UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

LISA N. RINGELESTEIN and DONALD RINGELESTEIN,	)	
	)	16 C 4970
Plaintiffs,	)	
	)	Judge Gary Feinerman
vs.	)	
	)	
JOHNSON & JOHNSON, JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, AND JANSSEN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Lisa and Donald Ringelestein, a married couple, brought this diversity suit against several pharmaceutical companies, alleging negligence, strict liability, breach of warranty, loss of consortium, fraud, and fraudulent concealment arising from their marketing of Levaquin, a prescription drug. Docs. 26, 39. Defendants have moved under Federal Rule of Civil Procedure 12(b)(6) to dismiss the fraud and fraudulent concealment claims. Doc. 27. The motion is granted in part and denied in part.

Background

In resolving a Rule 12(b)(6) motion, the court assumes the truth of the operative complaint's well-pleaded factual allegations, though not its legal conclusions. *See Zahn v. N. Am. Power & Gas, LLC*, 815 F.3d 1082, 1087 (7th Cir. 2016). The court must also consider "documents attached to the complaint, documents that are critical to the complaint and referred to in it, and information that is subject to proper judicial notice," along with additional facts set forth in Plaintiffs' brief opposing dismissal, so long as those additional facts "are consistent with

the pleadings." *Phillips v. Prudential Ins. Co. of Am.*, 714 F.3d 1017, 1020 (7th Cir. 2013). The facts are set forth as favorably to Plaintiffs as those materials allow. *See Pierce v. Zoetis*, 818 F.3d 274, 277 (7th Cir. 2016). In setting forth those facts at this stage, the court does not vouch for their accuracy. *See Jay E. Hayden Found. v. First Neighbor Bank, N.A.*, 610 F.3d 382, 384 (7th Cir. 2010).

Defendants manufacture Levaquin, an antibiotic in the fluoroquinolone family. Doc. 39 at ¶ 12, 19. From 2009 to 2015, Defendants conveyed information to the public concerning Levaquin's safety; the complaint does not specify the exact nature of that information. *Id*. at ¶ 15. During that time, the FDA drafted a report, which was not made public, detailing links between Levaquin and mitochondrial toxicity, ALS, Alzheimer's, and Parkinson's disease. *Id*. at ¶¶ 16-17. When an FDA advisory committee met in 2015 to consider fluoroquinolone drugs, an FDA employee stated that those drugs (including Levaquin) could result in multi-system disability. *Id*. at ¶ 18-19. The FDA now identifies "Fluoroquinolone-Associated Disability" as the set of "adverse reactions involving neuromuscular, neuropsychiatric, peripheral neuropathy, sense, skin and cardiovascular symptoms." *Id*. at ¶ 20. Plaintiffs allege that Defendants knew this information but did not share it with the public, Plaintiffs, or Plaintiffs' physicians. *Id*. at ¶ 27.

Lisa Ringlestein was prescribed and used Levaquin in June 2010 and April 2013. *Id*. at ¶¶ 28-30. After using the drug, she developed several health problems, including:

> orthopedic issues, neurological issues, mental status changes, fatigue, constant pain, loss of balance[,] incoordination, cardiovascular issues including racing of the heart, impaired cognitive function, an inability to tolerate cold temperatures, muscle twitching, numbness, tingling and crawly skin, burning sensations on her feet, severe anxiety, tingling in spine, neuropathy, and other symptoms, conditions, dysfunction and injury.

Id. at ¶ 34. In 2012 and 2013, Lisa underwent a variety of orthopedic surgeries, and in May 2014 she was diagnosed with "multiple tendon ruptures likely secondary to Levaquin." *Id*. at ¶¶ 35-39. In August 2015, after further assessments, a physician diagnosed Lisa with chronic pain and mitochondrial impairment/fluoroquinolone toxicity. *Id*. at ¶¶ 41-43. Her symptoms continue to this day. *Id*. at ¶ 40.

Plaintiffs allege that Defendants "concealed and provided inadequate information and warnings as to Levaquin." *Id*. at ¶ 46. They further allege that Defendants made representations through national advertising, promotional campaigns, and other marketing materials that were "false, misleading, materially incorrect in fact, and were made knowingly, intentionally, and/or willfully to deceive." *Id*. at 16 ¶ 79.

Discussion

I. Fraud Claim

"The elements of common law fraud are: (1) a false statement of material fact; (2) defendant's knowledge that the statement was false; (3) defendant's intent that the statement induce the plaintiff to act; (4) plaintiff's reliance upon the truth of the statement; and (5) plaintiff's damages resulting from reliance on the statement." *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 591 (Ill. 1996); *see also Geschke v. Air Force Ass'n*, 425 F.3d 337, 345 (7th Cir. 2005) (same). A fraud plaintiff in federal court must comply with Rule 9(b), which provides that "[i]n alleging fraud …, a party must state with particularity the circumstances constituting fraud … ." Fed. R. Civ. P. 9(b). "This ordinarily requires describing the 'who, what, when, where, and how' of the fraud, although the exact level of particularity that is required will necessarily differ based on the facts of the case." *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 615 (7th Cir. 2011); *see also Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994)

("[T]he reference to 'circumstances' in the rule requires the plaintiff to state the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff.") (some internal quotation marks omitted).

Plaintiffs' fraud claim does not satisfy Rule 9(b). The complaint makes a variety of allegations that, when the dots are connected in a particular way, could give notice of the offending conduct. While that might suffice for ordinary pleading under Rule 8(a)(2), which requires only "a short and plain statement of the claim showing that the pleader is entitled to relief," it does not suffice under Rule 9(b), which requires plaintiffs to "state with particularity the circumstances constituting fraud." For example, the complaint alleges that Defendants made representations "regarding the characteristics of and the quality of Levaquin and Levofloxacin, [which] were false, misleading, materially incorrect in fact, and were made knowingly, intentionally and/or willfully to deceive." Doc. 39 at 16 ¶ 79. However, the complaint does not describe *how* those representations were misleading. Elsewhere, the complaint alleges that Levaquin "was represented to be safe and free from latent defects, for use as directed on the label." *Id*. at ¶¶ 56, 60. However, the complaint does not say *who* made those representations. And while the complaint makes passing references to labels and package inserts, *id*. at ¶¶ 19, 32, 56, 60, 79, it does not specify their content or attach them as exhibits. In sum, while one might possibly connect the dots in a way that yields viable fraud allegations, the complaint itself does not do so. That is insufficient under Rule 9(b), so Count VI is dismissed, with the dismissal being without prejudice to repleading. *See Runnion v. Girl Scouts of Greater Chi. & Nw. Ind.*, 786 F.3d 510, 519 (7th Cir. 2015) ("Ordinarily … a plaintiff whose original complaint has been

dismissed under Rule 12(b)(6) should be given at least one opportunity to try to amend her complaint … .").

II. Fraudulent Concealment

"In order to state a claim for fraudulent concealment, a plaintiff must allege that the defendant concealed a material fact when he was under a duty to disclose that fact to [the] plaintiff." *Connick*, 675 N.E.2d at 593. Defendants first argue that the fraudulent concealment claim suffers from a Rule 9(b) particularity problem. Doc. 27 at 6. That is incorrect. The complaint alleges that Defendants concealed their knowledge of certain potential side effects of Levaquin. Doc. 39 at ¶¶ 15-16, 20, 23-24, 89-91.

Defendants next argue that they were under no duty to disclose safety information regarding Levaquin to Plaintiffs. Doc. 27 at 6. That is incorrect as well. A duty to disclose arises where "plaintiff and defendant are in a fiduciary or confidential relationship," or where "plaintiff places trust and confidence in defendant, thereby placing defendant in a position of influence and superiority over plaintiff." *Connick*, 675 N.E.2d at 593. Illinois courts have yet to decide whether the relationship between a pharmaceutical company and persons who use its drugs fits the bill, though in *Guvenoz v. Target Corp.*, 30 N.E.3d 404 (Ill. App. 2015), the court assumed an affirmative answer after the pharmaceutical company defendants did not contest the issue. *Id*. at 425.

Common sense suggests that pharmaceutical companies are in a "position of superiority" over patients who use their drugs. After all, the companies are well-positioned to understand the potential side effects of their drugs in a way their lay patients are not. *See Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009) ("[M]anufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge."). True enough, tort liability

for drug makers has traditionally been limited by principles such as the learned intermediary doctrine, which provides that if the prescribing physician is adequately warned of a drug's risks, the patient has no failure to warn claim against the pharmaceutical company. *See Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1126 (Ill. 2002). But Defendants have not raised the learned intermediary doctrine as a defense, and even if they had, its application would be questionable, certainly on the pleadings. *See In re Testosterone Replacement Therapy Prods. Liability Litig.*, 2017 WL 1836443, *8 n.2 (N.D. Ill. May 8, 2017) (expressing doubt that the learned intermediary doctrine would apply were, as here, a pharmaceutical company's marketing materials were directed not only to physicians, but to the general public as well).

In *In re Neurontin Marketing, Sales Practices, and Prods. Liability Litig.*, 618 F. Supp. 2d 96 (D. Mass. 2009), the MDL court noted that "[i]n the products liability area, courts have routinely held that a manufacturer of a drug has a duty to warn physicians, *and in some cases, warn patients*, about the dangers of the administration of a drug." *Id*. at 110 (emphasis added). The court ultimately held that "a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of the drug." *Ibid*. That decision did not involve Illinois law, but there is no basis in the Illinois cases to conclude that Illinois courts would reach a different result.

For these reasons, the court concludes that under Illinois law, a pharmaceutical company has a duty to disclose known risks of its drugs to patients and their physicians. This defeats Defendants' contention that Plaintiffs' fraudulent concealment claim should be dismissed on the ground that such a duty does not exist.

Conclusion

Defendants' motion to dismiss is granted as to the fraud claim and denied as to the fraudulent concealment claim. Plaintiffs have until June 21, 2017 to file an amended complaint with a repleaded fraud claim. If Plaintiffs amend the complaint, Defendants shall answer or otherwise plead to the amended complaint by July 12, 2017; if Plaintiffs do not amend the complaint, Defendants shall answer the surviving portions of the current complaint by June 28, 2017.

May 31, 2017

United States District Judge