STATE OF MINNESOTA
IN COURT OF APPEALS
A17-1124

Patricia A. Jones,
as Trustee for the Next of Kin of Kaitlyn M. Jones (deceased)
and Personal Representative to be appointed
for the Estate of Kaitlyn M. Jones (minor),
Appellant,

vs.

Medtronic, Inc., et al.,
Respondents.

Filed March 26, 2018
Affirmed in part, reversed in part, and remanded
Florey, Judge

Hennepin County District Court
File No. 27-CV-16-17488

Gale D. Pearson, Stephen J. Randall, Pearson, Randall & Schumacher, P.A., Minneapolis, Minnesota; and

Robert S. Peck (pro hac vice), Center for Constitutional Litigation, P.C., New York, New York (for appellant);

Andrew E. Tauber (pro hac vice), Mayer Brown, L.L.P., Washington, D.C.; and

Michael C. McCarthy, Nicole E. Narotzky, Keiko L. Sugisaka, Erica A. Holzer, Maslon L.L.P., Minneapolis, Minnesota (for respondents)

Considered and decided by Cleary, Chief Judge; Larkin, Judge; and Florey, Judge.

U N P U B L I S H E D O P I N I O N

FLOREY, Judge

Appellant is a mother whose daughter died due to an allegedly defective medical device manufactured by respondents. Appellant filed suit against respondents alleging several claims, including manufacturing defect, failure to warn, negligence, negligence per se, breach of express and implied warranties, negligent misrepresentation, and violations of various Minnesota and Florida consumer-protection statutes. The district court dismissed all claims as being either expressly or impliedly preempted by federal law. We affirm in part, reverse in part, and remand.

FACTS

Appellant Patricia A. Jones (Jones) is a Florida resident and the mother of Kaitlyn M. Jones (Kaitlyn). When she was young, Kaitlyn was diagnosed with cerebral palsy with spastic quadriplegia, which caused her muscle spasms. To help manage the spasticity, Kaitlyn had a device called the SynchroMed II Infusion Pump and System (SynchroMed II) implanted in her body in March 2011. This device delivers a programmed amount of medication into the patient's spine and was implanted in Kaitlyn to reduce or eliminate the need for oral medications to control her muscle spasms. Respondents (collectively referred to as Medtronic) designed and manufactured the SynchroMed II.

On July 31, 2014, Kaitlyn was taken to a hospital emergency room for extreme discomfort and pain. Doctors adjusted the medication dosage in her SynchroMed II, which seemed to help, and she was discharged and sent home. But the next morning, Jones and her husband discovered that Kaitlyn had died during the night. An autopsy showed that

the levels of medication in Kaitlyn's system were lower than expected. The medical examiner determined that Kaitlyn died from bowel ischemia, which was related to her withdrawal from the medication she should have received from the SynchroMed II. An analysis of the pump showed that there was a blockage in the device that likely caused it to deliver less than the required dosage of medication into Kaitlyn's body.

Jones, as trustee for the next of kin of Kaitlyn, filed a complaint alleging 12 claims against Medtronic, including: (1) manufacturing defect; (2) failure to warn; (3) negligence; (4) negligence per se; (5) breach of express warranty; (6) breach of implied warranty; (7) negligent misrepresentation; (8) violations of Florida law concerning deceptive, unconscionable, and unfair trade practices; (9) violations of Florida regulations concerning deceptive and unfair trade practices; (10) violations of Minnesota law prohibiting unlawful trade practices; (11) violations of Minnesota law prohibiting consumer fraud; and (12) violations of the Minnesota law regarding false advertising.

Medtronic filed a motion to dismiss Jones's complaint, which the district court granted. In its order for dismissal, the district court determined that all of Jones's claims were either expressly or impliedly preempted by federal law, or were not sufficiently pleaded to show an adequate causal connection between Medtronic's behavior and Kaitlyn's death. Additionally, the district court determined that Jones was precluded from bringing her claims under Minnesota's consumer-protection statutes because these statutes do not create a private right of action and Jones failed to meet the requirements to sustain claims under the private attorney general statute. Finally, the district court determined that

Jones's fraud claims did not meet the heightened pleading requirements in Minn. R. Civ. P. 9.02. Jones appealed.

D E C I S I O N

The question in this appeal is whether Jones's claims are preempted by federal law, specifically, the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399h (Supp. 2016). The district court held that all of Jones's claims were either expressly or impliedly preempted by this federal law. We review de novo a district court's decision to grant a motion to dismiss and whether federal law preempts state law. *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 409 (Minn. App. 2015).

Analyzing the preemption issue in this case is impossible without explaining some of the regulatory background. To start, a critical statute is the Medical Device Amendments of 1976 (MDA). Pub. L. No. 94-295, 90 Stat. 539 (1976). In 1976, Congress amended the FDCA by enacting the MDA whose purpose was to "provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474, 116 S. Ct. 2240, 2245 (1996) (quotation omitted). To help accomplish this purpose, the MDA classifies medical devices into three distinct classes of risk. *Id.* at 476, 116 S. Ct. at 2246. Class I devices pose the least risk, Class II devices pose a "more harmful" risk, and Class III devices—including the SynchroMed II device—pose "a potential unreasonable risk of illness or injury." *Id.* at 476-77, 116 S. Ct. at 2246 (quotation omitted).

Before a Class III medical device can enter the market, it must undergo a rigorous evaluation process from the Food and Drug Administration called premarket approval. *Id.*

at 477, 116 S. Ct. at 2246-47. Indeed, all parties agree that the SynchroMed II device at issue in this case underwent this premarket approval process. Once a Class III device emerges from premarket approval, the manufacturer cannot change any part of the device that would affect its safety or efficacy without approval from the Food and Drug Administration. 21 U.S.C. § 360e(d)(5)(A)(i).

Regulating these risky Class III medical devices is an enormously complicated task. To deal with this complexity and to create uniform standards across the country, Congress used its power under the Supremacy Clause to preempt state or local laws that would regulate these Class III devices. *See* U.S. Const. art. VI, cl. 2. The preemption provision in section 360k(a) of the MDA states:

> [N]o 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).

Section 360k(a)'s provision is known as an "express preemption" provision, which occurs when a federal statute explicitly states that federal law overrides state law. *Brandt v. Marshall Animal Clinic*, 540 N.W.2d 870, 878 n.4 (Minn. App. 1995), *review denied* (Minn. Feb. 9, 1996). The United States Supreme Court discussed section 360k(a) in *Riegel v. Medtronic, Inc.* where it created a two-step inquiry to determine if a state-law cause of action is expressly preempted by the provision: First, courts "must determine

whether the Federal Government has established requirements applicable" to the device, and second, courts "must then determine whether the [plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness." 552 U.S. 312, 321-22, 128 S. Ct. 999, 1006 (2008) (quotation omitted).

The Supreme Court in *Riegel* held that devices that pass through premarket approval, like the SynchroMed II, establish "requirements" under the first inquiry of the *Riegel* test. *Id.* at 322-23, 128 S. Ct. at 1006-07. Neither Jones nor Medtronic dispute this, and we may consider the first inquiry met for all of Jones's claims.[1] This focuses attention on the second inquiry. To satisfy the second inquiry and escape express preemption under the MDA's preemption provision, Jones must show that her state common-law claims "parallel" the requirements under federal law, specifically, the FDCA. *Lamere v. St. Jude Med., Inc.*, 827 N.W.2d 782, 790 (Minn. App. 2013) (quotation omitted) (citing *Lohr*, 518 U.S. at 496, 116 S. Ct. at 2256). In other words, Jones must show that her state-law claims are not different from—nor do they add to—federal requirements.

But showing a parallel state-law claim and escaping the express preemption provision is not enough—there is another step. The United States Supreme Court held in *Buckman Co. v. Plaintiff's Legal Comm.* that the FDCA does not provide a private right of

[1] The district court concluded that "[b]ecause Jones' Device received [premarket approval], the first step in the *Riegel* two-step analysis in this case is indisputably met."

action. 531 U.S. 341, 352-53, 121 S. Ct. 1012, 1019-20 (2001).[2] This means that Jones, as a private litigant, cannot bring a state-law claim solely for a violation of the FDCA because state-law claims are impliedly preempted. *Id.* Therefore, to avoid implied preemption under *Buckman*, a plaintiff must rely on traditional state tort law which predates the federal enactments in question. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

This area is notoriously complex, and this issue was discussed at length in *Riley*, which said that "*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." *Id.* In order to fit through that gap,

> [t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by [21 U.S.C.] § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

Id.

Jones alleged twelve different claims in her original complaint. We will analyze each claim's survivability under both express and implied preemption in the following discussion.

[2] A provision in the FDCA states that an action "for the enforcement, or to restrain violations, of [the FDCA] *shall be by and in the name of the United States*." 21 U.S.C. § 337(a) (emphasis added).

I. Jones's manufacturing-defect claim survives both express and implied preemption.

In count I of her complaint, Jones argues that the SynchroMed II contained a manufacturing defect and that Medtronic was negligent in addressing that defect. To allege a manufacturing defect claim in Minnesota, a plaintiff must show three elements: "(1) the product was in a defective condition unreasonably dangerous to the user, (2) the defect existed when it left the manufacturer's control, and (3) the defect was the proximate cause of the injury sustained." *Drager by Gutzman v. Aluminum Indus. Corp.*, 495 N.W.2d 879, 882 (Minn. App. 1993), *review denied* (Minn. Apr. 20, 1993).

To escape express preemption, Jones must show that her manufacturing-defect claim is parallel to—and not "different from" or "in addition to"—the requirements under the FDCA. *Riegel*, 552 U.S. at 321-22, 128 S. Ct. at 1006. To support her claim and show that it is parallel to federal regulations, Jones emphasizes that Medtronic manufactured the SynchroMed II in violation of 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. part 820.[3] Jones claims that Medtronic manufactured the SynchroMed II device knowing that it did not comply with federal regulations that allegedly prevent overinfusion and underinfusion and ensure an accurate delivery rate of medication. The district court dismissed this claim as being either expressly or impliedly preempted by the FDCA.

[3] The FDCA prohibits adulterated devices. 21 U.S.C. § 331. Adulterated devices include devices manufactured or installed in violation of good manufacturing practices. 21 U.S.C. §§ 351(h), 360j(f)(1)(A). 21 C.F.R. part 820 sets forth current good manufacturing practices (CGMP). 21 C.F.R. § 820.1(a) (2017). These regulations are described as an umbrella quality system providing general objectives for all device manufacturers. *In re Medtronic, Inc.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (quotation omitted).

We believe that Jones sufficiently pleaded a manufacturing-defect claim that escapes both preemption hurdles. First, Jones's complaint escapes express preemption by sufficiently pleading that the SynchroMed II device was "adulterated" as understood by 21 U.S.C. §§ 331, 351(h); this adulteration was unreasonably dangerous to users of the device; this adulteration was present when it left Medtronic's control; and the adulteration is what caused Kaitlyn's death—all of which meet the elements of a manufacturing-defect claim in Minnesota and none of which are different from, or in addition to, federal requirements. In other words, Jones's manufacturing-defect claim is parallel to the requirements of the FDCA and the claim survives express preemption. *Riegel*, 552 U.S. at 321-22, 128 S. Ct. at 1006.

Additionally, the claim survives implied preemption because it is rooted in traditional Minnesota tort law that would entitle Jones to recovery even in the absence of the FDCA. *See Lee v. Crookston Coca-Cola Bottling Co.*, 290 Minn. 321, 328-29, 188 N.W.2d 426, 432 (1971) (relying on the Restatement (Second) of Torts § 402A (1965) to outline the elements of a Minnesota claim for a manufacturing defect). Because Jones's claim survives both express and implied preemption, we conclude that it has passed through the "narrow gap" created by *Riegel* and *Buckman*. *Riley*, 625 F. Supp. 2d at 777.

Medtronic argues that Jones's complaint is not sufficiently pleaded to survive a motion to dismiss under Minnesota's pleading rules. But Minnesota only requires a plaintiff's civil complaint to "contain a short and plain statement of the claim showing that the pleader is entitled to relief and a demand for judgment for the relief sought . . . ." Minn. R. Civ. P. 8.01. And the Minnesota Supreme Court interprets the purpose of this rule as

"simply to give fair notice to the adverse party of the *incident* giving rise to the suit with sufficient clarity to disclose the pleader's theory upon which his claim for relief is based . . . ." *Walsh v. U.S. Bank, N.A.*, 851 N.W.2d 598, 602 (Minn. 2014) (quotation omitted). We believe that Jones's complaint gives more than "fair notice" to Medtronic that the SynchroMed II device was defectively manufactured and, as a result of that defect, harmed Kaitlyn. For all these reasons, the district court's dismissal of this claim should be reversed.

II. Jones's failure-to-warn claim survives both express and implied preemption.

Jones also alleges that Medtronic failed to warn about the dangers of the SynchroMed II in violation of both state law and premarket approval requirements. Minnesota's common law requires a plaintiff to prove a failure-to-warn claim by alleging a manufacturer's "failure to use reasonable care in giving adequate and accurate instructions as to the use of the product and a warning as to any dangers reasonably foreseeable in its intended use." *Peppin v. W.H. Brady Co.*, 372 N.W.2d 369, 374 (Minn. App. 1985) (quotation omitted) (citing *McCormack by McCormack v. Hankscraft Co. Inc.*, 278 Minn. 322, 332, 154 N.W.2d 488, 496 (1967)).

Jones generally alleges that Medtronic violated premarket approval requirements and two federal reporting requirements. The first, 21 U.S.C. § 360i(a)(1), requires medical device manufacturers to report to the FDA any malfunctions or defects in their devices that may have resulted in injury. The second, 21 C.F.R. § 803.50(a) (2017), requires the manufacturer to make these reports within 30 days of notice. Jones argues that her complaint sufficiently alleged that these federal reporting failures hid issues from the FDA

that would otherwise have been conveyed to medical professionals when Kaitlyn was admitted at the hospital, and therefore, Medtronic's failure to report these issues resulted in Kaitlyn's death.

Again, we believe this failure-to-warn claim survives preemption. Jones's complaint essentially alleges that Medtronic knew that the SynchroMed II was "adulterated" within the meaning of 21 U.S.C. §§ 331, 351(h) and that Medtronic's failure to comply with federal reporting requirements illustrates that it did not use reasonable care in warning about the foreseeable dangers of that adulteration. This parallels the reporting requirements singled out by Jones's complaint and survives express preemption. *Riegel*, 552 U.S. at 321-22, 128 S. Ct. at 1006. In addition, Jones's failure-to-warn claim clearly relies on a state-law claim that predates the FDCA, thereby surviving implied preemption. *See Lovejoy v. Minneapolis-Moline Power Implement Co.*, 248 Minn. 319, 325, 79 N.W.2d 688, 693 (1956) (stating that a manufacturer may be liable "if he knows or should know that the chattel is apt to cause bodily harm if not used in a specific manner if he fails to furnish adequate warning as to the dangers inherent in its use").

As before, Medtronic's argument that Jones's complaint is not sufficiently pleaded fails for the same reasons as before: the complaint adequately puts Medtronic on notice that it knew, or should have known, that the SynchroMed II was adulterated and that Medtronic failed to warn about the dangers of this adulteration. We conclude that Jones sufficiently pleaded her failure-to-warn claim, and the district court's dismissal of this claim should be reversed.

III. Jones's breach-of-express- and implied-warranty claims survive both express and implied preemption.

Jones's complaint also alleges that Medtronic breached both express and implied warranties with the SynchroMed II. To establish a breach of express or implied warranty in Minnesota, a plaintiff must prove (1) the existence of a warranty, (2) a breach of that warranty, and (3) a causal link between the breach and the alleged harm. *Peterson v. Bendix Home Sys., Inc.*, 318 N.W.2d 50, 52-53 (Minn. 1982).

The district court dismissed Jones's breach-of-warranty claims because they imposed "state-law requirements, which are different from and in addition to" federal requirements. But we recognized in *Angeles* that federal law plainly prohibits false or misleading warranties, so to avoid state-law liability, a manufacturer only needs to "refrain from making misleading warranties, which adds no burden beyond what federal law already imposes." 863 N.W.2d at 421 (quoting *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1042 (D. Haw. 2014)). Although *Angeles* involved promotion of off-label uses of a medical device, we believe the same reasoning holds true here. Jones's complaint alleges that Medtronic both expressly and impliedly warranted that the SynchroMed II was in compliance with federal regulations, even when it knew the device was adulterated, which allegedly caused Kaitlyn's death. Like in *Angeles*, federal law prohibited Medtronic from making misleading warranties about the SynchroMed II, and Medtronic could have avoided liability by refraining from making those misleading warranties—a parallel obligation to Minnesota law. For these reasons, we conclude that

Jones sufficiently pleaded her breach-of-express-and implied-warranty claims, and the district court erred by dismissing those claims.

IV. Jones's claims of negligence, negligence per se, negligent misrepresentation, and state consumer-protection violations are preempted.

While we conclude that Jones's previously discussed claims survive the preemption analysis, the remaining claims do not. We first turn to Jones's negligence and negligence per se claims. A Minnesota negligence claim required Jones to allege that Medtronic owed Kaitlyn a duty of care, Medtronic breached that duty of care, Kaitlyn was injured, and the injury was caused by Medtronic's breach. *See State Farm Fire & Cas. v. Aquila Inc.*, 718 N.W.2d 879, 887 (Minn. 2006).

Jones's negligence claims are primarily based on Medtronic's failure to follow federal current good manufacturing practices (CGMP).[4] Federal circuits are split on the question of whether violations of CGMP create parallel claims to escape express preemption. For instance, the district court noted that the Eighth Circuit has held that CGMP violations, standing alone and without pointing to specific violations of the FDA's premarket approval process for the medical device at issue, are simply too generic to be considered parallel claims for a manufacturing defect. *In re Medtronic, Inc.*, 623 F.3d at 1206-07 (holding that to survive express preemption, a plaintiff must adequately plead a violation of a specific step in the FDA's premarket approval process for a Class III device, not simply a CGMP violation); *but see Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir.

[4] As previously explained, these regulations create an umbrella quality system providing general objectives for all device manufacturers. *In re Medtronic, Inc.*, 623 F.3d at 1206.

2012) (holding that if a plaintiff pleads both a violation of CGMP in a Class III device and that this violation caused the injury, then that plaintiff has sufficiently pleaded a parallel claim to survive express preemption).

We acknowledged this split in authorities over CGMP violations in *Lamere*, but we decided the CGMP issue on other grounds. 827 N.W.2d at 790-91 (Minn. App. 2013). Still, we note that there is no Minnesota authority stating that violations of CGMP, standing alone, can sustain a negligence action. Further, we are not convinced that reliance on generalized CGMP violations alleges a violation of a state-law duty—a necessary ingredient in alleging a parallel claim that escapes express preemption. For these reasons, we conclude that Jones's negligence and negligence per se claims are preempted.[5]

Similarly, Jones's claim for negligent misrepresentation does not survive the preemption analysis. Jones rests this claim entirely on state law, writing, "[a]t all times relevant hereto, Medtronic had a duty under Florida and Minnesota law to advertise and represent correct information regarding the SynchroMed II Device, as such information involves public welfare and safety." This reliance on state law as the foundation of her claims fails to escape express preemption since Jones is not alleging any violation of

[5] We affirm the dismissal of Jones's negligence per se claim because the distinction between negligence per se and common-law negligence is where the duty originates. With negligence per se, the duty originates from statute, whereas traditional negligence duties originate in common law. *Kronzer v. First Nat'l Bank of Minneapolis*, 305 Minn. 415, 423, 235 N.W.2d 187, 192 (1975). Because of this, the preemption analysis is not affected either way. *See In re Medtronic*, 592 F. Supp. 2d 1147, 1163 (D. Minn. 2009) (explaining that the doctrine of negligence per se merely sets the standard of care but does not affect the preemption analysis), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

federal requirements and therefore, is making a claim in addition to or different from the FDCA. *Riegel*, 552 U.S. at 321-22, 128 S. Ct. at 1006.

Finally, Jones alleges that Medtronic violated multiple consumer-protection laws in Minnesota and Florida. These claims are similar to her other allegations in her complaint. For instance, Jones alleges that Medtronic engaged in unfair trade practices under Florida law by marketing and selling the SynchroMed II in ways "which shock the conscience, offend established public policy, and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers, acts and practices which are material and are likely to mislead consumers acting reasonably under the circumstances."

But Jones's complaint does not specify the federal claims these statutes would parallel in order to escape preemption. Instead, Jones appears to be using these consumer-protection statutes to allege additional, statutory claims as a way to hedge against the preemption analysis of her main claims. This is supported by Jones's reply brief where she writes that she included these consumer-protection claims out of "an abundance of caution." However, the language in each of these consumer-protection statutes is very different from any relevant federal rules that might run parallel. And while Jones is correct that different language does not necessarily imply nonparallel requirements, our reading of each statute leads us to the conclusion that they are not parallel to the FDCA and are therefore preempted.

Jones's allegations of negligence, negligence per se, negligent misrepresentation, and violations of Minnesota and Florida consumer protection-laws are all preempted by the FDCA, and the district court did not err in dismissing these claims. We affirm the

district court on these claims. However, Jones's allegations of a manufacturing defect, failure to warn, and breach of express and implied warranties are not preempted by federal law, and the district court erred in dismissing these claims. For the reasons discussed, we reverse and remand on these four claims.

Affirmed in part, reversed in part, and remanded.