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Current Topics in Medical Device Preemption

By Rami Fakhouri and Logan Steiner – January 27, 2023

In this article, we describe three recent trends bearing on preemption arguments in cases involving medical devices, including those with premarket approval (PMA). The first trend involves a deepening nationwide split in authority regarding the viability of certain failure-to-report claims. The second involves increasing willingness by courts to discard a presumption against preemption in certain medical device cases. And the third suggests that at least some courts will require plaintiffs to plead specific supporting facts when alleging manufacturing defect claims to try to bypass federal preemption.

The Rift Deepens over Preemption of Failure-to-Report Claims

The first trend we observe is an expansion of the ongoing divide in the courts over whether warning-based claims for failure to report adverse events to the U.S. Food and Drug Administration (FDA) survive preemption challenges.

We begin with an important bit of background. Since the Supreme Court's seminal decision nearly 15 years ago in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Court has not elaborated further on the nature and scope of the supposed "parallel claim" exception to express preemption under the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA). Under *Riegel*, the MDA expressly preempts all state law claims involving Class III medical devices with PMA unless those claims are premised on a "parallel" federal requirement. Further complicating matters for plaintiffs, state law drug and device claims seeking to enforce the FDCA are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Together, *Riegel* and *Buckman* leave what has been called a "narrow gap" for state law claims involving medical devices with PMA to survive preemption challenges. Plaintiffs must sue *for* conduct that violates the FDCA to avoid express preemption, but to avoid implied preemption, they cannot sue *because* that conduct violates the FDCA—they instead must ground their claims in traditional state tort law. *See, e.g., In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). Claims that medical devices suffer from manufacturing defects are among the state law claims most likely to survive preemption challenges by fitting through this "narrow gap."

On the question of whether state law warning-related claims for an alleged failure to report adverse events to the FDA fall within the "narrow gap," lower courts have divided. The battle began in the federal courts of appeals. Several circuits have found failure-to-report-to-the-FDA claims akin to the fraud-on-the-FDA claim that the Supreme Court found impliedly preempted in *Buckman*. *See Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017); *In re Medtronic*, 623 F.3d at 1205–6. Other circuits have found failure-to-report-to-the-FDA claims not preempted where state tort law purportedly recognizes a duty that is sufficiently "parallel" to the federal reporting obligation under 21 C.F.R. § 803.50. *See Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769–71 (5th Cir. 2011) (interpreting Mississippi law); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (interpreting Arizona law).

More recently, the battle has expanded to state supreme courts, where litigants have had mixed success arguing that state law does not recognize a "parallel" failure-to-report-to-the-FDA claim. The Supreme Court of Arizona held that no such claim exists, disagreeing with the Ninth Circuit's analysis of Arizona law in *Stengel*. *See Conklin v. Medtronic, Inc.*, 431 P.3d 571 (Ariz. 2018). Just this spring, however, the Supreme Court of Connecticut held the opposite in response to a certified question from the Second Circuit, recognizing a warning-based claim under Connecticut law for failure to report adverse events to the FDA. *See Glover v. Bausch & Lomb, Inc.*, 275 A.3d 168 (Conn. 2022). The First Circuit certified a similar question to the Massachusetts Supreme Judicial Court this year in *Plourde v. Sorin Group USA, Inc.*, 23 F.4th 29 (1st Cir. 2022), but that case settled before the court ruled.

We expect this discordant evolution of case law to continue unless and until the U.S. Supreme Court intervenes.

Courts Discard Presumption Against Preemption

Second, we have seen an increasing number of courts discard a presumption against preemption for claims involving Class III medical devices with PMA.

Some courts initially disagreed over the implications for medical device claims of a 2016 Supreme Court decision in the bankruptcy context explaining that, when an express preemption statute is at issue, courts should not invoke a presumption against preemption. *See Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016). In 2018, the Third Circuit declined to extend this principle from *Puerto Rico* to a medical device case, reasoning that products liability (unlike bankruptcy) is a field historically occupied by states. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 n.9 (3d Cir. 2018). Other courts in medical device cases continued to apply the presumption against preemption after *Puerto Rico*, without discussing that case. *See, e.g., Santoro v. Endologix Inc.*, No. 19-cv-01679-YY, 2020 WL 6295077, at *3 (D. Or. Oct. 6, 2020), *report and recommendation adopted*, No. 19-cv-1679-YY, 2020 WL 6287473 (D. Or. Oct. 27, 2020); *Lakey v. Endologix Inc.*, No. 19-cv-01531-YY, 2020 WL 6295080, at *3 (D. Or. Oct. 5, 2020), *report and recommendation adopted*, No. 19-cv-1531-YY, 2020 WL 6287472 (D. Or. Oct. 27, 2020).

Subsequently, however, numerous federal district courts have relied on *Puerto Rico* to find that the presumption against preemption does not apply in cases in which the MDA's express preemption clause applies. *See, e.g., Billetts v. Mentor Worldwide, LLC*, No. 19-cv-01026-AB, 2019 WL 4038218, at *6 (C.D. Cal. Aug. 27, 2019), *aff'd*, 847 F. App'x 377 (9th Cir. 2021); *Mikos v. Abbott Labs.*, No. 21-cv-912-GLR, 2021 WL 5416534, at *3 (D. Md. Nov. 18, 2021); *Poozhikala v. Medtronic Inc.*, No. 21-cv-8889-PA, 2022 WL 610276, at *3 n.1 (C.D. Cal. Jan. 31, 2022); *Garcia v. Bayer Essure, Inc.*, No. 21-cv-00666-MIS-JFR, 2022 WL 4536240, at *3 (D.N.M. Sept. 28, 2022). State appellate courts in Arizona, Illinois, and Indiana have found the same. *See Conklin*, 431 P.3d at 574; *Benyak v. Medtronic, Inc.*, 2018 IL App (1st) 172147-U, ¶¶ 24–25; *Bayer Corp. v. Leach*, 153 N.E.3d 1168, 1176 (Ind. Ct. App. 2020).

Given this recent trend, it seems increasingly likely that courts that have not yet ruled on the issue will decline to apply a presumption against preemption in cases involving Class III medical devices with PMA.

Courts Hold Plaintiffs Accountable When They Plead Manufacturing Defect Claims

Third, and finally, we have seen recent cases holding plaintiffs to a more demanding pleading standard when they attempt to allege a "parallel" manufacturing defect claim to defeat express preemption under the MDA.

Certain jurisdictions, including the Seventh and Eleventh Circuits, have adopted relatively lenient pleading standards for parallel manufacturing defect claims. *See, e.g.*, *Bausch v. Stryker Corp.*, 630 F.3d 546, 558–62 (7th Cir. 2010); *Mink*, 860 F.3d at 1329–30. More recently, however, other courts (both trial and appellate) have refused to allow plaintiffs to plead bare-bones manufacturing defect theories without factual support to bypass preemption and obtain discovery. Rather, these courts have required more specific facts linking plaintiffs' injuries to an identified manufacturing flaw to avoid dismissal. For example, the Ninth Circuit held plaintiffs to their burden of at least pleading the "nature" of the alleged manufacturing defect in *Weaver v. Ethicon, Inc.*, 737 F. App'x 315, 317–18 (9th Cir. 2018). And the Northern District of New York recently required a plaintiff to plead specific facts plausibly indicating a defect in the manufacturing process in *Dains v. Bayer HealthCare LLC*, No. 22-cv-208-BKS-TWD, 2022 WL 16572021, at *8 (N.D.N.Y. Nov. 1, 2022).

Although this trend is not uniform, other recent decisions reflect similar outcomes. *See, e.g.*, *Kline v. Mentor Worldwide, LLC*, No. 19-cv-02387-MCE-KJN, 2021 WL 1173279, at *6–7 (E.D. Cal. Mar. 29, 2021) (dismissing manufacturing defect claim because plaintiff's "conclusory allegations about unspecified [manufacturing] defects and general FDA violations d[id] not rise to the level the Ninth Circuit requires for parallel claims"); *Cline v. Medtronic, Inc.*, No. 20-cv-3826, 2021 WL 3860194, at *7–8 (S.D. Ohio Aug. 30, 2021) (dismissing manufacturing defect claim because plaintiff failed to plausibly plead (a) a causal link between the alleged defect and purported regulatory violations and (b) that a defect in his own device caused his injury); *Hawkins v. Bayer Corp.*, No. 21-cv-00646-RP, 2022 WL 2761379, at *6–7 (W.D. Tex. Feb. 1, 2022), *report and recommendation adopted*, No. 1:21-cv-646-RP, 2022 WL 2718541 (W.D. Tex. Feb. 23, 2022) (recommending dismissal of manufacturing defect claim because plaintiff failed to plead (a) a causal link between alleged defect and purported regulatory violations and (b) that a defect in her own device caused her injury); *Garcia*, 2022 WL 4536240, at *6–7 (dismissing manufacturing defect claim because plaintiff failed to identify regulatory violations that purportedly caused defects in her own device and thereby caused her injury).

Cases like these illustrate how the factual plausibility of plaintiffs' pleadings—and. in particular, the plausibility of plaintiffs' causation allegations—remains an important consideration in cases involving medical devices, especially those with PMA.

Rami Fakhouri is a partner and Logan Steiner is of counsel at Goldman Ismail Tomaselli Brennan & Baum in Chicago, Illinois.