Conklin v. Medtronic, Inc.

GINGER PIGOTT[1] AND RICHARD TABURA[2]

WHY IT MADE THE LIST

Conklin made the list of "top food and drug cases" in 2018 because in it the Arizona Supreme Court effectively invalidated *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013), a troublesome decision by the Ninth Circuit. In *Stengel,* the Ninth Circuit reversed the district court's order granting a motion to dismiss based on preemption. In so doing, the Ninth Circuit, sitting in diversity and purporting to apply Arizona law, had concluded that claims based on an alleged failure to report adverse events to the FDA ("failure-to-report claims") were neither expressly nor impliedly preempted. As outlined below, this opened-up a theory of liability that allowed a certain type of claim relating to a Premarket Approved device to proceed under circumstances where such claim might otherwise have failed entirely. In *Conklin*, the Arizona Supreme Court stated in no uncertain terms that the Ninth Circuit "incorrectly recited and applied Arizona law." Both *Stengel* and *Conklin* involved claims relating to Medtronic pain pumps, Class III Premarket Approved prescription implanted medical devices. The *Conklin* court held that failure-to-report claims were impliedly preempted. *Conklin*'s reasoning is consistent with the majority of other circuits and states who have rejected *Stengel*'s rationale. By invalidating *Stengel*, reliance on the decision is suspect going forward and it certainly should not be relied upon in courts applying Arizona state law. But its import is broader and demonstrates the ongoing chess match of preemption and the interplay of state and federal courts applying these important legal theories.

DISCUSSION

To properly understand the significance of the *Conklin* decision, we will first give a very brief background of Premarket Approved medical devices and the general application of preemption barring most state law claims. We will then give a brief overview of the *Stengel* decision. Then we will dissect the *Conklin* case, including a background of the facts and procedural history, then analysis of the Supreme Court of Arizona's holding that is the focus of this chapter. Finally, we will discuss the anticipated impacts of the *Conklin* decision.

The Rigorous Premarket Approval Process

Class III medical devices are thoroughly regulated by the FDA pursuant to the 1976 Medical Device Amendments ("MDA") to the Food Drug and Cosmetics Act

---

[1] Ginger Pigott is Vice Chair of the Pharmaceutical, Medical Device & Health Care Litigation Practice at Greenberg Traurig LLP in Los Angeles. She focuses her practice on products liability litigation with an emphasis on the defense of complex medical device and pharmaceutical products.

[2] Richard Tabura is an associate at Greenberg Traurig LLP in Los Angeles. He focuses his practice on pharmaceutical and medical device litigation.

("FDCA").[3] The FDA scrutinizes every aspect of Class III devices, including the design, manufacturing process, labeling, and warnings. FDA approval of such devices confirms their safety and efficacy. Once a device receives Premarket Approval, the MDA forbids changes in design, manufacturing, labeling, or other attributes that would affect safety or efficacy.[4] To make changes, FDA requires a supplemental Premarket Approval that is evaluated under essentially the same rigorous criteria as an original application.[5]

Even after the FDA grants Premarket Approval for a device, the device is "subject to reporting requirements."[6] Those requirements include "the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of,"[7] "and to report 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."[8] The documents to which this latter requirement refers are called "adverse event reports." These adverse event reports and the federal duty to inform the FDA, and whether Arizona imposes a separate but identical duty upon medical device manufacturers, is the key distinction between *Stengel* and *Conklin*. The Ninth Circuit applying Arizona law in *Stengel* determined there was such a duty in Arizona. The Supreme Court of Arizona, whose interpretation of Arizona state law is authoritative, held there was and is no such state duty to inform the FDA.

Preemption and Premarket Approved Medical Devices

The MDA contains an express preemption provision. The provision has been interpreted as setting forth the following two-part test for determining whether the MDA expressly preempts a claim: (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"?[9] The first part of the test is satisfied where a device has Premarket Approval.[10] While the second part of the test is one that has been well-litigated, in general, traditional state law tort claims are most often considered preempted because successful claims of a failure of design, manufacture or labeling (along with general breach of warranty and negligence claims) would require the manufacturer to have done something 'different from, or in addition to' what was required as part of the Premarket Approval, and that is not permitted.[11]

---

3 *See* 21 U.S.C. § 360c.

4 *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008).

5 *Id.* (citing 21 U.S.C. 360e(d)(6); 21 C.F.R. § 814.39 (c)).

6 *Id.* (citing 21 U.S.C. § 360i).

7 *Id.* (citing 21 C.F.R. § 814.84(b)(2)).

8 *Id.* (citing 21 C.F.R. § 803.50(a)).

9 *Id.* at 321-22.

10 *Id.* at 322-323.

11 *Id.* at 323; *see also, Blanco v. Baxter Healthcare*, 158 Cal.App.4th 1039, 1055-59 (2008) (finding all claims preempted notwithstanding a recall of the product at issue); *Lowe v. Medtronic Inc., et al.,* 2012 WL 3656468 (C.D. Cal. 2012) (motion to dismiss granted based on preemption); *Erickson v. Boston*

The MDA also impliedly preempts certain state law claims. The MDA states that "all . . . proceedings for the enforcement . . . of this chapter shall be by and in the name of the United States."[12] This has been interpreted to mean that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."[13] Thus, state tort law claims premised solely on noncompliance of the MDA are impliedly preempted.[14] This is sometimes referred to as "*Buckman* preemption."

Taken together, there is only a 'narrow gap' to survive both express and implied preemption in claims involving premarket approved medical devices.[15] "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violate[s] that federal requirement (avoiding implied preemption.)"[16] If a plaintiff can fit this 'narrow gap', they are said to have alleged a "parallel claim."

Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013)

To understand the significance of *Conklin*, one first must be familiar with the *Stengel* decision. The case was decided by the Ninth Circuit Court of Appeals who had the case before them based on diversity jurisdiction. The court purported to apply Arizona State Law.

The plaintiffs in *Stengel* made claims against Medtronic related to a Premarket Approved pain pump. In relevant part, the plaintiffs alleged that Medtronic had a "continuing duty to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product."[17] The *Stengel* plaintiffs further alleged that because Medtronic failed to comply with its duty under federal law, it breached its "duty to use reasonable care" under Arizona negligence law.[18] In short, they alleged that Medtronic's failure to warn the FDA (by not providing adverse event reports) was a violation of Arizona law.

The Ninth Circuit held that the *Stengel* Plaintiffs' failure-to-report claim under Arizona law was *not* preempted.[19] Without citing to any Arizona authority, the Ninth Circuit speculated that "Arizona law contemplates a warning to a third party such as the FDA."[20] As a result, the failure-to-report claims paralleled the federal-law duty under the MDA, fitting within the 'narrow gap' to survive express and implied preemption.

Scientific Corp., 846 F. Supp. 2d 1085 (C.D. Cal. 2011) (granting judgment on the pleadings on strict liability-failure to warn, strict liability-design and/or manufacturing defect, negligence, and gross negligence-malice as expressly preempted).

12 21 U.S.C. § 337(a).

13 *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

14 *Id.* at 352.

15 *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017).

16 *Id.*

17 *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013).

18 *Id.*

19 *Id.* at 1233.

20 *Id.*

The Conklin Case-Background

Conklin was an Arizona state court case involving a plaintiff who asserted products liability claims against Medtronic related to a Premarket Approved pain pump similar to the one involved in *Stengel*. As part of his claims, Conklin alleged that before his injury, Medtronic had failed to report adverse events to the FDA after the FDA approved the pain pump in its Premarket Approval. He further alleged that Medtronic's failure to report post-premarket approval adverse events to the FDA in violation of federal law gives rise to liability under Arizona common law[21] (*i.e.*, a "parallel" claim).

Medtronic moved to dismiss all of Conklin's claims based on express and implied preemption. The superior court agreed and dismissed the entire action with prejudice.[22] The Arizona court of appeals affirmed the dismissal of Conklin's claims based on design defect, manufacturing defect, and breach of warranty. However, the court of appeals vacated the dismissal of Conklin's failure-to-warn claim, which again was premised upon Medtronic's failure to report to the FDA adverse consequences involving the device.[23]

In holding that Conklin's failure-to-report claim was not preempted, the Arizona Court of Appeals relied on *Stengel*. The key to the appellate court's holding in *Conklin* (like *Stengel*) was that it held that Arizona state law imposed a duty to warn the FDA. Therefore, the failure-to-report claim was not solely premised upon a violation of the MDA, and thus not impliedly preempted.

Supreme Court of Arizona

The issue before the Supreme Court of Arizona was whether federal law preempts a failure-to-warn claim predicated solely on a medical device manufacturer's failure to submit adverse event reports to the FDA. Another way to look at the issue was whether Conklin's failure-to-warn claim fits within the "narrow gap" so as to avoid being expressly and impliedly preempted – i.e., (1) did Conklin's failure-to-warn claim assert a violation of a federal requirement (avoiding express preemption)? And (2) was Arizona law violated so that the basis of Conklin's claim was not solely predicated upon the violation of a federal requirement (avoiding implied preemption)? The Supreme Court of Arizona only addressed the latter question, and ultimately held that Conklin's failure-to-warn claim was impliedly preempted.[24]

The dispositive issue for the Supreme Court of Arizona was whether Conklin had a claim under Arizona state tort law based on Medtronic's failure to submit adverse event reports to the FDA. If not, the claim would solely be predicated upon the violation of the MDA and would be impliedly preempted under *Buckman*.[25]

The court assumed without deciding that adverse event reports are "warnings" under Arizona law.[26] The court went on to discuss the scope of a manufacturer's duty to warn. A manufacturer could discharge its duty to warn by relaying warnings to the

---

[21] *Conklin v. Medtronic, Inc.*, No CV-17-0322-PR, slip op. p. 2 ¶3 (Ariz. Dec. 18, 2018).

[22] *Id.* at 3.

[23] I*d.*

[24] *Id.* at 7.

[25] *Id.*

[26] *Id.*

actual consumer, or to a learned intermediary.[27] Under Arizona law, while a manufacturer could discharge its duty by warning a learned intermediary, it could not do so by warning any and all third parties.[28] The court then stated:

Arizona law does not permit a manufacturer to satisfy its duty to warn end-user consumers by submitting adverse reports to the FDA. And conversely, a manufacturer does not breach its duty to warn end users under Arizona law by failing to submit adverse event reports to the FDA. Conklin cites no authority, and we are aware of none, for the proposition that Arizona law requires a manufacturer to warn a federal agency.[29]

As a result, Conklin's alleged claims only purported to violate federal law, and not Arizona law, and his failure-to-warn claim was therefore impliedly preempted.[30]

The court then sharply disagreed with the Ninth Circuit in *Stengel,* dismantling its application of Arizona law.

[*Stengel*] was based on the unsupported premises that, "[u]nder Arizona law, a warning to a third party such as the FDA" and that, "[u]nder 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.'" [citations omitted]. Neither premise comports with Arizona law . . . established law does not recognize a claim merely for failure to provide something like adverse event reports (which may not qualify as "warnings" under Arizona law) to a government agency that has no obligation to relay the information to the patient. [emphasis added.][31]

Thus, the Supreme Court of Arizona declined to follow *Stengel*, stating that it "incorrectly recited and applied Arizona law." The superior court's judgement dismissing the entire action with prejudice was therefore affirmed, and the Supreme Court of Arizona vacated all of the statements in the court of appeals' opinion relating to Conklin's failure-to-warn claim that was inconsistent with its opinion.[32]

Impact

Conklin's impact is continuing to unfold. The obvious initial impact has been the apparent nullification of the Ninth Circuit's *Stengel* decision, which was premised upon unsupported and misapplied Arizona state tort law. There is no question that the independent duty required by the FDCA for a manufacturer to report adverse events to the FDA **does not** give rise to a cause of action in Arizona for an individual plaintiff under a common law failure to warn theory. This follows a line of other cases similarly declining the *Stengel* interpretation in other states.[33] In cases finding

---

[27] *Id.* at 8.

[28] *Id.*

[29] *Id.*

[30] *Id.* at 9.

[31] *Id.* at 10.

[32] *Id.* at 11.

[33] *See, e.g.*, *Norman v. Bayer Corp.*, No. 3:16-cv-00253 (JAM), 2016 U.S. Dist. LEXIS 96993, at *11-12 (D. Conn. July 26, 2016) (finding that failure-to-report claims were preempted and distinguishing *Stengel* on the ground that it did not accurately describe Connecticut law); *Pearsall v. Medtronic, Inc.*, 147 F. Supp. 3d 188, 201 (E.D.N.Y. 2015) (finding that failure-to-report claims were preempted and distinguishing *Stengel* on the ground that New York law did not parallel federal requirements); Aaron v.

these claims impliedly preempted, courts have analogized to *Buckman* and have held that such failure-to-report claims are nothing but an effort by plaintiffs to enforce the MDA.[34]

The broader impact for *Conklin* can be seen in how it speaks to federal courts attempting to read tea leaves with respect to unsettled state law. Indeed, *Conklin* should be viewed as a check on what commentators have described as "a usurpation of state court power for a federal court sitting in diversity to make up new theories of liability under state law."[35] Under the *Erie* doctrine, federal courts sitting in diversity are bound by state court decisions as well as state statutes when deciding questions of substantive law.[36] There can be no serious dispute that whether or not a manufacturer has an obligation to report adverse events to the FDA (aside from the requirements mandated by the MDA) is a "substantive" issue and not a "procedural" issue. The highest court of Arizona has spoken and has made clear that there is no duty for manufacturers to report adverse events to the FDA.

In addition, *Conklin* may have some restraining impact on courts that appear to look for ways to find some surviving claims once finding express or implied preemption has eliminated more traditional theories of recovery. We saw this trend after *Stengel*, where courts, particularly in the Ninth Circuit and its encompassing states, permitted failure-to-report claims to proceed in the face of preemption challenges. Many of these cases rely on *Stengel* without otherwise doing a thorough preemption analysis.[37] After *Conklin*, however, the support for such claims has taken a blow and it may cause courts to take a closer look at whether a failure to report claim is able to survive a preemption challenge.

In Arizona, at least, we should see failure-to-report claims disappear. It is likely these types of claims will diminish elsewhere in the Ninth Circuit and places where the *Stengel* rationale was adopted though that will depend on what else was behind the decision and whether higher courts in various states have also adopted a position based on other state law. We also expect to see the logic of *Conklin* being used broadly to remind federal courts sitting in diversity to closely look at the state law

---

Medtronic, Inc., 209 F. Supp. 3d 994, 1006 (S.D. Ohio 2016) (distinguishing *Stengel* on the ground that Ohio state law and the FDA's adverse event report rule were not parallel).

[34] *See, e.g., Bryant v. Medtronic, Inc.* (*In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*), 623 F.3d 1200, 1206-06 (8th Cir. 2010); *Pontious v. Medtronic, Inc.*, No. 11-4069-CM-GLR, 2011 U.S. Dist. LEXIS 140717, at *6-7 (D. Kan. Dec. 7 2011). Some courts, however, will allow failure-to-report claims particularly where all of the plaintiff's other claims were independently preempted. *See* Drug and Medical Device Product Liability Deskbook § 5.02.

[35] Jim Beck, *Breaking News – Arizona Supreme Court Repudiates Stengel,* Drug and Device Law Blog, (Dec. 18, 2018), https://www.druganddevicelawblog.com/2018/12/breaking-news-arizona-supreme-court-repudiates-stengel.html.

[36] *Erie R.R. v. Tompkins*, 304 U.S. 64, 78, 58 S. Ct. 817, 822 (1938).

[37] *See, Jones v. Medtronic, Inc.,* No. 15-15653, 2018 U.S. App. LEXIS 25474, at *2-3 (9th Cir. Sep. 7, 2018) (reversing a district court's dismissal of all of a formerly *pro se* plaintiff's causes of actions and remanding to permit the newly represented plaintiff to try and allege that Medtronic failed to report adverse events to the FDA, which the court held would not be preempted under *Stengel*); *Martin v. Medtronic, Inc.*, No. 1:15-cv-00994-DAD-MJS, 2017 U.S. Dist. LEXIS 169996, at *13-14 (E.D. Cal. Oct. 13, 2017) (holding that a plaintiff's failure to warn claim premised upon Medtronic's failure to report adverse events in accordance with the MDA is not preempted, citing to *Stengel*.); *Weaver v. Ethicon, Inc.*, No. 16cv257-GPC(BGS), 2016 U.S. Dist. LEXIS 169592, at *16, (S.D. Cal. Dec. 6, 2016) (relying on *Stengel* and holding that a failure to report adverse events to the FDA can form the basis of a parallel negligence claim that survives preemption.)

being applied and, if none is present, to respect the separation of state and federal power and not create new theories of liability under state law. For these reasons, the *Conklin* decision should be viewed as a major win for the rule of law and the application of implied preemption.