IN THE

# ARIZONA COURT OF APPEALS

**DIVISION ONE**

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RAYMOND R. CONKLIN, II, et al., *Plaintiffs/Appellants*,

*v.*

MEDTRONIC, INC., et al., *Defendants/Appellees*.

No. 1 CA-CV 16-0252
FILED 10-19-2017

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Appeal from the Superior Court in Maricopa County
No. CV2015-002965
The Honorable Lori Horn Bustamante, Judge

**AFFIRMED IN PART; VACATED IN PART; REMANDED**

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## OPINION

Presiding Judge Randall M. Howe delivered the opinion of the Court, in which Judge Lawrence F. Winthrop and Judge Jon W. Thompson joined.

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**H O W E**, Judge:

**¶1** Raymond R. Conklin, II and his wife Joanne M. Conklin appeal from the dismissal of their action against Medtronic, Inc. as preempted by federal law. We affirm as preempted the trial court's dismissal of the Conklin's product liability, breach of express warranty, and negligence causes of action. We vacate the trial court's dismissal of the Conklin's failure to warn, loss of consortium, and punitive damages claims because we hold that those claims are not expressly or impliedly preempted by federal law. We remand for further proceedings consistent with this opinion.

## FACTS AND PROCEDURAL HISTORY

**¶2** Medtronic designed, manufactured, and marketed the Medtronic SynchroMed II 40 ml infusion pump and catheter, Model 8637-40 ("Medtronic Pain Pump"). The Medtronic Pain Pump is a Class III medical device the Food and Drug Administration ("FDA") regulates under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). A Class III medical device is subject to the FDA's rigorous pre-market approval ("PMA") process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). After PMA, a device manufacturer must comply with federal medical device reporting requirements. 21 U.S.C. § 360i(a)(1). Specifically, a manufacturer must report to the FDA any information reasonably suggesting that the device "[m]ay have caused or contributed to a death or serious injury" or that "[h]as malfunctioned" and that any recurring malfunction "would be likely to cause or contribute to a death or serious injury." 21 C.F.R. § 803.50(a).

**¶3** In March 2008, a physician surgically implanted a Medtronic Pain Pump into Mr. Conklin to manage chronic pain. In February 2013, Mr. Conklin underwent hip surgery and later suffered permanent injury by drug over-infusion the Medtronic Pain Pump allegedly caused. The Conklins sued Medtronic alleging several Arizona common law tort claims, including product liability (design and manufacturing defect), failure to warn, negligence, breach of express warranty, and loss of consortium. The Conklins also sought punitive damages.

**¶4** The Conklins alleged that before Mr. Conklin was injured, the FDA had sent warning letters to Medtronic, advising that the Medtronic Pain Pump was adulterated and misbranded and stating that Medtronic had failed to report adverse events to the FDA after PMA. The Conklins also alleged that before the February 2013 injury occurred, the FDA had issued two Class I recalls of the Medtronic Pain Pump. The Conklins further alleged that after Mr. Conklin was injured, the FDA issued another Class I recall of the Medtronic Pain Pump regarding the unintended delivery of drugs that could result in a drug overdose. The Conklins alleged that Medtronic's failure to report post-PMA adverse events to the FDA in violation of federal law gives rise to liability under Arizona common law.

**¶5** Medtronic moved to dismiss for the failure to state a claim on the basis that federal law preempts the state-law claims. The trial court granted Medtronic's motion and dismissed the action with prejudice. Although the court found all claims preempted, it found additionally that the strict liability, breach of warranty, and derivative claims failed under Arizona law. The Conklins moved for reconsideration, which the trial court denied. The Conklins timely appealed.

## DISCUSSION

### 1. Preemption and Class III Medical Devices

**¶6** We review de novo the trial court's order granting a motion to dismiss for failure to state a claim. *Coleman v. City of Mesa*, 230 Ariz. 352, 355–56 ¶ 7 (2012). We assume the truth of the complaint's factual allegations and will uphold dismissal "only if as a matter of law plaintiffs would not be entitled to relief under any interpretation of the facts susceptible of proof." *Id.* at 356 ¶¶ 8–9.

**¶7** Congress has the power to preempt state law pursuant to the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. Congress may "withdraw specified powers from the States by enacting a statute containing an express preemption provision." *Arizona v.*

*United States*, 567 U.S. 387, 399 (2012). For federal questions such as preemption, United States Supreme Court decisions are binding, and we may look to circuit court cases as persuasive authority. *See Weatherford ex rel. Michael L. v. State*, 206 Ariz. 529, 532–33 ¶¶ 8–9 (2003).

**¶8** Medtronic has the burden to prove preemption. *See E. Vanguard Forex, Ltd. v. Ariz. Corp. Comm'n*, 206 Ariz. 399, 405 ¶ 18 (App. 2003). While federal laws are presumed not to preempt state laws, courts do not invoke that presumption when the federal statute contains an express preemption clause. *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016); *Cuomo v. Clearing House Ass'n, LLC*, 557 U.S. 519, 554 (2009); *Riegel*, 552 U.S. 312 (analyzing the MDA's express preemption provision without presuming preemption).

**¶9** The MDA expressly preempts certain state-law requirements concerning medical devices. The MDA states in pertinent part that no state "may establish or continue in effect with respect to a device . . . 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).

**¶10** For express preemption to apply, two conditions must be met: (1) the federal government must have established requirements applicable to the device at issue and (2) the plaintiff's common-law claims concerning the device must include requirements that are "different from, or in addition to" those federal requirements. 21 U.S.C. § 360k(a); *Riegel*, 552 U.S. at 321–23. If these two conditions are met, common-law claims challenging the safety or effectiveness of a medical device that received PMA from the FDA are expressly preempted. *Id.* In addition to express preemption, the MDA also impliedly preempts any action for the enforcement or restriction of violations of the FDCA because such actions can only be brought by or in the name of the United States. 21 U.S.C. § 337(a); *see Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

**¶11** Despite these preemption restrictions, a plaintiff's state-law claim concerning a medical device may be viable if it is a "parallel claim," a claim based on state requirements that are "equal to or substantially identical to, requirements imposed by or under the act." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495–97 (1996). Thus, a state-law claim is not preempted when it provides "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." *Riegel*, 552 U.S. at 330. As the Eighth Circuit explained in *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). Essentially, the state-law claim cannot exist "solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 352–53.

**2. Claims Analysis**

**¶12** Because the Medtronic Pain Pump is a Class III medical device, as a matter of law the PMA process imposes federal requirements contemplated by § 360k(a) for express preemption purposes. *Riegel*, 552 U.S. at 322–23. The Conklins do not dispute that the Medtronic Pain Pump received PMA. As such, part one of the express-preemption test under *Riegel* is automatically satisfied. *See id.*

**¶13** We must next analyze whether Arizona state law imposes on Medtronic a requirement different from or in addition to federal law or if the Conklins' state-law claims instead escape express and implied preemption. We address each claim in turn to determine if the claim is expressly or impliedly preempted, or if the claim is a viable parallel state-law claim.

**2a. Product Liability—Design and Manufacturing Defect**

**¶14** The Conklins alleged that the Medtronic Pain Pump was defective when manufactured in design and formulation and when it dispensed an excess of narcotic drugs to Mr. Conklin. To the extent the Conklins pled a strict liability cause of action based on defective design and manufacturing, on appeal they do not challenge the trial court's finding that such claim is expressly preempted. Medtronic argues that the claim is expressly preempted absent an allegation that the Medtronic Pain Pump was designed or manufactured in any manner other than what the FDA required. We agree with Medtronic.

**¶15** Success on these claims would require the jury to find that the design and manufacturing process the FDA approved through the PMA process was defective as a matter of state law, which would add requirements to the process that the FDA established and is thus expressly preempted. *See Riegel*, 552 U.S. at 325; *In re Medtronic*, 623 F.3d at 1206–07 (concluding that design and manufacturing defect claims were expressly preempted because they attacked "the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device"); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011).

**2b. Breach of Express Warranty**

**¶16** The Conklins further alleged that although Medtronic expressly warranted that the Medtronic Pain Pump was "safe and effective," the pump that Medtronic manufactured and sold "did not conform to these express representations because [it] caused serious injury . . . when used as recommended and directed." On appeal, Medtronic argues that § 360k expressly preempts this claim because it "would inescapably impose different or additional requirements than those imposed by the FDA's premarket-approved design, manufacturing, and labeling specifications." The Conklins do not argue on appeal that their breach of warranty claim is a parallel state claim that survives preemption. Instead, the Conklins argue only that the trial court incorrectly found on alternative grounds that this claim was untimely due to lack of notice.

**¶17** To succeed on their breach of express warranty claim, the Conklins must persuade a jury that the Medtronic Pain Pump was not safe and effective. Such a finding would be "contrary to the FDA's approval of the PMA" and is thus expressly preempted. *See In re Medtronic,* 623 F.3d at 1207–08. Because this claim is expressly preempted, we need not address the trial court's alternative basis for dismissing the claim.

**2c. Failure to Warn**

**¶18** The Conklins contend that Medtronic violated federal law by failing to report post-PMA adverse events concerning the Medtronic Pain Pump to the FDA and others, which in turn violated its duty under Arizona law to use reasonable care to warn Mr. Conklin of the dangers inherent in using the defective Medtronic Pain Pump. Specifically, the Conklins allege that Medtronic violated 21 C.F.R. § 803.50, 21 C.F.R. § 820.198(a)(3), and 21 U.S.C. § 360i. Because the Conklins' failure-to-warn claim is not expressly or impliedly preempted, the trial court erred by dismissing this claim.

**¶19** Relying on the Ninth Circuit's decision *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013), the Conklins argue that their failure-to-warn claim is a permissible parallel claim. Medtronic, on the other hand, contends that the post-sale duty to warn claim is expressly and impliedly preempted and does not parallel federal requirements regarding post-approval reporting because "the federal duty to submit [adverse reports] to the FDA is not identical to the state-law duty to warn doctors or their patients."

**¶20** Although *Stengel* involved a different Medtronic infusion pump, the plaintiffs there alleged, as the Conklins similarly do here, that Medtronic failed to report to the FDA adverse consequences involving its product post-PMA and that, because Medtronic "failed to comply with its duty under federal law, it breached its 'duty to use reasonable care' under Arizona negligence law." 704 F.3d at 1232. The Ninth Circuit concluded that the Arizona "failure-to-warn" claim was not preempted because Arizona law "impos[es] a general duty of reasonable care on product manufacturers" and includes a cause of action for failure to warn. *Id.* at 1233 (citing *Crouse v. Wilbur-Ellis Co.*, 77 Ariz. 359 (1954); and *Wilson v. U.S. Elevator Corp.*, 193 Ariz. 251 (App. 1998)).

**¶21** In so doing, the Ninth Circuit noted that Arizona law requires a manufacturer to "warn of dangers which he knows or should know are inherent in its use. This duty may be a continuing one applying to dangers the manufacturer discovers after sale." *Id.* (quoting *Rodriguez v. Besser Co.*, 115 Ariz. 454, (App. 1977), *abrogated on other grounds as recognized by Piper v. Bear Med. Sys.*, 180 Ariz. 170 (App. 1993)). In discussing whether an Arizona state-law failure-to-warn claim is preempted, the Ninth Circuit stated:

> If a more precise parallel were necessary, the Stengels have alleged it and Arizona law provides it. The Stengels' . . . claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA. Arizona law contemplates a warning to a third party such as the FDA. Under Arizona law, a warning to a third party satisfies a manufacturer's duty if, given the nature of the warning and the relationship of the third party, there is "reasonable assurance that the information will reach those whose safety depends on their having it."
>
> We do not decide whether plaintiffs can prevail on their state-law failure-to-warn claim. That question is not before us. But we do hold under *Lohr*, *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly,

> by the MDA. It is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*. The claim rests on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*.

*Id.*

**¶22** The *Stengel* decision is based on the premise that a manufacturer's continuing duty to warn of dangers discovered after sale in Arizona can be satisfied by warning a third party such as the FDA. *Id.* at 1233. We agree with *Stengel* that Arizona law contemplates that a warning to the FDA could satisfy Medtronic's general duty of reasonable care to warn. *See id.* This is so because the FDA, in turn, could have notified Mr. Conklin's doctor, thus discharging Medtronic's duty. *See Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 24 ¶¶ 13–14 (2016) (adopting the learned intermediary doctrine as set forth in Restatement (Third) of Torts: Prod. Liab. § 6(d) as to prescription drug manufacturers and holding that a manufacturer satisfies its duty to warn end users by giving appropriate warnings to learned intermediaries).

**¶23** The Conklins base their Arizona failure-to-warn claim on Medtronic's violation of the federal duty to report post-PMA adverse events to the FDA. "That requirement is not 'different from, or in addition to' the requirements imposed by federal law, because FDA regulations required Medtronic to file an adverse event report with the FDA if it learned of information 'reasonably suggest[ing]' that one of its devices '[m]ay have caused or contributed to a death or serious injury,'" which the Conklins alleged. *See Stengel*, 704 F.3d at 1234 (Watford, J., concurring). As such, this claim is not expressly preempted.

**¶24** Moreover, the cause of action for failure to warn is not impliedly preempted because the Conklins are not suing to enforce the FDCA, but to recover under Arizona state law for Medtronic's alleged failure to warn of dangers discovered after sale. *See Rodriguez*, 115 Ariz. at 459 (continuing independent state-law duty); *Buckman,* 531 U.S. at 352 (to avoid implied preemption, the claim must rely on "traditional state tort law which had predated the federal enactments in question"). To the extent that the Conklins allege a violation of any state-law duty to directly warn Mr. Conklin or his physicians, however, such claims are expressly preempted because those duties would be in addition to requirements imposed by federal law. *See Stengel*, 704 F.3d at 1234 (Watford, J., concurring).

**¶25** Medtronic argues that the Conklins did not adequately allege a causal connection between the failure to report adverse events and Mr. Conklin's injuries. But that is incorrect. The Conklins sufficiently alleged a causal connection under Arizona's notice pleading standard because the complaint alleged that (1) Medtronic had a continuing duty to monitor the product after PMA and to report to the FDA any adverse events attributable to the product; (2) Medtronic breached its Arizona duty to use reasonable care because it failed in its duty under federal law to report adverse events to the FDA; (3) a recall occurred post-injury; and (4) Mr. Conklin was injured. We note, however, that the Conklins will ultimately also have to prove that "if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached [Mr. Conklin's] doctors in time to prevent his injuries." *See id.*

**2d. Negligence Causes of Action**

**¶26** The Conklins alleged several negligence causes of action, including (1) negligent manufacture and design and (2) negligence per se. The Conklins contend that Medtronic negligently "designed, manufactured, tested, assembled, labeled, supplied, marketed, sold, advertised and failed to warn against" the Medtronic Pain Pump. As discussed above, the Conklins may bring their failure-to-warn claim against Medtronic because that claim is not expressly or impliedly preempted. *See supra* section 2c. As to the remaining allegations of negligent manufacture and design, the Conklins do not argue on appeal that these claims were improperly dismissed as preempted. As such, we consider any argument to the contrary waived. *Rice v. Brakel*, 233 Ariz. 140, 147 ¶ 28 (App. 2013) (failure to address basis of trial court's decision waives claim on appeal).[1]

**¶27** The Conklins argue next that Medtronic had a "continuing duty to monitor the product after premarket approval and to alert the FDA about complaints about the product's performance, including any adverse health consequences of which it became aware" pursuant to 21 C.F.R. § 820.198(a)(3) and to "submit medical device reports" to the FDA pursuant to 21 U.S.C. § 360i and 21 C.F.R. § 803.50. According to the Conklins, Medtronic's failure to adhere to these regulations is negligence per se.

[1] The Conklins also allege that to the extent they are unable to prove specific acts of negligent manufacture and design, they will rely on the doctrine of res ipsa loquitur. Because the claims for negligent manufacture and design are preempted, res ipsa loquitur is unavailable.

**¶28** The Conklins contend that a federal statute or regulation may be adopted as a standard of conduct to support a negligence per se claim. Medtronic argues that a negligence per se claim is impliedly preempted because the failure to report adverse events is an attempt to enforce the MDA. We agree with the Conklins.

**¶29** If a court decides to adopt a standard of care designed to protect the public safety that is set forth in a statute or regulation, a person who violates that statute or regulation is negligent per se. *Brannigan v. Raybuck*, 136 Ariz. 513, 517 (1983). Arizona law sets forth a specific paradigm for determining whether a court should adopt a particular statute or regulation as the standard of conduct for a negligence per se cause of action. *See Steinberger v. McVey ex rel Cty. of Maricopa*, 234 Ariz. 125, 139 ¶¶ 56–62 (App. 2014).

**¶30** As previously explained, *see supra* ¶¶ 23–24, the Conklins' failure-to-warn claim is not preempted. As such, nothing prevents the Conklins from requesting that the trial court apply the negligence per se doctrine to assist them in proving their failure to warn claim. *See Hughes*, 631 F.3d at 771–72 (concluding that "invoking the negligence per se doctrine to support a negligence claim that is otherwise parallel to federal requirements is not expressly preempted"). We express no opinion, however, on the trial court's ultimate resolution of that issue.

**2e. Loss of Consortium and Punitive Damages**

**¶31** Because the Conklins' failure-to-warn claim is not preempted, the Conklins may proceed with their derivative claim for loss of consortium. Moreover, although the Conklins did not allege an "evil mind," "[c]laims for punitive damages carry no special pleading requirements[.]" *Ezell v. Quon*, 224 Ariz. 532, 538 ¶ 23 (App. 2010). Thus, the trial court erred by dismissing these claims.

**3. Leave to Amend Complaint**

**¶32** The Conklins argue that the trial court improperly failed to allow them to remedy any defect by amending their complaint. Although the Conklins sought leave to amend as part of their response to Medtronic's motion to dismiss and at oral argument, a request for leave to amend must be made by separate motion that complies with the Arizona Rules of Civil Procedure. *See Blumenthal v. Teets*, 155 Ariz. 123, 131 (App. 1987). Moreover, a party who moves for leave to amend must attach a copy of the proposed amended pleading as an exhibit to a motion. Ariz. R. Civ. P. 15(a)(4). The Conklins did not separately seek leave and the record does not contain a

proposed amended complaint. Thus, the trial court did not abuse its discretion by impliedly denying leave. *See Cagle v. Carr*, 101 Ariz. 225, 227 (1966).

## CONCLUSION

**¶33** For the foregoing reasons, we affirm the dismissal of the Conklins' product liability, breach of express warranty, and negligence causes of action. We affirm the denial of the Conklins' request to amend the complaint. We vacate the dismissal of their failure to warn, loss of consortium, and punitive damages claims, however, and remand for further proceedings consistent with this decision.


AMY M. WOOD • Clerk of the Court
FILED: AA