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PREEMPTION**MEDICAL DEVICES**

Although the scope of federal preemption of state common law medical device claims has been vigorously debated since the Medical Device Amendments were enacted in 1976, a hot-button issue is the extent to which implied preemption may bar state device claims that parallel duties imposed by the federal Food, Drug, and Cosmetic Act, says Professor Jean Macchiaroli Eggen in this BNA Insight. The author analyzes recent cases and concludes that some parallel claims should survive implied preemption, and that a medical device manufacturer should not be immune from all state law claims simply because the device received marketing approval from the FDA.

Implied Preemption of Medical Device ‘Parallel Claims’

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When Congress enacted the Medical Device Amendments (“MDA”)¹ to the Food, Drug, and Cosmetics Act (“FDCA”)² in 1976, adding a preemption provision, it opened a legal can of worms that continues to menace the legal system more than three decades later.

The United States Supreme Court has reduced this confusion with regard to the express preemptive effect of the MDA preemption provision,³ but the Court has only begun to address the MDA’s implied preemptive effects.⁴ That job has largely been left to lower courts which have produced a potpourri of not entirely consistent decisions.

This article will methodically analyze those decisions and navigate through this murky jurisprudence to identify claims that are likely to survive an implied preemption challenge.

¹ See 21 U.S.C.A. § 360c et seq. (2012).

² *Id.* § 301 et seq. (2012).

³ See *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (plurality opinion).

⁴ See *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001).

The preemptive effect of the MDA is part of a larger and highly charged debate over whether federal preemption bars state-law product liability actions.⁵ Underlying this debate is the Supreme Court's recognition that there are two primary means by which federal law can preempt state law, both of which are derived from the Supremacy Clause of the United States Constitution.⁶ Express preemption of state law may occur when the federal statute in question contains an explicit preemption provision.⁷ Implied preemption may arise either when Congress intended the federal statutory scheme involved in the case to "occupy the field" on the subject in question⁸ or when the state law conflicts with federal law. This latter conflict preemption may occur either when it is impossible to comply with both the state requirement and the federal law or rule⁹ or when state law stands as an obstacle to the accomplishment of the purposes and objectives of the federal law.¹⁰ "State law" has been construed to include both state positive law enactments and state common law.¹¹ The Court has often, but not always, recognized a presumption against preemption,¹² particularly when the subject of the law in question falls within the traditional authority of the states.¹³

Medical device product liability claims raise issues of both express and implied preemption. On the express preemption front, the Supreme Court has made clear that state common-law claims known as "parallel claims" survive an express preemption analysis under the MDA's preemption provision. These claims are grounded upon a duty under state law that essentially parallels duties imposed on device manufacturers under the FDCA.¹⁴ The central question going forward is the extent to which these parallel claims may be impliedly preempted by the FDCA. These claims tend to be based in state law of misrepresentation, failure to warn, and/or manufacturing defects, all claiming that the defendant device manufacturer violated one or

more duties imposed under the MDA. To date, the only parallel claims that the Supreme Court has said are clearly impliedly preempted are claims based on fraud on the FDA in the application for marketing approval of a device.

This article examines whether parallel claims under state law in medical device cases, other than those alleging fraud on the FDA, should be impliedly preempted by the FDCA.¹⁵ Close examination of the lower court cases suggests that some parallel claims should survive implied preemption, whereas others may be barred. This article seeks to identify the types of parallel claims that are likely to survive a preemption challenge. As will be seen, plaintiffs will need to plead their claims carefully if they want to successfully navigate the narrow gap to the courthouse. And manufacturers can rest assured that they still have strong arguments for dismissal of at least some parallel claims that survive express preemption.

Preemption and the Medical Device Amendments of 1976

Pursuant to the MDA, all medical devices are classified into one of three categories. Class III devices, which are generally the most invasive, receive the greatest scrutiny by the FDA because of their use in supporting human life and their potential for unreasonable risk of injury.¹⁶ Class III devices are subject to the statutory premarketing approval ("PMA") process according to which the FDA scrutinizes data submitted by the manufacturer and makes a determination of safety and effectiveness.¹⁷ A common exception to the PMA process applies when the device in question is deemed to be the "substantial equivalent" of another device marketed prior to the enactment of the MDA.¹⁸ These so-called "section 510(k)" devices may obtain marketing approval solely upon the showing of substantial equivalency and do not undergo an FDA analysis of data to determine safety or effectiveness.¹⁹ Whether the device has been approved through the PMA process or by a showing of substantial equivalency, various additional FDA requirements apply, including Current Good

⁵ For thorough discussions of this debate, see Jean Macchiarioli Eggen, *The Mature Product Preemption Doctrine: The Unitary Standard and the Paradox of Consumer Protection*, 60 CASE W. RES. L. REV. 95 (2009); Jean Macchiarioli Eggen, *The Normalization of Product Preemption Doctrine*, 57 ALA. L. REV. 725 (2006).

⁶ U.S. CONST. art. VI, cl. 2. The Court has stated: "Congress' intent may be 'explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)).

⁷ See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 233-34 (1947).

⁸ See, e.g., *Kurns v. Railroad Friction Prods. Corp.*, 132 S. Ct. 1261 (2012) (asbestos-exposure case preempted by the federal Locomotive Inspection Act which was held to occupy the field of locomotive safety).

⁹ See *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

¹⁰ See *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

¹¹ *Riegel*, 552 U.S. at 324-25.

¹² *Compare Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) (recognizing that a presumption against preemption applies in both the express and implied preemption contexts) with *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870-71 (2000) (refusing to apply a presumption against preemption).

¹³ See *Rice*, 331 U.S. at 230 (stating that "[w]e 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.")

¹⁴ See *Lohr*, 518 U.S. at 495.

¹⁵ Throughout, this article presumes that the parallel claims discussed are not expressly preempted by the language of the MDA's express preemption provision.

¹⁶ 21 U.S.C.A. § 360c(a)(1)(C) (2012). Class I devices are non-invasive and pose a low risk of injury, as exemplified by crutches or tongue depressors. See *id.* § 360c(a)(1)(A). Class II devices pose some threat of injury. See *id.* § 360c(a)(1)(B).

¹⁷ See *id.* § 360e; *Riegel*, 552 U.S. at 318-19. The *Riegel* Court summarized the PMA process as follows: "[T]he FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness . . . [T]he FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application . . ." *Id.* at 323.

¹⁸ See 21 U.S.C.A. § 360c(i) (2012).

¹⁹ *Lohr*, 518 U.S. at 479 (noting that most devices on the market received approval through the § 510(k) process rather than the PMA process and that the § 510(k) process takes an average of 20 hours of FDA time compared to 1,200 for the PMA process).

Manufacturing Practices,²⁰ labeling requirements,²¹ and post-marketing reporting.²²

Any state-law tort claim for injuries associated with a medical device must first be examined in the context of the MDA's preemption provision, set forth in section 360k(a), which states:

[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 [the FDCA] 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 [the FDCA].²³

The Supreme Court has held that a state “requirement,” as used in the MDA's preemption provision and in any similar preemption provision of a federal statute, may include state common-law tort actions.²⁴ Thus, when faced with a preemption challenge to common-law tort claims, a court must analyze the plaintiff's claims to determine whether they are “different from or in addition to” the requirements of the MDA and whether they challenge the “safety or effectiveness” of the device.

Most common-law tort claims for injuries associated with a medical device directly challenge the safety or effectiveness of the device. Determining whether the claims are different from, or in addition to, requirements under the MDA is more difficult to ascertain, however. The Supreme Court has addressed this issue in two cases, representing medical devices that received marketing approval through two different routes. In the more recent of the two decisions, *Riegel v. Medtronic, Inc.*, the Court held that the MDA's preemption provision expressly preempted state-law tort claims arising from alleged defects in a Class III cardiac catheter that had received marketing approval through the full PMA process.²⁵ In contrast, the Supreme Court had held, in the earlier case of *Medtronic, Inc. v. Lohr*, that claims arising from alleged defects in a section 510(k) “substantially equivalent” heart pacemaker lead, were not preempted by the MDA's express preemption provision because the FDA had made no determination of safety and effectiveness, but had merely determined equivalency.²⁶ Neither case involved implied preemption.

In both cases, however, the Court acknowledged that a discrete category of claims based upon state requirements that “parallel” FDA requirements survives express preemption under the MDA's provision.²⁷ In *Lohr*, the Supreme Court observed: “Nothing in § 360k denies [the state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”²⁸ Because

any parallel claims were not based on requirements “different from or in addition to” the requirements set forth in the federal law, the express preemption provision did not bar them.²⁹ In *Riegel*, the Court reaffirmed this view.³⁰

A question left open in both cases was whether some or all parallel claims that survived express preemption analysis could nevertheless be barred by implied preemption. The Supreme Court addressed this issue in 2001 in the narrow context of claims for fraud on the FDA.

Implied Preemption Under *Buckman v. Plaintiffs' Legal Committee*

Neither the FDCA nor the MDA provides a private right of action for noncompliance with provisions of the Act, leaving parties to rely on the common law for a remedy. Because noncompliance—i.e., parallel—claims typically do not rely on requirements that are “different from or in addition to” the requirements imposed under the Act, the preemption provision does not apply.³¹ But that is not necessarily the end of the analysis. In *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court demonstrated that at least some medical device claims that survive express preemption could still be barred by an implied preemption analysis.³²

The claims at issue in *Buckman* alleged that a manufacturer of orthopedic bone screws had committed fraud on the FDA in the application for marketing approval of its device.³³ The device had received section 510(k) marketing approval as “substantially equivalent” to a device on the market at the time of the effective date of the MDA.³⁴ The plaintiffs, relying on state common-law fraud doctrine, claimed that the manufac-

²⁹ *Id.* at 496-97. The Court stated: “The presence of a damages remedy does not amount to the additional or different ‘requirement’ that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.” *Id.* at 495.

³⁰ *Riegel*, 552 U.S. at 330.

³¹ This is not to say that courts might not have to decide as a preliminary matter whether a particular claim is in fact a parallel claim. See, e.g., *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012) (currently on petition for certiorari to the U.S. Supreme Court) (holding that the plaintiff's claim for violation of the formal provisions of the premarket approval for the device relied on state-law requirements that were different from, or in addition to, the federal requirements and were therefore expressly preempted by § 360k).

³² *Buckman*, 531 U.S. at 348. For an in-depth discussion of *Buckman*, see Jean Macchiaroli Eggen, *Shedding Light on the Preemption Doctrine in Product Liability Actions: Defining the Scope of Buckman and Sprietsma*, 6 DEL. L. REV. 143, 155-68 (2003).

³³ *Buckman*, 531 U.S. at 347.

³⁴ See 21 U.S.C.A. § 360c(i) (2012); *id.* § 360e(b)(1)(B). The manufacturer, AcroMed Corporation, with the assistance of its consulting company (Buckman Company), had initially applied for § 510(k) marketing approval of the device for use in spinal surgery. After two unsuccessful applications, the manufacturer filed separate applications for the two major components of the device, seeking § 510(k) approval for use in the long bones of the arms and legs, and the device received approval. *Buckman*, 531 U.S. at 346. Health care practitioners used the device for insertion in the pedicles of patients' spines, an “off-label” use allowed as “an accepted and necessary corollary of the FDA's mission to regulate in this area without di-

²⁰ See 21 C.F.R. Part 820 (2012).

²¹ See *id.* § 801.109.

²² See 21 U.S.C.A. § 360i (2012).

²³ *Id.* § 360k(a).

²⁴ *Riegel*, 552 U.S. at 324-25.

²⁵ See *id.* at 330.

²⁶ *Lohr*, 518 U.S. at 495. The claims addressed in *Lohr* included negligent design, manufacturing, and sale; strict liability for design defect and/or manufacturing defect; and failure to warn. *Id.* at 481.

²⁷ See *Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495 (referring to parallel claims as “identity of requirements” claims and holding them not expressly preempted).

²⁸ *Lohr*, 518 U.S. at 495.

turer had fraudulently provided misleading information in its application to the FDA for the purpose of obtaining marketing approval, resulting in their injuries from an off-label use of the device.³⁵ The Court, treating these claims as parallel claims, held that the claims were impliedly preempted because they conflicted with the federal scheme set forth in the FDCA for policing fraud on the agency.³⁶ The Court began by stating that because the plaintiffs' fraud-on-the-FDA claims were not within a field traditionally left to the states, the claims were not entitled to a presumption against preemption.³⁷ Rather, the Court reasoned, the relationship between the FDA and the manufacturer in this case was uniquely federal because it "originates from, is governed by, and terminates according to federal law"³⁸ Moreover, the FDCA contains a mechanism for investigating, punishing, and deterring fraud of the type claimed by the plaintiffs.³⁹

The *Buckman* Court discussed at length the "delicate balance of statutory objectives" in the FDCA, in which Congress envisioned a distinct and exclusive role for the FDA in policing fraud on the agency.⁴⁰ The balance, the Court emphasized, would be skewed by allowing state-law fraud-on-the-FDA claims. Referring specifically to section 510(k) devices, the Court said that the "process imposes upon applicants a variety of requirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies [as 'substantially equivalent']."⁴¹ In preempting the fraud-on-the-FDA claims, the Court determined that the FDA has exclusive authority to detect, punish, and deter this kind of fraud.⁴²

The *Buckman* Court did not address, directly or indirectly, parallel claims not based on fraud, but based on negligence or strict liability. Several courts have addressed this issue in the context of parallel claims, with a mixture of results.

rectly interfering with the practice of medicine." *Id.* at 350. See generally 21 U.S.C.A. § 396 (2012).

³⁵ *Buckman*, 531 U.S. at 347.

³⁶ *Id.* at 348.

³⁷ *Id.* at 347. The Court stated: "Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'" *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); cf. *United States v. Locke*, 529 U.S. 89, 108 (2000) (declining to apply a presumption against preemption in a case involving federal oil tanker statutes because of the unique federal interest in maritime commerce).

³⁸ *Buckman*, 531 U.S. at 347.

³⁹ *Id.* at 349. The Court cited the following provisions: 18 U.S.C.A. § 1001 (2012) (authorizing criminal sanctions); 21 U.S.C.A. § 332 (2012) (authorizing injunctive relief); *id.* § 333(f)(1)(A) (authorizing civil penalties); *id.* § 334(a)(2)(D) (authorizing seizure of the medical device); *id.* § 372 (granting the FDA the power to investigate fraud).

⁴⁰ *Buckman*, 531 U.S. at 348.

⁴¹ *Id.* at 348-49.

⁴² *Id.* at 349. In addition to provisions within the FDCA, the Court cited to a general federal provision for punishment of fraud on the federal government. See *id.* at 349 n.3 (citing 18 U.S.C. § 1001(a) (1994 Supp. V)).

Conflicting 'Parallel Claims' Cases

In April 2012, the Ninth Circuit Court of Appeals, in *Stengel v. Medtronic Inc.*,⁴³ became the most recent circuit to weigh in on the implied preemption issue. On July 25, 2012, the court agreed to a rehearing en banc of the case.⁴⁴ While awaiting the rehearing, however, much can still be gleaned from the panel's opinion about the preemption issues currently in play regarding parallel medical device claims. In *Stengel*, the Ninth Circuit panel relied on *Buckman* in holding that certain parallel claims based in negligence were impliedly preempted by the FDCA. A husband and wife brought claims against the manufacturer of a PMA pain pump for injuries sustained by the husband that resulted in permanent paraplegia. Many of the plaintiffs' tort claims were expressly preempted by the MDA preemption provision.⁴⁵ Among the plaintiffs' claims were several parallel claims, including a claim that Medtronic had breached a continuing post-marketing duty imposed by the MDA and its regulations to monitor its device and report any adverse health effects, resulting in the injury to the plaintiffs.⁴⁶ The Ninth Circuit panel first held that the parallel claims were not barred by the express preemption provision, stating: "To the extent Medtronic's alleged violations of FDA regulations are actionable under state law, the state obligations parallel the federal requirements, and thus are not expressly preempted."⁴⁷ The panel went on to opine that these failure-to-warn claims were, however, impliedly preempted under *Buckman*.

The panel found "no meaningful distinction" between the parallel claims alleged by the Stengels and the fraud-on-the-FDA claims held to be preempted in *Buckman* because the claims in both cases "exist solely from the violation of FDCA requirements."⁴⁸ The Stengels' allegations related directly to several FDA regulations, including the general duty of post-marketing surveillance,⁴⁹ the duty to investigate the cause of each adverse event reported,⁵⁰ and certain file-keeping requirements.⁵¹ The panel concluded that the policies underlying the *Buckman* decision applied equally to the Stengels' parallel claims, stating: "Congress has established the premarket approval process as an important balance between getting help to patients who need it as soon as possible and protecting patients who will use the newly proposed help."⁵² In its opinion, the panel interpreted *Buckman* to encompass implied preemption of parallel claims based upon breach of post-approval duties.

The Ninth Circuit panel's opinion was not inconsistent with the earlier decision of the District of Minne-

⁴³ *Stengel v. Medtronic Inc.*, 676 F.3d 1159, 1161 (9th Cir. 2012).

⁴⁴ *Stengel v. Medtronic Inc.*, No. 10-17755, 2012 BL 187443 (9th Cir. Jul. 25, 2012).

⁴⁵ *Stengel*, 676 F.3d at 1162.

⁴⁶ *Id.* at 1163.

⁴⁷ *Id.*

⁴⁸ *Id.* at 1163-64 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001)).

⁴⁹ See 21 C.F.R. § 803.50 (2012).

⁵⁰ See *id.* § 803.50(b)(3).

⁵¹ See *id.* § 820.198.

⁵² *Stengel*, 676 F.3d at 1167.

sota in *Riley v. Cordis Corp.*,⁵³ but the *Riley* court drew a clearer and finer line between claims that would be impliedly preempted and those that would not. The complaint in *Riley* was a typical “kitchen sink” complaint, with numerous claims pleaded on various tort theories.⁵⁴ Among the claims were allegations of fraudulent and negligent misrepresentation, based upon certain alleged representations of material fact that Cordis made without the approval of the FDA, thereby rendering the device “misbranded” under the FDCA.⁵⁵ The court held that the claims were impliedly preempted insofar as they relied on misrepresentations made by Cordis directly to the FDA during the PMA process,⁵⁶ regardless of whether the basis of the claim was fraud or negligence. In contrast, however, those claims based upon misrepresentations made to the public in violation of FDA requirements were not preempted because “false or misleading advertising can give rise to liability under state law even in the absence of the applicable federal law.”⁵⁷

Furthermore, the *Riley* court indicated that parallel claims other than those based on misrepresentation might survive as well. Thus, regarding *Riley*’s argument that the manufacturing defect claims were not impliedly preempted because Cordis was required to follow “good manufacturing practices” pursuant to FDA regulations, the court suggested some such claims might survive. But because the claims were not clearly pleaded, the court dismissed them without prejudice.⁵⁸

In *Hughes v. Boston Scientific Corp.*,⁵⁹ the Fifth Circuit was more skeptical of using implied preemption to bar claims that survived express preemption under the MDA. The plaintiff claimed burns and other injuries from a PMA device designed for treatment of excessive uterine bleeding. Among the allegations was a claim that Boston Scientific had manufactured and distributed the device in violation of the PMA by failing to disclose certain adverse incidents resulting, or likely to result, in serious injuries or death.⁶⁰ The plaintiff argued that Boston Scientific had used an impermissible “algorithm” to determine which adverse events should be reported, which resulted in excluding some events that the regulation required to be reported.⁶¹

⁵³ *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009).

⁵⁴ *Id.* at 780 n.5.

⁵⁵ *Id.* at 785. The cardiac stent involved in the case was a “restricted device” pursuant to 21 U.S.C.A. § 360j(e) (2012). A restricted device will be deemed to be misbranded “if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations” promulgated pursuant to § 360j(e). *Id.* § 352(q).

⁵⁶ *Riley*, 625 F. Supp. 2d at 785-86.

⁵⁷ *Id.* at 785.

⁵⁸ *See id.* at 789. The court responded to the plaintiff’s argument that his manufacturing-defect claim was not preempted because the requirements were imposed by federal law. The court stated: “*Riley* may well be right. But *Riley*’s manufacturing-defect claim is so poorly pleaded that it must be dismissed even if it is not preempted.” *Id.*

⁵⁹ *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011).

⁶⁰ *Id.* at 765-66. *See generally* 21 U.S.C. § 360i(a)(1) (2012) (authorizing regulations requiring the device manufacturer to report information that “reasonably suggests” that the device has caused or is likely to cause death or serious injury); 21 C.F.R. § 803.50(a) (2012) (imposing reporting requirements).

⁶¹ *Hughes*, 631 F.3d at 766.

The Fifth Circuit held that those claims that could be characterized as parallel claims were not preempted, either expressly or impliedly.⁶² The parallel claims fell into two categories. The court characterized the first type as claims for negligent failure to warn of the hazards of the device “to the extent that this claim is predicated on Boston Scientific’s failure to report ‘serious injuries’ and ‘malfunctions’ of the device as required by the applicable FDA regulations.”⁶³ In contrast to the Ninth Circuit panel, the Fifth Circuit distinguished these claims from the fraud-on-the-FDA claim asserted in *Buckman*, stating that the latter was “a freestanding federal cause of action.”⁶⁴ In *Hughes*, however, the negligent failure to warn claim was grounded in Mississippi state tort law. The second type of parallel claim alleged in *Hughes* was for defective manufacture of the device in violation of the MDA’s manufacturing regulations. The court relied on its earlier decision in *Gomez v. St. Jude Med. Daig. Div., Inc.*, in which it had held that claims for negligent manufacturing based upon violations of the FDA’s specifications survived implied preemption.⁶⁵ The Fifth Circuit held that *Riegel* supported allowing both categories of parallel claims “because states may impose an additional ‘damages remedy for claims premised on violation of FDA regulations.’”⁶⁶

The Seventh Circuit Court of Appeals reached a similar result as the Fifth Circuit on defective manufacturing claims. In *Bausch v. Stryker Corp.*,⁶⁷ the plaintiff alleged that Stryker marketed a defective hip replacement system in violation of federal law, resulting in injury. Shortly after the device was implanted in the plaintiff, the FDA notified Stryker that the hip system failed to comply with federal regulatory standards because a component part was deemed “‘adulterated due to manufacturing methods.’”⁶⁸ As a result, the plaintiff was forced to undergo further major surgery to remove and replace the device and suffered other injuries.⁶⁹ Accordingly, the plaintiffs alleged claims in strict liability and negligence for product defect and, among other theories, based their claims upon violations of regulatory manufacturing standards.⁷⁰ The Seventh Circuit held that the parallel manufacturing defect claims were not impliedly preempted. The court emphasized that at least some of the plaintiffs’ manufacturing defect claims for violation of FDA regulations were founded on recognized state tort-law duties that implicated traditional state interests.⁷¹ The court rejected Stryker’s argument that the duty not to market an “adulterated” device was purely a federal regulatory duty finding no counterpart in state tort law. Rather, the court stated: “While there may not be a ‘traditional state tort law’ claim for an ‘adulterated’ product in so many words, the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dan-

⁶² *Id.* at 769.

⁶³ *Id.*

⁶⁴ *Id.* at 775.

⁶⁵ *See Gomez v. St. Jude Daig. Div., Inc.*, 442 F.3d 919, 933 (5th Cir. 2006).

⁶⁶ *Hughes*, 631 F.3d at 775 (quoting *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008)).

⁶⁷ *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), cert. denied, 132 S. Ct. 498 (2011).

⁶⁸ *Id.* at 559 (quoting the FDA’s letter to Stryker).

⁶⁹ *Id.* at 549.

⁷⁰ *Id.* at 559.

⁷¹ *Id.* at 557.

gers with their products by complying with federal law.”⁷² Furthermore, the court held that *Buckman* was not controlling because the claims were not based upon fraud on the federal agency.⁷³

Navigating the ‘Narrow Gap’: Should Any Parallel Claims Survive Preemption?

The Fifth Circuit read *Lohr*, *Riegel*, and *Buckman* to imply that all parallel claims, other than those narrowly asserting fraud on the FDA, survive both express and implied preemption. Other courts, including the Ninth Circuit panel, however, interpreted *Buckman* to bar a much broader range of parallel claims. Eventually, the Supreme Court may be faced with a sufficiently clear conflict among the circuits to warrant a grant of certiorari. The rehearing en banc of *Stengel* could go a long way toward determining whether such a conflict exists. For the present, it is useful to examine the implications of the decisions as the lower courts continue to address the difficult implied preemption issues presented by parallel claims.

Supreme Court precedent on parallel claims and implied preemption is found in a single case—*Buckman*. Both *Lohr* and *Riegel* had addressed parallel claims purely in the context of express preemption, finding that such claims would not be barred by the MDA’s preemption provision. *Buckman* dealt exclusively with fraud-on-the-FDA claims, however. To what extent does *Buckman* bar other categories of parallel claims? The *Buckman* Court indicated that at least some parallel device claims would survive implied preemption. Noting that the *Lohr* Court “did not squarely address the question of implied pre-emption,” the Court nevertheless indicated that the *Lohr* parallel claims were distinguishable from those asserted in *Buckman*: “[I]t is clear that the [*Lohr*] claims arose from the manufacturer’s alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. . . . In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements.”⁷⁴ The full implications of this statement will continue to challenge the courts.

The most reasonable interpretation of the FDCA and the MDA, as seen through the prism of the Supreme Court decisions, is that some parallel claims do survive implied preemption, creating what the *Riley* court referred to as the “narrow gap” through which medical device claims must fit to avoid express and implied preemption.⁷⁵ To survive preemption, the *Riley* court said, “[t]he plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).”⁷⁶ The *Riley* court’s articulation of this “narrow gap” is a sensible in-

terpretation of congressional intent and Supreme Court precedent. But application of this rule in practice is trickier.

Section 337(a) of the FDCA states: “[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.”⁷⁷ The section seems to exist primarily to make clear that the FDCA creates no private right of action under the Act for harmful products that violate the provisions of the Act.⁷⁸ In section 360k of the MDA—the preemption provision—Congress has barred some state requirements, including some state common-law claims. But nothing in the MDA specifically, or the FDCA generally, suggests that Congress intended to bar all state claims. Yet, for some claims that survive express preemption under section 360k, such as the claims in *Buckman*, principles of implied conflict preemption could nevertheless create a barrier to suit because state tort judgments would conflict with the enforcement role of the FDA.⁷⁹

Reading section 337(a) and *Buckman* together, it is not unreasonable to conclude that the enforcement of a violation of at least some requirements to disclose information directly to the FDA—whether fraudulent or negligent—would be within the exclusive authority of the federal agency. As the *Riley* court stated, parallel state-law claims for misrepresentation or nondisclosure to the FDA fall within the rule of *Buckman* because “the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist.”⁸⁰

Several policy justifications favor extending implied preemption to any misrepresentation or nondisclosure claims in the process of an application for marketing approval. First, the *Buckman* Court recognized the need to provide incentives for manufacturers to apply for marketing approval for beneficial medical devices. Second, the Court stated that the specter of “50 States’ tort regimes” would burden manufacturers seeking marketing approval for devices with reasonable off-label uses.⁸¹ Applicants should not be given reason “to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court.”⁸² Third, devices that have been granted marketing approval on the basis of false or incomplete information are likely to do identical damage in the health care setting, whether the information was imparted fraudulently or negligently. Fourth, drawing a line between fraud/intent and negligence is

⁷² 21 U.S.C.A. § 337(a) (2012).

⁷³ See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788 (3d Cir. 1999). The remainder of § 337 addresses situations in which a State may bring an enforcement action.

⁷⁴ *Buckman*, 531 U.S. at 349. The Court stated: “[W]ere plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case.” *Id.* at 353.

⁷⁵ *Riley*, 625 F. Supp. 2d at 777 (citing *Buckman*, 531 U.S. 341, 352-53 (2001)). The court went on to say that some parallel claims will survive preemption—those that are “premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.” *Id.*

⁷⁶ *Buckman*, 531 U.S. at 350.

⁷⁷ *Id.* at 351.

⁷² *Id.* The court bolstered its decision with a same-evidence analysis, in which it concluded that evidence of violation of the federal regulations would be the same evidence necessary to prove breach of the duty under state law. *Id.*

⁷³ *Id.*

⁷⁴ *Buckman*, 531 U.S. at 352-53.

⁷⁵ *Riley*, 625 F. Supp. 2d at 777 (cited favorably in *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)).

⁷⁶ *Riley*, 625 F. Supp. 2d at 777.

often too difficult.⁸³ Moreover, allowing such claims based on negligence or strict liability, but not based on fraud or intent, would encourage plaintiffs to artfully plead their misrepresentation or nondisclosure claims as failure to exercise due care so as to circumvent a narrow reading of *Buckman*, a clearly undesirable and unintended result.

These policies and considerations have less force outside the context of representations made to the FDA during the application process, including, for example, nondisclosures during the post-marketing phase in violation of FDA reporting requirements. It is unlikely, for example, that a manufacturer would be deterred from seeking marketing approval for its device because of the possibility of later tort liability for failing to make required material representations after the device is on the market. Similarly, misrepresentations or failure to disclose risks to the public outside the application do not implicate the policies cited in *Buckman*.

Notwithstanding these distinctions, some strong arguments exist to apply implied preemption to some of the claims outside the application process. Although post-marketing surveillance and reporting are closely aligned with state tort duties to warn about risks, these specific claims exist because of FDA requirements. As such, they invoke *Buckman*'s exhortation to avoid infringing upon the role of the FDA in enforcing the Act by creating conflicting duties under state law. How likely is such a conflict? Once the device is on the market, state tort duties and FDA post-marketing requirements tend to merge. Courts will continue to engage in the difficult task of line-drawing on one side or another of these claims.

In contrast, two types of parallel claims seem clearly to fit through the "narrow gap." The first is the category of misbranding claims addressed in *Riley*. This duty to refrain from misbranding arises from the FDA regulations, but the representations were made to the public in violation of the FDA-approved label. States have a much stronger interest in this behavior than in representations made directly to the FDA. These claims are based upon state tort duties not to deceive and to warn of risks and should be allowed to go forward to the extent that they are based upon failure to comply with the FDA requirements. As the court in *In re Medtronic, Inc., Implantable Defibrillators Litigation* explained: "States may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries."⁸⁴

The second category is parallel manufacturing claims. There is support from several of the Circuit Courts of Appeals to allow these claims. In *Hughes*, the Fifth Circuit, relying on its earlier decision in *Gomez*,⁸⁵ held that manufacturing claims that survived express

preemption were not impliedly preempted.⁸⁶ In *Bausch*, the Seventh Circuit explained:

[T]he federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.⁸⁷

Accordingly, the court held that the plaintiffs' parallel manufacturing claims survived implied preemption.⁸⁸ In *Stengel*, the Ninth Circuit panel also recognized that some parallel claims based upon manufacturing duties could survive implied preemption, at least if the claims are properly pleaded.⁸⁹

Manufacturing claims do not implicate FDA procedures in the same way as claims for fraud on the FDA. To the contrary, both specifications in a PMA application and the general requirements of good manufacturing practices leave to the manufacturer the decisions as to how its own process best meets those standards. The *Lohr* Court explained:

The generality of [the MDA's manufacturing and labeling] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question [and] reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases⁹⁰

The *Buckman* Court barred the fraud-on-the-FDA claims because the FDA's power to police fraud "achieve[s] a somewhat delicate balance of statutory objectives."⁹¹ That balance of competing considerations is absent in the manufacturing claims.

The Pleading Conundrum

The decisions clearly show that incomplete or improper pleading may lead to implied preemption even if a jurisdiction allows at least some parallel claims. Following the Supreme Court's decisions in *Bell Atlantic Corp. v. Twombly*⁹² and *Ashcroft v. Iqbal*,⁹³ attorneys recognized that a new era had dawned in pleading in the federal courts and in state courts that have adopted the Federal Rules of Civil Procedure. Taken together, these two cases clarified—and likely altered—the standard for pleading in Rule 8(a) and held that general pleading of legal conclusions or a "formulaic recitation of elements"⁹⁴ is not entitled to an assumption of truth on a motion to dismiss.⁹⁵ In general, this rule requires more factual detail to withstand dismissal than courts previously required under Rule 8(a)'s "short and plain statement" language.⁹⁶ The new requirements have

⁸³ But some courts have engaged in such line-drawing in an effort to limit the impact of *Buckman*. See *Brown v. DePuy Spine, Inc.*, Nos. BRCV2006-00208, BRCV2006-00209, BRCV2006-00211, BRCV2006-00630, 2007 BL 240313 (Mass. Super. Ct. Apr. 09, 2007), at *24-25 ("A state claim alleging negligence based on failure to disclose known risks to the FDA and, thereafter, to patients is not impliedly preempted because liability does not exist solely by proof of a violation of FDA disclosure requirements.")

⁸⁴ *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899-900 (D. Minn. 2006).

⁸⁵ See *Gomez*, 442 F.3d at 933.

⁸⁶ *Hughes*, 631 F.3d at 775.

⁸⁷ *Bausch*, 630 F.3d at 557.

⁸⁸ *Id.* at 558.

⁸⁹ *Stengel*, 676 F.3d at 1165.

⁹⁰ *Lohr*, 518 U.S. at 501.

⁹¹ *Buckman*, 531 U.S. at 348.

⁹² *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

⁹³ *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

⁹⁴ *Twombly*, 550 U.S. at 555.

⁹⁵ *Iqbal*, 556 U.S. at 680.

⁹⁶ Fed. R. Civ. P. 8(a)(2) provides: "A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief"

seemed especially onerous for plaintiffs in products liability lawsuits, who may not have access to proprietary information or who have been injured by products that may be technologically or mechanically complex. These plaintiffs have typically relied on the discovery process to determine the precise nature of the product defects that may have caused their injuries.

The impact of this burden could be seen in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*.⁹⁷ The Eighth Circuit affirmed the district court's dismissal of the manufacturing defect claims because the plaintiffs "simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA's PMA approval of this Class III device."⁹⁸ The court also held that the district court had not abused its discretion in refusing to allow a "belated" request for discovery to determine the nature of any violation.⁹⁹ In *Bausch*, the Seventh Circuit was more sympathetic to the plaintiff's predicament, however. The court held that the plaintiff had sufficiently pleaded her claims from the information available to her, which did not include confidential information contained in the PMA application.¹⁰⁰ Moreover, the court reversed the district court's refusal to allow the plaintiff to file an amended complaint, citing the liberal standard for amendment in Rule 15(a)(2) of the Federal Rules.¹⁰¹

It is clear from these conflicting cases that courts have different opinions as to how strictly the rule of *Twombly* and *Iqbal* should be applied in cases that involve highly technical or confidential information. This issue has featured prominently in some preemption decisions, and its potential impact on the applicability of preemption cannot be underestimated.

The Narrow Gap: What to Expect From Courts

In *Buckman*, the U.S. Supreme Court said that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'" and refused to apply a presumption against preemption.¹⁰² Matters related to public health and safety, however, have been traditionally governed by state law, except insofar as federal interests are so strong that federal law supplants a narrow area of state law.¹⁰³ This distinction frames the central question in medical device parallel-claims preemption. Going forward, there are several important issues related to parallel claims that the courts must address, including:

■ **What is the scope of implied preemption under *Buckman*?** The Supreme Court's persistence in singling out parallel claims as a special category unaffected by the MDA's preemption provision and, at least in some circumstances, surviving implied preemption, suggests

⁹⁷ *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010).

⁹⁸ *Id.* at 1207.

⁹⁹ *Id.*

¹⁰⁰ *Bausch*, 630 F.3d at 561.

¹⁰¹ *Id.* at 562.

¹⁰² *Buckman*, 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

¹⁰³ See *Boyle v. United Technologies*, 487 U.S. 500, 511 (1988) (displacing state law with government contractor defense because of unique federal concerns).

that the most expansive view of implied preemption is incorrect and that at least some parallel claims should be allowed. Otherwise, all state tort-law claims based on medical devices would be preempted, and the Court's distinction would be illusory and meaningless.¹⁰⁴

■ **Did Congress envision a substantial role for the tort system in remedying injuries from medical devices?** In its preemption decisions, the Supreme Court has often acknowledged the role of tort litigation in achieving the balance of health and safety objectives between federal and state law. In *Geier v. American Honda Motor Co.*,¹⁰⁵ the Court stated that "occasional nonuniformity is a small price to pay for a system in which juries not only create, but also enforce, safety standards, while simultaneously providing necessary compensation to victims. That policy by itself disfavors pre-emption, at least some of the time."¹⁰⁶ In the context of medical devices, the limited resources of the FDA to conduct post-market surveillance¹⁰⁷ make tort law an important vehicle for deterrence in order to encourage public safety. In an economic climate of tight agency resources, many courts would be reluctant to completely eliminate state-law tort actions as a means of achieving the necessary goals of safety and effectiveness of medical devices.

■ **Will the pleading strictures of *Twombly* and *Iqbal* result in potentially valid parallel claims being preempted?** Courts should honor the spirit of pleading rules and freely allow amendment of the complaint and sufficient discovery to obtain information necessary to plead parallel claims. Rule 15(a)(2) of the Federal Rules, for example, explicitly states that when leave of court is required for amendment, "[t]he court should freely give leave when justice so requires."¹⁰⁸ If additional information, unavailable to the plaintiff without discovery, would enable clarification of the claims, then allowing amendment following at least some discovery—and delaying a motion to dismiss until after that time—would not undermine the *Twombly/Iqbal* rule. Rather, it would assure that the pleading rules are applied properly.

Conclusion

Since the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, plaintiffs have had a perception that "par-

¹⁰⁴ Cf. Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841 (2008) (going a step further and proposing that injured persons be allowed to bring state tort actions based on fraud against the FDA as a complement to agency action in the interest of optimal safety).

¹⁰⁵ *Geier*, 529 U.S. at 886 (holding state tort actions impliedly preempted).

¹⁰⁶ *Id.* at 871.

¹⁰⁷ In 2006, a report commissioned by the FDA concluded that the agency lacked sufficient institutional resources for appropriate post-market surveillance of prescription drugs. U.S. Gov't Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-Making and Oversight Process* 24-29 (2006), <http://www.gao.gov/new.items/d06402.pdf>. A report of the Institutes of Medicine (IOM) of the National Academies of Science concluded more generally that the FDA "lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future." *Inst. of Med. of the Nat'l. Acads., The Future of Drug Safety: Promoting and Protecting the Health of the Public* 193 (Alma Baciu et al. eds., 2006).

¹⁰⁸ Fed. R. Civ P. 15(a)(2).

allel claims” in medical device cases survive a preemption challenge. While parallel claims survive an express preemption challenge based upon the preemption provision contained in section 360k(a) of the MDA, it is clear that only some types of parallel claims will survive

the harsher hand of implied conflict preemption. The “narrow gap” for allowable claims may be getting narrower, as some courts have recently suggested. Courts should exercise caution before narrowing the gap to choke off all common-law remedies.