UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

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| TRACY GARNER,<br><br>Plaintiff,<br><br>v.<br><br>JOHNSON & JOHNSON, JANSSEN RESEARCH AND DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS INC., and ZYDUS PHARMACEUTICALS (USA) INC., A DIV. OF CADILA HEALTHCARE,<br><br>Defendants. | ) | Case No. 1:16-cv-01494-SLD-JEH |

ORDER

Before the Court are a Motion to Dismiss for Failure to State a Claim, ECF No. 10, by Defendants Johnson & Johnson, Janssen Research & Development LLC, and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively, "Janssen") and an Amended Motion to Dismiss, ECF No. 17, by Defendant Zydus Pharmaceutical (USA), Inc. ("Zydus"). All Defendants seek dismissal of the Amended Complaint, ECF No. 3, by Plaintiff Tracy Garner.

BACKGROUND[1]

On December 24, 2014, Plaintiff Garner, a citizen of Knox County, Illinois, was prescribed generic levofloxacin, a strong fluoroquinolone antibiotic, to treat a urinary tract infection. Garner took the drug, manufactured by Zydus, in its prescribed dosage. At some point thereafter, Garner began to experience adverse reactions and suspected they were connected to

[1] For the purpose of resolving a motion to dismiss, the factual allegations in a plaintiff's complaint are assumed to be true. *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011). Therefore, unless otherwise noted, the facts set forth here are drawn from Garner's Amended Complaint, ECF No. 3.

her use of the levofloxacin: a non-exhaustive list of those reactions included peripheral neuropathy,[2] fluoroquinolone toxicity, mental status changes, chronic pain, fatigue, gastrointestinal problems, tinnitus, and skin changes.

The United States Food and Drug Administration ("FDA") originally approved levofloxacin in 1996 under the brand name "Levaquin," as it was originally created, manufactured, and marketed by Janssen. Levaquin has been widely used across the world, at one point ranking first in the world for prescribed antibiotics. The Ortho-McNeil website[3] stated about Levaquin that it "has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections." Compl. ¶ 35. The FDA approved levofloxacin for generic manufacture and sale in the United States in 2011. At that point, pharmaceutical company Zydus began to manufacture a generic form of levofloxacin that contained the same active ingredient as, and was the bioequivalent and therapeutic equivalent of, Levaquin. As required by the FDA, Zydus adopted warning labels for levofloxacin identical to those used by Janssen.

Plaintiff alleges that scientific evidence, beginning in 1992, showed a link between levofloxacin and a heightened risk of long term and irreversible peripheral neuropathy and other medical conditions, including some of the ones experienced by Garner. In 2002 and 2003, reports to the FDA's Adverse Event Reporting System showed that other users of fluoroquinolones had developed long-lasting peripheral neuropathy. In 2013, the FDA drafted a memo regarding the connection between disabling peripheral neuropathy and fluoroquinolone

[2] Neuropathy, according to the National Institute of Health, means "nerve disease or damage"; peripheral neuropathy refers to damage in the peripheral nervous system that connects to and sends information to the brain and spinal cord. NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, NAT'L INST. OF HEALTH, "Peripheral Neuropathy Fact Sheet" (Dec. 2014) https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Peripheral-Neuropathy-Fact-Sheet

[3] Garner alleges that Ortho-McNeil is a wholly owned subsidiary of Johnson & Johnson and that it, in concert with the other defendants, created the Levaquin warning label.

use that linked the drug to ALS, Alzheimer's, and Parkinson's disease. That memo was never made public. A January 2014 medical paper further questioned the risk-benefit analysis of using fluoroquinolones and linked fluoroquinolones to peripheral neuropathy. A Citizen's Petition filed with the FDA on September 8, 2014 chronicled adverse events reported after patients took fluoroquinolones, including disorientation, agitation, depression, attention deficit, panic attacks, memory impairment, and nervousness.

Garner alleges that "Defendants" (she does not ascribe the action to any one defendant in particular) failed to heed these "safety signals," despite public representations by Johnson & Johnson that it monitors the "safety and effectiveness" of medications it produces, in cooperation with the FDA. Instead, Defendants conveyed false information about the drug's safety.

On November 5, 2015, almost a year after Garner was prescribed levofloxacin, the FDA Advisory Committee held a meeting at which it considered the risk-benefit analysis of fluoroquinolone antibacterial drugs. An FDA employee stated that the FDA became aware of the danger of fluoroquinolones in causing multi-system disability as early as 2013, but it had not suggested any changes to the levofloxacin safety warning label. The Adverse Event Reporting System now identifies fluoroquinolone adverse reactions involving the neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, and cardiovascular systems. These reactions are now identified by a new term, "Fluoroquinolone-Associated Disability" ('FQAD"). As of May 2016, the FDA strongly advises against the use of fluoroquinolones for the treatment of simple infections including sinusitis, bronchitis, and urinary tract infections, stating that they should be used only for patients who do not have other treatment options.

Garner filed suit on December 22, 2016, alleging that the Court could exercise diversity jurisdiction under 42 U.S.C. § 1331. Garner is a resident and citizen of Illinois. Johnson &

Johnson, Janssen Research & Development LLC ("Janssen R&D"), and Zydus are all New Jersey corporations with principal places of business in New Jersey, except for Janssen R&D, which has its principal place of business in Pennsylvania. Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho-McNeil") is a Delaware corporation with its principal place of business in New Jersey. Against Defendant Janssen, Garner alleges five counts including (I) negligence, (II) negligent misrepresentation, (III) fraud, (IV) fraudulent concealment, and (V) product liability negligence. Against Zydus, Garner alleges eight counts, including: (VI) negligence, (VII) negligent misrepresentation, (VIII) fraud, (IX) fraudulent concealment, (X) product liability, (XI) breach of express warranty of merchantability, (XII) breach of implied warranty of merchantability, and (XIII) strict liability. Janssen and Zydus filed motions to dismiss the amended complaint, pursuant to Federal Rule of Civil Procedure 12(b)(6). *See* Janssen Mot. Dismiss, ECF No. 10; Zydus Am. Mot. Dismiss, ECF No. 17. Janssen admits it researched, developed, and sold Levaquin but argues that because Garner took the generic form of levofloxacin, which it did not manufacture, it cannot be liable for her injury. Janssen Mot. Dismiss 2–4. Janssen argues that the Court should reject the theory of liability, known as innovator liability, which would impose a duty of care on Janssen to Garner. Zydus puts forth that it cannot be liable either, arguing that since the warning labels on generic drugs are required by law to mirror the brand name label, Garner's claim against Zydus is preempted by federal law. Zydus Mot. Dismiss 3.

## DISCUSSION

### I. Legal Standard on a Motion to Dismiss

A court will dismiss a complaint if it does not state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Federal Rule of Civil Procedure 8(a) requires a plaintiff to provide "a short and plain statement of the claim showing that the pleader is entitled to relief[.]"

Fed. R. Civ. P. 8(a). The pleader's claim must be facially plausible, meaning that the factual allegations allow the court to draw a "reasonable inference" that the purported misconduct occurred. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). This means that a complaint must provide "allegations that raise a right to relief above the speculative level." *Tamayo v. Blagojevich*, 526 F.3d 1074, 1084 (7th Cir. 2008). A complaint must also describe its claims in sufficient detail to give a defendant "fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (alteration in *Bell Atlantic*). A court may dismiss a complaint "on the basis of a dispositive issue of law." *Neitzke v. Williams*, 490 U.S. 319, 327 (1989).

## II. Analysis

### A. The Hatch-Waxman Act

The holders of patents for brand name drugs must go through a lengthy approval process with the FDA, often including extensive and expensive clinical trials and testing, before a new drug can hit the market. *Mutual Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2470–71 (2013). Mindful of the rigor required for the submission of a new-drug application for brand name drugs ("NDA"), Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, which amended the Food, Drug, and Cosmetics Act ("FDCA"). 21 U.S.C. § 355. In the interest of making innovative drugs available in generic (and cheaper) form on an expedited basis, the Hatch-Waxman Act allows generic drug manufacturers to use an abbreviated new drug application process ("ANDA"). To make it to market, the generic drug must establish it: (1) is the chemical equivalent of the brand name drug, including the identification of active ingredients, route of administration, dosage form, and strength, 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii); (2) is the bioequivalent of the brand name drug, such that it has the same "rate and extent of absorption," 21 U.S.C. §§ 355(j)(2)(A)(iv), (8); and

(3) has the identical FDA-approved label of the brand name drug, § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

Under the Hatch-Waxman regime, a brand-name manufacturer is "responsible for the accuracy and adequacy of its label," and a manufacturer of generic drugs is "responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011). Federal drug regulations prevent generic manufacturers from independently modifying the label at any time while the drug is on the market. 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10).

B. Claims Against Zydus

Garner brings eight counts against Zydus: (VI) negligence, (VII) negligent misrepresentation, (VIII) fraud, (IX) fraudulent concealment, (X) product liability, (XI) breach of express warranty, (XII) breach of implied warranty of merchantability, and (XIII) strict liability. *See* Compl. 24–38.

The Supreme Court, in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013), examined whether failure to warn and design defect claims against generic drug manufacturers are preempted by the FDCA because of the labeling identity requirement, answering that inquiry affirmatively. In *Mensing*, the Court determined that "federal drug regulations applicable to generic drug manufacturers directly conflict with and thus preempt . . . state law claims" that are based on the manufacturer's alleged failure to provide adequate warning labels." *Mensing*, 564 U.S. at 609. The Court extended the *Mensing* holding in *Bartlett*, finding that "state-law design-defect claims that turn on the adequacy of a drug's warning" were preempted. *Bartlett*, 133 S.Ct. at 2470. It made this determination by examining what exactly the tort law of New Hampshire, the state at issue,

would have required of the generic manufacturer; if federal law prohibits "the remedial action required to avoid liability" under state law, the claim is preempted. *Id.* at 2475–78. The Court noted that changing the chemical makeup of a drug to make it safer, or changing the labeling of the drug, were not viable options for a generic manufacturer under the FDCA, *id.* at 2474–76; the Court also rejected the respondent's argument that the generic manufacturer should have pulled the drug from the market to resolve safety issues that could not be addressed through redesigning the drug or from strengthened labeling. *Id.* at 2474–2478. These decisions did not address the possible liabilities of brand-name manufacturers, which the Supreme Court had held could be liable when a plaintiff ingests and is harmed by the brand-name drug. *See Wyeth v. Levine*, 555 U.S. 555 (2009).[4]

The Seventh Circuit has already noted that the *Mensing* decision "makes it difficult if not impossible to hold the generic manufacturer liable" for claims of injury caused by a drug's inadequate labeling. *In re Glaxosmith Kline*, No. 14-2051, 557 F. App'x 578 (7th Cir. Jun. 4, 2014) (non-precedential ruling on writ of mandamus in *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 711 (N.D. Ill. 2014)). In particular, the Circuit has adopted *Mensing*'s holding that "the FDCA preempts any state law that requires companies to improve generic drug labels." *Wagner v. Teva Pharm. USA, Inc.*, 840 F.3d 355, 358 (7th Cir. 2016). Though Garner spills much ink to convince the Court otherwise, her negligence (Count VI), negligent misrepresentation (Count VII), and product liability design-defect (Count X), fraud (VIII), and fraudulent concealment (IX) claims fall squarely into the category of cases the Supreme Court has identified as preempted. Plaintiff alleges in each count that Zydus withheld information,

[4] In *Wyeth*, the Supreme Court held that a federal regulation, known as the "changes being effected" ("CBE") regulation, permitted brand name manufacturers to unilaterally strengthen its warning label before it was approved by the FDA and rejected the brand name manufacturer's argument that federal regulations made complying with state law duties impossible. *Wyeth*, 555 U.S. at 571 (citing 21 C.F.R. §§ 314.70(c)(6)(iii)(A),(C)).

failed to propose stronger labels, failed to issue warnings, and failed to warn about the risks. Count I–Count V, Compl. To avoid liability for any of these claims, Zydus would have had to make unilateral changes to its labels or the drug's design—changes that would have been forbidden by FDA regulations.

1. Negligence

In the State of Illinois, a plaintiff making a negligence claim "must allege facts that establish the existence of a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012). A duty to warn exists when "there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant[,] possessed of such knowledge, knows or should know that harm might or could occur if no warning is given." *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123 (Ill. 2002) (quoting *Schellenberg v. Winnetka Park Dist.*, 596 N.E.2d 93, 97 (Ill. App. Ct. 1992)). Garner's negligence claim is rooted in allegations that "Zydus had a duty to exercise reasonable care in the sale and/or distribution of levofloxacin along with its label, warnings, and advertisements into the stream of commerce[,]" also alleging that Zydus' continued distribution of the drug and its failure to warn patients was negligent when it knew or should have known that the drug was unreasonably dangerous. Count VI, Compl. ¶¶ 74–81. Garner alleges a failure to warn claim precisely within the purview of preemption in *Mensing*, and any claim regarding the design of the labeling, *see* Compl. 25–26, is also destined to fail due to the FDCA requirements and the *Mensing*/*Bartlett* framework.

2. Negligent Misrepresentation

Similarly, Garner's negligent misrepresentation claim relies on allegations that Zydus provided inadequate and untruthful information about the drug. The elements of the claim are:

> (1) a false statement of material fact; (2) carelessness or negligence in ascertaining the truth of the statement by the party making it; (3) an intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statement; (5) damage to the other party resulting from such reliance; and (6) a duty on the party making the statement to communicate accurate information.

*First Midwest Bank, N.A. v. Stewart Title Guar. Co.*, 843 N.E.2d 327, 334–35 (Ill. 2006). Here, Plaintiff alleges the information provided was false, which implies that different information should have been provided.

The regulations require a generic drug's labeling to match the brand name drug's label. 21 U.S.C. § 355(j)(2)(A)(v). Labeling is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held "that the phrase 'accompanying such article' is not restricted to labels that are on or in the article on package that is transported," *Kordel v. United States*, 335 U.S. 345, 349 (1948), and deferred to the FDA's interpretation that "Dear Doctor" letters qualify as "labeling," *Mensing*, 564 U.S. at 615 (explaining why "Dear Doctor" letters explicating new risks are not a solution, because generic manufacturers are barred by the FDCA from making representations that stray from the brand name labeling or imply that the generic is therapeutically different). Garner also alleges that Zydus could have done more extensive testing on the product, *id.* at ¶¶ 92–95: even if it had conducted such tests, again, the result would have been that it could not unilaterally change its safety labeling.

Further, Garner's reliance on the Food and Drug Administration Amendments Act of 2007 ("FDAAA") does not avail her: the Seventh Circuit has already noted that while the FDAAA may have allowed more space for generic manufacturers to report and recommend safety issues and negotiate changes to safety labeling for postmarket drugs, *see* in relevant part 21 U.S.C. § 355(o)(4), it did not change the fact that generic manufacturers may not act to

change their labels without prior FDA approval. *Wagner*, 840 F.3d at 358–59; *Houston v. United States*, No. 15-2411, 638 F. App'x 508, 513–14 (7th Cir. Feb. 3, 2016) (finding that despite amendments of FDAAA, federal law "still forbid[s] a generic-drug maker from violating the duty of sameness without FDA permission").

3. Fraud

Garner attempts to allege fraud (Count VIII) and fraudulent concealment (Count IX) claims based on the "representations, through national advertising, promotional campaigns, [and] related materials," Count VIII, Compl. ¶ 80, distributed to physicians. Common law fraud is closely tied to negligent misrepresentation, except that the defendant must have had knowledge that his statement was false. *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 591 (1996). As is the case generally with fraud claims, the plaintiff must allege "with specificity and particularity facts from which fraud is the necessary or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations, and to whom they were made." *Id.; see* Fed. R. Civ. P. 9(b). The related tort of fraudulent concealment requires allegations that the "defendant concealed a material fact when he was under a duty to disclose that fact to plaintiff." *Id.* at 593. For the reasons already discussed, federal law limited the type of information Zydus could distribute. Garner's allegations reciting the elements of the claim without providing the specificity required are insufficient. In any case, Garner fails to allege facts in her complaint regarding any such advertising campaign undertaken by Zydus, or any intent to mislead.

4. Strict Liability

"The theory of strict liability is that one who sells a defective product unreasonably dangerous to the user is liable for the resulting injury." *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324,

328 (Ill. 1990). "[A] physical defect in the product itself, a defect in the product's design, or a failure of the manufacturer to warn of the danger or to instruct on the proper use of the product" may render it unreasonably dangerous. *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008), opinion modified on denial of reh'g (Dec. 18, 2008). Garner argues that her strict liability claim succeeds either because levofloxacin was sold with "insufficient warning" about its unreasonable danger, or because it was marketed to treat simple infections despite a risk-utility analysis that would militate against it, and was therefore defective in design. Pl.'s Resp. Zydus Mot. Dismiss 10–11, ECF No. 19. Both of these claims fundamentally would require either a change in labeling or a change in the chemical makeup of the drug, which Zydus could not do, or a "stop-selling" approach, which the Supreme Court has declared unreasonable. *Bartlett*, 133 S.Ct. at 2477–78; *see also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1140–41 (8th Cir. 2014) (examining that the theory of design defect product liability, whether based in a consumer expectation test of unreasonable dangerousness, or a risk-utility test, is immaterial to the preemption analysis).

5. Warranties

Garner's other claims against Zydus—breach of express warranty (Count XI) and breach of implied warranty of merchantability (Count XII)—face a similar fate. "In a breach of express warranty action under the [Illinois UCC], plaintiff must show a breach of an affirmation of fact or promise that was made a part of the basis of the bargain." *Oggi Trattoria & Caffe, Ltd. v. Isuzu Motors Am., Inc.*, 865 N.E.2d 334, 340 (Ill. App. Ct. 2007) (quoting *Hasek v. DaimlerChrysler Corp.*, 745 N.E.2d 627, 634 (Ill. App. Ct. 2001)).

> [T]he burden of proof is on the plaintiff to show by a preponderance of the evidence the terms of the warranty, the failure of some warranted part, a demand upon the defendant to perform under the terms of the warranty, a failure of the

> defendant to do so, a compliance with the terms of the warranty by the plaintiff, and damages measured by the terms of the warranty.

*Oggi*, 865 N.E.2d at 340 (quoting Hasek, 745 N.E.2d at 638). A breach of implied warranty of merchantability requires that a plaintiff plead: "(1) a sale of goods, (2) that the seller of the goods is a merchant with respect to those goods, and (3) that the goods were not of merchantable quality." *Smith v. Boehringer Ingelheim Pharm., Inc.*, 886 F. Supp. 2d 911, 929 (S.D. Ill. 2012) (quoting *Maldonado v. Creative Woodworking Concepts, Inc.*, 796 N.E.2d 662, 666 (Ill. App. Ct. 2003)). Whether a product is "of merchantable quality" turns on whether it is fit "for the ordinary purposes for which [it is] used." *Id.*

Garner does not explicitly blame the labeling when alleging these claims; however, reviewing Zydus' express warranties and determining whether levofloxacin is fit for its ordinary purpose (treatment of common bronchitis, urinary tract infection and other non-life threatening bacterial infections) and the risk of injury therein, requires a review *of the safety labeling*. Therefore, Garner's warranty claims sound in a failure to warn theory of liability. *See* Compl. 35–37, 58; Count XI, Compl. ¶ 73–75; Count XII, Compl. ¶ 79. "Although *Mensing* and *Bartlett* dealt with failure to warn and design defect claims, respectively, federal courts have extended their rationale to similar state law claims" when those claims rely on "the generic manufacturer's failure to provide adequate information" and are therefore preempted. *Wagner*, 840 F.3d at 358 (quoting *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014)); *Houston*, No. 15-2411, 638 Fed App'x at 513–14 (affirming dismissal of the defective design, negligence, consumer fraud, battery, and breach of express and implied warranty claims of plaintiff injured by generic drug). *See also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139–40 (8th Cir. 2014) (incorporating the *Mensing* holding, and finding that the FDCA preempted the plaintiff's breach of implied warranty claim because the generic manufacturer "could only avoid liability under Missouri law

by redesigning its product, changing its labeling, or leaving the market"); *In re Darvocet*, 756 F.3d at 934–35 (discussing how the combination of the duty of sameness in labeling with the rejection of the "stop selling" argument insulates generic manufacturers from breach of express or implied warranty claims).

For the above reasons, all of Garner's claims against Zydus fail as a matter of law and must be dismissed.

C. Claims Against Janssen

Garner brings five claims against Janssen: (I) negligence, (II) negligent misrepresentation, (III) fraud, (IV) fraudulent concealment, and (V) product liability negligence. Janssen argues that because it did not manufacture, distribute, or sell the generic form of levofloxacin taken by Garner that it owed her no duty of care. Janssen Mem. Supp. Mot. Dismiss 7, ECF No. 10.

1. Negligence

Garner alleges that "Janssen was negligent in Levofloxacin's design and warnings[.]" Pl.'s Resp. Janssen's Mot. Dismiss 6–13. She further argues that the labeling sameness requirement made it clearly foreseeable that any mistake in a brand name drug's label would be repeated in the labeling of the generic drug, imposing a duty of care upon Janssen. *Id.* at 12. Janssen recommends that the Court follow *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), a Fourth Circuit case holding that brand name manufacturers may not be held liable (in that case, under a theory of negligent misrepresentation) for injuries caused by the product of another manufacturer. *Foster*, 29 F.3d at 170–71. *Foster* held that "impos[ing] a duty [on brand name manufacturers] would be to stretch the concept of foreseeability too far." *Id.* at 171. Most courts faced with so called "innovator liability" have followed *Foster*, but the

Seventh Circuit has not yet weighed in. *See e.g. Houston*, 638 F. App'x. at 513–14 (noting that the Seventh Circuit "has not addressed whether a consumer of a generic drug may sue the brand-name manufacturer" but avoiding the issue due to an expired statute of limitations). Therefore, the Court examines Illinois tort principles to determine the extent to which Janssen may be held liable under law.

To reiterate, a plaintiff attempting to state a claim for common law negligence "must allege facts that establish the existence of a duty of care owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach." *Simpkins*, 965 N.E.2d at 1096. In Illinois, while the law does not generally impose an affirmative duty to protect strangers, the existence of a duty of care "does not depend upon contract, privity of interest or the proximity of relationship, but extends to remote and unknown persons." *Simpkins*, 965 N.E.2d at 1097 (quoting *Widlowski v. Durkee Foods, Div. of SCM Corp.*, 562 N.E.2d 967, 968 (Ill. 1990)). Under Illinois law, the analysis of whether a duty of care exists in a relationship is "nebulous" but guided by four factors: (1) the reasonable foreseeability of the injury, (2) the likelihood of the injury, (3) the magnitude of the burden of guarding against the injury, and (4) the consequences of placing that burden on the defendant. *Simpkins*, 965 N.E.2d at 1097.

In the well-regulated pharmaceutical industry, Janssen, a brand-name manufacturer, is surely not blindsided to find out that the equivalent of its Levaquin labels was imposed on generic versions of levofloxacin and that doctors and patients would rely on the labeling composed by Janssen even when using the generic drug. *See Dolin v. SmithKline Beecham Corp.*, 62 F.Supp.3d at 711. Further, it is a common practice, and therefore foreseeable, for a doctor to prescribe a name brand drug and the pharmacy to fill it with the generic version. The likelihood that Janssen's alleged design or labeling negligence would cause injury is high.

Janssen still shoulders the responsibility of updating Levaquin's safety labels so the burden of guarding against injury is marginally low. *See Dolin*, 62 F. Supp. 3d at 715 (noting that the brand-name defendant "will not be tasked with the burden of crafting one new warning label for [its own drug], and then other discrete warnings for various generic iterations of the drug—that all of the iterations of [the drug] are bio-equivalent and require the same warning is precisely the point.").

Other courts have expressed trepidation about the consequences of holding brand-name manufacturers liable for injury caused by generics. *See e.g. In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014) (citing "grave health policy consequences associated with recognizing brand manufacturer liability in these situations[,] including higher priced brand name drugs and fewer innovative drugs."). Finding a duty of care in this scenario does not signal the Court's intent to hold brand-name manufacturers liable for the manufacturing errors of an entire industry—to make it an "insurer[]" of the industry, as Janssen suggests. Janssen's Reply 10. This decision simply allows Garner to attempt to recover for deficiencies in levofloxacin's label from the one entity, under federal law, that has unilateral ability to strengthen the label. In considering the factors important in determining the existence of a duty relationship, the Court finds that a sufficient relationship exists between Janssen and Garner who ingested the generic equivalent of Levaquin for the law to impose a duty of care upon Janssen to adequately warn of the risks of levofloxacin. Garner alleges Janssen breached that duty when it failed to strengthen the warning labels.

The next step in the negligence analysis is identifying causation: liability for negligence may not be "imposed based merely on a breach of duty, without causation being established." *Lewis v. Lead Indus. Ass'n, Inc.*, 793 N.E.2d 869, 874 (Ill. App. Ct. 2003). Garner alleges

Janssen created levofloxacin's safety labeling, that it failed to warn of certain side effects, and that if she had known of those side effects she would have not taken levofloxacin. The Court agrees: an extra link in the causal chain (here, the transfer of the identical label from the branded drug to the generic drug) does not break it. It is possible for a plaintiff to show that injuries caused by mislabeling on a generic medication can be directly traced back to the brand name manufacturer's creation of the label. *See Pecher v. Owens-Illinois, Inc.*, 859 F.3d 396, 401 (7th Cir. 2017) (citing favorably *Dolin*, 62 F. Supp. 3d at 711, and opining that "the branded manufacturer can be said to have 'caused' any mislabeling by a generic drug manufacturer, even if the branded drug manufacturer had no hand in the manufacture or distribution of the drug or the labels."). Much of the case law refusing to hold a manufacturer liable for another manufacturer's product occur in cases when it is unclear which manufacturer, in a sea of manufacturers working in an industry, has created the faulty product. *See Lewis*, 793 N.E.2d. at 875. As the *Dolin* court noted, that is not the question here. Instead, the Court is deciding whether to hold a brand name company "liable for tortious conduct that was extrinsic to the manufacturing process and that contributed to Plaintiff's injury." *Dolin*, 62 F. Supp. 3d at 718. Garner has adequately alleged causation.

2. Negligent Misrepresentation

Garner next asserts a claim for negligent misrepresentation against Janssen. This claim requires:

> (1) a false statement of material fact; (2) carelessness or negligence in ascertaining the truth of the statement by the party making it; (3) an intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statement; (5) damage to the other party resulting from such reliance; and (6) a duty on the party making the statement to communicate accurate information.

*First Midwest Bank, N.A.*, 843 N.E.2d at 334–35. Janssen's duty to communicate accurate information about levofloxacin exists for the same reasons discussed above in connection to the common law negligence claim. Garner has alleged that Janssen's label may not have contained a sufficiently strong warning regarding the use of levofloxacin for the treatment of simple infections. Garner alleges that Janssen promoted levofloxacin to physicians as safe and effective for treatment of conditions like a urinary tract infection, without taking reasonable care—for instance, via testing—to ensure that the drug was, in fact, safe for those purposes. Janssen, according to Garner, intended that representations regarding the drug's safety and recommended use, made on its safety labeling and in its marketing materials, would lead doctors to prescribe the drug to patients, who could suffer its adverse effects. Janssen has successfully alleged a claim against Janssen for negligent misrepresentation.

3. Product Liability

The product liability negligence claim requires largely the same allegations as the other negligence claims, and for that reason it survives. Product liability negligence claims are rare, but they utilize the framework of a common law negligence claim (requiring a duty of care, breach of that duty, and proximate causation of injury due to the breach), taking into account that "[a] manufacturer has a non-delegable duty to design reasonably safe products." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 270 (Ill. 2007). Admittedly, because Janssen did not physically manufacture the pill taken by Garner, the claim presents some analytical complexities. However, a plaintiff may plead a product liability negligence claim by pointing to a way in which "the product was unreasonably dangerous and defendant failed to warn of its dangerous propensity." *Blue v. Envtl. Eng'g, Inc.*, 828 N.E.2d 1128, 1141 (Ill. 2005). The fundamental crux of Garner's claim is that levofloxacin was not properly labeled for the purpose for which it

was marketed, and Janssen is the undisputed creator of those labels. Compl. 22–23. Garner pleads her negligence claim sufficiently, and the closely related product liability negligence claim stands as well. *Blue*, 828 N.E.2d at 1141 (clarifying that "a design defect suit [as opposed to a suit based on a manufacturing defect] is more akin to a negligence claim.").

Lastly, Garner has raised claims of fraud and fraudulent concealment. She alleges that Janssen intentionally disseminated false, misleading material in advertising and promotional campaigns and that it did not timely disclose risks associated with the use of levofloxacin. *See* Compl. 20–22. A plaintiff must allege, "with specificity and particularity, facts from which fraud is the necessary or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations, and to whom they were made." *Connick v. Suzuki Motor Co.*, 675 N.E.2d at 591. Garner does not do this. She argues that inferences of fraud can be made from the presumption that "Janssen would want doctors to prescribe Levaquin, or its generics" and so would be driven to make misrepresentations on the labeling, or perhaps that Janssen wanted to avoid liability by continuing to advertise levofloxacin as "safe and effective" rather than making changes to the labeling. Resp. Janssen Mot. Dismiss 15–16. These allegations are speculative and do not raise a probable inference of fraudulent conduct. The fraud and fraudulent concealment claims against Janssen (Counts III and IV) are dismissed.

## CONCLUSION

For the foregoing reasons, Zydus' Amended Motion to Dismiss, ECF No. 17, is GRANTED as to the counts against Zydus (Counts VI-XIII). Janssen's Motion to Dismiss, ECF No. 10, is GRANTED IN PART, as to Counts III and IV. Garner's claims against Janssen for common law negligence, negligent misrepresentation, and product liability negligence (Counts I,

II, and V) may proceed. Janssen's Motion for Leave to File a Reply, ECF No. 23, is GRANTED.

Entered September 6, 2017.

s/ Sara Darrow
SARA DARROW
UNITED STATES DISTRICT JUDGE