UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

BARBARA METZ and
DONALD METZ,

Plaintiffs,

vs. **Case No.: 8:10-CV-2658-T-27AEP**

WYETH, LLC, *et al.*,

Defendants.
_____/

ORDER

BEFORE THE COURT are Defendant Actavis Elizabeth LLC's Motion to Dismiss Plaintiffs' First Amended Complaint (Dkt. 91) and Motion for Summary Judgment (Dkt. 109). Upon consideration, the Motion to Dismiss will be **GRANTED** in part and **DENIED** in part. The Motion for Summary Judgment will be **GRANTED**.

Introduction

Plaintiffs, Barbara Metz and Donald Metz, filed this action against Wyeth LLC ("**Wyeth**"), Schwarz Pharma, Inc. ("**Schwarz**") and Actavis Elizabeth, LLC d/b/a Purepac Pharmaceuticals ("**Actavis**") for injuries arising from the use of metoclopramide, marketed by Wyeth and Schwarz under the brand name Reglan.[1] Actavis manufactured, marketed, and sold metoclopramide as a generic equivalent of Reglan.

As discussed below, the majority of Plaintiffs' claims are impliedly preempted under *PLIVA, Inc. v. Mensing*, --- U.S. ---, 131 S. Ct. 2567 (2011). Moreover, to the extent that any of Plaintiffs'

[1] The Court previously granted summary judgment in favor of Schwarz and Wyeth. *See* Dkt. 95.

claims survive preemption under *Mensing*, such claims are barred by the learned intermediary doctrine under Florida law.

Summary of Plaintiffs' Claims

Plaintiffs' First Amended Complaint (the "**Amended Complaint**") asserts claims against Actavis for negligence (Count I), strict liability (Count II), breach of warranties (Count III), misrepresentation and fraud (Count IV), and negligence *per se* (Count V).

One February 23, 2012, this Court entered an Order directing Plaintiffs to file a more definite statement (1) separately identifying those claims (*i.e.*, legal theories) they contend are not preempted under *Mensing*, and (2) summarizing the alleged factual basis (including causation) for each such claim. *See* Dkt. 122. In response, Plaintiffs furnished a More Definite Statement. *See* Dkt. 125. While the Amended Complaint and More Definite Statement purport to assert a variety of claims based on differing legal and factual theories, Plaintiffs' counsel conceded during oral argument that each of the substantive claims are based, at least in part, on the failure of Actavis to effectively communicate to Plaintiff's treating physician the limitation on duration of use added to the label for metoclopramide in 2004.[2]

Motion to Dismiss

Actavis moves to dismiss the Amended Complaint based on the recent decision of the United States Supreme Court in *PLIVA, Inc. v. Mensing*, --- U.S. ---, 131 S. Ct. 2567 (2011), which held that failure to warn claims against generic drug manufacturers were impliedly preempted under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("**FDCA**").

---

[2] On or about July 26, 2004, the FDA approved a labeling change for brand-name Reglan which stated that "[t]herapy should not exceed 12 weeks in duration ... ."

Standard

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires that a complaint provide "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

Although a complaint need not include detailed factual allegations, it must contain sufficient factual allegations, which, when taken as true, "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint as alleged-but it has not 'show[n]'-'that the pleader is entitled to relief.'" *Id.* at 1950 (quoting Fed. R. Civ. P. 8(a)(2)). A well-pleaded complaint, however, may survive a motion to dismiss even if it appears "that recovery is very remote and unlikely." *Bell Atlantic Corp.*, 550 U.S. at 555 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

While the Court must accept all factual allegations as true in evaluating a motion to dismiss under Rule 12(b)(6), the tenet does not apply to legal conclusions. *Ashcroft*, 129 S. Ct. at 1949. Similarly, a court may dismiss a complaint on a dispositive issue of law. *Marshall County Bd. of Educ. v. Marshall County Gas Dist.*, 992 F.2d 1171, 1174 (11th Cir. 1993).

Discussion

Actavis argues that under *Mensing*, it was required to use the same label as the branded drug and was not at liberty to communicate information inconsistent with that label. As a result, Actavis contends the Plaintiffs' claims are preempted by federal law because they all arise from Actavis' alleged knowledge of certain risks and its failure to communicate those risks to consumers, the government, and the medical community.

Plaintiffs respond that they have alleged causes of action that are not preempted by federal law. Specifically, Plaintiffs argue that their claims are not preempted because they do not seek to hold Actavis liable for failing to take actions that are prohibited by federal law. In addition, Plaintiffs argue that *Mensing* only involved the adequacy of a drug label, not the manner in which warnings relating to a drug were communicated. Thus, Plaintiffs argue their claims based on Actavis' failure to provide physicians with any warning relating to metoclopramide, "especially in light of changes made to the label for metoclopramide in 2004 prohibiting its long-term use," are not preempted.

In *Mensing*, consumers sued generic manufacturers of metoclopramide alleging that the generic manufacturers violated state tort law (specifically, that of Minnesota and Louisiana) by failing to provide adequate warnings to consumers, the federal government, and the medical community. The consumers alleged that "despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label," none of the manufacturers had changed their labels to adequately warn of the danger. *Mensing*, 131 S. Ct. at 2573. Moreover, the consumers in *Mensing* alleged that the manufacturers ignored scientific and medical literature establishing a higher risk of developing tardive dyskinesia, failed

to request that the FDA approve a revised label, and failed to report safety information directly to the medical community. *See Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 562 F.Supp.2d 1056, 1058 (D. Minn. 2008).

The manufacturers argued that because federal law required them to use the same safety and efficacy labeling as their brand-name counterparts, it was impossible to simultaneously comply with both federal law and a state tort-law duty that required them to use a different label. The Court agreed and held that federal law preempted the consumers' state law claims. *Mensing*, 131 S. Ct. at 2581. The Court based its conclusion on the fact that the manufacturers could not unilaterally strengthen their warning labels nor could they send additional (*i.e.*, different) warnings to prescribing physicians and other healthcare professionals advising of new information and increased risks. *Id.* at 2575-76. The Court further held that complete preemption existed even assuming that the manufacturers had a duty to propose stronger warning labels to the FDA if they believed such warnings were needed. *Id.* at 2577.

Count I – Negligence

Plaintiffs' claim that Actavis was negligent in failing to take additional steps to warn doctors and/or consumers of information already appearing in, or recently added to, the label for metoclopramide, including the prohibition on long-term use added in 2004, ***may not*** be preempted to the extent Actavis could have taken such steps consistent with federal law. *See Fisher v. Pelstring, M.D.*, No. 4:09-cv-00252-TLW, 2011 WL 4552464, at *3, 31-32 (D. S.C. Sept. 30, 2011) (denying motion to dismiss negligence action based on allegations that generic manufacturer should have done more to communicate FDA approved labeling changes); *Brasley-Thrash v. TEVA Pharmaceuticals USA, Inc.*, No. 10-00031-KD-N, 2011 WL 4025734, at *3 (S.D. Ala. Sept. 12,

2011) (recognizing that claims based on generic drug manufacturer's failure to provide warnings consistent with the label and packaging materials were not preempted); *see also Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at *5 (D. Vt. Feb. 3, 2012) (denying motion to dismiss state law claims against generic manufacturers for distributing generic metoclopramide without the labeling approved for Reglan in 2004); *De Valle v. PLIVA, Inc.*, No. B-11-113, 2011 WL 7168620, at *7-8 (S.D. Tex. Dec. 21, 2011) (recognizing that generic drug manufacturer's failure to update label based on 2004 amendment could place claims outside of the preemption described in *Mensing*). In short, it would not be impossible[3] for Actavis to comply with its obligations under federal and state law to the extent state law is determined to require Actavis to more effectively communicate the FDA approved label to medical providers and/or consumers. *See Couick v. Wyeth, Inc.*, No. 3:09-cv-210-RJC-DSC, 2012 WL 79670, at *3 (W.D.N.C. Jan. 11, 2012) (noting generic manufacturer failed to meet burden of proving impossibility).

Plaintiffs' claim that Actavis breached its duty to Plaintiffs because it failed to use due care in informing itself about the properties of metoclopramide is preempted by federal law to the extent Plaintiffs contend that Actavis should have used such information to provide different or additional information to consumers, the medical community, or the FDA. *See Lyman*, 2012 WL 368675, at *4 (dismissing state law tort claims based on generic drug manufacturer's failure to review all adverse drug information). To the extent that Plaintiffs contend that had Actavis remained informed about the properties of metoclopramide it would have known the importance of providing more effective notice to physicians, this allegation is related to, and subsumed within, Plaintiffs' overall negligence theory of liability.

---

[3] "[T]he question for 'impossibility is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S.Ct. at 2579.

Count II – Strict Liability

Plaintiffs' strict liability claim is, in essence, a claim based on Actavis' failure to provide an adequate warning as to the risks associated with the long-term use of metoclopramide. That is, Plaintiffs do not contend that metoclopramide is unreasonably dangerous when used consistent with the FDA approved label (*i.e.*, short term use), but rather contend that it was unreasonably dangerous because Actavis knew that it was being used for longer periods. In essence, Plaintiffs contend that Actavis should have either (1) redesigned the drug to alleviate the existing design defect,[4] or (2) stopped offering metoclopramide for sale given its knowledge that metoclopramide was often prescribed for periods exceeding twelve weeks.

A claim that Actavis should have redesigned metoclopramide to alleviate the risks associated with its long-term use would be preempted under *Mensing*. *See Lyman* , 2012 WL 368675, at *4 (dismissing design and manufacturing defect claims as preempted under *Mensing* because generic metoclopramide was required to be the bioequivalent to the reference listed drug Reglan); *In re Fosamax (Alendronate Sodium) Products Liability Litigation (No. II)*, No. 08-008 (GEB-LHG), 2011 WL 5903623, at *6 (Nov. 21, 2011) (same). To the extent Plaintiffs contend that Actavis should have pulled the generic version of metoclopramide from the market, such claim is also preempted. *See Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) (noting that mere fact that manufacturers could pull generic drug from the market did not save claims from impossibility preemption under *Mensing*); *Gross v. Pfizer, Inc.*, No. 10-cv-00110-AW,

---

[4] Under Florida law, a plaintiff need not identify whether a strict liability claim is based on a design, as opposed to a manufacturing, defect. *McConnell v. Union Carbide Corp.*, 937 So.2d 148, 152 (Fla. 4th DCA 2006). Nevertheless, to the extent Plaintiffs purport to state a claim based on an alleged manufacturing defect, the Complaint lacks sufficient allegations to support such a claim. *See Fisher*, 2011 WL 4552464, at *33-34 (dismissing manufacturing defect claim when plaintiff failed to show that metoclopramide plaintiff ingested deviated from design specifications or that it was rendered unsafe by an error in the manufacturing process).

2011 WL 5865267, at *5 (D. Md. Nov. 22, 2011) (dismissing negligence claim against generic drug manufacturer based on the continuing sale of metoclopramide, concealment of important safety information, and failure to test and inspect product). As a result, the Amended Complaint fails to state a claim against Actavis based on a theory of strict liability. *See Grinage v. Mylan Pharmaceuticals, Inc.*, No. CCB-11-1436, 2011 WL 6951962, at *6 (D. Md. Dec. 30, 2011) (dismissing design defect claim because consumer expectation test considered same factors as failure-to-warn analysis and plaintiff failed to allege design defect under risk-utility analysis); *Fisher*, 2011 WL 4552464, at *15 (granting summary judgment for generic drug manufacturer on design defect claim when plaintiff failed to demonstrate existence of an alternative feasible design).

Count III – Breach of Implied Warranties

Under *Mensing*, Plaintiffs' implied warranty claim is also preempted by the FDCA to the extent it stems from Actavis' failure to provide additional warnings relating to the risks associated with long-term metoclopramide use or Actavis' failure to stop manufacturing and marketing the generic version of metoclopramide. *See Schrock v. PLIVA USA, Inc.*, No. CIV-08-453-M, 2011 WL 6130924, at *2 (W.D. Okla. Dec. 8, 2011); *cf. In re Fosamax Prods. Liab. Litig.*, No. 08-008 (GEB-LHG), 2011 WL 5903623, at * (D. N.J. Nov. 21, 2011) (when breach of implied warranty claim necessarily alleged that generic manufacturers should have changed product design, such claim was preempted).[5]

[5] As noted, to the extent Plaintiffs contend that Actavis should have pulled the generic version of metoclopramide from the market, such claim is preempted. *See Fullington*, 2011 WL 6153608, at *6 (noting that mere fact that manufacturers could pull generic drug from the market did not save claims from impossibility preemption under *Mensing*); *Gross*, 2011 WL 5865267, at *5(dismissing negligence claim against generic drug manufacturer based on the continuing sale of metoclopramide, concealment of important safety information, and failure to test and inspect product).

Unlike Plaintiffs' strict liability claim which must demonstrate that metoclopramide was unreasonably dangerous when used in a manner consistent with the FDA approved label, an implied warranty claim ***may*** survive preemption based on a showing that Actavis knew metoclopramide was likely to be used to treat GERD for longer than twelve weeks and implicitly warranted that it was safe and effective for such use despite the warning to the contrary in the FDA approved label. That is, it is conceivable that Actavis could have taken additional steps consistent with the FDCA and the FDA approved label to impact the manner in which physicians prescribed metoclopramide (*i.e.*, the "intended" use) and that a claim based on this failure to act ***may*** survive preemption under *Mensing*. *See Couick*, 2012 WL 79670, at *7 ("While Defendant's labeling and warnings may play a role in establishing their products' intended purpose or their customer's reliance, Plaintiff's claim is not that Defendants failed to adequately warn about the risks."); *Fisher*, 2011 WL 4552464, at *18-19, 29 (denying generic drug manufacturer's motion to dismiss plaintiff's implied warranty claims because "there is an issue of fact as to whether [the generic manufacturer] knew the metoclopramide it manufactured was being used for long-term treatment of gastrointestinal issues").

Count IV – Misrepresentation and Fraud

While styled as a claim for misrepresentation and fraudulent concealment, the essence of Plaintiffs' claim is that Actavis fraudulently concealed the labeling changes made in 2004 together with other adverse information relating to the long-term use of metoclopramide.[6] Any claim based on Actavis' failure to provide additional information regarding the dangers associated with

[6] This is not a situation where Plaintiffs allege that Actavis failed to revise its label to conform with the 2004 amendment. *Compare Fisher*, 2011 WL 4552464, at *3, 31-32 (denying motion to dismiss fraud claim when Plaintiffs alleged that generic drug manufacturer concealed facts by failing to include the 2004 warning in its label for metoclopramide). As Plaintiffs note, those label changes mitigated to a large extent the effect of any prior false statements of risk appearing in the label for metoclopramide. Of course, any claims relating to false statements remaining in the label for metoclopramide after 2004 are clearly preempted under *Mensing*.

metoclopramide (regardless of whether Actavis had a duty to furnish such information to the FDA) is preempted under *Mensing*. *See Grinage*, 2011 WL 6951962, at *7; *Gross*, 2011 WL 5865267, at *4.[7] Plaintiffs' claims relating to inadequate post-marketing testing, failure to report adverse events, and failure to review safety issues relating to metoclopramide are also preempted under *Mensing*. That is, even if Actavis conducted additional testing or was aware of new risks (or additional adverse events) associated with metoclopramide, Actavis could not furnish this information directly to consumers or the medical community. At most, Actavis could have petitioned the FDA to modify the label for metoclopramide. *Gross*, 2011 WL 5865267, at *4. In any event, the Amended Complaint fails to plead fraud with particularity as required by Rule 9(b), Federal Rules of Civil Procedure. *See Moore v. Mylan Inc.*, No. 1:11-CV-03037-MHS, 2012 WL 123986, at *9 (N.D. Ga. Jan. 5, 2012). As a result, the Amended Complaint fails to state a claim against Actavis for misrepresentation or fraud.

Count V – Negligence *Per Se* ("Parallel" State and Federal Law Claims)

Plaintiffs' negligence *per se* claim is subject to dismissal because Florida law does not recognize a claim based upon a theory of negligence *per se* for an alleged violation of the FDCA. *See Pantages v. Cardinal Health 200, Inc.*, No. 5:08-cv-116-Oc-10GRJ, 2009 WL 2244539, at *2 (M.D. Fla. July 27, 2009) (noting that violation of a federal statute was not negligence *per se* under Florida law unless the legislature intended a private right of action under the statute); *Blinn v. Smith & Nephew Richards, Inc.*, 55 F.Supp.2d 1353, 1361 (M.D. Fla. 1999) ("[a] [p]laintiff cannot use a negligence *per se* claim to create a private cause of action for [a][d]efendant's alleged violations of

[7] To the extent Plaintiffs contend that Actavis failed to supply relevant information to the FDA, Plaintiffs' claim may be viewed as relying on a fraud-on-the-FDA theory of liability. It is undisputed that "fraud on the FDA claims" are impliedly preempted by the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

the FDCA"); *Stevens v. Danek Medical, Inc.*, No. 95-14293-CIV-PAINE, 1999 WL 33217282, at *5-6 (S.D. Fla. Apr 16, 1999) (granting motion for summary judgment in favor of defendants because Florida law does not recognize a negligence *per se* claim based on a violation of FDCA); *see also Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1285 n.9 (11th Cir. 2002) (noting in *dicta* the holding in *Blinn* that there is no negligence *per se* claim under Florida law for a violation of the FDCA); *cf. Jupiter Inlet Corp. v. Brocard*, 546 So.2d 1, 2–3 (Fla. 4th DCA 1988) (OSHA does not provide a basis for a private right of action and violations of it do not constitute negligence *per se*). *But see Fisher*, 2011 WL 4552464, at *30-31 (citing cases recognizing viability of negligence *per se* based on violations of FDA requirements).[8] Furthermore, even if Plaintiffs could assert a negligence *per se* claim, they must allege facts supporting causation. Plaintiffs allege no fact supporting their conclusory allegation that Actavis' failure to obey an FDA requirement caused their injuries. *See Rounds v. Genzyme Corp.*, No. 8:10-cv-2479-T-23TBM, 2010 WL 5297180, at *3 (M.D. Fla. Dec. 20, 2010). As a result, the Amended Complaint fails to state a claim against Actavis based on a negligence *per se* theory of liability.[9]

---

[8] Similarly, Plaintiffs' negligence *per se* claim is barred to the extent Plaintiffs rely on Actavis' failure to comply with administrative regulations rather than substantive regulations establishing a specific standard of care owed by generic drug manufacturers. *See Iacangelo v. Georgetown Univ.*, 595 F.Supp.2d 87, 92 (D. D.C. 2009).

[9] To the extent Plaintiffs attempt to bring a private action to enforce FDA rules and regulations, such an action is expressly foreclosed by 21 U.S.C. § 337(a) ("proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act] shall be by and in the name of the United States"). *See Couick*, 2012 WL 79670, at *5; *see also Buckman Co.*, 531 U.S. at 349 ("The FDCA leaves not doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."). Thus, a private action alleging that Actavis breached an independent duty to Plaintiffs by failing to abide by FDA requirements must be dismissed. *Couick*, 2012 WL 79670, at *7 (dismissing claim based on generic drug manufacturer's failure to abide by FDA requirements); *see also Morris v. Wyeth, Inc.*, No. 09-0854, 2012 WL 601455, at *5 (W.D. La. Feb. 23, 2012) (dismissing failure to test and warn claim because the FDCA creates no private right of action).

Motion for Summary Judgment

While the majority of Plaintiffs' claims, however styled, are preempted under *Mensing*, it is arguable that claims based on Actavis' failure to more effectively communicate the warnings contained in the FDA approved label survive preemption under *Mensing*.[10] As Actavis argues in its motion for summary judgment, however, such claims are barred by the learned intermediary doctrine under Florida law.

Standard

Summary judgment is proper if following discovery, the pleadings, depositions, answers to interrogatories, affidavits and admissions on file show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); Fed. R. Civ. P. 56. "An issue of fact is 'material' if, under the applicable substantive law, it might affect the outcome of the case." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1259-60 (11th Cir. 2004) (internal citations omitted). "An issue of fact is 'genuine' if the record taken as a whole could lead a rational trier of fact to find for the nonmoving party." *Id.* at 1260. All the evidence and factual inferences reasonably drawn from the evidence must be viewed in the light most favorable to the nonmoving party. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970); *Jackson v. BellSouth Telecomms.*, 372 F.3d 1250, 1280 (11th Cir. 2004).

The Court will not weigh the evidence or make findings of fact. *Anderson*, 477 U.S. at 249; *Morrison v. Amway Corp.*, 323 F.3d 920, 924 (11th Cir. 2003). Rather, the Court's role is limited

---

[10] Courts addressing the issue after *Mensing* have disagreed whether a "failure to more effectively communicate" claim is preempted by the FDCA. *Compare, e.g., Kellogg v. Wyeth*, No. 2:07-cv-82, 2012 WL 368657 (D. Vt. Feb. 3, 2012), and *Moretti v. Pliva, Inc.*, No. 2:08-cv-00397-JCM, 2012 WL 628502 (D. Nev. Feb. 27, 2012), with *Whitener v. Pliva, Inc.*, No. 10-1552, 2011 WL 6056546 (E.D. La. 2011)

to deciding whether there is sufficient evidence upon which a reasonable juror could find for the non-moving party. *Id.*

Discussion

The duty of a manufacturer to warn of the risk associated with a prescription drug or medical device runs to a physician, the so-called "learned intermediary," rather than the patient. *See Christopher v. Cutter Laboratories*, 53 F.3d, 1184, 1192 (11th Cir. 1995) (stating that "a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products"); *Felix v. Hoffmann–LaRoche, Inc.*, 540 So.2d 102 (Fla. 1989); *Beale v. Biomet, Inc.*, 492 F.Supp.2d 1360, 1365 (S.D. Fla. 2007). "[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." *Christopher*, 53 F.3d at 1192. "Whether the physician in fact reads the warning, or passes its contents along to the recipient of the drug is irrelevant." *E.R. Squibb and Sons, Inc. v. Farnes*, 697 So.2d 825, 827 (Fla. 1997); *Felix*, 540 So.2d at 102–05. The adequacy of a warning, *i.e.*, the existence of a "learned intermediary," is an issue of law if the warning is accurate, clear, and unambiguous. *Felix*, 540 So.2d at 105; *Beale*, 492 F.Supp.2d at 1368–69; *Buckner v. Allergan Pharm., Inc.*, 400 So.2d 820 (Fla. 5th DCA 1981).

Plaintiffs do not argue that Actavis failed to update its label for generic metoclopramide to incorporate the 2004 label revision. As such, the product label furnished by Actavis contained the accurate, clear, and unambiguous warning that "[t]herapy should not exceed 12 weeks in duration

... ."[11] This warning, which was available both in the package insert and on the internet at www.fda.gov, satisfied Actavis' duty to provide Plaintiff's treating physician with adequate information about the risks associated with metoclopramide use (including the FDA indicated prohibition on long term use). *See Rounds v. Genzyme Corp.*, 440 Fed. Appx. 753, 755-56 (11th Cir. 2011), *petition for cert. filed,* No. 11-971, 11A525 (Feb. 6, 2012).[12] The physician then owed a duty to Plaintiff to apprise himself of the risk associated with metoclopramide and to exercise his judgment in prescribing the product and informing her of the risk. *See Rounds*, 440 Fed. Appx. at756.[13] Thus, Actavis is entitled to summary judgment with respect to all of Plaintiffs' claims that rely on the theory that Actavis should have more effectively communicated the warnings contained in the FDA approved label. *See Felix*, 540 So.2d at 105.

Conclusion

The majority of Plaintiffs' claims are preempted by federal law under *Mensing* or otherwise fail to state a claim upon which relief may be granted under Florida law. *See, e.g., Guarino v. Wyeth, LLC*, No. 10-cv-2885, 2011 WL 5358709 (M.D. Fla. Nov. 7, 2011) (dismissing claims that generic manufacturer's label was "inaccurate, misleading, materially incomplete, false and otherwise inadequate" and that manufacturer failed to send Dear Doctor letters to prescribing physicians under *Mensing*); *Morris v. Wyeth, Inc.*, 3:09-cv-854, 2011 WL 502448 (M.D. Fla. Oct. 20, 2011)

---

[11] To the extent Plaintiffs dispute the adequacy of the post-2004 label, Actavis properly notes that there is no duty to communicate an inadequate warning. *See Bowman v. Wyeth, LLC*, No. 10-1046 (JNE/SER), 2012 WL 684116, at *7 (D. Minn. March 2, 2012) (noting that there is not duty for a manufacturer to provide an inadequate warning). In any event, claims based on the content of the warning provided by Actavis are preempted by the FDCA under *Mensing*.

[12] This is true even if Actavis knew or should have known that the medical profession was not warning patients of allegedly known harmful side effects of metoclopramide use. *See Buckner v. Allerrgan Pharm., Inc.*, 400 So. 2d 820, 823-84 (Fla. 5th DCA 1981).

[13] The fact that federal law, including the FDCA, may have imposed on Actavis a more substantial duty *vis-a-vis* a treating physician does not change the analysis of what Florida law requires under the learned intermediary doctrine.

(dismissing plaintiff's claims against generic drug manufacturer for negligence, strict liability, breach of warranties, misrepresentation, fraud, and negligence *per se*). To the extent Plaintiffs' claims based on an alleged failure to effectively communicate the warning contained in the 2004 label survive preemption, such claims are barred by the learned intermediary doctrine under Florida law.

Accordingly, it is **ORDERED AND ADJUDGED**:

(1) Defendant Actavis Elizabeth LLC's Motion to Dismiss Plaintiffs' First Amended Complaint (Dkt. 91) is **GRANTED** to the extent that the First Amended Complaint purports to assert state law claims preempted by federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq*. Specifically, Plaintiffs' claims for strict liability (Count II), misrepresentation and fraud (Count IV), and negligence *per se* (Count V) are **DISMISSED** with prejudice.

(2) The Motion for Summary Judgment of Defendant's Actavis Elizabeth, LLC (Dkt. 109) is **GRANTED**. The Clerk is directed to enter final judgment in favor of Defendant Actavis Elizabeth, LLC and against Plaintiffs Barbara Metz and Donald Metz.

(3) All pending motions are **DENIED** as moot. The Clerk is directed to **CLOSE** this case.

DONE AND ORDERED in chambers this 28th day of March, 2012.

JAMES D. WHITTEMORE
United States District Judge

Copies to:
Counsel of Record