ARIZONA SUPREME COURT
ORAL ARGUMENT CASE SUMMARY

RAYMOND R. CONKLIN, II, et al. v. MEDTRONIC, INC., et al.
CV-17-0322-PR

PARTIES:

Petitioners/Defendants: Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. ("Medtronic").

Respondents/Plaintiffs: Raymond R. Conklin, II and Joanne M. Conklin ("the Conklins").

FACTS:

Background Facts. This petition arises from a lawsuit filed by the Conklins in which they made a variety of product liability claims against Medtronic concerning an allegedly defective medical device. Medtronic's product ("the Pain Pump") is a Class III medical device under the Medical Device Amendments of 1976 ("the MDA") to the Food, Drug, and Cosmetic Act ("the FDCA"). Under 21 U.S.C. § 360i(a)(1), manufacturers must make certain reports, including notifying the Federal Drug Administration ("FDA") of any information reasonably suggesting that the device "[m]ay have caused or contributed to a death or serious injury" or that it "[h]as malfunctioned" and any recurring malfunction "would be likely to cause or contribute to a death or serious injury." 21 C.F.R. § 803.50(a). Such incidents are generally called "adverse events."

In 2008, a physician surgically implanted a Pain Pump into Raymond Conklin to help him manage chronic pain from an earlier hip surgery. In 2013, Conklin underwent hip surgery again and later suffered permanent injury allegedly caused by the Pain Pump over-medicating him.

The Conklins then sued Medtronic for failure-to-warn (in strict liability and negligence) and for other claims. They alleged that before Conklin was injured, the FDA sent warning letters to Medtronic stating that it had failed to report "adverse events" to the FDA. They also alleged that Medtronic's failure to comply with the FDA reporting requirements violated Medtronic's duty under Arizona law to warn Conklin and that this failure proximately caused his injury.

Medtronic filed a motion to dismiss, contending (among other things) that the MDA preempted the Conklins' claims. The trial court agreed and dismissed the complaint. The Conklins then filed an appeal in the Court of Appeals.

The Court of Appeals' Opinion. The Court of Appeals affirmed the trial court's dismissal of most of the claims, but it vacated the dismissal of the Conklins' failure-to-warn claims. *Conklin v. Medtronic, Inc.*, 244 Ariz. 139 (App. 2017). The court first restated the preemption principles that apply here. It explained that 21 U.S.C. § 360k(a) of the MDA *expressly* preempts a state common-law claim if "(1) the federal government [has] established requirements applicable to the device at issue and (2) the plaintiff's common-law claims concerning the device . . . include[] requirements that are 'different from, or in addition to' those federal requirements." It also noted that 21 U.S.C. § 337(a) of the FDCA also *impliedly* preempts any action for the enforcement or restriction of violations of the FDCA because the statute says that such actions can only be brought by the United States or in the name of the United States.

The court explained that these two statutes permit a state-law claim to be asserted only if it fits within "a narrow gap" between express and 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 . . .).'" (Quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).) To navigate this "narrow gap," the court elaborated, "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 under the act.'" (Quoting *Medtronic, Inc. v, Lohr*, 518 U.S. 470, 495-97 (1996).) "Thus," the court continued, "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, the federal requirements.'" (Quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).) The court added, however, that "the state-law claim cannot exist 'solely by virtue of the FDCA disclosure requirements.'" (Quoting *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 352-53 (2001).)

The court explained that the Conklins argued their failure-to-warn claims were permissible "parallel" claims that are not expressly or impliedly preempted. It further noted that Medtronic argued in response that the claims were preempted and not "parallel" claims because the federal duty to submit "adverse event" reports to the FDA is not identical to the state-law duty to warn doctors and their patients.

The court agreed with the Conklins. It relied primarily on a federal Ninth Circuit decision, *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013). In that case, the Ninth Circuit held that the MDA did not preempt a failure-to-warn claim involving a medical device. The court ruled that by failing to report "adverse events" to the FDA as required under federal law, it also breached Arizona's tort duty for manufacturers to warn of dangers inherent in a product's use.

The Court of Appeals agreed with *Stengel*. Because the Arizona tort duty to warn was not "different from, or in addition to, any requirement" under the MDA, the court ruled that the Conklins' failure-to-warn claims were not expressly preempted. It noted that comparable to a manufacturer's tort duty, FDA regulations required them 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." It also ruled that the Conklins' claim was 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."

ISSUES:

Medtronic is asking the Arizona Supreme Court to address the following issues:

(1) "Whether failure-to-warn claims predicated on a failure to submit adverse-event reports to the FDA are expressly preempted by 21 U.S.C. § 360k(a)."

(2) "Whether failure-to-warn claims predicated on a failure to submit adverse-event reports to the FDA are impliedly preempted by 21 U.S.C. § 337(a)."