IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

Thomas Swalls,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 20 L 9238
	)	
George Thott, M.D., Walgreen Co., Eli Lilly and Company, and Boehringer Ingelheim Pharmaceuticals, Inc.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

A negligence cause of action cannot stand if the defendant owed the plaintiff no duty. A strict liability cause of action is sufficiently pleaded if the defendant had actual knowledge of the product defect causing the plaintiff's injury. Here, the plaintiff's allegation that the defendant sold a drug to the plaintiff despite a federal warning is insufficient to support a negligence cause of action, but is sufficient, at least temporarily, to support a strict product liability claim. For those reasons, the defendant's motion to dismiss is granted in part and denied in part.

Facts

In January 2011, Eli Lilly and Company and Boehringer Ingelheim Pharmaceuticals, Inc. announced the formation of a joint venture to develop pharmaceutical compounds for the treatment of diabetes. One compound was the oral agent BI10773, a SGLT-2 inhibitor (empagliflozin), eventually marketed as Jardiance. On August 1, 2014, the Food and Drug Administration approved Jardiance for use in the treatment of type-2 diabetes.

In February 2018, Dr. George Thott prescribed Jardiance to Thomas Swalls for treatment of his type-2 diabetes. On August 29, 2018, the FDA issued a warning regarding the connection between SGLT-2 inhibitors, such as Jardiance, and the development of genital, perianal, and gluteal necrotizing fasciitis, including Fournier's gangrene. On September 11, 2018, Thott issued his last Jardiance prescription to Swalls. Swalls had filled his Jardiance prescriptions at a Walgreen Company location.

On October 5, 2018, doctors diagnosed Swalls with necrotizing fasciitis of the genitals and genital area, including, the scrotum, groin, and posterior right thigh, Fournier's gangrene, ketoacidosis, and kidney disease. Swalls subsequently underwent multiple debridement surgeries. Swalls' post-surgical condition required extensive medical care and treatment.

On August 28, 2020, Swalls filed a seven-count complaint against the named defendants. Counts two, three, and four are directed against Walgreen. Count two is pleaded in negligence and alleges that, among other things, Walgreen marketed, tested, promoted, and sold Jardiance to Swalls and had analyzed Jardiance's safety, efficacy, and suitability. Walgreen allegedly knew or should have known Jardiance was unreasonably dangerous and defective and increased the risks of necrotizing fasciitis before it filled Thott's last Jardiance prescription for Swalls in September 2018.

In count two, Walgreen is alleged to have owed Swalls a duty to use reasonable care in marketing, promoting, labeling, supplying, and selling Jardiance. Swalls claims that Walgreen breached its duty by failing, among other things, to: (1) warn Swalls of hazards associated with Jardiance; (2) remove Jardiance from the market; (3) instruct Swalls of methods to reduce Jardiance consumption; (4) provide warnings, instructions or other information to reflect the symptoms, scope, and severity of Jardiance's side effects; (5) disclose Jardiance's clinical safety and effectiveness profile; (6) exercise due care in advertising; (7) stop selling Jardiance after the FDA's August 29, 2018 warning; and

(8) warn Swalls of Jardiance's dangers and risks associated after the FDA's August 29, 2018 warning.

Count three is pleaded in strict liability based on a failure to warn. Walgreen allegedly possessed greater knowledge than Swalls of Jardiance's dangers and risks but failed to warn him, particularly about necrotizing fasciitis, including Fournier's gangrene. Swalls alleges that, had he received such a warning, he would have discontinued taking Jardiance and avoided his injuries.

Count four is pleaded in strict liability based on a design defect. Walgreen is alleged to have placed Jardiance into the stream of commerce by selling Jardiance to Swalls in a defective and unreasonably dangerous condition. Swalls acknowledges that Jardiance reached consumers, including him, in the condition in which it was manufactured and sold. As a result, Swalls used Jardiance in a manner normally intended, recommended, promoted, and marketed by Walgreen. Swalls alleges that Jardiance failed to perform safely in a reasonably foreseeable manner, specifically increasing the risk of Fournier's gangrene, ketoacidosis, and severe kidney disease, thereby making Jardiance an unreasonably dangerous product when used in the intended manner. Swalls alleges that safer alternatives were available to him, including diet and exercise. Based on the FDA's August 29, 2018 warning, Walgreen knew Jardiance presented an unreasonable risk of Fournier's gangrene, ketoacidosis, and severe kidney disease, but continued to sell the drug in conscious disregard of the foreseeable harm to Swalls.

On February 16, 2021, Walgreen filed a motion to dismiss counts two, three, and four. Walgreen seeks to dismiss count two based on the carve out for pharmacies and pharmacists from the learned-intermediary doctrine as well as Swalls' failure to attach a physician's report as required by the Code of Civil Procedure. *See* 735 ILCS 5/2-622. Walgreen argues counts three and four should be dismissed because, pursuant to the seller's exception applicable in strict product liability cases, *see* 735 ILCS 5/2-621, the

manufacturer of Jardiance is already known and it is not Walgreen, and none of the statutory exceptions apply. On March 18, 2021, Swalls filed a response to Walgreen's motion. On April 7, Walgreen filed its reply. This court has reviewed the parties' submissions, including all exhibits.

Analysis

The Code of Civil Procedure authorizes the filing of one pleading incorporating motions to dismiss under sections 2-615 and 2-619. 735 ILCS 5/2-619.1. A section 2-615 motion tests a complaint's legal sufficiency, while a section 2-619 motion admits a complaint's legal sufficiency, but asserts defenses outside the pleading to defeat the claim. *Bjork v. O'Meara*, 2013 IL 114044, ¶ 21; *Patrick Eng., Inc. v. City of Naperville*, 2012 IL 113148, ¶ 31. A court considering either motion must accept as true all well-pleaded facts and reasonable inferences, *Doe v. Chicago Bd. of Educ.*, 213 Ill. 2d 19, 23-24 (2004), but not conclusions unsupported by facts, *Pooh-Bah Enterps., Inc. v. County of Cook*, 232 Ill. 2d 463, 473 (2009). *See also Hanks v. Cotler*, 2011 IL App (1st) 101088, ¶ 17. "The purpose of a section 2-619 motion is to dispose of issues of law and easily proved issues of fact early in the litigation." *Czarobski v. Lata*, 227 Ill. 2d 364, 369 (2008).

Walgreen argues first that count two should be dismissed because it owed Swalls no duty of care. Duty is a question of law to be decided by a court. *See Burns v. City of Centralia*, 2014 IL 116998, ¶ 13. To determine if a duty exists, a court is to analyze whether a relationship existed between the plaintiff and the defendant for which the law would impose a duty on the defendant for the plaintiff's benefit. *See Doe-3 v. McLean Cty. Unit Dist. No. 5 Bd. of Directors*, 2012 IL 112479, ¶ 22, *quoting Marshall v. Burger King Corp.*, 222 Ill. 2d 422, 436 (2006). The "relationship" is "a shorthand description for the analysis of 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 the burden on the

defendant." *Id.*, *citing Simpkins v. CSX Transp., Inc.*, 2012 IL 110662, ¶ 18.

Apart from the specific relationship between the litigants, there exists a general duty of care. As to that relationship,

> 'every person owes a duty of ordinary care to all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequence of an act, and such a duty does not depend upon contract, privity of interest or the proximity of relationship, but extends to remote and unknown persons.' Thus, if a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. This does not establish a 'duty to the world at large,' but rather this duty is limited by the considerations discussed above.

Simpkins, 2012 IL 110662, ¶ 19 (citations omitted).

A duty analysis in this case begins with acknowledging Illinois' adoption of the learned intermediary doctrine. *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill. 2d 507 (1987). That doctrine provides "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." *Id.* at 517 (citing cases). Pharmacies and pharmacists are generally exempt for the learned intermediary doctrine and have no duty to warn patients. *DiGiovanni v. Albertson's, Inc.*, 405 Ill. App. 3d 932, 935 (1st Dist. 2010) (citing cases). Thus, "the duty to warn of side effects is not placed on the pharmacist, it is placed on the prescribing physician." *Urbaniak v. American Drug Stores, LLC*, 2019 IL App (1st) 180248, ¶ 13 (citing cases).

One court has explained the rationale for the pharmacies-and-pharmacists exemption as follows:

> Determining which medication is to be utilized in any given case requires an individualized medical judgment, which . . . only the patient's physician can provide. That physician, having prescribed the drug, presumably knows the patient's current condition, as well as the patient's complete medical history. To impose a duty to warn on the pharmacist would be to place the pharmacist in the middle of the doctor-patient relationship, *without* the physician's knowledge of the patient. Furthermore, under Illinois law, the duty of the manufacturer runs to the physician and not to the patient. Therefore, it is illogical and unreasonable to impose a greater duty on the pharmacist who properly fills a prescription than is imposed on the drug's manufacturer.

Fakhouri v. Taylor, 248 Ill. App. 3d 328, 332-33 (1st Dist. 1993) (citation omitted, emphasis in original). Based on these general principles, it is plain that pharmacies and pharmacists owe a customer no more than simple duty of ordinary care. *Eldridge v. Eli Lilly & Co.*, 138 Ill. App. 3d 124, 126 (4th Dist. 1985). That standard means pharmacies and pharmacists generally have no independent duty to warn a consumer about a prescribed drug's specific potential dangers. *Jones v. Irvin*, 602 F. Supp. 399, 402 (S.D. Ill. 1985) (applying Illinois law); *Eldridge*, 138 Ill. App. 3d at 127.

At the same time, a pharmacist's duty to its customers requires "the highest degree of prudence, thoughtfulness and diligence, and it is proportioned to the danger involved." *Eldridge*, 138 Ill. App. 3d at 126 (citing *Jones v. Walgreen Co.*, 256 Ill. App. 308 (1932)). In a pharmacy setting, a duty to warn may exist if there is unequal knowledge of a dangerous condition and the defendant, with that information, knows or should know harm could occur if no warning were given. *Kennedy v. Medtronic, Inc.*, 366 Ill. App. 3d 298, 304-05 (1st Dist. 2006) (citing *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 186 (2002)); *Urbaniak*, 2019 IL App (1st) 180248, ¶14. That duty of care is, however, quite narrow. *Happel*, 199 Ill. 2d at 189, 197. Pharmacies are shielded

unless they have particular knowledge of a particular customer unknown to the prescribing physician. *Walton v. Bayer Corp.*, 643 F.3d 994, 999 (7th Cir. 2011) ("[In] Illinois, a manufacturer or a pharmacy must warn a customer of dangers known to it of which physicians have not been warned, but not of dangers of which physicians have been warned"); *see also Happel*, 199 Ill. 2d at 195 ("The scope of the protection provided to pharmacists by the learned intermediary doctrine is limited, particularly in situations such as the instant case where a pharmacy has knowledge that a prescribed medication is contraindicated for a specific customer."). As the court explained in *Happel*, "a narrow duty to warn either the prescribing physician or the patient exists where . . . a pharmacy has *patient-specific information* about drug allergies, and knows that the drug being prescribed is contraindicated for the *individual patient*. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger." *Happel*, 199 Ill. 2d at 197 (emphasis added).

The narrow duty owed by pharmacies and pharmacists does not exist in this case between Walgreen and Swalls. Swalls' alleged injury from Jardiance was neither reasonably foreseeable nor likely and, therefore, cannot support the existence of a duty owed by Walgreen to Swalls. The FDA's August 29, 2018 warning did not prohibit Walgreen's sale of Jardiance to any customer, including Swalls. The warning also did not prohibit physicians from prescribing the medication to patients. Further, Walgreen was in no position to know that Swalls would be predisposed to an adverse reaction to Jardiance after selling him the drug for eight months. Swalls does not allege that Walgreen knew of contraindications to Jardiance particular to Swalls that were unknown to Thott, or, for that matter, any other health information. In sum, this court has found no Illinois case, and has Swalls has not cited any, imposing a duty to warn on a pharmacy or a pharmacist if an FDA public warning was equally available to the prescribing physician. This court declines to do so now.

There also exists no rationale to impose on Walgreen the burden to warn or the consequences of failing to do so. To find

that a duty exists in this instance would impose an enormous burden on Walgreen and subject it to liability that has never been imposed by an Illinois court. It is fair to assume that Walgreen has thousands of customers in this state and that a substantial number of them had been prescribed Jardiance by their physicians. For Walgreen pharmacists to inform each customer of FDA warnings would be a substantial burden and impermissibly insert the pharmacist into the physician-patient relationship. Such a burden is unwarranted and unsupported by the case law.

Swalls also argues that Walgreen owed him a duty of care other than a duty to warn. That argument is questionable because many of Walgreen's alleged breaches of duties of care are simply variations of the duty to warn. This court will, nonetheless, address independently Swalls' claims that Walgreen owed him a duty to: (1) remove Jardiance from the market; (2) stop selling Jardiance after the FDA's August 29, 2018 warning; disclose accurately Jardiance's clinical safety and effectiveness profile; and (4) act like a reasonably prudent retailer under similar circumstances.

Much of this court's duty analysis above applies equally to Swalls' duty of care arguments. It is first noted that Swalls fails to cite any case law supporting his proposition that Walgreen had a duty to stop selling Jardiance after the FDA issued its warning. Indeed, the Pharmacy Practice Act explicitly provides that nothing in the statute shall prevent pharmacists "from supplying . . . bona fide patients such drugs, medicines, or poisons as may seem . . . appropriate[.]" 225 ILCS 85/4(a). As noted above, the FDA's August 29, 2018 warning did not make it reasonably foreseeable that Swalls would have an adverse drug reaction based on Walgreen's past sales of Jardiance to him. The increased likelihood of injury is defeated by the explicit text of the FDA's warning.[1] The FDA explained that out of an estimated 1.7 million

[1] *See* "FDA warns about rare occurrences of a serious infection of the genital area with SGLT2 inhibitors for diabetes," U.S. Food & Drug Administration, August 29, 2018, *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrences-serious-infection-genital-area-

patients prescribed an SGLT-2 inhibitor, only 12 had developed Fournier's gangrene. The FDA noted the risk of developing Fournier's gangrene was very low, only 0.00000706% of patients taking SGLT-2 inhibitors. The magnitude of the burden on Walgreen to stop selling Jardiance would be enormous and lead to potentially worse consequences. To accept Swalls' argument would mean Walgreen customers who had been prescribed Jardiance by their physicians would be denied the opportunity to purchase a medication that helped control their diabetes. That is an unacceptably cruel fate this court will not impose on other diabetes patients who are Walgreen customers. Further, a ban on Jardiance sales is not a commercially acceptable result given that it would undermine the very foundation of the physician-patient relationship.

Last, and certainly least, is Swalls' argument that Walgreen had a duty to market, promote, label, supply, dispense, distribute, and sell a product that did not present risk of harm or injury. These claims are nothing more than manufactured iterations on the previous hollow duty-to-warn claims. Further, Swalls failed to cite any case law supporting the existence of such a duty, and this court could not find any.

Swalls' causes of action in count three—strict liability for failure to warn—and count four—strict liability for design defect—are each subject to the seller's exception. 735 ILCS 5/2-621. The exception allows a non-manufacturer-defendant to file an affidavit certifying the correct identity of the allegedly defective product's manufacturer. 735 ILCS 5/2-621(a). With that information provided, the court "shall order the dismissal" of the certifying party. 735 ILCS 5/2-621(b). The only exceptions are if the plaintiff can show the non-manufacturer exercised some significant control over the product's design or manufacture, had actual knowledge of the product defect that caused the injury,

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sglt2-inhibitors-diabetes#:~:text=Cases%20of%20necrotizing%20fasciitis%20of,urgent%20antibiotics%20and%20surgical%20intervention, last visited April 14, 2021.

death, or damage, or created the product defect. 735 ILCS 5/2-621(c)(1)-(3).

Swalls has not pleaded any facts suggesting Walgreen designed or manufactured Jardiance, 735 ILCS 5/2-621(c)(1), or created the defect, 735 ILCS 5/2-621(c)(3). Those exceptions are defeated by the uncontested affidavit of Patrick Lupo, Walgreen's Vice President of Biopharmaceutical Development and Specialty Supply Chain. Lupo averred that Walgreen did not manufacture Jardiance, and identified Eli Lilly and Boehringer Ingelheim as Jardiance's co-promoters and co-developers. Lupo further identified Boehringer Ingelheim as Jardiance's manufacturer. Lupo further averred that:

> Walgreen Co. did not exercise any control over the design or manufacture of Jardiance, it did not provide instructions or warnings to the manufacturer regarding any alleged product defect, it had no actual knowledge of any defect in the product which caused injury, and it did not create any defect in the product that caused injury.

The remaining question is whether Walgreen had actual knowledge of the product defect. 735 ILCS 5/2-621(c)(2). The court in *Murphy v. Mancari's Chrysler Plymouth, Inc.* addressed the implications of the actual-knowledge-of-the-defect exception contained in section 2-621(c)(2).

> [A] plaintiff relying upon the 'actual knowledge of the defect' exception contained in section 2-621(c)(2) (735 ILCS 5/2-621(c)(2) (West 2006)) to avoid dismissal of its strict liability claim against a nonmanufacturer defendant must allege that the nonmanufacturer defendant had actual knowledge of the physical characteristics of the product that the plaintiff claims were unreasonably dangerous and that said characteristics made the product unreasonably dangerous.

381 Ill. App. 3d 768, 770 (1st Dist. 2008). The court further recognized that "the obvious interpretation of section 2-621(c)(2) requires a plaintiff to show that a presumptively dismissed defendant had actual knowledge of the unreasonably dangerous nature of the physical characteristics/design of the product, not just actual knowledge that the physical characteristics/design existed, in order to avoid dismissal of that defendant." *Id.* at 775.

Here, both parties have contributed to a procedural conundrum. On one hand, Swalls failed to file an affidavit seeking to depose Lupo as to Walgreen's alleged lack of actual knowledge. *See* Ill. S. Ct. R. 191. Swalls also failed to submit a counter-affidavit, meaning Lupo's is unrebutted. That would suggest Lupo's averments are true. *Harrison v. Hardin Cnty. Comm. Unit Sch. Dist. No. 1*, 197 Ill. 2d 466, 476 (2001) (Harrison, C.J., specially concurring, joined by Kilbride, J.) (facts contained in affidavit in support of summary judgment not contradicted by counter-affidavit are admitted and taken as true for motion purposes). On the other hand, Lupo failed to explain in his affidavit how Walgreen did not have actual knowledge of Jardiance's specific dangers, including Fournier's gangrene, given the FDA's August 29, 2018 warning. Since a court must make all inferences in the non-moving party's favor, *Doe*, 213 Ill. 2d at 23-24, this issue is best left for a subsequent motion based on a factual record.

Conclusion

For the reasons presented above, it is ordered that:

1. Walgreen's motion to dismiss is granted in part and denied in part;
2. The motion is granted as to count two, which is dismissed with prejudice;

3. The motion is denied as to counts three and four; and
4. Walgreen is given until May 17, 2021 to answer counts three and four.

John H. Ehrlich, Circuit Court Judge

Judge John H. Ehrlich

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