## *Conklin v. Medtronic, Inc.*

**Full Citation:** Conklin v. Medtronic, Inc., 431 P.3d 571 (Ariz. 2018).
**Date Filed:** December 18, 2018
**Opinion's Author:** Justice Pelander
**Joined By:** Chief Justice Bales, Vice Chief Justice Brutinel, and Justices Timmer, Bolick, Gould, and Lopez.

*Practitioners: For quick reference, please see the "Issue" and "Holding" sections.*

**Facts:** Conklin injured his hip years ago and had a Medtronic SynchroMed II 40ml infusion pump and catheter ("Pain Pump") surgically implanted in 2008 to manage the pain. In 2013, Conklin had another hip surgery from which he suffered a permanent injury. Conklin claims that injury was caused by drug over-infusion from his continued use of the Pain Pump. Conklin and his wife sued Medtronic for various tort claims, including strict liability and negligence claims for failure to provide adequate and timely warnings. Conklin also alleged that Medtronic's failure to report those adverse events to the Federal Drug Administration ("FDA") amounts to liability under Arizona common law.

> **Background of legal claims.** The FDA must approve new drugs introduced into the market. Similarly, as a result of the Medical Device Amendments ("MDA"), the federal government has oversight for medical devices, as well. The MDA requires a pre-market approval ("PMA") process for certain types of devices. The Pain Pump is one of those devices, and it was granted PMA before Conklin's first surgery in 2008.
>
> Once PMA has been granted, the manufacturer of the medical device cannot make "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" without FDA permission.[1] The MDA also requires a report of any "incidents in which the device may have caused or contributed to death or serious injury[] or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred."[2] This kind of report is referred to as an adverse event report.[3]
>
> Conklin's suit is based on Medtronic's failure to comply with the reporting requirements. Before Conklin's surgery in 2013, the FDA warned Medtronic that they had failed to report adverse events and issued multiple recalls of the Pain Pump. Conklin alleges that this failure to report gives rise to Arizona common law and tort law claims. However, the MDA contains a preemption provision:
>
> > "[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] Conklin v. Medtronic, Inc., 431 P.3d 571, 574 (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 319 (2008)).
[2] *Id.* at 574–75 (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 319 (2008)).
[3] *Id.*

(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."[4]

**Procedural History:** This case is before the Arizona Supreme Court. Medtronic moved to dismiss the claims under Arizona Rule of Civil Procedure 12(b)(6), arguing that Conklin's claims are preempted under federal law. The superior court agreed and dismissed the action with prejudice.

The court of appeals affirmed in part and vacated in part. The court affirmed that Conklin's product liability and negligence claims were preempted. The court determined that those claims were expressly preempted. But the court vacated the superior court's dismissal of Conklin's failure-to-warn claim, finding it was neither expressly nor impliedly preempted.

The Supreme Court of Arizona reviewed the trial court's dismissal of the complaint under Rule 12(b)(6) and the preemption issues de novo.

**Issues:**

- (1) Does federal law preempt an Arizona common law failure-to-warn claim based on a medical device manufacturer's failure to submit adverse event reports to the FDA?
- (2) Does federal law preempt a state tort law claim based on a medical device manufacturer's failure to submit adverse event reports to the FDA?

**Holding:**

- (1) Yes, the MDA preempts an Arizona common law failure-to-warn claim based on a medical device manufacturer's failure to submit adverse event reports to the FDA.
- (2) Yes, the MDA preempts a state tort law claim based on a medical device manufacturer's failure to submit adverse event reports to the FDA when there is no independent state law duty to submit such reports to the FDA.

**Disposition:** The superior court's judgment dismissing this action with prejudice is affirmed.

[4] 21 U.S.C. § 360k(a).

**Rule:** A two-part test is used to determine whether a state claim is federally preempted by the MDA:

> "(1) Has 'the Federal Government . . . established requirements applicable to [the medical device]'?
> (2) If so, are the common law claims based on state law requirements 'with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness'?"[5]
>
> **Express or Implied Preemption**. If the state law requirements are "different from or in addition to" the requirements imposed by the MDA, the state law claims are expressly preempted.[6] In addition, state law claims based "solely on noncompliance with the MDA are impliedly preempted"[7] because all "proceedings for the enforcement [of the MDA] shall be by and in the name of the United States."[8]

**Reasoning:**

- **Common Law Claim.**
  - **Prong One.** The first prong in the preemption test is "indisputably met here."[9] The Federal Government established requirements applicable to the Medtronic Pain Pump through the MDA.[10]
  - **Prong Two.** Conklin's allegation that Medtronic violated an Arizona common duty to directly warn him or his physicians is expressly preempted because such a duty is "different from, or in addition to" the federal requirements.[11]

- **Tort Law Claim.**
  - **Prong One**. This prong is met because the MDA has established requirements applicable to the Pain Pump.[12]
  - **Prong Two**. Because only federal law, not state law, imposes a duty on Medtronic to submit adverse event reports to the FDA, Conklin's failure-to-warn state tort law claim is impliedly preempted.[13]

    In Arizona, manufacturers have a duty to warn consumers of foreseeable risks of harm from using their products.[14] A manufacturer satisfies its duty to warn by giving appropriate warnings to the specialized class of persons who may

---

[5] *Conklin*, 431 P.3d at 575 (citing *Riegel*, 552 U.S. at 321–22).
[6] *Id.* (citing *Riegel*, 552 U.S. at 330).
[7] *Id.*
[8] *Id.* (quoting 21 U.S.C. § 337(a)).
[9] *Id.*
[10] *Id.*
[11] *Id.* at 576 (quoting 21 U.S.C. § 360k(a)(1)).
[12] *Id.* at 575.
[13] *Id.* at 578.
[14] *Id.* at 577 (citing Watts. v. Medicis Pharm. Corp., 365 P.3d 944, 949 (Ariz. 2016)).

prescribe or administer the product.[15] Such a "learned intermediary" then takes on the duty to pass on the warnings to the users.[16]

Conklin, relying on *Stengel v. Medtronic, Inc.*,[17] argued that the FDA qualifies as a learned intermediary, and therefore, reporting to them satisfies their duty-to-warn requirements under Arizona law. However, the Arizona Supreme Court disagreed with Conklin and *Stengel*.[18] While the facts of that case were similar, its conclusion was based on the erroneous conclusion that "under Arizona law, a warning to a third party satisfies a manufacturer's duty if . . . there is reasonable assurance that the information will reach those whose safety depends on their having it."[19] However, correctly stated, Arizona law "does not recognize a claim merely for failing to provide something like adverse event reports . . . to a government agency that has no obligation to relay the information to the patient."[20]

The FDA is not a learned intermediary or other relevant third party, and as such, reporting adverse events to the FDA does not satisfy a manufacturer's duty to warn under Arizona tort law.[21] Without a separate state law duty to report to the FDA, Conklin's failure-to-warn claim "is an attempt to enforce a federal law requirement" and is impliedly preempted under the MDA.[22]

---

[15] *Id.* (citing *Watts*, 365 P.3d at 947).
[16] *Id.* (citing *Watts*, 365 P.3d at 948).
[17] 704 F.3d 1224 (9th Cir. 2013).
[18] *Conklin*, 431 P.3d at 578.
[19] *Id.* at 579 (quoting *Stengel*, 704 F.3d at 1233).
[20] *Id.*
[21] *Id.*
[22] *Id.* at 578.