UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

ALEXANDRIA DIVISION

KATHLEEN M. HARRIS

VERSUS

MERCK & CO., INC., ET AL.

CIVIL ACTION NO. 12-1446

JUDGE TRIMBLE

MAGISTRATE JUDGE KIRK

# MEMORANDUM RULING

Before the court is a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) filed by defendant Merck & Co., Inc. ("Merck").[1] For the reasons expressed below, the court finds that Merck's motion should be GRANTED in part and DENIED in part.

## I. BACKGROUND

### A. Relevant Facts

Plaintiff Kathleen M. Harris ("Plaintiff") brings suit against defendant Merck & Co, Inc. ("Merck") and other manufacturers of the name brand drug Zocor and its generic equivalents, commonly known as "simvastatin."[2] Plaintiff alleges that Zocor, a prescription drug used to treat elevated cholesterol, is "defective, dangerous to human health, unfit and unsuitable to be marked and sold in commerce, and lacked proper warnings as to the dangers associated with its use."[3]

[1] R. 38.

[2] The court notes that all generic equivalent manufacturers (Lupin Pharmaceuticals, Inc., Teva Pharmaceuticals, Inc., Dr. Reddys Laboratories, Inc. and Ranbaxy Laboratories, Inc.) were all voluntarily dismissed from this suit by notice dated October 9, 2012 [R. 54]. Plaintiff also brings suit against Shering Plough Corp. and Merck Shering Plough Pharmaceuticals. It appears that service has not been perfected as to these two defendants and no answer has been filed by either such defendant. The court finds, therefore, that dismissal of these defendants is appropriate pursuant to Fed. R. Civ. P. 4.

[3] R. 1 at ¶ 13.

Plaintiff asserts that she was prescribed and began taking a daily 80 milligram dose of Zocor and/or its generic equivalent in August of 2001 and continued to take the drug as prescribed until January of 2012.[4] Plaintiff alleges that, as a result of ingesting the drug, she now suffers from "muscle and kidney problems"[5] and has and will experience "physical injuries, pain, and suffering, loss of enjoyment of life, lost wages, lost earning capacity, medical expenses, medical monitoring expenses, embarrassment and humiliation, fright and apprehension, emotional distress and other damages..."[6] Plaintiff's complaint now asserts claims under the Louisiana Products Liability Act ("LPLA"), La. R.S. 9:2800.51, et seq., and Louisiana law of redhibition, La. Civ. C. Art. 2520, et seq., following the voluntary dismissal of all other claims in conjunction with a prior Rule 12(f) motion to strike, also filed by Merck.[7]

Merck filed the instant motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), asserting that plaintiff's complaint fails to state claims as to which relief may be granted. This motion has been fully briefed by the parties.

**B. Applicable Standard**

In order to survive a motion to dismiss, a complaint must contain sufficient factual allegations which, when accepted as true for the purpose of such motion, state a claim for relief that is "plausible on its face."[8] A claim for relief is "plausible on its face" when it alleges facts which, when taken as true, enable the court to reasonably infer liability on the part of the defendant for the alleged conduct at issue.[9]

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[4] Id. at ¶ 19.
[5] Id. at ¶ 20.
[6] Id. at ¶ 21.
[7] Id. at ¶¶ 32-34. Merck's motion to strike was granted by order of October 3, 2012 based on plaintiff's consent. See R. 49, 53.
[8] Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007); Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Hale v. King, 642 F.3d 492, 499 (5th Cir. 2011).
[9] Twombly, 550 U.S. at 556; Iqbal, 556 U.S. at 678; Hale, 642 F.3d at 499.

Although the court must accept all well-plead facts as true, legal conclusions and "threadbare recitals" of the elements of a cause of action do not constitute well-plead facts and are insufficient to preserve claims against dismissal.[10] Dismissal is, however, improper if the allegations "support relief on any possible theory."[11]

## II. ANALYSIS

### Plaintiff's LPLA claims

The LPLA provides the exclusive basis of liability for manufacturers for damage caused by their products in Louisiana.[12] Accordingly, a plaintiff may only recover damages based on a theory of liability set forth in the LPLA.[13]

The LPLA provides, in part, that

> [t]he manufacturer of a product shall be liable to the claimant for damage proximately caused by a characteristic of the product that renders the product unreasonably dangerous when such damage arose from a reasonably anticipated use of the product by the claimant or another person or entity.[14]

This provision is interpreted by courts as requiring that a plaintiff demonstrate the following:

1. the defendant is the manufacturer of the product at issue; and
2. the plaintiff's damage was proximately caused by a characteristic of the product; and
3. the characteristic of the product which caused the damage made the product "unreasonably dangerous;" and
4. the plaintiff's damage arose from a reasonably anticipated use of the product.[15]

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[10] Patrick v. Wal-Mart, Inc. – Store No. 155, 681 F.3d 614, 622 (5th Cir. 2012) quoting Iqbal, 556 U.S. at 678.
[11] Wilson v. Birnberg, 667 F.3d 591, 595 (5th Cir. 2012) quoting Cinel v. Connick, 15 F.3d 1338, 1341 (5th Cir. 1994).
[12] La. R.S. 9:2800.52; Brown v. R.J. Reynolds Tobacco Co., 52 F.3d 524, 526 (5th Cir. 1995).
[13] Id.; Lewis v. Intermedics Intraocular, Inc., 56 F.3d 703, 706 (5th Cir. 1995).
[14] La. R. S. 9:2800.54(A).
[15] Matthews v. Remington Arms Co., Inc., 641 F.3d 635 (5th Cir. 2011); Stahl v. Novartis Pharm. Corp., 283 F.3d 254 (5th Cir. 2002).

The LPLA instructs that a product is "unreasonably dangerous" only when

> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
> (2) The product is unreasonably dangerous in design as provided in R. S. 9:2800.56;
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R. S. 9:2800.57; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.[16]

Merck asserts that plaintiff's complaint fails to allege sufficient facts to state claims for relief under the LPLA. We address each LPLA claim below.

*Construction or composition claim*

Merck alleges that plaintiff fails to allege facts which suggest that the medication at issue "deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer"[17] as required by applicable statute. Plaintiff does not address this argument in her opposition.

We have reviewed plaintiff's complaint thoroughly. Paragraph 32 of plaintiff's complaint lists the four available claims under the LPLA, but alleges no facts consistent with a claim for a defect in construction or composition under La. R.S. 9:2800.55, cited above.

While plaintiff is not required to plead facts which raise the complaint's plausibility to the level of probability, plaintiff is required to plead sufficient facts to raise the complaint's plausibility beyond the level of mere suspicion.[18] Thus, reciting the allegation that defendant is liable to plaintiff for "providing a product that was unreasonably dangerous in construction or composition..." is insufficient to satisfy the requirements of Fed. R. Civ. P. 8(a) as those have

[16] La. R. S. 9:2800.54.
[17] La. R. S. 9:2800.55; R. 38 at p. 6.
[18] Twombly, 550 U.S. at 556.

been interpreted by the Fifth Circuit Court of Appeals and the United States Supreme Court.[19] Moreover, it appears that plaintiff does not contest the dismissal of this purported claim.

Accordingly, Merck's motion to dismiss will be granted with respect to plaintiff's purported LPLA construction or composition claim.

*Design defect claim*

La. R. S. 9:2800.56 provides that

> [a] product is unreasonably dangerous in design if, at the time the product left its manufacturer's control:
>
> (1) [t]here existed an alternative design for the product that was capable of preventing the claimant's damage; and
>
> (2) [t]he likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.

Merck asserts that plaintiff's complaint fails to allege sufficient facts regarding plaintiff's purported design defect claim. Specifically, Merck points out that plaintiff does not allege the existence of an alternative design which would have prevented plaintiff's alleged damages.

Plaintiff argues that her complaint does meet the pleading standard in that it clearly alleges that the 80 milligram dose was the cause of her injuries and that other, smaller doses would have prevented the injuries. The court agrees that these factual allegations are found

[19] Id. at 556 n. 3 (explaining that Rule 8(a) expressly requires not only notice to defendant of the "nature" of plaintiff's claim, but also the "grounds" upon which such claim rests); Lormand v. U.S. Unwired, Inc., 565 F.3d 228, 232 (5th Cir. 2009).

within plaintiff's complaint and are sufficient under Rule 8(a) to apprise Merck of the crux of plaintiff's LPLA claim, which is that the risks associated with an 80 milligram dose were known to the manufacturer and outweighed the benefits of such dose, rendering the medication unreasonably dangerous when prescribed in 80 milligram doses.[20] Although we agree with the result reached by the court in Ivory v. Pfizer, Inc.,[21] cited by Merck, we find plaintiff's complaint more complete than that of Ivory, in that it alleges a defect in the dosage design and asserts that a lower dose design would have prevented plaintiff's injuries.

Accordingly, Merck's motion to dismiss will be denied as to plaintiff's LPLA design defect claim, which will be preserved for further proceedings.

*Failure to warn claim*

La. R.S. 9:2800.57 provides, in part, that

> a product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.[22]

Merck asserts that plaintiff's complaint fails to allege facts sufficient to state an LPLA claim for failure to warn, particularly in light of Louisiana's "learned intermediary doctrine."

Courts interpreting Louisiana law apply the "learned intermediary doctrine" to products liability claims involving prescription drugs. Under this doctrine, the manufacturer of the drug at issue fulfills its duty to the drug consumer by reasonably informing prescribing physicians of the

[20] R. 1 at ¶¶
[21] Civ. Act. No. 09-0072 (W.D. La. 9/30/09) 2009 WL 3230611.
[22] La. R.S. 9:2800.57(A).

dangers associated with a particular drug.[23] A plaintiff must, therefore, demonstrate (1) that the defendant manufacturer failed to warn or to adequately warn the prescribing physician; and (2) that the manufacturer's failure to warn or to adequately warn was the cause in fact and proximate cause of the plaintiff's injury.[24]

Merck asserts that plaintiff's complaint fails in several aspects relative to plaintiff's failure to warn claim. First, Merck points out that plaintiff fails to identify a specific prescribing physician which she claims was inadequately warned. Although this information will certainly be of the utmost relevance in the next phases of litigation of this case, we do not find that plaintiff is required to disclose the name of a particular physician in her complaint. Merck cites no authority, nor are we aware of any, requiring that a specific physician be identified by name in the pleadings.

Next, Merck asserts that plaintiff's allegation that

> [i]f Merck had [rendered an adequate warning concerning Zocor], prescribers such as Plaintiff's prescriber would not have prescribed Zocor in patients, such as the Plaintiff, and would have switched from Zocor to safer products, or would have refrained wholly from any use of Zocor[25]

is inadequate under the two-part test applied by courts under the learned intermediary doctrine.

Our review of the complaint at issue reveals that, while barely sufficient, plaintiff's allegations do meet the most minimal threshold under the learned intermediary doctrine. Plaintiff alleges that her prescribing physician was not rendered an adequate warning and/or was deliberately misled regarding hazards of Zocor and further alleges that an adequate warning

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[23] Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 265 (5th Cir. 2002) citing Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987).
[24] Id. at 266 citing Willett v. Baxter Int'l. Inc., 929 F.2d 1094, 1098 (5th Cir. 1991).
[25] R. 1 at ¶ 28.

regarding the potential for myopathy and rhabdomyolysis in patients taking an 80 milligram dose would have deterred her physician from prescribing an 80 milligram dose to plaintiff.[26]

Finally, Merck asserts that plaintiff's failure to allege what warning would have been adequate, when compared with the warning issued by the manufacturer, renders plaintiff's claim insufficient. Merck cites no authority wherein dismissal was deemed appropriate on the basis that plaintiff's complaint did not offer an alternative warning which, having not been used by the manufacturer, rendered the manufacturer's conduct unreasonable in light of the risk.[27] We think this type of argument is more suited for post-discovery motion practice or, possibly, trial, but should not be required at the pleading stage. Accordingly, Merck's motion will be denied as to plaintiff's LPLA failure to warn claim.

*Express warranty claim*

La. R.S. 9:2800.58 provides that

> [a] product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and that claimant's damage was proximately caused because the express warranty was untrue.

La. R.S. 9:2800.53(6) defines an "express warranty" as

> a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship possesses specified characteristics or qualities or will meet a specified level of performance. "Express warranty" does not mean a general opinion about or general praise of a product. A sample or model of a product is an express warranty.

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[26] Id. at ¶¶ 28, 31.

[27] Grenier v. Medical Engineering Corp., 243 F.3d 200 (5th Cir. 2001), cited by Merck, involved the Fifth Circuit's review of a summary judgment proceeding before a district court, not a district court's ruling on a Rule 12(b)(6) motion, and, therefore, involves differing standards than are applicable to the present matter.

Merck asserts that plaintiff's complaint is insufficient to state a claim for breach of express warranty under the LPLA because it fails to identify specific language of any express warranty it alleges was offered by Merck as to Zocor.

Plaintiff points out paragraphs 26, 27 and 29 of the complaint as alleging the existence of an express warranty as to Zocor by Merck. These paragraphs allege

> ...Merck had a significant market share based upon claims of Zocor's efficacy, a very aggressive marketing program which included financial incentives to sales teams, infusion of numerous sales representatives and massive direct-to-consumer advertising and physician sampling program...
>
> [a]s a result of such marketing, Zocor gained a significant market share in competition with other cholesterol lowering medications, that Merck would not have gained if Merck had not suppressed information about Zocor and/or made false representations of Zocor's superiority and efficacy...
>
> [f]rom approximately 1998 through the present, Merck continued to engage in a common scheme of marketing, distributing and/or selling Zocor under the vise /sic/ that it was safe and efficacious for persons such as Plaintiff before, during and after Plaintiff developed kidney problems.[28]

The court agrees that these paragraphs, though not a superlative fulfillment of the standard, do meet the very basest requirements of Rule 8(A) and interpretive jurisprudence. We add that these paragraphs, when paired with plaintiff's allegation that "[i]f Merck had not engaged in this conduct, prescribers such as Plaintiff's prescriber would not have prescribed Zocor in patients, such as the Plaintiff, would have switched from Zocor to safer products, or would have refrained wholly from any use of Zocor" do meagerly assert that Merck expressly warranted its drug, Zocor, to plaintiff's prescribing physician and, as discussed above, further alleges that plaintiff sustained damages as a result of plaintiff's physician being induced to prescribe Zocor by Merck's express warranties. Again, plaintiff's complaint leaves much to be

[28] R. 1 at ¶¶ 26, 27 and 29.

desired in terms of clarity, but, bound as we are to resolve such doubt in favor of preservation of claims, we find that Merck's motion must be denied as to plaintiff's LPLA express warranty claim.[29]

**Plaintiff's redhibition claim**

La. Civ. C. Art. 2520 provides that

> [t]he seller warrants the buyer against redhibitory defects, or vices, in the thing sold.
>
> A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect. The existence of such defect gives a buyer the right to obtain rescission of the sale.
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> A defect is redhibitory also when, without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price. The existence of such a defect limits the right of a buyer to a reduction of the price.

As acknowledged by both parties, the LPLA allows for a redhibition claim only to the extent that plaintiff seeks recovery of economic losses.[30] Merck asserts that plaintiff's redhibition claim must fail because plaintiff's complaint fails, as argued above, to state a claim for defect. Having already deemed plaintiff's complaint sufficient as stating a claim for design defect under the LPLA, we also reject this argument relating to redhibition and find that plaintiff's redhibition claim should be preserved for further proceedings. Accordingly, Merck's motion will be denied in this respect.

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[29] Evans v. I-Flow Corp., 2012 WL 1970882 (W.D. La. 5/31/2012) (denying Rule 12(b)(6) dismissal of LPLA express warranty claim premised on plaintiff's failure to cite specific warranty language and distinguishing requirements at summary judgment stage as applied in Grenier to those applicable to Rule 12(b)(6) motions).

[30] Pipitone v. Biomatrix, Inc., 288 F.3d 239 (5th Cir. 2002); Grenier v. Medical Engineering Corp., 243 F.3d 200 (5th Cir. 2001); Jefferson v. Lead Industries Ass'n., Inc., 106 F.3d 1245 (5th Cir. 1997).

**Plaintiff's medical monitoring claims**

Merck asserts that plaintiff's purported claim for medical monitoring expenses must fail because her claim relates only to the medical condition of rhabdomyolysis, which plaintiff does not allege she suffers from at this time. Merck further asserts that, because she seeks medical monitoring for a currently asymptomatic condition, plaintiff is required to demonstrate the seven factors announced by the Louisiana Supreme Court in Bourgeois v. A.P. Green Indust., Inc., often cited as "Bourgeois I."[31]

Medical monitoring claims seek recovery of costs of periodic medical monitoring for the purpose of detecting the onset of physical harm.[32] In Bourgeois I, the court instructed that plaintiffs seeking medical monitoring damages must show:

> (1) significant exposure to a proven hazardous substance;
>
> (2) an increased risk of contracting a serious latent disease proximately caused by exposure to a proven hazardous substance;
>
> (3) a risk of contracting a serious latent disease which is (a) greater than the risk would of disease would have been had plaintiff not been exposed to the hazardous substance and (b) greater than the risk to the public at large of contracting the same serious latent disease;
>
> (4) the availability of a monitoring procedure which makes early detection of the disease possible;
>
> (5) the monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles;
>
> (6) the prescribed monitoring regime is different from that normally recommended in the absence of exposure to the hazardous substance; and

[31] 716 So. 2d 355 (La. 1998).
[32] Id. at 358.

(7) there is some demonstrated clinical value in the early detection and diagnosis of the disease.[33]

Plaintiff argues that she need not demonstrate these factors because she suffers from manifest physical illness or injury as required under La. Civ. C. Art 2315(B). Specifically, plaintiff points out that the complaint alleges that she suffers from muscle and kidney problems.

We have studied plaintiff's complaint and find that plaintiff's claim for medical monitoring damages should not be dismissed at this stage of litigation, though as with most of plaintiff's other claims, it is not superlative. Plaintiff clearly alleges physical injury to her muscles and kidneys caused by prolonged exposure to an 80 milligram dose of Zocor. It will be up to plaintiff to demonstrate in future proceedings that these are conditions for which medical monitoring is necessary. As to plaintiff's exposure to Zocor and the alleged risk of rhabdomyolysis, if plaintiff is not currently diagnosed with such condition, she will be required to demonstrate the Bourgeois I factors, though, once again, we find that requiring plaintiff to meet these factors at the pleading stage is not contemplated by Rule 8(a). Accordingly, Merck's motion to dismiss will be denied as to plaintiff's medical monitoring claims.

## III. CONCLUSION

For the reasons stated herein, the court finds that Merck's motion to dismiss should be granted as to plaintiff's purported LPLA manufacturing defect claim, but should be denied as to plaintiff's remaining LPLA claims for design defect, failure to warn and breach of express warranty. Similarly, Merck's motion to dismiss should be denied as to plaintiff's redhibition and medical monitoring claims. The court will issue a judgment in conformity with these findings.

**Alexandria, Louisiana**
**November 1, 2012**

**JAMES T. TRIMBLE, JR.**
**UNITED STATES DISTRICT JUDGE**

[33] Id. at 360 – 362.