2018 IL App (1st) 172147-U

No. 1-17-2147

Order filed June 14, 2018

Fourth Division

IN THE

APPELLATE COURT OF ILLINOIS

FIRST DISTRICT

TRACEY BENYAK,	)	Appeal from the
	)	Circuit Court of
Plaintiff-Appellant,	)	Cook County
	)	
v.	)	
	)	
MEDTRONIC, INC.; MEDTRONIC USA, INC.; JUAN ALZATE, MD; and AMERICAN CENTER FOR SPINE & NEUROSURGERY, LLC,	)	No. 16 L 7581
	)	
Defendants,	)	Honorable
	)	John P. Callahan, Jr.
(MEDTRONIC, INC. and MEDTRONIC USA, INC., Defendants-Appellees).	)	Thomas J. Lipscomb,
	)	Judges presiding.

PRESIDING JUSTICE BURKE delivered the judgment of the court.
Justices Gordon and Ellis concurred in the judgment.

ORDER

¶ 1 *Held*: We affirm the circuit court's dismissal of plaintiff's complaint where her claim that a medical device was defectively designed and manufactured was preempted by federal law and her claim of negligent instruction was not cognizable under Illinois law. Plaintiff's request on appeal to have her case remanded to the circuit

with leave to amend her complaint is waived where she failed to amend her complaint in the circuit court despite the court's permission.

¶ 2 Plaintiff, Tracey Benyak (plaintiff), sued defendants, Medtronic, Inc. and Medtronic USA, Inc. (collectively, defendants), as well as Juan Alzate, MD and the American Center for Spine & Neurosurgery, LLC, on claims of negligence after a medical device implanted in her body to alleviate pain allegedly repositioned and caused her significant injuries. Defendants filed a motion to dismiss based on her claims being preempted by the federal Medical Device Amendments of 1976 (21 U.S.C. § 360c *et seq.* (2012)) and independently, being insufficiently pled. Subsequently, plaintiff voluntarily dismissed the cause of action against Dr. Alzate and the American Center for Spine & Neurosurgery, LLC. Thereafter, the circuit court granted defendants' motion to dismiss on preemption grounds, but granted plaintiff leave to serve written discovery on defendants and to file an amended complaint. Plaintiff chose not to do either, and the court dismissed her complaint with prejudice.

¶ 3 Plaintiff now appeals the circuit court's dismissal, contending that it erred when it found her state-law claims were preempted by federal law. For the reasons that follow, we affirm.

¶ 4 I. BACKGROUND

¶ 5 In August 2016, plaintiff filed a two-count complaint sounding in negligence. According to Count I of the complaint, plaintiff suffered from abdominal and back pain, and to help alleviate the pain, she had an intrathecal pump implanted in her body in March 2012. Plaintiff believed the device was the Medtronic SynchroMed II programmable pump. Over approximately the next 30 months, plaintiff had various complications with the pump because it had changed positions, or inverted, in her body multiple times. The complaint alleged that, at the time defendants had marketed the device for sale, it was in an unreasonably dangerous condition

because it was "subject to unintended turning" in a patient's body. The complaint alleged that defendants "defectively designed and/or manufactured the intrathecal pump" in one or more of the following ways: "[c]arelessly and negligently designed said its [*sic*] intrathecal pump" and "[c]arelessly and negligently instructed medical providers regarding measures to prevent unintended turning of the intrathecal pump." As a direct and proximate cause of defendants' negligence, the complaint claimed that plaintiff suffered significant injuries.

¶ 6 Count II, which is not relevant to this appeal, claimed that Dr. Alzate and the American Center for Spine & Neurosurgery, LLC, were negligent when they failed to properly implant the intrathecal pump in plaintiff's body.

¶ 7 Defendants filed a motion to dismiss Count I under section 2-615 of the Code of Civil Procedure (735 ILCS 5/2-615 (West 2012)), contending that her state-law claims of negligence were preempted by the Medical Device Amendments of 1976 (21 U.S.C. § 360c *et seq.* (2012)) and independently, she failed to sufficiently plead a claim against them.

¶ 8 Subsequently, plaintiff moved to voluntarily dismiss her cause of action against Dr. Alzate and the American Center for Spine & Neurosurgery, LLC. The circuit court granted the motion and dismissed them from the litigation without prejudice.

¶ 9 On May 5, 2017, following briefing on defendants' motion to dismiss, the circuit court granted the motion but allowed plaintiff leave to serve additional written discovery on defendants within 7 days and to file an amended complaint within 28 days.[1]

¶ 10 On June 2, 2017, plaintiff filed a motion for an extension of time to file her amended complaint. The circuit court granted the motion and ordered plaintiff to file her amended

[1] Judge John P. Callahan, Jr., entered this order.

complaint by July 5, 2017. On August 3, 2017, with plaintiff not having filed an amended complaint, the circuit court dismissed her cause of action against defendants with prejudice.[2]

¶ 11 Plaintiff timely filed a notice of appeal, in which she stated that, "[i]n lieu of filing an amended complaint," she "stood on the allegations contained in her original complaint."

¶ 12 II. ANALYSIS

¶ 13 Plaintiff first contends that the circuit court erred in dismissing her cause of action against defendants because the court incorrectly found her claims preempted by federal law.

¶ 14 A. Standard of Review

¶ 15 A motion to dismiss under section 2-615 of the Code of Civil Procedure (735 ILCS 5/2-615 (West 2012)) challenges the legal sufficiency of a complaint by alleging defects apparent on its face. *In re Estate of Powell*, 2014 IL 115997, ¶ 12. When analyzing such a motion, the circuit court is required to accept all well-pled facts in the complaint as true, as well as any reasonable inferences from those facts. *Id.* The key component of any complaint is its factual allegations because Illinois is a fact-pleading jurisdiction, meaning the "plaintiff must allege facts sufficient to bring his or her claim within the scope of the cause of action asserted." *Turner v. Memorial Medical Center*, 233 Ill. 2d 494, 499 (2009). Mere conclusions that are unsupported by specific facts are insufficient to plead a viable cause of action. *In re Estate of Powell*, 2014 IL 115997, ¶ 12. When analyzing a motion to dismiss, we must review the complaint's allegations in the light most favorable to the plaintiff. *Id.* A dismissal is proper only when "it is clearly apparent from the pleadings that no set of facts can be proven that would entitle the plaintiff to recover." *Id.* We review the propriety of a dismissal under section 2-615 *de novo*. *Lutkauskas v. Ricker*, 2015 IL

[2] Judge Thomas J. Lipscomb entered this order.

117090, ¶ 29. This case also involves whether federal law preempts state law, which we also review *de novo*. *Kinkel v. Cingular Wireless LLC*, 223 Ill. 2d 1, 15 (2006).

¶ 16 B. The Medical Device Amendments of 1976

¶ 17 In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA) (Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*)), which gave the Food and Drug Administration (FDA) the authority to regulate the safety of food, medical drugs and cosmetics. From 1938 until the mid-1970s, while the FDA regulated medical drugs as part of the FDCA, the regulation of medical devices was primarily left to the states. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). In 1976, that changed when Congress enacted the Medical Device Amendments of 1976 (MDA), which amended the FDCA (Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. § 360c *et seq.*)), and created a comprehensive federal regulatory system of medical devices. *Riegel*, 552 U.S. at 316.

¶ 18 This new regulatory framework divided medical devices into three different classes based upon their relative safety risks. *Id.* at 316-17. Class I devices—for example, examination gloves and elastic bandages—pose the least risk and thus are subject to the least amount of oversight, such as labeling requirements. *Id.* at 316. Class II devices—for example, surgical drapes and powered wheelchairs—pose more risk and require additional oversight, such as performance standards. *Id.* at 316-17. Class III devices—for example, implanted cerebella stimulators and replacement heart valves—pose the most risk and receive "the most federal oversight." *Id.* at 317. A Class III medical device is a device that sustains or supports life, or presents a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C) (2012). The parties agree that the intrathecal pump at issue is the Medtronic SynchroMed II pump, and it is a Class III medical device. See also *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 982 (N.D. Ohio 2017)

(Medtronic SynchroMed II pump is a Class III medical device); *Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 965 (S.D. Tex. 2016) (same).

¶ 19 As part of the MDA, the FDA required that certain, newer Class III devices undergo a rigorous evaluation process known as premarket approval. *Riegel*, 552 U.S. at 317-18. The premarket approval process requires a manufacturer to submit a multivolume application (*id.* at 317) containing the device's design specifications, manufacturing processes and proposed labeling, which includes use instructions. 21 U.S.C § 360e(c) (2012); 21 C.F.R. §§ 801.5, 801.15 (2012). The FDA spends roughly 1,200 hours reviewing each application and approves an application only if there is a reasonable assurance that the device is safe and effective. *Riegel*, 552 U.S. at 318. If the FDA approves the device, the manufacturer cannot make any "changes in design specifications, manufacturing processes, labeling, or any other attribute" that would jeopardize the device's safety or effectiveness without FDA approval. *Id.* at 319. If the manufacturer of a device desires to make changes, it must submit an application for supplemental premarket approval where the FDA reviews the application under mostly the same criteria as the initial application. *Id.*

¶ 20 A Class III device that was already on the market prior to the MDA's effective date of May 28, 1976, was grandfathered in and did not need to undergo premarket approval. *Riegel*, 552 U.S. at 317. A device created after the MDA's effective date also does not need to undergo premarket approval if the FDA finds the device is " 'substantially equivalent' to another device exempt from premarket approval." *Id.* (quoting 21 U.S.C § 360c(f)(1)(A) (2012)). But before a new device that is not substantially equivalent to another device exempt from premarket approval can enter the market, it must undergo premarket approval. *Id.* However, premarket

approval for a Class III device is rare, as the overwhelming majority of devices enter the market without premarket approval. *Id.*

¶ 21 C. The MDA and Preemption

¶ 22 Accompanying the comprehensive regulatory framework of the MDA, Congress included an express preemption clause providing that:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a) (2012); see *Riegel*, 552 U.S. at 316 (observing this language is an express preemption provision).

Subsection (b) allows the FDA to exempt states and local requirements from preemption upon application (21 U.S.C. § 360k(b) (2012); *Riegel*, 552 U.S. at 316), but this exception is not at issue in this appeal.

¶ 23 Under the supremacy clause of the United States Constitution, the laws of the United States "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Under the supremacy clause, state law is " 'without effect' " where it conflicts with federal law. *Busch v. Graphic Color Corp.*, 169 Ill. 2d 325, 334 (1996) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). A federal statute will preempt state law in

any of three circumstances: "(1) express preemption—where Congress has expressly preempted state action; (2) implied field preemption—where Congress has implemented a comprehensive regulatory scheme in an area, thus removing the entire field from the state realm; or (3) implied conflict preemption—where state action actually conflicts with federal law." *Carter v. SSC Odin Operating Co.*, 237 Ill. 2d 30, 39-40 (2010).

¶ 24 Even if Congress has included an express preemption provision in a statute, such language informs "us that Congress intended to supersede or modify state law to some extent, but courts must still deal with the task of determining the substance and scope of Congress' displacement of state law." *Performance Marketing Ass'n v. Hamer*, 2013 IL 114496, ¶ 51. Preemption is not favored (*Bishop v. Burgard*, 198 Ill. 2d 495, 501 (2002)), and because of this, we generally begin with the presumption that Congress did not intend to preempt state law. *Performance Marketing*, 2013 IL 114496, ¶ 50 (citing *Maryland*, 451 U.S. at 746). However, if a federal law contains an express preemption provision, we do not apply the presumption against preemption. *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016).

¶ 25 Here, because of the express preemption provision in the MDA (see 21 U.S.C. § 360k(a) (2012); *Riegel*, 552 U.S. at 316), we apply no presumption against preemption. In determining the substance and scope of Congress' displacement of state law, we look for guidance from the United States Supreme Court, who has analyzed the MDA's preemption provision in two cases. First, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996), the Court held that, despite the MDA's preemption provision, state-law tort claims are not always preempted by the MDA. It concluded that, when state-law claims impose duties "parallel" to the duties found in the MDA, those claims are not preempted. *Id.*

¶ 26 Expanding on *Lohr*, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008), the United States Supreme Court developed a two-step inquiry for analyzing whether the MDA preempts a state-law claim. First, a court must determine whether the federal government has established requirements applicable to the particular medical device. *Id.* at 321. Under this inquiry, the Court explained that "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. Consequently, if a Class III device has undergone premarket approval, the federal government has established requirements applicable to that device. *Id.*

¶ 27 Under the second inquiry, a court must determine whether the state-law claim would impose requirements related to safety and effectiveness " 'different from, or in addition to,' " the federal requirements. *Id.* at 322 (quoting 21 U.S.C. § 360k(a) (2012)). If a state-law claim imposes a requirement for a medical device that is different from, or in addition to, the requirements already imposed by the MDA, state law and federal law are not parallel, but rather in tension. *Id.* at 330. But if a state-law claim is "premised on a violation of FDA regulations," that claim imposes requirements that parallel the federal requirements. *Id.* Ultimately, if the federal government has established requirements applicable to the particular medical device and the state-law claim would impose requirements related to safety and effectiveness different from, or in addition to, the federal requirements, the MDA will expressly preempt the state-law claim. *Id.* at 321-22.

¶ 28 Although the *Riegel* Court provided the framework for analyzing whether the MDA preempts state-law claims, it did not use its framework in the case. See *id.* at 330. Rather, the Court concluded that it could not address the plaintiffs' contention that their lawsuit had raised

parallel state-law claims where they failed to raise the contention before the Second Circuit Court of Appeals and in their petition for *certiorari*. *Id.* Thus, the *Riegel* Court left for the lower courts to develop the law regarding precisely in what circumstances state-law claims would impose requirements parallel to federal requirements. Nevertheless, what *Riegel* "made clear [is] that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." (Emphasis in original.) *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010).

¶ 29 However, even if a state-law claim is not expressly preempted by the MDA, such a claim may still be impliedly preempted under section 337(a) of the FDCA (21 U.S.C. § 337(a) (2012)). Generally, section 337(a) provides that "all such proceedings for the enforcement" of the provisions in the FDCA, which includes the MDA, "shall be by and in the name of the United States." In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352 (2001), the United States Supreme Court analyzed section 337(a) and found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." In a footnote, the Court emphasized that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n. 4. Consequently, if a plaintiff attempts to enforce duties relegated to the FDA, so-called "fraud-on-the-FDA claims," such a claim will be impliedly preempted under section 337(a) of the FDCA. *Id.* at 348.

¶ 30 Under *Riegel* and *Buckman*, there is a small window in which a state-law claim may escape express or implied preemption. *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1204 (8th Cir. 2010). To do so, " '[t]he plaintiff must be

suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by [section] 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).' " (Emphasis in original.) *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

¶ 31 Lastly, before turning to the facts of the instant case, we must briefly mention *Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928, the only Illinois decision after *Riegel* to discuss preemption under the MDA at the motion-to-dismiss stage. In *Norabuena*, the preemption issue focused on whether common-law failure-to-warn claims imposed requirements parallel to federal requirements. *Id.* ¶ 24. This court found that, "in the manner pled by [the] plaintiffs," their state-law claims imposed requirements parallel to the federal requirements concerning misbranding, and therefore, their failure-to-warn claims were not expressly or impliedly preempted. *Id.* ¶ 31. Despite this finding, this court ultimately concluded that the plaintiffs' complaint failed to allege specific factual allegations that the defendant's misbranding proximately caused the plaintiffs' complained of injuries. *Id.* ¶ 38. We accordingly found that the circuit court properly dismissed the plaintiffs' complaint. *Id.* ¶ 39. Although *Norabuena* involved common-law failure-to-warn claims, which are not at issue here, *Norabuena* is instructive because the decision observed that the manner in which allegations are pled guides the analysis of whether a state-law claim involves requirements different from, or in addition to, the federal requirements. See *id.* ¶ 31; see also *In re Medtronic*, 623 F.3d at 1207 (concluding that the plaintiffs' manufacturing defect claims failed because "*as pleaded and argued*," the claims were "a frontal assault on the FDA's decision" to approve a medical device following the premarket approval process) (emphasis in original.)

¶ 32 D. The Instant Case

¶ 33 Turning to the instant case, based on the parties' agreement that the intrathecal pump at issue is the Medtronic SynchroMed II pump and it is a Class III medical device that has passed an arduous premarket approval process (see *Riegel*, 552 U.S. at 317-19), they agree that the federal government has established requirements applicable to the medical device, satisfying the first step of the *Riegel* test. Where their agreement ends, however, is with respect to the second step of the *Riegel* test, where we must determine whether plaintiff's state-law claims involve requirements related to safety and effectiveness different from, or in addition to, the federal requirements. See *id.* at 323. Narrowing the focus on the second inquiry, it is clear that safety is at the heart of plaintiff's state-law claims of negligence against defendants. Thus, the critical issue in this appeal is whether plaintiff's state-law claims, as pled, involve requirements different from, or in addition to, the federal requirements.

¶ 34 Plaintiff's complaint alleged a single count of negligence against defendants based on two overarching claims: a design and manufacturing defect, and negligent instruction to health care providers on using the intrathecal pump. We take each claim in turn.

¶ 35 1. Design and Manufacturing Defect Claim

¶ 36 In plaintiff's claim for a design and manufacturing defect, she alleged that the intrathecal pump was subject to improper "unintended turning." Based on this turning, she claimed that defendants defectively designed and manufactured the intrathecal pump. However, nowhere in the complaint did plaintiff make any factual allegation that the intrathecal pump sold by defendants was designed differently from the device approved by the FDA during the premarket approval process. See *In re Medtronic*, 623 F.3d at 1206 (finding that "absent concrete allegations that the product sold by [the defendant] was not the product design approved" by the FDA, the allegations in the plaintiffs' complaint were "not parallel claims" and thus were

expressly preempted). Similarly, nowhere in the complaint did plaintiff make any factual allegation that defendants failed to manufacture the intrathecal pump in compliance with the manufacturing protocols approved by the FDA during the premarket approval process.

¶ 37 Absent such factual allegations, plaintiff, in essence, posits that the intrathecal pump should have been designed and manufactured differently than what the FDA approved during the premarket approval process, which necessarily would impose a requirement for the intrathecal pump that is different from, or in addition to, the requirements already imposed by the FDA. See *Walker v. Medtronic, Inc.*, 670 F.3d 569, 580-81 (4th Cir. 2012) (finding "[t]he consensus of the federal courts post-*Riegel* *** have held that common law tort claims based on the failure of devices that were designed, manufactured, and sold in accordance with the terms of their premarket approval were preempted"). As pled in her complaint, plaintiff's state-law claim of a design and manufacturing defect would impose requirements related to safety and effectiveness different from, or in addition to, the federal requirements. Therefore, plaintiff's claim of a design and manufacturing defect is expressly preempted by the MDA. See *In re Medtronic*, 623 F.3d at 1207 (holding that, where a plaintiff "failed to adequately plead that [a medical device] manufacturer violated a federal requirement specific to the FDA's [premarket] approval," dismissal was proper).

¶ 38 In contrast to plaintiff's claim as pled, in *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790, 799-800 (W.D. La. 2008), the United States District Court for the Western District of Louisiana found that a plaintiff's claim that the defendant failed to properly manufacture and package a medical device was not expressly preempted because it was based on the defendant's alleged failure to comply with explicit FDA specifications. See also *Bausch*, 630 F.3d at 556 (holding that claims for defective manufacturing "are not expressly preempted by federal law *to*

the extent they are based on defendants' violations of federal law") (Emphasis added.) Had plaintiff made a specific factual allegation concerning how the intrathecal pump was not designed or manufactured in accordance with its premarket approval, *i.e.*, the federal requirements of the FDA, it is possible the claim could have survived preemption. However, she made no such allegations in her complaint.

¶ 39 Nevertheless, plaintiff argues that her state-law claim of a design and manufacturing defect imposed a requirement parallel to an existing federal requirement. She asserts that the premarket approval process "[e]stablished a requirement for the internally-implanted SynchroMed II Pump" and her lawsuit was "based on the pump's failure to meet that requirement." Later in her brief, she further argues that "the ability of the pump to remain upright at issue here is a requirement for the Pump per the [premarket approval]." But in her complaint, plaintiff merely alleged that the pump was "subject to unintended turning" and never specifically identified any specific requirement resulting from the premarket approval process. Understandably, at the time plaintiff filed her complaint, she might not have had enough facts to support her allegations, which is why the circuit court allowed her leave to serve written discovery on defendants and file an amended complaint. Had she taken the opportunity to conduct the discovery, she could have bolstered the allegations of her complaint and perhaps, her state-law claim would not have been expressly preempted by the MDA. But she chose not to conduct the discovery nor file an amended complaint, resulting in her design and manufacturing defect claim, as pled in her complaint, being expressly preempted.

¶ 40 2. Negligent Instruction Claim

¶ 41 In plaintiff's claim for negligent instruction, she alleged that defendants "[c]arelessly and negligently instructed medical providers regarding measures to prevent unintended turning of the

intrathecal pump." Although the circuit court dismissed all of the claims of plaintiff's complaint based on preemption grounds, we may affirm such a dismissal on any basis supported by the record, regardless of whether the court relied on that basis. *HBLC, Inc. v. Egan*, 2016 IL App (1st) 143922, ¶ 25. And here, regardless of whether the MDA preempted plaintiff's negligent instruction claim, the claim itself is not cognizable under Illinois law. *Waugh v. Morgan Stanley & Co.*, 2012 IL App (1st) 102653, ¶ 42 (holding "that claims sounding in educational malpractice, that is, claims alleging negligent instruction, are not cognizable in Illinois"). But even if this claim were cognizable under Illinois law, it would still fail for the same reason her design and manufacturing defect claim failed, as nowhere in plaintiff's complaint did she make any factual allegation that defendants instructions on using the intrathecal pump deviated from those approved by the FDA during the premarket approval process. Absent such factual allegations, her claim cannot impose requirements that parallel the federal requirements and the claim would be expressly preempted by the MDA.

¶ 42 Despite these fatal issues with plaintiff's negligent instruction claim, she argues that the claim is more akin to the "learned intermediary doctrine" than the negligent instruction claim at issue in *Waugh*. Under the learned intermediary doctrine, typically at issue when drug manufacturers are defendants, the manufacturer has a duty to warn prescribing physicians "of the known adverse effects of a particular prescription drug" with the understanding that the physician, using his or her expertise, will weigh the relative risk of the drug with its benefits. *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 522-23 (1987). Under the doctrine, the doctor is the learned intermediary between the manufacturer and the patient. *Id.* at 519.

¶ 43 We must reject this argument. Importantly, her complaint never used the phrase "learned intermediary." While this is not necessarily fatal, as pleadings must be liberally construed in order to achieve substantial justice (735 ILCS 5/2-603(c) (West 2012)), even under the most liberal construction of plaintiff's claim, we cannot construe it as being one brought under the learned intermediary doctrine. Therefore, with respect to the negligent instruction claim, the circuit court properly dismissed it.

¶ 44 E. Plaintiff's Remand Request

¶ 45 Plaintiff lastly contends that, even if we affirm the dismissal of her complaint, her case should be remanded to the circuit court with leave to re-plead her cause of action. We disagree.

¶ 46 In the proceedings below, after the circuit court initially dismissed plaintiff's complaint, it granted her leave to serve additional written discovery on defendants and file an amended complaint. But plaintiff failed to do either. And in her notice of appeal, she asserted that, "[i]n lieu of filing an amended complaint," she "stood on the allegations contained in her original complaint." Because plaintiff already had the opportunity to amend her complaint in the circuit court, but intentionally chose not to, she has waived any right to a remand with leave to amend her complaint. See *Purmal v. Robert N. Wadington & Associates*, 354 Ill. App. 3d 715, 729 (2004). Accordingly, the circuit court's dismissal with prejudice must be affirmed.

¶ 47 III. CONCLUSION

¶ 48 For the foregoing reasons, the judgment of the circuit court of Cook County is affirmed.

¶ 49 Affirmed.