.71, regarding the submission of supplemental applications and other changes to an approved abbreviated application." § 314.97. In other words, the regulations affecting generic drug applications state explicitly that the CBE provisions apply to generic drug manufacturers just as they do to name-brand manufacturers. *Id*. at 15 (emphasis in original.)

Of course, this Court need not resolve the question of whether the CBE process is available to generic manufacturers because generic manufacturers may, at a minimum, propose a label change to the FDA for consideration. *See Mensing*, 588 F.3d at 608; 57 Fed. Reg. 17961. The ability to propose such changes does not in any way interfere with the generic manufacturers duty to ensure that its drug and label is the "same as" the name-brand inasmuch as the FDA regulation makes clear that if the proposed change is accepted, it would be applied uniformly to all name-brand and generic manufacturers of the drug in question; thus, keeping the generic and name-brand labels the same. *See* 57 Fed. Reg. 17950, 17961 cmt. 40. It would, therefore, be possible for a generic manufacturer to comply with both FDA rules and regulations and, at the same time, honor its state law duty to take the necessary steps to warn the public of any known risks associated with the use of its drug. Nor would the state law duty to warn of known risks serve as an obstacle to fulfilling the purposes of federal law.

The question of whether the FDA would have accepted any proposed revision to the warning label is not before the Court. The only question relevant to the federal preemption inquiry is whether there is sufficient evidence to demonstrate "clear and manifest [Congressional] purpose" to preempt state law in this area. The Court finds no such intent. Instead, as the Supreme Court observed in *Levine*, the absence of any Congressional preemption intent and the existence of state law remedies for a failure to warn of attendant risks are convincing evidence that Congress intended to allow state law claims to continue to play an important role in ensuring that prescription medications are safe for public consumption. *See Levine*, 129 S. Ct. at 1202.

Moreover, there is no reason to believe that this desire to ensure drug safety is reserved solely for name-brand medications. "Although it is clear that the Hatch-Waxman Amendment was devised to allow generic manufacturers to get their drugs to market both cheaply and quickly, this purpose was to be achieved by permitting manufacturers to forego duplicative clinical trials. It was *not* to be achieved by permitting manufacturers to engage in negligent activities." *Stacel*, 620 F. Supp. 2d at 907 (emphasis in original). *See Foster*, 29 F.3d at 170. Nothing in the FDA's rules and regulations would lead to the conclusion that generic drug manufacturers may hide behind deficient name-brand labeling, and ignore with impunity subsequent data that would suggest a previously unknown risk associated with the medication that they have brought to market.

The Court finds the reasoning in *Mensing*[10] and *Stacel* persuasive, and rules that Plaintiff's state law failure-to-warn claims against the generic manufacturer are not preempted by federal law. *Levine*, 129 S. Ct. at 1199-1200. Such a ruling takes into account the fact that each drug manufacturer "bears responsibility for the content of its labels at all times," *id* at 1198, and promotes the ultimate goal of the FDCA to ensure that all marketed drugs remain safe. *See id.* (Congress "determined that widely available state

[10] The Court notes that generic manufacturer relied heavily upon the district court's ruling in *Mensing, supra*. In light of the fact that this decision has since been reversed, and this Court finds the reasoning of the Eighth Circuit in reversing the district court's decision persuasive, generic manufacturer's position is significantly undermined. It is further undercut by the fact that the Supreme Court in *Levine* refused to lend weight to the FDA's interpretation on preemption, which generic manufacturer also relied upon in bringing the present motion. *See Levine*, 129 S. Ct. at 1201.

rights of action provided appropriate relief for injured [drug] consumers" and that "state-law remedies further consumer protection by motivating manufacturers […] to give adequate warnings.") Actavis's motion to dismiss is denied. Plaintiff may proceed against generic manufacturer on her state law claims.

Preemption under *Buckman*

Actavis also insists that Plaintiff's state law failure-to-warn claims are preempted under the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The Court does not find this argument persuasive.

In *Buckman*, the plaintiffs argued that a medical device would not have been approved by the FDA if it were not for the fraudulent statements made to the FDA by a consulting company working for the device's manufacturer. The statements offered by the consulting company were required under the governing federal statute, the Medical Device Amendments of 1972, which amended the FDCA. Since enforcing the FDCA falls exclusively to the federal government, the Court in *Buckman* found that the plaintiffs could not maintain a private cause of action that attempted to usurp the government's authority in this area. In reaching this conclusion, the Court noted that the plaintiffs' claims "existed solely by virtue of the FDCA disclosure requirements." *Id.* at 353.

Relying on *Buckman*, Actavis argues that "Plaintiff's state law tort claims are preempted to the extent any element of those claims requires proof that Actavis intentionally concealed scientific and medical literature from the FDA." (Mot. at 24.) This is not, however, the first time that Actavis has raised this argument. In *Couick v. Wyeth, Inc.*, 2009 WL 4644394 (W.D.N.C. Dec. 7, 2009), the court rejected this

preemption argument, finding that *Buckman* did not apply. In reaching this conclusion, the court in *Couick* distinguished *Buckman*, noting that:

> Plaintiff asserts claims for state-law negligence, breach of undertaking special duty, misrepresentation, constructive fraud, fraud by concealment, infliction of emotional distress, unfair trade practices, and breach of warranties. These claims involve multiple overlapping allegations. The constructive fraud and fraud by concealment claims come the closest to raising a *Buckman* issue, as they sound in fraud. However, both claims focus on fraud that is allegedly perpetrated against patients and doctors rather than the FDA. The constructive fraud count alleges defendants made misrepresentations in advertisements, promotional materials, and other communications. The fraudulent concealment count alleges defendants concealed from physicians the serious side effects caused by prolonged use of metoclopramide. Such allegations, while potentially in violation of the FDCA, would exists as state-law claims absent the FDCA. These claims "rely[] on traditional state tort law which […] predicate[s] the federal enactment in question." *Buckman*, 531 U.S. at 353. Thus, plaintiff's fraud claims arise from state law, and "not solely from the violation of the FDCA requirements." *Id*. at 352. Therefore, plaintiff's claims are not preempted under *Buckman*.

Id. at *5.

Here, Plaintiff also raises multiple state law tort claims, including several claims sounding in fraud. These claims, like the fraud claims in *Couick*, focus on fraud that was "allegedly perpetrated against patients and doctors rather than the FDA." *Id.* Indeed, the complaint allegations clearly cite the concealment of information from patients and physicians as the cause of Plaintiff's injuries. (*See* Compl. at ¶¶ 91, 94, 115, 122, 138, 158, 164.) The only allegation that comes close to raising fraud against the FDA would be Plaintiff's claim that defendants "failed to exercise reasonable care in performing, and failed to fulfill, the undertakings assumed in FDA regulations." (*Id*. at ¶ 142.) However, even if the complaint does allege that Defendants violated federal drug regulations, the claims sound in state tort law and would exist even without these federal

regulations. *See Couick*, 2009 WL 4644394, at *5 ("[S]imply because conduct violates the FDCA does not mean a state-law claim based on the same conduct depends on the FDCA's existence.") Plaintiff's claims, including her fraud claims, arise under state law, and do not exist "solely by virtue" of federal drug regulations. *Buckman*, 531 U.S. at 353. Plaintiff's claims are not, therefore, preempted under *Buckman*.

IV. Conclusion

For all of the foregoing reasons, Actavis's motion to dismiss on the basis of federal preemption (Doc. No. 13) is **DENIED**. Further, Plaintiff shall show cause by March 5, 2010 as to why Defendants Pliva and Teva should not be dismissed, under Fed. R. Civ. P. 4(m), for want of service.

IT IS SO ORDERED.

Dated: February 19, 2010

HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE