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BLOG

District Court Recognizes *Loper Bright* Does Not Undermine Basis for Express-Preemption Defense in Medical Device Cases

AUGUST 22, 2025

In what appears to be the first case to consider the issue, an Eastern District of Missouri court recently rejected the argument that the Supreme Court's *Loper Bright Enterprises v. Raimondo*[1] decision overruling *Chevron* deference undermines the basis for express preemption in medical device cases.

Express preemption can be an effective defense in products cases involving medical devices. As readers of this blog may know, the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA) established a comprehensive federal regulatory scheme for medical devices.[2] That regulatory scheme includes an express preemption provision that limits the ability of states to impose their own requirements on medical devices that differ from or add to federal requirements. *See* 21 U.S.C. § 360k(a).

In *Riegel v. Medtronic, Inc.*,[3] the Supreme Court interpreted section 360k(a) in the context of Class III medical devices, which undergo the FDA's most stringent premarket-approval process.[4] The manufacturer of a balloon catheter argued design defect and labeling claims were preempted because they would impose requirements "different from, or in addition to" those established through the FDA's premarket approval process.[5] The Court agreed, holding that state common-law claims—such as negligence, strict liability, or breach of warranty—are state-law "requirements."[6] And if such claims challenge the safety or effectiveness of a Class III medical device that received premarket approval, they seek to impose obligations "different from, or in addition to" federal requirements and are expressly preempted by the MDA.[7] This makes sense. Otherwise, allowing juries to apply varying tort laws in 50 states would effectively impose differing "requirements" that would undermine Congress's goal of ensuring nationwide uniformity for devices subject to rigorous FDA review.[8]

Not surprisingly, plaintiffs look for creative ways to avoid express preemption under the MDA. Some have already relied[9] on the Supreme Court's *Loper Bright* decision last year, where it overruled the *Chevron* doctrine and held that "courts . . . may not defer to an agency interpretation of the law simply because a statute is ambiguous."[10] The Court explained that "[c]areful attention to the judgment of the Executive Branch may help inform that inquiry," such that when "a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it."[11] The decision thus makes clear that under the Administrative Procedure Act, courts are required to determine for themselves whether an agency has exercised authority consistent with its statutory grant, while recognizing that agency expertise may still be considered but is not controlling.

Whether federal law preempts state products-liability suits often involves interpretation of statutory provisions, regulations implementing those provisions, and agency guidance providing the context necessary to interpret those provisions. Sometimes, the relevant federal agency appears in the litigation and takes a position on whether the specific claims at issue are preempted. Indeed, the Supreme Court in *Riegel* considered FDA's interpretation of the MDA's preemption clause expressed in two sources: (1) an amicus brief by the United States (on behalf of FDA) that argued that the word "requirements" in section 360k(a) includes common-law duties; and (2) an FDA regulation (21 C.F.R. § 808.1(d)(1)) stating that the MDA's preemption clause does not extend to "[s]tate or local requirements of general applicability where the purpose of the requirement relates [] to other products in addition to devices."[12] The Court's holding in *Loper Bright* that courts may not defer to agency interpretations of law simply because a statute is ambiguous gives plaintiffs a potential hook to try to chip away at decisions—in the preemption context or elsewhere[13]—that rely on a federal agency's interpretation of the law.

In a July 21, 2025 opinion, Judge Stephen R. Clark of the Eastern District of Missouri rejected that avenue of attack for a plaintiff suing the manufacturer of an FDA-approved heart pump in *Ehlers v. Abiomed, Inc.*, 2025 WL 2029662 (E.D. Mo. July 21, 2025). The plaintiff alleged that Abiomed's Impella device was defectively manufactured and breached expressed and implied warranties, resulting in a patient's death following open-heart surgery.[14] The court held that all of the plaintiff's claims were preempted by federal law because the device had received FDA premarket approval, and further denied leave to amend the complaint, finding that the proposed amendments would be futile.[15]

In a footnote, the court addressed—apparently *sua sponte*—whether "the Supreme Court's recent jurisprudence on agency deference . . . call[s] *Riegel*'s statutory interpretation into question."[16] The court concluded it did not. First, the court recognized that while the *Riegel* Court noted the FDA's support for the interpretation that "requirements" in section 360k(a) includes common-law duties, the *Riegel* Court expressly found it unnecessary to rely on the agency's view because the statutory text itself was clear.[17] Second, regarding the FDA regulation purportedly limiting the MDA's preemption clause (21 C.F.R. § 808.1(d)(1)), the *Ehlers* court observed that *Riegel* considered but ultimately declined to rely on the regulation, finding it added "nothing to the analysis but confusion" and therefore neither accepted nor rejected its relevance.[18] On that basis, the *Ehlers* court reasoned that *Riegel*'s statutory interpretation rested on the text itself, not the FDA's interpretation, and thus *Loper Bright* does not undermine *Riegel*'s preemption holding.

The *Ehlers* court's brief discussion correctly concluded that *Loper Bright* does not undermine the basis for express preemption of state products-liability suits involving FDA-approved medical devices. But the court's attention to the issue is a good reminder that plaintiffs have found and will continue to find ways to use the decision against defendants asserting preemption defenses. In fact, while the court quickly dismissed the argument as meritless, plaintiffs elsewhere have already argued that *Loper Bright* invalidated the entire preemption doctrine as unconstitutional.[19] We expect plaintiffs to continue to look for ways to use *Loper Bright* against defendants asserting preemption defenses.

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[1] 603 U.S. 369 (2024).

[2] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.).

[3] 552 U.S. 312 (2008).

[4] *Id.* at 315.

[5] *Id.* at 320–21.

[6] *Id.* at 323–25.

[7] *Id.*

[8] *See id.* at 326.

[9] *See In re Suboxone (Buprenorphine/Naloxone) Film Prods. Liab. Litig.*, 761 F. Supp. 3d 1069, 1086 (N.D. Ohio 2024) (rejecting argument that *Loper Bright* invalidated the entire preemption doctrine as unconstitutional).

[10] 603 U.S. at 412–13.

[11] *Id.*

[12] 552 U.S. at 326, 328 (quoting 21 C.F.R. § 808.1(d)(1).

[13] *See, e.g.*, *Limits to Loper Bright*, Drug & Device Law Blog (Nov. 18, 2024) (describing how to "defend against the other side's attempts to use *Loper Bright* for nefarious purposes"), https://www.druganddevicelawblog.com/2024/11/limits-to-loper-bright.html.

[14] *Id.* at *1.

[15] *Id.* at *7–8, 15.

[16] *Id.* at *4.

[17] *Id.* at *4 (citing *Riegel*, 552 U.S. at 326–27).

[18] *Id.* (citing *Riegel*, 552 U.S. at 329–30).

[19] *See In re Suboxone (Buprenorphine/Naloxone) Film Prods. Liab. Litig.*, 761 F. Supp. 3d 1069, 1086 (N.D. Ohio 2024).

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Bryce Cooper

Patrick Hogan

Linda M. Blair

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