Illinois Official Reports

Appellate Court

***Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928**

Appellate Court Caption	SENAYDA NORABUENA and MIGUEL TORRES, Plaintiffs-Appellants, v. MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., and NORTHWESTERN MEMORIAL HEALTHCARE, Defendants (Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc., Defendants-Appellees).
District & No.	First District, Third Division Docket No. 1-16-2928
Filed	September 20, 2017
Decision Under Review	Appeal from the Circuit Court of Cook County, No. 15-L-011806; the Hon. John P. Callahan, Judge, presiding.
Judgment	Reversed and remanded.
Counsel on Appeal	Ryan M. Griffin and Scott M. Duxbury, of Goldstein, Bender & Romanoff, of Chicago, for appellants. Daniel L. Ring and Laura Babinsky, of Mayer Brown LLP, of Chicago, and Andrew E. Tauber (*pro hac vice*) and John T. Lewis (*pro hac vice*), of Mayer Brown LLP, of Washington, D.C., for appellees.

Panel PRESIDING JUSTICE COBBS delivered the judgment of the court, with opinion.
Justices Fitzgerald Smith and Lavin concurred in the judgment and opinion.

OPINION

¶ 1 Plaintiffs Senayda Norabuena and Miguel Torres appeal from the trial court's dismissal of their complaint asserting strict-liability and negligence claims for failure to warn as well as loss of consortium claims against defendants Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc. (collectively Medtronic). They contend that the trial court erroneously found that their claims were both expressly and impliedly preempted by federal law. Medtronic responds that the claims were properly dismissed as preempted and, alternatively, that the complaint was insufficiently pled. We hold that the claims are not preempted but the complaint failed to adequately plead that Medtronic's actions proximately caused plaintiffs' injuries. Accordingly, dismissal should have been without prejudice, and we reverse and remand.

¶ 2 I. BACKGROUND

¶ 3 A. The Device

¶ 4 This case centers on a prescription medical device called the Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device (Infuse), which is an implantable apparatus used in spinal fusion surgeries. The device is manufactured by Medtronic and includes two components: a titanium spinal fusion cage and a recombinant human bone morphogenetic protein paired with a collagen sponge. It is subject to regulation by the United States Food and Drug Administration (FDA) as a Class III medical device.

¶ 5 The FDA granted premarket approval of the Infuse on July 2, 2002. The premarket approval included an approved warning label indicating that the device was for use at one level of the spine and it should be implanted via an anterior approach. The label also warned that "ectopic or exuberant bone formation" had been observed when the Infuse was implanted via a posterior approach and the device's metal cage was not used.

¶ 6 B. Plaintiff's Surgery

¶ 7 Norabuena sought treatment for back and leg pain at Northwestern Memorial Hospital. Dr. Michael Haak diagnosed her with lumbar degenerative disc disease and left lumbar radiculopathy. On September 24, 2012, Haak performed surgery on Norabuena using the Infuse in an "off-label" manner, implanting it at multiple levels in a posterior approach without using the device's cage. Following the surgery, Norabuena continued to have pain. On November 19, 2013, a different doctor informed Norabuena that heterotopic bone had formed to the left of her spinal canal and was likely causing her pain.

¶ 8 C. The Complaint

¶ 9 Norabuena and Torres, her husband, filed a nine-count complaint against Medtronic and Northwestern Memorial Healthcare[1] on November 18, 2015. Norabuena asserted a strict-liability claim for defective warnings and a negligence claim for failure to warn against each of the defendants. Torres asserted a derivative loss of consortium claim against each defendant. In the complaint, they alleged that Medtronic promoted off-label uses of the Infuse through an advertising campaign as well as royalty payments to spine surgeons for research, training, and consulting. The paid surgeons then further promoted off-label uses through medical publications, seminars, and direct consultations with other surgeons. Plaintiffs alleged that Medtronic's promotional campaign emphasized the benefits of the Infuse in off-label applications while devaluing or omitting the potential adverse effects of such uses. Medtronic also violated federal requirements outlined in the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 301 *et seq.* (2012)) when it "failed to adequately warn and/or apprise the FDA of known adverse side effects" of the Infuse and when it placed a "misbranded" device into commerce by failing to warn of its adverse effects.

¶ 10 Medtronic initially moved to dismiss the complaint as inadequately pled under section 2-615 of the Code of Civil Procedure (Code) (735 ILCS 5/2-615 (West 2014)). The trial court denied the motion on June 10, 2016, finding that plaintiffs had sufficiently pled a cause of action "so that the defense can respond."

¶ 11 On August 16, 2016, Medtronic filed a motion to dismiss pursuant to section 2-619(a)(9) of the Code (735 ILCS 5/2-619(a)(9) (West 2014)), arguing that plaintiffs' claims were preempted by federal law. The trial court granted the motion and dismissed the complaint, ruling that plaintiffs' claims were expressly preempted by section 360k(a) of the FDCA (21 U.S.C. § 360k(a) (2012)) and impliedly preempted by section 337(a) (21 U.S.C. § 337(a) (2012)).

¶ 12 II. ANALYSIS

¶ 13 A. Standard of Review

¶ 14 Plaintiffs' complaint was dismissed under section 2-619(a)(9) of the Code. A section 2-619 motion admits the legal sufficiency of the complaint but argues that some defense or affirmative matter defeats the claim. *Ball v. County of Cook*, 385 Ill. App. 3d 103, 107 (2008). The defendant bears the burden of proving such an affirmative defense exists. *Daniels v. Union Pacific R.R. Co.*, 388 Ill. App. 3d 850, 855 (2009). We review the trial court's dismissal of a complaint under section 2-619 *de novo*. *Evanston Insurance Co. v. Riseborough*, 2014 IL 114271, ¶ 13. Further, we may affirm a dismissal on any basis apparent from the record. *In re Detention of Duke*, 2013 IL App (1st) 121722, ¶ 11.

¶ 15 B. Preemption

¶ 16 Plaintiffs contend that the trial court erred in finding that their claims were expressly preempted by section 360k(a) and impliedly preempted by section 337(a) because their complaint asserted state-law tort claims that are parallel to federal regulations. They argue that

[1]Northwestern Memorial Healthcare was not a party to Medtronic's motion to dismiss and is not an appellee in the current appeal.

the claims are parallel to federal regulations that (1) prohibit false and misleading statements, (2) prohibit promotional materials without adequate warnings, and (3) require the submission of adverse event reports. Medtronic responds that the plaintiffs' claims would impermissibly impose state-law requirements that are different from, and additional to, federal requirements.

¶ 17 The supremacy clause of article VI of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land; *** any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Thus, preemption doctrine requires that any state law is null and void if it conflicts with federal law. *Carter v. SSC Odin Operating Co.*, 237 Ill. 2d 30, 39 (2010). Federal law preempts state law in three different 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." *Id.* at 39-40. The question of preemption, therefore, rests primarily upon Congress's intent. *City of Chicago v. Comcast Cable Holdings, L.L.C.*, 231 Ill. 2d 399, 405 (2008).

¶ 18 The FDA was initially responsible for the regulation of new medical drugs while the regulation of medical devices was left primarily to the states. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). However, in the 1970s, Congress amended the FDCA, creating "a regime of detailed federal oversight" over medical devices. *Id.* at 316; see also Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540 (1976) (adding 21 U.S.C. § 360c). The new regulatory scheme divided medical devices into different classes based upon their associated risks. *Riegel*, 552 U.S. at 316. Class III devices, like the Infuse, receive the most strenuous federal oversight. *Raleigh v. Alcon Laboratories, Inc.*, 403 Ill. App. 3d 863, 872 (2010). For such devices, the FDA grants premarket approval only after a rigorous review, typically including a multivolume application with complete reports of the studies and investigations of a device's safety and effectiveness; a list of the device's elements, ingredients, and workings; descriptions of its production, processing, and packing; samples or components required by the FDA; and a sampling of the planned labeling. *Riegel*, 552 U.S. at 317-18 (citing 21 U.S.C. § 360e(c)(1) (2006)). After the FDA grants approval, a manufacturer is forbidden from "mak[ing], without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319.

¶ 19 Section 360k(a) of the FDCA provides an express preemption clause, which states:

> "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).

Also relevant to our review is section 337(a) of the FDCA (21 U.S.C. § 337(a) (2012)), which provides that all proceedings for the enforcement of the FDCA's provisions, barring exceptions irrelevant to the current proceeding, "shall be by and in the name of the United States."

¶ 20 The United States Supreme Court has addressed preemption in the context of premarket approval on three occasions. It first significantly examined section 360k(a)'s preemption provision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Holding that state-law tort suits are not always preempted, the Court explained that tort suits that do not impose new "requirements" on manufacturers are not preempted so long as they only impose duties "parallel" to duties found in the FDCA. *Id.* at 495.

¶ 21 The Supreme Court later elaborated on *Lohr*'s holding in *Riegel*. In that case, the Court considered whether plaintiff's state-law claims against the manufacturer of a Class III, premarket-approved balloon catheter were preempted under section 360k(a). *Riegel*, 552 U.S. at 330. In considering the section, it established a two-step process for analyzing preemption claims: (1) a determination whether the federal government had established requirements applicable to the device and, if so, (2) whether a plaintiff's claims are based on requirements imposed by the state are different from, or in addition to, the federal requirements related to safety and effectiveness. See *id.* at 321-22; see also *Raleigh*, 403 Ill. App. 3d at 873. The Court explained that the premarket approval process imposed federal "requirements," triggering the preemption clause of section 360k(a), and that the tort duties underlying common-law claims would also constitute "requirements" under the section. *Riegel*, 552 U.S. at 322-25. Ultimately, it concluded that the state tort law underlying the plaintiffs' claims would require a manufacturer's device to be safer than the model device approved by the FDA, and therefore those requirements were preempted. *Id.* at 330 However, the Court explained that preemption only applies to devices that "violated state tort law notwithstanding compliance with the relevant federal requirements." *Id.* It further noted "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (quoting *Lohr*, 518 U.S. at 495).

¶ 22 Finally, our analysis is also informed by the Supreme Court's discussion of implied preemption under the FDCA in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). There, the Court addressed section 337(a) of the FDCA, in which it found "clear evidence that Congress intended that the [amendments to the FDCA] be enforced exclusively by the Federal Government." *Id.* at 352. Therefore, it held, section 337(a) preempts any state tort claim that exists "solely by virtue" of an FDCA violation. *Id.* at 353. At the same time, the Court left undisturbed the portion of *Lohr* allowing state lawsuits based on state common-law torts that "predate[ ]" the FDCA but "parallel" its regulations. *Id.*

¶ 23 Plaintiffs' complaint asserts that the Infuse is a Class III medical device that has gained premarket approval from the FDA. It is clear, under the Supreme Court's guidance, that the device is therefore subject to federal requirements. The question that remains is whether plaintiffs' state-law claims involve requirements that are impermissibly different from, or in addition to, the federal requirements or permissibly parallel to the federal regulations. Moreover, under *Buckman*, any parallel state-law requirements must not exist solely as a remedy for the federal violation. Our research has revealed no Illinois case addressing the issue of parallel requirements. Because our decision requires the interpretation of federal law, we look to the federal circuit courts of appeals for guidance. See *State Bank of Cherry v. CGB Enterprises, Inc.*, 2013 IL 113836, ¶ 33.

¶ 24 Three of the federal circuit courts have addressed in opinions[2] whether common-law failure to warn claims, like those raised by plaintiffs, are parallel to FDA regulations. First, in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 765 (5th Cir. 2011), the plaintiff suffered severe burns when hot liquid leaked from a Class III medical device. She sued the device's manufacturer under Mississippi law, alleging a violation of a state-law duty to warn. *Id.* The Fifth Circuit held that the plaintiff's state-law failure to warn claim was not preempted "to the extent that this claim is predicated on [the manufacturer]'s failure to comply with the applicable federal statutes and regulations." *Id.* at 764. The court stated explicitly that its holding extended to both express and implied preemption: "We conclude that [plaintiff]'s failure to warn claim is neither expressly nor impliedly preempted by the [amendments to the FDCA] to the extent that this claim is premised on [the manufacturer]'s violation of FDA regulations with respect to reporting burns caused by the [device]." *Id.* at 776. The court explained that the claims were not the type of claim barred by *Buckman* because Mississippi tort law recognized a failure to warn claim based on the failure to inform the FDA of dangers. See *id.* at 775.

¶ 25 The Ninth Circuit Court of Appeals, in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013), examined allegations that a manufacturer had allegedly learned about certain risks of its device after it had received premarket approval but failed to notify the FDA before the plaintiff suffered harm. The plaintiff brought a state-law negligence claim against the manufacturer for failing to disclose the newly discovered risks to the FDA in violation of duties established by federal and state law. *Id.* at 1226. The Ninth Circuit held that the plaintiff's failure to warn claim under Arizona law was parallel to the federal regulations requiring notifying the FDA because Arizona law "has long been concerned with the protection of consumers from harm caused by manufacturers' unreasonable behavior. Plaintiffs' claim is brought under settled Arizona law that protects the safety and health of Arizona citizens by imposing a general duty of reasonable care on product manufacturers," including by requiring manufacturers to disclose risks discovered after sale. *Id.* at 1233. Thus, it held that the claim was not preempted. *Id.*

¶ 26 The Tenth Circuit addressed the issue in *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1336 (10th Cir. 2015). There, the plaintiff raised, *inter alia*, allegations substantially similar to plaintiffs' here. See *id.* at 1337-38. The court first noted that all of the plaintiff's claims for which she had not identified a parallel federal regulation were clearly preempted. *Id.* at 1340-41. It went on to address the plaintiff's claims for failure to warn, negligence, and negligent misrepresentation, which plaintiff argued were parallel to regulations found in section 352 of the FDCA (21 U.S.C. § 352 (2012) and 21 C.F.R. § 801.5 (2012)). *Caplinger*, 784 F.3d at 1341. Explaining that those regulations together required that "a device's warning label must not be 'false or misleading in any particular,' " the court held that most of the plaintiff's general tort claims were far broader than the federal regulations, and thus preempted. *Id.* (quoting 21 U.S.C. § 352(a) (2012)). The court also noted that the Medtronic device at issue was a prescription device, and explained:

[2] The Second Circuit also addressed a similar case involving the device in question in a nonprecedential summary order in *Otis-Wisher v. Medtronic, Inc.*, 616 Fed. App'x 433, 434 (2d Cir. 2015). Although the court held that the plaintiff's failure to warn claims were preempted, the order's summary nature leaves too few details to significantly guide our analysis.

> "[T]hat usually means it isn't possible to prepare adequate directions for its safe use by laymen. [21 C.F.R.] § 801.109. And for precisely this reason, 21 C.F.R. § 801.109 generally absolves manufacturers from liability under § 352 and § 801.5 so long as they label their prescription devices in a certain manner approved by the FDA." *Id.*

¶ 27 Having reviewed the federal case law, it is clear that plaintiffs' claims are preempted to the extent that they are not premised entirely on an identified parallel federal regulation. Plaintiffs have identified two primary federal regulations which they believe are parallel to their claims: (1) a requirement to submit reports of adverse events to the FDA and (2) a prohibition against misbranding.

¶ 28 Plaintiffs argue that their claims are not preempted because, similarly to the plaintiffs in *Hughes* and *Stengel*, they allege Medtronic failed to report adverse events to the FDA as required as a condition to the Infuse's premarket approval. However, although plaintiffs have identified a federal requirement that their complaint alleges Medtronic violated, there is no Illinois requirement that parallels it. Plaintiffs asserted claims for failure to warn. Although Illinois recognizes that a manufacturer may satisfy its duty to warn by conveying information to third-party learned intermediaries (see *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 519 (1987)), this is not synonymous with an affirmative duty to warn a federal regulatory body. The learned intermediary doctrine states that a manufacturer has a duty "to warn prescribing physicians of a drug's known dangerous propensities" under the understanding that those physicians will use their expert knowledge in adequately warning the patient. *Martin v. Ortho Pharmaceutical Corp.*, 169 Ill. 2d 234, 238 (1996). We cannot find that this duty is parallel to the federal requirement. Although the federal appellate courts found differently in *Hughes* and *Stengel*, those opinions were based upon duties found under Mississippi and Arizona law, respectively, and are therefore distinguishable.

¶ 29 Plaintiffs also argue that their claims parallel federal regulations against misbranding through section 352(q) of the FDCA (21 U.S.C. § 352(q) (2012)). That section states that a device is misbranded "if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title." *Id.* Section 321(n) states that where there is an allegation of misbranding:

> "in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article." 21 U.S.C. § 321(n) (2012).

Thus, it is clear that misbranding may occur under federal requirements, where advertising is misleading due to a failure to reveal pertinent facts regarding the risks or consequences of the device in question's usage.

¶ 30 In order to establish a strict-liability failure to warn claim under Illinois law, a plaintiff must prove that the manufacturer did not disclose an unreasonably dangerous condition or instruct on the proper use of the product as to which the average consumer would not be aware. *Salerno v. Innovative Surveillance Technology, Inc.*, 402 Ill. App. 3d 490, 499 (2010). The duty to warn arises where the product possesses dangerous tendencies, the manufacturer knows of the nonobvious risks of harm, and knows or should know that harm may occur without instruction or a warning. *Id.* Similarly, in order to prove a negligent failure to warn

claim, a plaintiff must show that the manufacturer negligently failed to instruct or warn of a danger of the product and that failure proximately caused the plaintiff's injuries. See *Solis v. BASF Corp.*, 2012 IL App (1st) 110875, ¶ 56.

¶ 31 Plaintiffs' complaint asserts claims for failure to warn based on its allegations that Medtronic produced and disseminated advertising which was "false, misleading, and deceptive" in that it "concealed known dangerous side effects regarding off-label uses." In other words, Medtronic's advertising was misleading because it failed to reveal material facts regarding the consequences of using the Infuse in the manner suggested by the advertising. Thus, in the manner pled by plaintiffs, the failure to warn claims parallel the federal requirements regarding misbranding: both prohibit the omission of material risks of the device when marketing a product. As such, plaintiffs' claims are neither expressly nor impliedly preempted insofar as they parallel the federal prohibition against misbranding.

¶ 32 Medtronic argues that the claims are preempted because plaintiffs are attacking the sufficiency of the FDA-approved label or categorically attacking the promotion of off-label uses. This misconstrues plaintiffs' complaints. Plaintiffs do not attack the sufficiency of the Infuse's labeling but rather the allegedly deceptive marketing practices of Medtronic after approval was given. We note that unlike the label, the promotion of the device was not pre-approved by the FDA. Medtronic also argues that the claim must be preempted because, it asserts, the only possible way to provide additional warning would be through changing the labeling, an action that cannot be made without further FDA approval. This argument is unpersuasive. The regulations promulgated by the FDA clearly indicate that labeling and advertising are separate actions. See, *e.g.*, 21 U.S.C. § 321(n) (2012) (describing misbranding when "the labeling or advertising is misleading"). Much as the FDA did not prohibit Medtronic from promoting the off-label uses of the Infuse (see *Buckman*, 531 U.S. at 350 ("Similarly, 'off-label' usage of medical devices *** is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.")), Medtronic has pointed to no FDA regulations that prohibited it from providing additional warnings during that promotion.

¶ 33 We briefly acknowledge that plaintiffs also argued that their claims paralleled 21 C.F.R. § 801.5 (2012), which requires adequate direction be given such that a "layman can use a device safely and for the purposes for which it is intended." However, as the Tenth Circuit noted in *Caplinger*, a prescription device cannot typically be explained in instructions easily grasped by laymen, and thus section 801.5 is inapplicable to devices which bear a FDA-approved label. See *Caplinger*, 784 F.3d at 1341; see also 21 C.F.R. § 801.109 (2012).

¶ 34 C. Adequacy of the Pleadings

¶ 35 Medtronic argues, in the alternative, that the trial court erroneously denied its petition to dismiss plaintiffs' complaint under section 2-615 of the Code (735 ILCS 5/2-615 (West 2014)) because it was inadequately pleaded. Plaintiffs respond that Medtronic has waived this argument by failing to file a cross-appeal from the trial court's June 10, 2014, order, which denied Medtronic's initial motion to dismiss. As we have already ruled that plaintiffs' claims are preempted except where they rely on assertions that Medtronic omitted necessary information regarding material risks of the Infuse in promoting the device, we address this argument only as to those claims.

¶ 36 Before addressing the merits of Medtronic's argument, we must determine whether it is properly before this court. Once a trial court enters a finding under Illinois Supreme Court Rule 304(a) (eff. Feb. 26, 2010) as to an order of dismissal, earlier adverse findings against the dismissed defendant also become final and appealable. *Argonaut-Midwest Insurance Co. v. E.W. Corrigan Construction Co.*, 338 Ill. App. 3d 423, 426-27 (2003). Generally, "[w]here a general decision for the appellee contains findings unfavorable to the appellee and no cross-appeal is filed, the adverse findings are not properly before the reviewing court." *Cincinnati Insurance Co. v. Chapman*, 2016 IL App (1st) 150919, ¶ 27. If the appellee fails to file a cross-appeal, the reviewing court is confined to the issues raised by the appellant and will only consider the issues raised by the appellee where they are related to the appellant's issues. *Ruff v. Industrial Comm'n*, 149 Ill. App. 3d 73, 79 (1986). However, when reviewing a dismissal under section 2-619 of the Code, we may affirm that dismissal for any reason evident in the record. *Gunthorp v. Golan*, 184 Ill. 2d 432, 438 (1998). Additionally, a party is not required to file a cross-appeal where they do not seek reversal of the judgment below. *People ex rel. Hartigan v. Knecht Services, Inc.*, 216 Ill. App. 3d 843, 852 (1991). Plaintiffs appeal from the trial court's order dismissing their complaint. Medtronic does not seek to reverse judgment. Accordingly, we may consider the adequacy of the pleadings in determining whether to affirm that dismissal.

¶ 37 A section 2-615 motion to dismiss presents the question of whether the facts alleged in the complaint, viewed in the light most favorable to the plaintiff, are sufficient to entitle the plaintiff to relief as a matter of law. *Chandler v. Illinois Central R.R. Co.*, 207 Ill. 2d 331, 348 (2003). When reviewing such a dismissal, we presume that the motion admits all well-pleaded facts and all reasonable inferences from those facts. *Napleton v. Village of Hinsdale*, 229 Ill. 2d 296, 320 (2008). A cause of action should be dismissed only when it is clearly apparent that no set of facts can be proved that will entitle a plaintiff to recovery. *Id.* at 305. Our supreme court has repeatedly stated "that Illinois is a fact-pleading jurisdiction." *Marshall v. Burger King Corp.*, 222 Ill. 2d 422, 429 (2006). As such, notice to the defendants is not enough; instead, the plaintiff must allege facts "sufficient to bring a claim within a legally recognized cause of action [citation], not simply conclusions." See *id.* at 429-30. Because such a determination raises issues of law, we review orders granting section 2-615 dismissals *de novo*. *Heastie v. Roberts*, 226 Ill. 2d 515, 530-31 (2007).

¶ 38 As we previously stated, to assert claims under both negligent and strict-liability theories, plaintiffs were required to plead facts alleging that Medtronic failed to instruct or warn of a danger of the product and that failure proximately caused the plaintiff's injuries. See *Salerno*, 402 Ill. App. 3d at 499; *Solis*, 2012 IL App (1st) 110875, ¶ 56. Under the learned intermediary doctrine, Medtronic was only required to provide sufficient warnings to Norabuena's surgeon. See *Martin*, 169 Ill. 2d at 238. After reviewing the complaint, we find that plaintiffs allege numerous instances of promotion where Medtronic allegedly withheld or omitted information regarding adverse events and risks associated with off-label use of the Infuse. However, there are no specific factual allegations in the complaint asserting that Norabuena's surgeon encountered or relied on any of the asserted promotional marketing. Each count instead sets forth the conclusory statement that Norabuena's injuries were caused "as a direct and proximate result" of one or more of Medtronic's actions or omissions. Bare legal conclusions are insufficient to state a legal claim (*Marshall*, 222 Ill. 2d at 430), and therefore we must find that the complaint failed to sufficiently allege facts indicating that Medtronic's actions or

omissions proximately caused the complained of injuries. As the loss of consortium counts are derivative of the failure to warn claims, they must also fail. *Brown v. Metzger*, 118 Ill. App. 3d 855, 858-59 (1983) ("[W]here the impaired spouse's claim fails as a matter of law, the deprived spouse's claim for loss of consortium must likewise fail.").

¶ 39 Accordingly, we hold that the dismissal of plaintiffs' complaint was proper. However, as we rely on different reasoning than the trial court, we must further address the issue of whether that dismissal should have been made with prejudice. A dismissal under section 2-615 of the Code should be made with prejudice only where it is clearly apparent that the plaintiffs can prove no set of facts entitling recovery. *Illinois Graphics Co. v. Nickum*, 159 Ill. 2d 469, 488 (1994). The trial court has discretion to deny leave to amend a complaint, but "the trial court should exercise its discretion liberally in favor of allowing amendments if doing so will further the ends of justice, and it should resolve any doubts in favor of allowing amendments." *In re Application of the County Collector*, 343 Ill. App. 3d 363, 370 (2003). A court should typically "give a plaintiff at least one opportunity to cure the defects in his or her complaint." *Id.* As the trial court did not dismiss the complaint for insufficient pleadings, it did not consider whether plaintiffs should have the opportunity to amend their complaint. We find that although the pleadings are insufficient, it is not clearly apparent that plaintiffs can prove no set of facts entitling recovery. Accordingly, the dismissal should be without prejudice, and plaintiffs should be given the opportunity to amend their complaint.

¶ 40 III. CONCLUSION

¶ 41 For the foregoing reasons, we hold that plaintiffs' failure to warn claims are not expressly or impliedly preempted insofar as they assert claims that Medtronic misbranded its Infuse by omitting material information regarding risks of off-label uses. However, we hold that the complaint failed to sufficiently plead that Norabuena's injuries were proximately caused by Medtronic's actions or omissions, and thus dismissal without prejudice was warranted. Accordingly, we reverse the judgment of the circuit court of Cook County dismissing plaintiffs' complaint with prejudice and remand this cause to the circuit court of Cook County for further proceedings consistent with this opinion.

¶ 42 Reversed and remanded.