

**STOPPING THE CONFUSION:
WHY WIDENING THE PREEMPTION GAP
THROUGH THE PARALLEL-CLAIMS
EXCEPTION PROMOTES OFF-LABEL USES
OF MEDICAL DEVICES**

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ABSTRACT: This Comment discusses how the circuit split on medical device preemption impacts and curtails off-label usage of Class III medical devices. In some jurisdictions, this deepening circuit split, arising from the Supreme Court’s jurisprudence on the Medical Device Amendments to the Food, Drug, and Cosmetic Act, provides effective immunity from tort liability brought by plaintiffs injured by a medical device. The confusing landscape caused by the split has particularly affected off-label use of Class III medical devices. Off-label uses, widely utilized throughout the medical community, should be promoted by the courts as they ease administrative burden and encourage medical ingenuity. Although the Food and Drug Administration lacks control over off-label usages, the tort system is uniquely placed to ensure accountability and recovery. When courts preclude tort claims following an injury from a device used off label, such usage inevitably decreases as healthcare providers and patients alike fear the inability to recover for potential harm. This Comment proposes an expansion of the parallel-claims exception that the Supreme Court has enunciated as a mechanism through which plaintiffs can bring tort claims without being preempted.

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When Debra Martin went into surgery on July 14, 2010, she expected her doctor to fuse the L4-5 and L5-S1 segments along her spine.¹ To perform this surgery, her surgeon used Medtronic’s Infuse Bone Graft medical device (Infuse), which was designed to treat degenerative disc disease and intended for use in “anterior lumbar interbody fusion (ALIF) surgeries on a single level between L4 and S1.”² Physicians typically use this device in place of difficult and

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1. *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1032 (D. Ariz. 2014).

2. *Id.* at 1031.

often painful bone transplants.³ However, Ms. Martin alleged the physician in her procedure used it in an unapproved way.⁴ According to Ms. Martin's allegations, the use was off label both because the surgeon utilized a posterior approach and because he failed to use the LT-Cage as was required.⁵

Doctors often employ off-label uses of both devices and pharmaceuticals when they believe such usage is the best option for the patient.⁶ The Food and Drug Administration (FDA) states: "Good medical practice and the best interests of the patient require that physicians use . . . devices according to their best knowledge and judgment."⁷ The allowance of off-label uses, while not regulated by the FDA, is highly beneficial to society's general welfare as it reduces regulatory backlog, protects the sacred doctor-patient relationship, and puts physicians in a position to provide the best care based on their knowledge and experience.⁸ However, manufacturers should ensure that their products are safe and used accurately by healthcare providers. The Infuse device became the center of a controversy for its manufacturer, Medtronic, when news broke that Medtronic illegally paid physicians to promote the off-label use of the device while also failing to notify the FDA about certain adverse events, including several deaths, associated with the device.⁹ At the height of the controversy, the Infuse device was being used off label in 85 percent of all cases.¹⁰

Based on the Infuse's off-label use, Ms. Martin was later diagnosed with bony overgrowth at L5-S1 and suffered from a cyst where the surgery occurred, thus requiring "extensive medical treatment."¹¹ Bony overgrowth is a known

3. See José P. Sierra, *Medtronic InFUSE Cases Signal That Off-Label Promotion Probably Not Illegal*, LEXOLOGY (Oct. 3, 2013), <https://www.lexology.com/library/detail.aspx?g=514a7228-7022-4ae0-9470-461f859be41e> [<https://perma.cc/539Q-J3VD>].

4. *Martin*, 32 F. Supp. 3d at 1032.

5. *Id.*

6. See *Off-Label Use of Orthopedic Drugs and Devices: A Common, But Sensitive, Decision*, ORTHOPEDICS TODAY (Sept. 2010), <https://www.healio.com/orthopedics/business-of-orthopedics/news/print/orthopedics-today/%7B7b9e50c5-951c-4c7f-a7a0-796987fa346d%7D/off-label-use-of-orthopedic-drugs-and-devices-a-common-but-sensitive-decision> [<https://perma.cc/SG3R-72N5>].

7. "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices, U.S. FOOD & DRUG ADMIN. (Jan. 1998), <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm> [<https://perma.cc/6ZLG-MKPQ>].

8. See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998).

9. See, e.g., *Ohio Judge Dismisses Hundreds of Off-Label Medtronic Infuse Patient Lawsuits*, SPINALNEWS INT'L (Oct. 14, 2016), <https://spinalnewsinternational.com/ohio-judge-dismisses-hundreds-of-off-label-medtronic-infuse-patient-lawsuits/> [<https://perma.cc/M89Q-3HV7>].

10. Tom Lamb, *The Widespread "Off-Label" Use of Medtronic Infuse Bone Graft and Associated Reports of Adverse Events Involving Serious Injury*, FOOD DRUG INJ. WATCH (Oct. 8, 2013), <https://www.drug-injury.com/druginjurycom/2013/10/medtronic-infuse-bone-graft-off-label-surgery-reports-side-effects-adverse-events-injury-patients.html> [<https://perma.cc/AQ4C-MBFY>].

11. *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1032 (D. Ariz. 2014) (quoting Complaint for Damages at ¶ 30, Docket No. 1). Compare Lamb, *supra* note 10 (describing the FDA's approved usage of the Medtronic Infuse device), with *Martin* 32 F. Supp. 3d at 1032 (plaintiff's allegations of the surgeon's actual usage of the Medtronic Infuse device). Ms. Martin is one of many patients who suffered bony overgrowth and other complications because of the Infuse device. See, e.g., *Lew v. Medtronic, Inc.*, No. CV 14-08303-JLS (VBKx), 2014 WL 7185299, at *1 (C.D. Cal. Dec. 16, 2014); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692 (S.D. Tex. 2014); *Scovil v. Medtronic, Inc.*,

side effect of off-label or improper use of the Infuse device.¹² Bony overgrowth can be an excruciating condition that often causes the onset of arthritis, osteoarthritis, nerve damage, and other bone and ligament problems.¹³ Despite her extreme suffering, allegedly as a result of the off-label use of this device, Ms. Martin is unable to seek civil damages against Medtronic for her injuries.¹⁴ This is because the Infuse product falls within the jurisdiction of the FDA under the Medical Device Amendments (MDA).¹⁵ The constitutional doctrine of express preemption bars some tort suits in this setting.¹⁶ Even when such a device is used off label, as in Ms. Martin's case, and the use occurs outside of the FDA's regulation, such claims still are preempted.¹⁷

The interpretation of two landmark Supreme Court cases involving express preemption of common law claims under the MDA, which brought medical devices under the purview of the Food, Drug, and Cosmetic Act (FDCA), has created a deepening circuit split over recent decades.¹⁸ Express preemption, as opposed to implied preemption, occurs when federal legislation has language that specifically preempts certain types of claims, as here.¹⁹ Under the express preemption analysis, circuits generally agree plaintiffs can only bring common law claims where the claim involves a requirement that is "parallel" to a federal requirement, but there is continuing division over what constitutes a parallel claim.²⁰ The jurisdictions that institute a wide interpretation of what claims are preempted, combined with their policies of heightened pleading standards and a narrow interpretation of the parallel-claims exception, effectively give complete civil tort immunity to medical device manufacturers.²¹

995 F. Supp. 2d 1082 (D. Ariz. 2014); *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202 (N.D. Cal. 2013).

12. *Lew*, 2014 WL 7185299, at *3.

13. Apostolos Kontzias, *Osteoarthritis (OA)*, MERCK MANUAL CONSUMER VERSION, <https://www.merckmanuals.com/home/bone,-joint,-and-muscle-disorders/joint-disorders/osteoarthritis-oa> [<https://perma.cc/4TF7-ST4R>].

14. *See generally* *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026 (D. Ariz. 2014) (The court granted defendants' motion to dismiss plaintiff's claims based on finding that the claims were preempted.).

15. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. ch. 9); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996).

16. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 314 (2008); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 580 (4th Cir. 2012); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1297 (11th Cir. 2011); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1201 (8th Cir. 2010).

17. *See, e.g.*, *Riegel*, 552 U.S. at 314; *Martin*, 32 F. Supp. 3d at 1041–45.

18. *Compare Walker*, 670 F.3d at 581 (holding a plaintiff's common law claims were preempted under the MDA) *with* *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) (holding common law claims were not preempted under the MDA because they were parallel to federal requirements).

19. *See generally* Neil M. Issar, *Preemption of State Law Claims Involving Medical Devices: Why Increasing Liability for Manufacturers Is a Perilous but Pivotal Proposition*, 17 VAND. J. ENT. & TECH. L. 1085 (2015).

20. *See Walker*, 670 F.3d at 580–81; *Wolicki-Gables*, 634 F.3d at 1300–03; *Bryant*, 623 F.3d at 1205.

21. *Walker*, 670 F.3d at 580–81; *Wolicki-Gables*, 634 F.3d at 1300–03; *Bryant*, 623 F.3d at 1205.

Other circuits have made it easier for plaintiffs to bring these claims.²² The landscape of this split is particularly complex when it comes to claims that involve the application of off-label uses of Class III medical devices, which command the highest level of FDA scrutiny under the MDA.²³ While the FDA has approved all Class III devices to be on the market, physicians often use them in ways that the FDA did not approve.²⁴ Off-label use, while heavily scrutinized, is fully legal and often promoted by courts.²⁵ In fact, courts have recognized that off-label uses can even be the standard of care.²⁶ However, the express preemption doctrine significantly impacts off-label use. When circuits significantly restrict or wholly prevent common law claims that arise from off-label use of a medical device from proceeding, healthcare providers and patients alike are discouraged from pursuing such off-label uses because they are not adequately protected or ensured a remedy in the case of a mishap. As discussed throughout this Comment, off label uses are highly valuable and must be encouraged and protected by our legal system. This includes carving out legal doctrines under the express preemption analysis that prevents its chilling effect on such off label usage.

The current legal landscape leaves plaintiffs and manufacturers confused or unaware of when and to what extent claims of this nature may proceed.²⁷ Part I of this Comment discusses the express preemption doctrine as it applies to all common law claims involving Class III medical devices under MDA. Part II lays out how the circuits have split over preemption of common law claims involving medical devices in general, particularly as it pertains to the parallel claims exception. Part III explains how the issue of express preemption uniquely affects claims that revolve around the off-label use of medical devices and why such off-label usage is valuable to society. Finally, Part IV argues that circuit courts have moved to extremes to resolve the issue. Thus, the focus should be on both justice for plaintiffs to be able to bring claims through the parallel-claims exception when injured and deference to the FDA in handling issues falling under the FDCA and MDA.

22. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013), cert. denied, 573 U.S. 930 (2014); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 776 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010).

23. See generally *Issar*, *supra* note 19.

24. See, e.g., *id.* at 1087.

25. See, e.g., *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514 n.3 (8th Cir. 1996); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1496 (D.C. Cir. 1996); *United States v. Evers*, 453 F. Supp. 1141, 1149–50 (M.D. Ala. 1976), *aff'd*, 643 F.2d 1043, 1052–53 (5th Cir. 1981); *Jones v. Petland Orlando Store*, 622 So. 2d 1114, 1115 (Fla. Dist. Ct. App. 1993).

26. See *Southard v. Temple Univ. Hosp.*, 781 A.2d 101, 106 (Pa. 2001) (stating that a specific off-label use of a medical device was the standard of care within the surgical community).

27. See *Jarret Sena, The Contours of the Parallel Claim Exception: The Supreme Court's Opportunity to Define the Ill-Defined*, 42 *FORDHAM URB. L.J.* 291, 295–96 (2014).

I. THE MDA PREEMPTS MANY COMMON LAW CLAIMS

Ms. Martin is unable to recover from the results of the off-label use of the Infuse device because the MDA preempts many common law state claims.²⁸ Because medical devices like the Infuse Bone Graft are under the federal purview of the FDA, the MDA often preempts state tort claims.²⁹ Pursuant to the Supremacy Clause of the United States Constitution, “the Laws of the United States . . . shall be the supreme Law of the Land”³⁰ However, it can be observed that courts “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”³¹ Congressional purpose can be readily determined here by looking at the text and enactment of the present statute, the MDA.

Congress enacted the MDA “to provide for the safety and effectiveness of medical devices intended for human use.”³² Before the enactment of the MDA, the FDCA provided for the premarket approval of new drugs but not for new medical devices.³³ With rising concerns about consumer safety, Congress decided to give the FDA similar power over medical devices as it already had over pharmaceuticals under the FDCA.³⁴ The MDA thus created a legislative scheme that gave massive oversight in this area to the federal government, specifically the FDA, while reducing state control almost entirely.³⁵

The MDA classifies medical devices into three categories.³⁶ Class I medical devices have no “potential unreasonable risk of illness or injury” and include products like elastic bandages or examination gloves.³⁷ Class II medical devices are subject to “special controls” and are potentially more harmful, such as powered wheelchairs.³⁸ Class III medical devices, the subject of this Comment, are those devices that “present[] a potential unreasonable risk of illness or injury.”³⁹ This category includes devices such as “replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators.”⁴⁰ This category also includes the Infuse device used on Ms. Martin.⁴¹ Class III devices are subject to the highest level of federal oversight, and the manufacturer of the device must provide “reasonable assurance” to the FDA that the device is effective and safe

28. See 21 U.S.C. § 360k(a) (2012).

29. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996).

30. U.S. CONST., art. VI, cl. 2.

31. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

32. See generally *Medical Device Amendments of 1976*, Pub. L. No. 94-295 § 1. 90 Stat. 539 (1976).

33. *Lohr*, 518 U.S. at 475.

34. *Id.* at 476.

35. See generally *Issar*, *supra* note 19.

36. See 21 U.S.C. § 360c(a) (2012).

37. 21 U.S.C. § 360c(a)(1)(A)(ii)(II); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

38. 21 U.S.C. § 360c(a)(1)(B); *Riegel*, 552 U.S. at 316.

39. 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

40. *Riegel*, 552 U.S. at 317.

41. *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1030 (D. Ariz. 2014).

to put on the market.⁴² While this sounds simple, the process for approval of Class III medical devices is “a rigorous one.”⁴³

There are two primary methods a device manufacturer can pursue to achieve Class III device approval. The first method, which will be the primary focus of this Comment, is the premarket approval (PMA) process.⁴⁴ The PMA process requires the manufacturers to submit extensive amounts of information to the FDA, which it then reviews for an average of 1,200 hours per each device submission.⁴⁵ Additionally, the FDA can approve devices through the “grandfathering” process.⁴⁶ Under this process, devices that were already in existence at the time of the MDA were grandfathered in without needing PMA.⁴⁷ Pursuant to the same process, a device that is “substantially equivalent” to a device already on the market also can be grandfathered in for approval.⁴⁸ Similarly, the “substantially equivalent” process, known as the 510(k) process, is the most commonly used process for getting devices onto the market.⁴⁹ Under the 510(k) process, the FDA spends only on average 20 hours reviewing the submission, and thus it is far less rigorous than the PMA process.⁵⁰

In addition to classifying medical devices and creating a scheme for such devices entering onto the market, the MDA includes an express preemption provision.⁵¹ This provision (subsection 360k(a)) provides that

[n]o state . . . may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act 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.⁵²

42. 21 U.S.C. § 360e(d)(2)(A) (2012); *see also* *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

43. *Lohr*, 518 U.S. at 477.

44. *See generally id.*

45. *Id.*

46. *Id.* at 478.

47. *Id.*; *see also* 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (2019).

48. *See* 21 U.S.C. § 360e(b)(1)(B); *Lohr*, 518 U.S. at 478.

49. 21 U.S.C. § 510(k); *Lohr*, 518 U.S. at 479.

50. *Id.* Devices may also be approved under an investigational device exemption (IDE), which allows unapproved Class III devices to be on the market solely for human trials. This allows manufacturers to submit “a device that otherwise would be required to comply with a performance standard or to have premarket approval . . . for the purpose of conducting investigations of that device.” 21 C.F.R. § 812.1(a) (2019). This process is not at issue in this Comment.

51. *See* 21 U.S.C. § 360k(a) (2012).

52. *Id.* There has been much ink spilled over the topic of preemption as it generally applies to medical devices. *See generally, e.g.,* Issar, *supra* note 19; William M. Janssen, *Iqbal* “Plausibility” in *Pharmaceutical and Medical Device Litigation*, 71 LA. L. REV. 541 (2011); Sena, *supra* note 27. However, the lack of Supreme Court insight into resolving this deepening circuit split makes the topic ripe for consideration. Furthermore, while many scholars have weighed in on whether to widen or narrow the preemption gap as it generally applies to devices, the issue of the circuit split as it specifically affects claims involving off-label uses of Class III medical devices has yet been untiled.

The full extent to which this provision expressly preempts common law claims against manufacturers for problems arising from Class III medical devices has been the topic of much debate.

The Supreme Court has twice addressed the express preemption of medical devices under the MDA.⁵³ The first case the Court decided, *Medtronic, Inc. v. Lohr*, established, *inter alia*, that manufacturers do not enjoy complete immunity from liability under the MDA, and thus the MDA does not preempt all state law claims.⁵⁴ In that case, which involved a plaintiff injured by a faulty pacemaker that went through the 510(k) grandfathering rather than the PMA process of approval, the Court read subsection 360k(a) narrowly.⁵⁵ The Court emphasized the language of subsection 360k(a), holding the MDA preempts state requirements that “‘with respect to’ medical devices [are] ‘different from, or in addition to,’ federal requirements” and that “relate to the safety or effectiveness of the device”⁵⁶ Furthermore, the Court held the MDA preempts common law state claims where the state requirements the plaintiff was attempting to invoke have “the effect of establishing a substantive requirement for a specific device.”⁵⁷ The MDA did not preempt common law claims in question under this interpretation because, instead of going through the PMA process where the FDA does establish device-specific requirements, the FDA approved the device through the 510(k) process that established no device-specific requirements.⁵⁸

Lower courts have read *Lohr* as establishing that for courts to invoke preemption, the “requirements” in question under 360k(a) must be specific to the device in question.⁵⁹ Additionally, *Lohr* established the “parallel” requirements rule.⁶⁰ The Court in *Lohr* stated the MDA did not preempt the common law claims when the claims “parallel federal requirements.”⁶¹ Circuit courts are divided on when a state-law tort claim based on common law requirements parallels a federal requirement.⁶²

53. *See, e.g., Lohr*, 518 U.S. 470.

54. *Id.* at 487.

55. *Id.*

56. *Id.* at 500 (quoting 21 U.S.C. § 360k(a)).

57. *Id.*

58. *Id.* at 501. A subsequent case the Court decided was *Buckman Co. v. Plaintiffs’ Legal Comm.*, which read an implied preemption meaning into the MDA. 531 U.S. 341, 352 (2001). There remains a circuit split over the exact reach of this ruling, and this Comment argues briefly that the preemption gap as it applies to implied preemption should be read narrowly to include exclusively *Buckman*-type fraud-on-the-FDA claims. However, this Comment will focus exclusively on express preemption as a matter of statutory interpretation and case law analysis.

59. *See Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1230–31 (9th Cir. 2013), cert. denied, 573 U.S. 930 (2014); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 581 (4th Cir. 2012); *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 770 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 620 F.3d 546, 554 (7th Cir. 2010); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1208 (8th Cir. 2010).

60. *See generally Lohr*, 518 U.S. at 495.

61. *Id.*

62. *See Stengel*, 704 F.3d at 1032; *Walker*, 670 F.3d at 581; *Wolicki-Gables*, 634 F.3d at 1300; *Hughes*, 631 F.3d at 772; *Bausch*, 620 F.3d at 558; *Bryant*, 623 F.3d at 1205.

The second Supreme Court decision on express preemption of medical devices was *Riegel v. Medtronic, Inc.*, which left room for wide interpretations, ultimately causing the circuit split at hand.⁶³ In *Riegel*, plaintiffs brought a claim after a catheter was used in an off-label manner, causing the patient's coronary artery to rupture.⁶⁴ The plaintiffs brought claims of strict liability, breach of implied warranty, and negligence based on allegations that "Medtronic's catheter was designed, labeled, and manufactured in a manner that violated New York common law."⁶⁵ The Court found the MDA preempted these claims.⁶⁶ To reach this holding, the Court used a two-prong analysis.⁶⁷ The Court first asked whether the federal government had established requirements specific to this catheter device based on the *Lohr* device-specific requirement.⁶⁸ The Court determined the PMA process always imposes such device-specific requirements.⁶⁹ Then, it further inquired into whether those requirements on which plaintiffs base their common law claims are "different from, or in addition to" the federal requirements that "relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under subsection 360k(a).⁷⁰ The Court found that safety and effectiveness were "the very subjects of the Riegels' common law claims," and thus the primary concern was whether the requirements imposed by common law tort claims were "different from, or in addition to," federal requirements.⁷¹ The Court held the plaintiff premised their common law claims on requirements that were "different from, or in addition to," the federal requirements established under the PMA process.⁷² The Court reasoned "requirements" under the meaning of the MDA included common law tort liability.⁷³

Lower courts have understood *Riegel* to establish all devices that have gone through the PMA process automatically meet the first criteria for the two-prong test.⁷⁴ When a device has gone through the PMA process and thus has device-specific requirements as laid out in *Lohr*, the Court must then only determine whether the requirements on which the plaintiff premised his common law claims are "different from, or in addition to," the device-specific requirements

63. See generally *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

64. *Id.* at 320.

65. *Id.*

66. *Id.* at 330.

67. *Id.* at 321–22.

68. *Id.* at 321.

69. *Id.* at 322–23.

70. *Id.* at 323 (quoting 21 U.S.C. § 360k(a) (2012)).

71. *Id.*

72. *Id.* at 323–24.

73. *Id.* at 324–25 ("[E]xcluding common law duties from the scope of pre-emption would make little sense.").

74. See Elizabeth Miner & Reed Smith, *Express and Implied Preemption for Premarket-Approved Medical Devices: Dual Shield Against Tort Claims*, MED. DEVICE ONLINE (April 9, 2018), <https://www.meddeviceonline.com/doc/express-and-implied-preemption-for-premarket-approved-medical-devices-a-dual-shield-against-tort-claims-0001> [<https://perma.cc/UU9J-X2T9>].

that existed under the PMA and that “relate to safety and effectiveness.”⁷⁵ Because the claims all inherently “relate to the safety and effectiveness” of the device, the relevant consideration for this Comment is whether the common law requirement is “different from, or in addition to,” the federal requirements under the MDA. Therefore, if the common law requirement is “different from, or in addition to,” the federal requirements, then the claim will be preempted.⁷⁶ *Riegel* also reemphasized the parallel claims exception from *Lohr*, stating “§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”⁷⁷

Lower courts have interpreted *Lohr* and *Riegel* together as requiring a two-step analysis for determining if the MDA preempts common law claims.⁷⁸ First, the alleged conduct must violate the FDCA. Next, the plaintiff must have a cause of action under state law that is independent of the FDCA. This analysis gives rise to the preemption gap, which describes the space through which plaintiffs can bring a common law claim that the MDA does not preempt.⁷⁹ The circuits have created various interpretations of the preemption gap, either by widening it to allow for more common law claims through the gap and establishing plaintiff-friendly standards, narrowing it to prevent such claims and therefore protect manufacturers and prevent frivolous suits, or further parsing the preemption doctrine.⁸⁰

II. THE DEEPENING CIRCUIT SPLIT OVER PREEMPTION AND THE PARALLEL —CLAIMS EXCEPTION HURTS PLAINTIFFS

Because *Lohr* and *Riegel* left ample room for interpretation of when the MDA expressly preempts common law tort recovery claims, a deepening circuit split has arisen over when and how to apply such preemption to medical devices.⁸¹ The circuits are divided not only on whether to widen or narrow the

75. *Riegel* 552 U.S. at 320; *see also id.* at 321–22.

76. *Id.* at 324.

77. *Id.* at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

78. *See generally* *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), cert. denied, 573 U.S. 930 (2014); *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012); *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296 (11th Cir. 2011); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 620 F.3d 546 (7th Cir. 2010); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010); *Kemp v. Medtronic*, 231 F.3d 216 (6th Cir. 2000).

79. *See Bryant*, 623 F.3d at 1204; *see also Mullin’ Over Preemption: Lohr, FDA Regulations, and Mullins*, A.B.A. (Feb. 5, 2016), <https://apps.americanbar.org/litigation/committees/masstorts/articles/winter2016-0216-mullin-over-preemption-lohr-fda-regulations-preemption-mullins.html> [<https://perma.cc/474L-Y3TZ>].

80. *See generally Mullin’ Over Preemption: Lohr, FDA Regulations, and Mullins*, *supra* note 79.

81. *See generally* cases cited *supra* note 78.

preemption gap, but also on what a parallel claim is, and how plaintiffs should be required to plead.⁸²

While the Court in *Lohr* and *Riegel* both emphasized the parallel-claims exception to express preemption, lower courts have experienced difficulty parsing out when such an exception applies.⁸³ Litigants recently petitioned the Supreme Court recently to review a parallel claims case to define its applicability, but the Court denied certiorari.⁸⁴ The case in question, *Stengel v. Medtronic, Inc.*, discussed whether a common law claim alleging a medical device manufacturer failed to disclose newly discovered adverse consequences of a Class III medical device constituted a parallel claim so as not to be preempted.⁸⁵ The Ninth Circuit, siding with the plaintiffs, held the MDA did not expressly preempt such failure-to-warn claims because the claim “rest[ed] on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*.”⁸⁶ In holding such a claim fit into the parallel claim exception, the Ninth Circuit joined the Fifth and Seventh Circuits that had favorable rulings for plaintiffs in similar parallel claim cases.⁸⁷

The Fifth Circuit in *Hughes v. Boston Scientific Corp.* similarly held the MDA did not preempt a plaintiff’s failure-to-warn claim against a medical device manufacturer because the plaintiff predicated their claim on the manufacturer’s failure to comply with federal requirements.⁸⁸ The plaintiff based the claim on the allegation that the manufacturer failed to comply with Medical Device Reporting (MDR) as is required after the PMA process is complete.⁸⁹ The court reasoned the alleged failure to comply with MDR requirements was premised on a violation of federal requirements, and therefore such claims were not based on requirements “different from, or in addition to,” federal requirements.⁹⁰ However, the court found the plaintiff’s claims of products liability, including claims of “failure to provide adequate warnings or instructions communicating dangers associated with the [device],” did seek to impose different or additional requirements.⁹¹ The court reasoned these claims relied on finding liability even though the manufacturer complied with the applicable

82. See cases cited *supra* note 78. While this Comment focuses primarily on the first and second issue, pleading requirements under the new, aptly named “Twiqbal” standard (named after *Ashcroft v. Iqbal* and *Bell Atlantic v. Twombly*) poses significant challenges for plaintiffs that are worth discussing. While the new pleading requirements left much of the world of civil procedure spinning, its effects on medical device tort claim plaintiffs were extreme. See *Janssen, supra* note 52, at 541–42.

83. *Bryant*, 623 F.3d at 1204 (stating that the “contours of the parallel claim exception . . . are as-yet ill-defined.”).

84. See generally *Stengel*, 704 F.3d 1224.

85. *Id.* at 1232.

86. *Id.* at 1233.

87. *Id.*; see also *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 764 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010).

88. *Hughes*, 631 F.3d at 764.

89. *Id.* at 765.

90. *Id.* at 769.

91. *Id.* at 768–69.

FDA requirements involving design, manufacturing, and safety requirements.⁹² Because the plaintiff premised these claims on requirements that were not parallel, but rather “different from, or in addition to,” federal requirements, they were expressly preempted.⁹³

Finally, the Seventh Circuit in *Bausch v. Stryker Corp.* also sided with plaintiffs, holding that the claim was parallel to federal requirements.⁹⁴ The plaintiffs based their claim on alleged violations of federal law by the manufacturer when they manufactured Class III medical device Trident.⁹⁵ The plaintiff was allegedly injured when she had the Trident hip replacement system implanted six days after the FDA informed the manufacturer that a component of the device was adulterated.⁹⁶ The court stated that to preclude these claims would be to provide complete immunity from civil action to these manufacturers.⁹⁷ The court stated that “[t]he idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counterintuitive.”⁹⁸ The court said further that *Riegel* only protects manufacturers from civil liability “to the extent that it has complied with federal law, but it does not extend protection from liability where the claim is based on a violation of federal law.”⁹⁹

These decisions, favoring widening the preemption gap when it comes to parallel claims so that fewer common law claims are preempted, represent the best approach for several reasons. This standard allows for preemption when the common law claims directly oppose federal requirements, while still allowing claims that do not impose different or additional requirements to proceed. This provides deference to the important constitutional doctrine of preemption, and thereby also to the FDA as the federal agency in charge of enforcement against medical device manufacturers, by not allowing claims to proceed that go against the federal statutory scheme. Therefore, this approach affords plaintiffs the ability to adequately redress their wrongs while still affording the Constitution and the FDA their due deference.

Other courts have been unwilling to interpret the parallel claims exception in such a way as to provide opportunities for plaintiffs to bring claims against manufacturers. The Fourth, Eighth, and Eleventh Circuits have all held that a state law claim is not parallel and thus does not survive preemption when a plaintiff bases his claim on a generalization or industry-wide federal duty that applies to all medical devices rather than to a device-specific requirement.¹⁰⁰

92. *Id.* at 769

93. *Id.* at 768.

94. *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010).

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.* at 552 (emphasis in original).

100. See *Walker v. Medtronic, Inc.*, 670 F.3d 569, 580–81 (4th Cir. 2012); *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1302 (11th Cir. 2011); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1201 (8th Cir. 2010). While the circuit split over pleading standards for plaintiffs' common law

The Fourth Circuit in *Walker v. Medtronic, Inc.* held that the MDA preempted the plaintiff's claims of negligence, strict liability, and breach of warranty.¹⁰¹ The plaintiff brought suit when her husband died as a result of an alleged malfunction of an approved Class III medical device, alleging that the device "failed to comply and operate in terms of its Pre-Market Approval."¹⁰² Although the plaintiff claimed that the allegations were within the parallel claim exception and thus not preempted, the court rejected this analysis.¹⁰³ The court reasoned that, although the FDA sometimes requires formal performance standards for post-approval devices, no such standards were required here.¹⁰⁴ Therefore, claims of post-approval malfunction would establish requirements that were "different from, or in addition to," federal requirements because they would be imposing performance standards for post-approval devices where the FDA chose not to impose such standards. Thus, the MDA preempted the claims, and the court left decedent's wife without a damages remedy against the manufacturer.¹⁰⁵

The Eighth Circuit in *Bryant v. Medtronic, Inc.* similarly made it more difficult for plaintiffs to sue under the parallel claims exception.¹⁰⁶ The plaintiff brought claims asserting various common law claims after the manufacturer recalled a medical device.¹⁰⁷ The court held that the MDA expressly preempted such claims because they established requirements that were "different from, or in addition to," federal requirements and the parallel claim exception was not applicable.¹⁰⁸ The court deferred to the FDA, stating that the claims went against the statutory scheme of the MDA and therefore were preempted.¹⁰⁹

Finally, the Eleventh Circuit in *Wolicki-Gables v. Arrow Int'l, Inc.* sided with the Fourth and Eighth Circuits in restricting the landscape in which plaintiffs can bring claims. There, the plaintiff became a partial paraplegic because of issues with a Class III medical device and brought claims for product liability and negligence.¹¹⁰ The plaintiff argued that the MDA did not preempt his claims because of the parallel claims exception.¹¹¹ The court held that such claims were not sufficiently parallel.¹¹² It explained that, for a state requirement to be parallel

medical device claims is outside the scope of this Comment, the circuit split over parallel requirements is deeply intertwined with the issue. While plaintiff-friendly circuits do not require plaintiffs to plead device-specific requirements and thus have more relaxed pleading standards, the plaintiff-hostile circuits require more of their plaintiffs both for procedural pleading, as well as to establish a parallel claim exception to preemption.

101. *Walker*, 670 F.3d at 581.

102. *Id.* at 576.

103. *Id.* at 576–79.

104. *Id.* at 579.

105. *Id.* at 581.

106. *See Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1205–07 (8th Cir. 2010).

107. *Id.* at 1203.

108. *Id.* at 1204, 1207.

109. *See id.* at 1206.

110. *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1298–99 (11th Cir. 2011).

111. *Id.* at 1300.

112. *Id.* at 1303.

to a federal requirement, “the plaintiff must show that the requirements are ‘*genuinely* equivalent.’”¹¹³ To establish parallel claims, the court held “[a] plaintiff must allege that ‘the defendant violated a particular federal specification referring to the device at issue.’”¹¹⁴ It explained that the claims here—alleging that the manufacturer failed to design the device in a way that would prevent injury, reasonably manufacture the device, and provide adequate warnings—did not “set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.”¹¹⁵

In addition to the division over the interpretation of the parallel-claims exception, circuits similarly are split over whether to more generally narrow or widen the preemption gap. The plaintiff-friendly circuits—the Ninth, Fifth, and Seventh, as discussed above—held in favor of widening the preemption gap.¹¹⁶ These circuits have argued that to narrow the preemption gap to effectively preclude most if not all common law claims would provide complete civil immunity for manufacturers, which surely was not Congress’ intention in passing the MDA.¹¹⁷

The more restrictive circuits for plaintiffs—the Fourth, Eighth, and Eleventh, as discussed above—have preferred to narrow the preemption gap to favor manufacturers.¹¹⁸ Along with the cases already discussed in relation to the parallel claims exception, the Sixth Circuit similarly weighed in on whether to expand the preemption gap.¹¹⁹ The plaintiffs’ claims, which the MDA preempted, involved, *inter alia*, negligence per se and failure to warn, all largely based on a lack of a requirement for the thickness or coverage of a part of the device referred to as the platinum sputter barrier.¹²⁰ The claims were based off the insertion and later failure of a pacemaker medical device that the FDA approved via the PMA process.¹²¹ After discovering a “significant risk of failure” of the device, the manufacturer issued a Health Safety Alert for the device.¹²² The court held that the MDA preempted such claims.¹²³ It reasoned that the plaintiffs’ claims would establish requirements that were “different from, or in addition to,” the FDA requirements under the PMA process because the FDA did

113. *Id.* at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original).

114. *Id.* at 1301 (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

115. *Id.* at 1301–02 (quoting *Ilarraza*, 677 F. Supp. 2d at 589).

116. *See generally* *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 573 U.S. 930 (2014); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010).

117. *See* *Bausch*, 630 F.3d at 549.

118. *See generally* *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012); *Wolicki-Gables*, 634 F.3d 1296; *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010).

119. *See* *Kemp v. Medtronic*, 231 F.3d 216, 221 (6th Cir. 2000).

120. *Id.* at 218–19.

121. *Id.* at 219.

122. *Id.*

123. *Id.* at 216.

not establish any requirements for the thickness of the barrier.¹²⁴ The court further reasoned that to allow a jury to find in favor of the plaintiffs would require a finding that the manufacturer failed to meet requirements that were outside of those established by the FDA.¹²⁵

III. AN EXPANSIVE PREEMPTION INTERPRETATION REDUCES OFF-LABEL USES

While the preemption doctrine touches all aspects of medical device common law claims, its effects on those claims that involve the application of off-label uses of Class III medical devices are unique. Off-label use of a medical device occurs when a physician uses a device in a way in which the FDA did not approve.¹²⁶ This can include implanting the device in an unapproved fashion (for example, using a posterior approach rather than anterior, as happened to Ms. Martin) or using the device to treat an ailment for which the FDA did not approve the device's use.¹²⁷ Off-label uses are not outlawed and are actually codified in law.¹²⁸ There is a substantial history of off-label uses being employed for both pharmaceuticals and medical devices.¹²⁹ Historically, the FDA tolerated healthcare providers promoting off-label uses of medical devices because it is good for the social welfare and decreases burdens on the FDA.¹³⁰ The FDA has repeatedly stated that such off-label uses are permitted and primarily regulated by the healthcare facility in question rather than by the FDA.¹³¹ For example, the Agency stated in 1982 that, "The [FDCA] does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."¹³² In fact, approximately half of all Americans take medications in an off-label fashion.¹³³ While there have been debates about whether the FDA actually should regulate this wide-sweeping off-label use, the legislature decidedly curtailed the practicability of such regulations by restricting the FDA's budget and

124. *Id.* at 229.

125. *Id.* at 230.

126. *See generally* Beck & Azari, *supra* note 8.

127. *See id.* at 71–72.

128. *See* 21 U.S.C. § 396 (2012).

129. *See* Beck & Azari, *supra* note 8, at 77–78.

130. *Id.* at 77.

131. *See, e.g.,* Beck & Azari, *supra* note 8, at 76–78; *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4, 4–5 (1982) (cited in 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994)).

132. *Use of Approved Drugs for Unlabeled Indications*, *supra* note 131, at 5.

133. A. Devesh Tiwary, *Off-Label Use of Prescription Drugs Should Be Regulated by the FDA* 1 (2003) (unpublished third-year law student paper) (on file with the Harvard University DASH repository), <http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852151> [<https://perma.cc/9VMZ-JMHG>].

refusing to expand their regulatory duties.¹³⁴ Thus, the FDA does not regulate off-label uses but instead leaves them in the hands of the physicians who employ them.

The right of physicians to employ off-label uses in their practice was codified in 21 U.S.C. § 396, which states, “nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease” Additionally, courts routinely have recognized that off-label usage is appropriate, as have many state legislatures.¹³⁵ This is, as discussed, because it alleviates regulatory burdens by continuing to expand and experiment with healthcare products, which elevates the social welfare. However, the federal government generally discourages such off-label practice. For example, insurance programs that receive federal funding, including Medicaid, do not reimburse physicians when they use a device in an off-label manner.¹³⁶

Furthermore, manufacturers generally are prohibited from promoting off-label uses of their products.¹³⁷ The legislature has forbidden such promotion through the provisions in the FDCA that prohibit the “introduction or delivery for introduction into interstate commerce of any . . . device . . . that is adulterated or misbranded.”¹³⁸ A device is considered to be misbranded when its label is false in any way, and this has been expanded to include when the label contains information about unapproved (i.e., off-label) uses.¹³⁹ Thus, while device manufacturers are unable directly to promote off-label uses, they may provide physicians with information on such uses, thus ensuring that manufacturers educate

134. See generally C. Lee Ventola, *Off-Label Drug Information: Regulation, Distribution, Evaluation, and Related Controversies*, 34 PHARMACY & THERAPEUTICS 428 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799128/pdf/ptj34_8p428.pdf [<https://perma.cc/ML5U-GDJ8>].

135. See, e.g., *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001) (“[O]ff-label’ usage of medical devices . . . is an accepted and necessary corollary of the FDA’s mission to regulate [medical devices] without directly interfering with the practice of medicine.”); *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1496 (D.C. Cir. 1996); *Weaver v. Reagan*, 886 F. 2d 194, 198 (8th Cir. 1989) (“[T]he fact that FDA has not approved labeling of a drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate.”); *United States v. Evers*, 453 F. Supp. 1141, 1149–50 (M.D. Ala. 1976), *aff’d*, 643 F.2d 1043, 1052–53 (5th Cir. 1981); *Alvarez v. Smith*, 714 So. 2d 652, 653 (Fla. Dist. Ct. App. 1998) (“[A] physician is free to use a medical device for an off-label purpose” (quoting *In re Orthopedic Bone Screw Products Liab. Litig.*, 1996 WL 107556, at *5 (E.D. Pa. Mar. 8, 1996)); see also ALA. CODE §§ 27-1-10.1(a), (c) (West, Westlaw through Act 2019-540); GA. CODE ANN. § 33-53-2 (West, Westlaw through 2019 Legis. Sess.); 5 ILL. COMP. STAT. § 375/6.4 (West, Westlaw through P.A. 101-66).

136. See 42 U.S.C. §§ 1396b(i)(10) (2012); 1396r-8(k)(3)(2000).

137. See generally Kevin Costello & Eric Johnston, *Practice Tips: Manufacturer Liability for Off-Label Uses of Medical Devices*, L.A. LAW., Apr. 2008, at 18 (2008).

138. See 21 U.S.C. § 331(a) (2012).

139. See generally 21 U.S.C. § 352 (2012).

healthcare providers before they implement off-label uses.¹⁴⁰ In this way, manufacturers are absolved of liability for promotion while still upholding their duty to ensure physicians use their products in a safe way.

Off-label usage of devices, as well as drugs, is a vital part of modern medicine. Without giving healthcare providers the ability and autonomy to use products in off-label fashions, effective and safe treatment options would often be overlooked or never discovered.¹⁴¹ Additionally, it gives healthcare providers rather than bureaucrats control over their own industry, while still allowing for safety measures that the FDA implements through its rigorous approval process. Without this regulation, a manufacturer could put a device on the market that had no labeled uses, had not been adequately tested for safety or efficiency, and was extremely dangerous. However, by minimizing excessive regulation of off-label uses, society benefits from the overall regulatory scheme without the administrative frustrations that often prevent new, safe, and effective treatments. Similarly, without off-label use, product costs would increase as manufacturers would bear the cost of product experimentation.¹⁴² Removing off-label use also would delay the process of finding new products by putting it through the bureaucratic, rather than medical, process.¹⁴³ Finally, it would stand in the way of useful and necessary treatments; and it would interfere with the sacred doctor-patient relationship.¹⁴⁴

However, off-label prescribing involves significant concerns. Because the FDA does not regulate or approve the particular use, patients may face potential risk or danger from the experimentation with the device.¹⁴⁵ This puts the patient in a “patient-as-guinea-pig” position where she may be the first, or one of the first, to try a device in a particular way. The FDA thus has been charged with balancing two competing interests: preventing marketing of dangerous products

140. Elizabeth Richardson, *Health Policy Brief: Off-Label Drug Promotion*, HEALTH AFFAIRS, June 30, 2016, at 2, https://www.healthaffairs.org/doi/10.1377/hpb20160630.920075/full/healthpolicybrief_159.pdf [<https://perma.cc/APZ7-PW85>].

141. For example, the antidepressant Wellbutrin would not have been discovered as an effective tool for quitting smoking without physician experimentation. W. David Bradford et al., *Off-Label Use of Pharmaceuticals: Trends and Drivers* 8–9 (Apr. 2014), <https://pdfs.semanticscholar.org/d08a/b5e8c8653b6bb4943d8269174ec02566f691.pdf> [<https://perma.cc/NQ8G-U397>]. Similarly, beta-blockers—now regularly-prescribed for anxiety symptoms—would still be used exclusively to treat hypertension; Viagra would be used only for heart conditions and not erectile dysfunction; and thalidomide would have been taken off the market after causing birth defects when used in its on-label purpose of preventing morning sickness, but it is now used to effectively treat leprosy and blood cancer. *Id.* at 6, 9; Aimee Swartz, *Viagra and Many Other Drugs Were Discovered by Chance. Now Science Is Hoping to Change That*, WASH. POST, May 13, 2018, https://www.washingtonpost.com/national/health-science/viagra-and-many-other-drugs-were-discovered-by-chance-now-science-is-hoping-to-change-that/2018/05/11/8b13e058-47ce-11e8-9072-f6d4bc32f223_story.html?utm_term=.615e26a6b1f2 [<https://perma.cc/ZDL3-CWKX>].

142. See Tiwary, *supra* note 133, at 1.

143. *Id.*

144. *Id.*

145. See Rebecca Dresser & Joel Frader, *Off-Labeling: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 477, 483 (2009).

while ensuring that manufacturers market effective products without undue delay.¹⁴⁶ The FDA is uniquely situated to be able to balance these interests, and taking away that ability can harm the population. Common off-label uses also can allow manufacturers to side-step the process when they are aware that such uses are occurring but do not want to go through the cumbersome process of approval. Despite these drawbacks, the healthcare field and the FDA decided that the benefits of off-label uses by physicians outweigh the potential disadvantages. The legal system must respond in kind by carving out legal doctrines that are unique to common law tort cases arising out of the off-label use of medical devices.

Express preemption as it applies to common law claims that arise out of cases involving off-label use of medical devices, such as in Ms. Martin's case, have traditionally been treated similarly to preemption cases that do not involve off-label usage.¹⁴⁷ However, the effects that these holdings have are different and potentially more impactful. If patients are unable to recover for harms caused through the off-label use of a device, they may elect to refuse off-label treatment. Even where patients lack the knowledge to make such a decision, healthcare providers will similarly be disinclined to continue off-label usage in their practice knowing that patients will be unable to recover from manufacturers if injured.

Assuming it is in the best interest of society to allow for off-label uses, as this Comment argues, a radical reduction in off-label uses could harm not only patients but also manufacturers if they can only sell their products for the use for which it is labeled. Furthermore, when an off-label use injures a plaintiff and is attributable to the manufacturer, the FDA may be less likely to act because it does not regulate such usages. While laws exist that regulate the promotion of off-label use, the FDA does not regulate the actual uses of off-label devices. Instead, the FDA gives physicians wide latitude to pursue off-label uses as they see fit.¹⁴⁸ Therefore, the FDA rarely seeks action against manufacturers of devices that are used off-label. This leaves not only the injured patient without a damages remedy, but also allows the manufacturers to effectuate nearly complete civil immunity for their wrongs. There is a substantial cost to overall social welfare that courts exact when they prevent patients from pursuing claims against manufacturers while those same manufacturers similarly are let off the hook by the FDA. This cost to social welfare, which the legal and healthcare

146. *Id.* at 2–3.

147. *See, e.g.,* *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013); *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069 (D. Or. 2013).

148. *See* 21 U.S.C. § 396 (2012) (“Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship”). While this Comment deals with liability of manufacturers, physicians are also an integral part of this analysis. Healthcare providers can, of course, be liable under medical malpractice doctrines for their involvement in off-label uses that harm patients. Similarly, manufacturers can join physicians as codefendants or third parties at fault in lawsuits that result when a patient is harmed from an off-label use of a medical device.

communities both have an interest in preventing and fixing, can be rectified by allowing claims against these manufacturers under appropriate circumstances.

With these potentially severe effects for preemption of common law claims arising from medical devices, there are strong policy reasons in favor of widening the preemption gap to allow more claims from plaintiffs. As stated, to hold otherwise would provide almost complete immunity for manufacturers of Class III medical devices, a result Congress could never have intended.¹⁴⁹ Additionally, while the federal government has an interest in such issues, matters of health and safety are traditionally within the police powers of the state and should be left as such.¹⁵⁰ In addition to state deference, there is a long history behind the “presumption against the pre-emption of state police power regulations.”¹⁵¹ Furthermore, to narrow the preemption gap would be to potentially prevent physicians from employing off-label uses in their practice, which is a result that our healthcare field has decided is undesirable because of its serious negative ramifications for patients’ health.

Furthermore, the FDA simply does not provide sufficient comprehensive regulation to justify the preemption of common law claims. Off-label uses are decidedly good for our healthcare system, yet the FDA is unable to regulate them. If the FDA is unable to regulate them, the tort system must step in to provide alternative remedies and to establish sufficient deterrence to ensure manufacturer responsibility. The tort system is, for many areas of the law, the supplement for when the system is not expansive enough to provide all the necessary means of deterrence and remedies; this is arguably the case for the FDA. The FDA does not have all-encompassing abilities; therefore, the 510(k) process exists to lift the burden on the FDA so the latter can focus its attention largely on more pressing issues with new devices.¹⁵² The tort system similarly may be of use; without such a system, the preemption doctrine will significantly diminish, if not lose entirely, its deterrent effect on manufacturers.

There are significant arguments, however, to narrow the preemption gap in favor of manufacturers. This would encourage manufacturers to experiment with medical devices because they would not fear an onslaught of tort litigation. Additionally, by reducing the use of off-label experimentation by physicians, courts would be able to draw a line to protect patients. To allow patients routinely to become guinea pigs for uses that manufacturers have not adequately tested or the FDA has not approved raises many issues with which society would have to grapple. But while such experimentation can be dangerous, with proper regulation by the healthcare community, it will also significantly advance health initiatives by both encouraging physician ingenuity and protecting the sacred

149. *See* *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010).

150. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (“Because these are primarily and historically . . . matters of local concern, the States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”) (internal quotations omitted).

151. *Id.* at 485 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992)).

152. *See generally* INST. OF MED. OF THE NAT’L ACADS., *MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* (2011).

doctor-patient relationship. Upholding the preemption doctrine also gives deference to the legislature in its clearly designed statutory scheme. Congress unmistakably gave wide and almost exclusive latitude to the FDA to enforce and regulate these matters under both the FDCA and MDA, and courts stepping in to reinterpret the statute is, *arguendo*, an inappropriate use of judicial power.

IV. THE PARALLEL-CLAIMS EXCEPTION SHOULD BE BROADLY INTERPRETED TO PROVIDE JUSTICE FOR PLAINTIFFS AND DEFERENCE TO THE FDA

Given the complex landscape of the preemption doctrine as it applies to medical devices, it is evident why the circuits are far from uniform in their analysis of the matter. However, such inconsistency is harmful: it confuses potential plaintiffs, wastes the time and money of attorneys and courts who must litigate the matter, and causes uncertainty for medical device companies whose legal fates depend on which jurisdiction plaintiffs sue them in. The Supreme Court should clarify the issue for all parties. The Court should adopt a more bright-line rule that allows plaintiffs to bring claims when harmed by off-label uses through the parallel claims exception while still providing due deference to the FDA. Off-label uses are highly valued and should be encouraged. Ensuring that injured patients can achieve a remedy for their suffering, therefore, will mean they are not deterred from pursuing off-label treatments. Thus, off-label uses will continue to be promoted with an expansive interpretation of the parallel-claims exception, while balancing the interests of promoting off-label uses and protecting the FDA's abilities.

Under the precedent of *Lohr* and *Riegel*, the primary avenue for bringing common law claims should be under the parallel-claims exception. Because this exception gives deference to subsection 360k(a) and therefore to the FDA, it presents a middle-of-the-road approach. It provides plaintiffs a remedy at law when they are injured, often grievously, by medical device manufacturers, while not stepping on the FDA's toes of authorization and approval. The circuit court which most closely followed this approach was the Fifth in *Hughes v. Boston Scientific Corp.*, which allowed the plaintiff's claims for failure to warn to proceed while holding that the MDA preempted the other claim for product liability.¹⁵³

As it concerns off-label uses, deference to the FDA is less vital because the FDA has explicitly stated that it has foregone the oversight of such activity.¹⁵⁴ However, because the MDA, and specifically subsection 360k(a), still applies to the analysis, the preemption doctrine and the necessary congressional deference is still required. Therefore, the parallel-claims exception should be interpreted broadly to effectively resolve this issue while still providing deference to the FDA. Such a broad interpretation of the parallel-claims exception would involve preempted claims that directly establish requirements that are "different

153. *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 767 (5th Cir. 2011).

154. *See Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

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from, or in addition to,” federal requirements while still allowing claims for requirements that are essentially the same as those federal requirements. For example, the MDA would not preempt a plaintiff suing a manufacturer alleging a failure to adequately meet post-approval performance standards that the FDA put in place. This is because that claim parallels the requirements which the FDA previously put in place. Conversely, the MDA would preempt a plaintiff who is trying to claim negligence based on a manufacturer’s failure to maintain adequate post-approval performance standards where the FDA did not establish such standards because those requirements are “in addition to” the FDA’s requirements.

While expanding the parallel claims exception to allow these claims is adverse to the holding of many of the circuits, it is in line with the strongest policy arguments that pervade tort doctrine. Without allowing at least some number of these claims to proceed, the deterrence value for manufacturers to comport with the activities that society expects will be lacking. Furthermore, to hold that plaintiffs who have been, through no fault of their own, grievously injured by the off-label use of a medical device would be unjust. Where the tort system has been created to fill in the gaps of other doctrinal laws that are not all expansive, its applicability in these circumstances will only strengthen and protect the off-label use that society wishes to promote.

Under the proposed resolution, Ms. Martin would be able to successfully bring a claim that would allow her to recover for the harm she has suffered at the manufacturer’s hands. However, such a claim would not be contrary to or in violation of 360k(a) and thus is not interfering with the FDA’s advisory rights. Instead, it is using the tort system to intentionally fill in the gaps left by the FDA’s inability to be wholly expansive and therefore providing justice to injured patients.



After the landmark decisions of *Lohr* and *Riegel*, the Supreme Court ultimately confused the preemption landscape so thoroughly as to leave many plaintiffs, such as Debra Martin, without a damages remedy, even after these plaintiffs suffered severe injuries from off-label usage of medical devices. While some circuits have widened the preemption gap, many circuits still hold that injured plaintiffs have no remedy against manufacturers. As plaintiffs continue to bring common law state claims, the widening circuit split and its attendant costs continue to waste money, time, and other resources. This is often at the injured plaintiffs’ expense. The Supreme Court should weigh in to clarify the preemption doctrine as it generally applies to common law claims arising under the MDA, because the need for clarification is especially urgent in claims arising from the off-label use of medical devices. As this Comment argues, off-label usage by healthcare professions greatly benefits society and should be promoted because it promotes the doctor-patient relationship, encourages medical innovation, and alleviates administrative inefficiency and burdens. However, courts put off-label usage at risk of being diminished when plaintiffs see the inability

to bring tort claims in the face of potential injury. When a patient or doctor is aware of the limitations in bringing such a claim, off-label uses will decline. This weighs in favor of the Supreme Court widening the preemption gap to allow more common law claims to proceed. Additionally, a narrow preemption interpretation provides immunity to manufacturers that often face no repercussions from the FDA for problems arising from off-label uses. In this way, the FDA does not provide comprehensive regulation over medical devices, and it is the tort system that should fill the gaps through the judicial system to ensure justice for plaintiffs.

It is through the parallel-claims exception, announced both in *Lohr* and *Riegel*, that the Court can expand the preemption gap. Because this exception provides an avenue through which injured plaintiffs may bring common law claims when the claims impose requirements that are parallel to federal requirements, it does not conflict with the preemption doctrine or the FDA's precedential control, as established under the MDA. With this application of a wider preemption gap through the parallel-claims exception, plaintiffs like Ms. Martin will be afforded a damages remedy for their often-severe injuries, ensuring manufacturer accountability, justice for the injured party, and the continuance of the valuable practice of off-label usage of medical devices.