2013

The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars

J. David Prince
Mitchell Hamline School of Law, david.prince@mitchellhamline.edu

Follow this and additional works at: http://open.mitchellhamline.edu/wmlr

Recommended Citation
Available at: http://open.mitchellhamline.edu/wmlr/vol39/iss4/2
THE PUZZLE OF PARALLEL CLAIMS, PREEMPTION, 
AND PLEADING THE PARTICULARS

J. David Prince†

I. INTRODUCTION............................................................................. 1034
II. THE PREEMPTION DOCTRINE..................................................... 1037
III. THE FDA APPROVAL PROCESS FOR MEDICAL DEVICES........ 1038
IV. EXPRESS PREEMPTION UNDER THE MDA—LOHR AND 
   RIEGEL.................................................................................. 1042
V. IMPLIED PREEMPTION UNDER THE FDCA—BUCKMAN......... 1048
VI. THE “NARROW GAP” ............................................................... 1050
VII. WHAT IS A “PARALLEL” CLAIM? ............................................ 1050
VIII. WHAT IS A FEDERAL “REQUIREMENT”? ............................... 1051
IX. GENERAL OR DEVICE-SPECIFIC REQUIREMENT? ............... 1054
X. VIOLATION OF FEDERAL REQUIREMENT? ............................. 1066
XI. STATE-LAW DUTY SAME AS DUTY IMPOSED UNDER 
    FEDERAL LAW? ..................................................................... 1066
XII. APPLY “SAME ELEMENTS” TEST? ......................................... 1068
XIII. THE SCOPE OF EXPRESS PREEMPTION................................. 1070
XIV. WHICH PARALLEL CLAIMS ARE IMPLIEDLY PREEMPTED? ...... 1071
XV. THE SCOPE OF IMPLIED PREEMPTION .................................. 1079
XVI. PLAINTIFFS’ PLEADING PROBLEMS ..................................... 1081
XVII. CONCLUSION ....................................................................... 1084

I. INTRODUCTION

In March 2005, Marlyn Riley suffered a heart attack resulting from a blood clot that had formed at the site of a stent, a small mesh tube surgically implanted in one of his coronary arteries to open the artery and improve blood flow.1 The stent was manufactured by Cordis, a subsidiary of Johnson & Johnson, and had been approved for use by the Food and Drug Administration (FDA) after a comprehensive and rigorous review for safety and

† Professor of Law, William Mitchell College of Law.
efficacy by that agency that led to approval for marketing the device on April 24, 2003, about a week before it was implanted in Mr. Riley. Riley sued Cordis for the injuries that he had suffered as a result of the heart attack. The complaint, filed in federal district court in Minnesota, alleged “just about every conceivable legal theory,” including allegations of negligence and negligence per se, strict liability for design defect and for failure to warn, breach of express and implied warranties, negligent misrepresentation, and fraud. The defendants moved for judgment on the pleadings, arguing that Riley’s claims were preempted by provisions of the federal Food, Drug, and Cosmetics Act (FDCA), including the 1976 Medical Device Amendments (MDA) to that act. Riley argued in response that his state law claims were not preempted because they merely paralleled federal law and would not impose requirements on the defendants that were different from or in addition to those imposed by federal law. The court dismissed all claims, finding them to be either expressly or impliedly preempted, or not pled with sufficient specificity so that the court could determine whether they were preempted.

In its analysis, the Riley court referred to the U.S. Supreme Court’s preemption decision in Riegel v. Medtronic, Inc., which explained that in order to escape the express preemption clause, added at 21 U.S.C 360k(a) by the MDA, a state-law claim must be premised on the breach of a duty that is the same as the duty imposed under the FDCA or one of its implementing regulations. “Put differently,” the Riley court said, “the conduct that is alleged to give the plaintiff a right to recover under state law must be conduct that is forbidden by the FDCA.”

However, that is not the end of the inquiry. Even if a claim escapes express preemption, it may be impliedly preempted in light of Buckman Co. v. Plaintiffs’ Legal Committee, a case in which the

2. Id. at 773–75.
3. Id. at 780 n.5. The court described the complaint as “the quintessential ‘kitchen-sink’ complaint, in which he has thrown just about every conceivable legal theory up against the wall—sometimes over and over again—in the hope that something will stick.” Id. The court concluded that the complaint “manage[d] to be both prolix and uninformative.” Id. at 787.
4. Id. at 773.
5. Id. at 781.
6. Id. at 773.
8. Id. at 330.
Supreme Court held that a private litigant cannot sue a defendant for violating the FDCA because enforcement of that act is exclusively the province of the FDA. Nor can a private litigant bring a state-law claim when the substance of that claim is for violating the FDCA—“that is, when the state claim would not exist if the FDCA did not exist.”

In conclusion, the Riley court said that Riegel and Buckman create a narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption. The 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). For a state-law claim to survive, then, the claim must be 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.

Not surprisingly, plaintiffs’ lawyers have seized on the concept of an un-preempted “parallel” state-law claim in order to avoid the preemptive effects of Riegel, generating a considerable amount of case law addressing the question: What is a parallel claim? By eliminating plaintiffs’ ability to challenge most product design and warning decisions made by the manufacturers of PMA devices, Riegel has encouraged more suits focusing on whether manufacturers violated FDA regulations, failed to follow the manufacturing processes approved by the FDA, withheld data on safety and effectiveness in order to secure premarket approval, or withheld data in violation of post-approval reporting requirements. And in light of Buckman, plaintiffs must also ask, which of these parallel claims are preempted? The surviving claims must avoid both express and implied preemption, fitting within the “narrow gap” between the two, which was first described by the Riley court.

This article will analyze the issues raised by these cases and first attempt to extract from them the characteristics of a state-law claim that merely parallels federal law—and is thus not expressly

10. 531 U.S. 341, 349 n.4 (2001). 21 U.S.C. § 337(a) (2006) provides that “all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.”
12. Id. at 777.
13. Id.
preempted—from those state-law claims that are preempted because they impose on the defendant a requirement that is “different from, or in addition to” federal requirements. This discussion will show that an important unsettled question in the express preemption cases is the question of how specific the applicable federal law or regulation must be to amount to a “requirement.” The answer to this question determines whether the scope of express preemption under the MDA is broad or narrow. Second, the article will analyze the implied preemption cases in an attempt to identify the features of those cases in which the plaintiff is suing for a device manufacturer’s conduct that violates the FDCA, but is not suing because the conduct violates the FDCA. This part of the discussion will show that there also are conflicting views about the scope—whether broad or narrow—of the implied preemptive effect of the federal law. Those conflicting views are reflected in the courts’ answers to the question of whether a state-law claim is impliedly preempted only when it amounts to a fraud-on-the-FDA claim, or more broadly whenever it is a private action that, in effect, enforces a violation of an FDA requirement.

Finally, the article will explore the struggle faced in many instances at the pleading stage by plaintiffs attempting to craft their complaint so as to avoid dismissal on the pleadings.

II. THE PREEMPTION DOCTRINE

The doctrine of preemption derives from the Supremacy Clause of the United States Constitution, which provides that the laws of the United States “shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” Thus, “state law that conflicts with federal law is ‘without effect.’” Congress may preempt state law in three ways: “State action may be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative

14. Id. at 775 (citing 21 U.S.C. § 360k(a)(1)).
15. Id.
16. See id. at 777.
18. U.S. CONST. art. VI, cl. 2.
field, or by implication because of a conflict with a congressional enactment."  

For preemption purposes, “state law” includes not only statutes, regulations, and executive pronouncements, but also common law.  

State regulation can be as effectively exerted through an award of damages as through some form of preventive relief.  

State-law causes of action must give way when such claims encroach on the objectives that Congress has addressed directly or indirectly through federal statutes or administrative regulations. Thus, “[c]entral to determining questions of preemption is divining Congress’ intent.”  

In the last two decades the United States Supreme Court has created a complex body of law surrounding preemption, beginning in 1992 with *Cipollone v. Liggett Group, Inc.*, which established preemption as a major defense in the field of product liability litigation.  Three of the Court’s most influential exercises in preemption analysis, *Medtronic, Inc. v. Lohr*, *Buckman Co. v. Plaintiffs’ Legal Committee*, and *Riegel v. Medtronic, Inc.* arose in the context of product liability claims involving medical devices.  

## III. The FDA Approval Process for Medical Devices  

Understanding and applying these Supreme Court decisions, as well as the wealth of lower court decisions interpreting them, requires an understanding of both the complex regulatory scheme created by the Medical Device Amendments of 1976 to the
Federal Food, Drug, and Cosmetics Act, the statute under which the FDA regulates prescription drugs and medical devices, and the enforcement provisions of the FDCA. The statute has both express and implied preemptive effects on state-law-based causes of action.

The approval process for medical devices differs significantly depending upon a device’s classification under the law. The MDA divides medical devices into three categories, each with separate regulations relating to approval. Class I medical devices pose no unreasonable risk of illness or injury and are subject to only minimal regulation by “general controls.” Class II devices, which are more complex and pose greater potential health risks than Class I devices, are subject to more extensive “special controls.” The most extensive regulation involves Class III devices, which present “a potential unreasonable risk of illness or injury” or are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.” Because of their potential risks, Class III medical devices are subject to an involved premarket approval (PMA) process within the FDA before they may be marketed. The PMA process requires the applicant to demonstrate “a ‘reasonable assurance’ that the device is both ‘safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.’”

During the PMA process, manufacturers must present the FDA with full reports of all studies that have been published or should reasonably be known to the manufacturer; a full description of the device’s components, ingredients, and properties, and principles of operation; a full description of the methods and facilities for

31.  Id. § 360c(a)(1)(A).  Examples of Class I devices include bed boards and tongue depressors. 21 C.F.R. §§ 880.6070, 6230. To learn the classification of a medical device and its FDA approval status, consult http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm.
manufacturing, processing, and packaging of the device; samples, 
or device components required by the FDA; and an example of the 
proposed labeling.\footnote{35. See 21 U.S.C. § 360e(c)(1).} The FDA also may refer the device to an 
outside panel of experts\footnote{36. 21 C.F.R. § 814.44(a) (2012).} and may ask the manufacturer for 
additional information before deciding whether to grant 
approval.\footnote{37. 21 U.S.C. § 360e(c)(1)(H) (Supp. 2011).} PMA of a device may be conditioned on adherence to 
various requirements.\footnote{38. Id. §§ 360c(d)(1)(B)(ii), 360j(e)(1) (2006). For example, the device 
may be restricted to use in patients who do not have certain medical conditions. Id. § 360j(e)(1).} 

However, Class III devices that fall within one of three 
recognized exceptions are exempt from the time-consuming PMA 
process.\footnote{39. PMA review is estimated to consume approximately 1200 hours of FDA 
time. Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008); Medtronic, Inc. v. Lohr, 
518 U.S. 470, 477 (1996).} One exception allows for “grandfathered” devices 
manufactured prior to MDA enactment to remain on the market.\footnote{40. 21 U.S.C. § 360e(b)(1)(A).} 
A second exception allows a manufacturer to show that its product 
is “substantially equivalent” to devices in existence in 1976 so that 
approval can be expedited through what is known as “premarket 
notification” or the “§ 510(k) process.” A substantial proportion 
of Class III device approvals are made under this expedited 
§ 510(k) review process\footnote{41. Id. § 360c(b)(1)(A); Kemp v. Medtronic, Inc., 231 F.3d 216, 221 (6th Cir. 
2000) (noting that “premarket notification” is referred to as “the § 510(k) process” 
and that this limited form of review “averages only 20 hours of review as opposed 
to some 1200 hours in the PMA process”).} that focuses not on the device’s safety and 
efficacy, but on its equivalency to an already approved device. And 
finally, a third exception is the investigational device exemption, or 
“IDE,” which applies to experimental technology and allows for 
unapproved devices to be used in research trials involving human 
subjects.\footnote{42. The majority of Class III devices submitted for FDA consideration— 
hundreds each year—are variants on products like standard pacemakers that were 
already in the market when the MDA was enacted in 1976. Only about twenty to 
fifty new PMA applications are reviewed in a typical year. Barnaby J. Feder, Medical 
Device Ruling Redraws Lines on Lawsuits, N.Y. TIMES, Feb. 22, 2008, 
example, the FDA authorized the marketing of 3,148 devices under § 510(k) and 
granted premarket approval to just 32 devices.” Riegel, 552 U.S. at 317 (citing P. 
Hutt, R. Merrill & L. Grossman, FOOD AND DRUG LAW 992 (3d ed. 2007)).} The purpose of IDE approval is “to encourage . . . the
discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.”

Approval by the FDA of a device for marketing does not end the regulatory process, however. After a device is approved, the MDA forbids any changes in the design of the device, its manufacturing processes, labeling, or any other aspect of the device that would affect safety or efficacy without first filing a supplemental PMA application and obtaining the FDA’s approval of the change. These supplemental applications are “evaluated under largely the same criteria as an initial application.”

A medical device manufacturer must also comply with post-approval reporting requirements. These requirements include the submission of reports from clinical investigations or studies involving the device of which the manufacturer knows or should know, and reports of incidents in which the device “[m]ay have caused or contributed to a death or serious injury” or has malfunctioned and “would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.” The FDA has the power to withdraw approval of the device based on newly reported information or existing data and must withdraw its approval if it determines that a device is unsafe or ineffective under the conditions in its labeling. The agency also has the authority to order a labeling change based on newly acquired information and the power to require the manufacturer to notify all affected individuals, or require repair or replacement of a device if it concludes that the device “presents an unreasonable risk of substantial harm to the public.”

“a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.” 21 C.F.R. § 812.1 (2012).

44. 21 U.S.C. § 360j(g)(1).
45. Id. § 360j(g)(2)–(3).
46. Id. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a).
47. Riegel, 552 U.S. at 319.
49. 21 C.F.R. § 814.84(b)(2).
50. Id. § 803.50(a).
51. 21 U.S.C §§ 360e(e)(1), 360h(e) (2006); Riegel, 552 U.S. at 319–20.
52. 21 U.S.C. § 360f(a)(2).
53. Id. § 360h.
All medical devices, not just Class III devices, must comply with the FDA’s current good manufacturing practices (CGMP) regulations, which set forth a quality control system and “govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.” The manufacturer must adopt procedures and controls relating to product design and manufacturing, quality assurance, and corrective or preventive action, but the CGMP requirements “leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective.”

Finally, the FDCA limits the power to enforce the act to the FDA and to the States. Section 337 of the act provides that, except for the power granted to States to sue in their own name for violations of the act, “all . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.” This provision is meant to preclude private enforcement of the act. “Congress has determined that there should be no private, federal cause of action for the violation [of the FDCA].”

IV. EXPRESS PREEMPTION UNDER THE MDA—LOHR AND RIEGEL

In addition to its many procedural requirements, the MDA also contains an express preemption provision:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for

54. Id. § 360j(f); 21 C.F.R. § 820.1–250.
55. 21 C.F.R. § 820.1(a)(1).
Because the regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

human use any requirement—
(1) which is different from, or in addition to, any
requirement applicable under this chapter 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. 59

Under the FDA’s interpretive regulations, “any requirement” by a
state includes any court decision that “is different from, or in
addition to, any requirement applicable to such device under any
provision of the Act and which relates to the safety or effectiveness
of the device.” 60 However, such “[s]tate or local requirements are
preempted only when the [FDA] has established specific
counterpart regulations or there are other specific requirements
applicable to a particular device.” 61

The United States Supreme Court first addressed whether the
MDA preempts certain common law products liability claims in
Medtronic, Inc. v. Lohr. 62 The plaintiff in the case, Lora Lohr, was
“dependent on pacemaker technology for the proper functioning
of her heart.” 63 She required emergency heart surgery when her
pacemaker failed, allegedly as the result of a defective lead, the part
of the device that “transmits the heartbeat-steadying electrical
signal from the ‘pulse generator’ to the heart itself.” 64 The
pacemaker lead was manufactured by Medtronic. 65 It was a Class III
device approved by the FDA under section 510(k) of the MDA after
having been found “substantially equivalent to devices introduced
into interstate commerce” prior to the effective date of the Act. 66
In its approval letter to the manufacturer, the agency emphasized
that its “determination should not be construed as an endorsement
of the pacemaker lead’s safety.” 67 Lohr and her husband filed suit
in a Florida state court against Medtronic, which removed the case
to federal district court and filed a motion for summary judgment,

60. 21 C.F.R. § 808.1(b).
61. Id. § 808.1(d). These interpretive regulations reflect the U.S. Supreme
Court’s decision in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) discussed infra
in notes 72–86 and accompanying text.
63. Id. at 480.
64. Id. at 480–81.
65. Id. at 480.
66. Id.
67. Id.
arguing that Lohr’s claims for negligence and strict liability were preempted under § 360k(a) of the MDA.68

In its decision, the Court in Lohr held that claims arising from alleged defects in a pacemaker lead, a Class III device that had been approved under the section 510(k) notification process as “substantially equivalent” to an already-approved device, were not preempted by the MDA’s express preemption provision because the FDA had not reviewed the device for safety and effectiveness but only had determined that it satisfied the law’s equivalency standard.69 State law regulating the device’s safety did not, therefore, conflict with any FDA safety determinations. However, the Court also said that even if there were FDA-established safety standards applying to a device, “[n]othing 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.”70 The Lohr court’s conclusion that a “parallel” claim is not expressly preempted was confirmed more than a decade later in Riegel v. Medtronic, Inc.71

In 1996, Charles Riegel underwent an angioplasty to dilate his coronary artery.72 During an angioplasty, a balloon catheter is used by a physician to open patients’ clogged arteries, essentially by inserting the catheter into the clogged artery, inflating it like a balloon, and then deflating and removing the catheter.73 During Riegel’s procedure, his doctor inserted an Evergreen Balloon Catheter, manufactured by Medtronic, into Riegel’s artery and inflated the device several times, up to a pressure of ten atmospheres.74 On the final inflation, the catheter burst, and Riegel began to rapidly deteriorate.75 He developed a complete heart block, lost consciousness, was intubated and placed on advanced life support, and was rushed to the operating room for

68. Id. at 481.
69. Id. at 495.
70. Id.
72. Id. at 320.
73. Id.
74. The warning label stated that the Evergreen catheter was contraindicated for use in patients with coronary artery disease like Riegel’s and also warned that it should not be inflated beyond its rated burst pressure of eight atmospheres. Despite these label warnings, Riegel’s doctor chose to use this device in this way. Id.
75. Id.
emergency coronary bypass surgery. Riegel survived, but suffered severe injuries and permanent disabilities. The FDA had approved Medtronic’s PMA for the Evergreen Balloon Catheter in 1994 and had subsequently approved Medtronic’s PMA supplements, which requested approval for revised labeling for the device.

Riegel and his wife sued Medtronic, alleging that the catheter was designed, labeled, and manufactured in a manner that violated state common law and that these defects caused Riegel’s injuries. The complaint raised a number of state common law claims that were dismissed by the federal district court, which held that the claims were preempted under the MDA, a result affirmed on appeal by the Second Circuit.

On appeal, the U.S. Supreme Court concluded that the MDA preemption clause does bar common-law tort claims challenging the safety or effectiveness of a PMA-approved medical device, such as the balloon catheter involved in Riegel, that has undergone the full-blown “rigorous” FDA premarket approval process. “Generalized common law theories of liability . . . are precisely the types of claims the MDA sought to preempt.” The court affirmed the view taken in earlier preemption cases that conflicting state law “requirements” may take the form of common-law duties, explaining that common-law liability is premised on the existence of a legal duty—a state-law obligation—and that a tort judgment for damages can be “a potent method of governing conduct and controlling policy.” However, the court also said that state law requirements are preempted only if they are “different from, or in addition to” federal requirements, affirming Lohr on this point. Such claims are not preempted if the state-imposed duties merely

---

76. Id.
77. Id.
78. Id.
79. Id.
80. Id. at 320–21.
81. Id. at 317–18, 323 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996)).
83. Riegel, 552 U.S. at 324 (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521 (1992)).
84. Id. at 312 (citing 21 U.S.C. § 360k(a)(1)); see also Wolicki-Gables v. Arrow Int’l, Inc., 634 F.3d 1296, 1300 (11th Cir. 2011).
“‘parallel,’ rather than add to, federal requirements.” Therefore, in order to determine whether a particular claim is preempted, a court must “look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit asserting those causes of action would have and determine whether they threaten the federal PMA process requirements.”

Typical design defect and failure to warn claims, whether brought as strict liability or negligence claims, essentially challenge the design or warning choice made by the manufacturer. But PMA approval of a Class III device includes specific FDA examination and approval of a device’s design and accompanying label warnings. Therefore, a state-law-based determination that a device was defectively designed or was not accompanied by an adequate warning would be in direct conflict with the FDA’s prior determination to the contrary. For example, in Clark v. Medtronic, Inc., the plaintiff, who had received an implantable cardiac defibrillator (ICD) to treat a heart arrhythmia, experienced “inappropriate shocks” from the device and eventually had it replaced with a different ICD. He brought several state-law claims including claims for negligent design and negligently failing to warn of the shock risk. The federal district court ruled that all of his claims were preempted. Clark relied on the doctrine of res ipsa loquitur for the proposition that, if the manufacturer had fully complied with FDA requirements, he would not have experienced problems with the device and that, therefore, the device must not have been manufactured in accordance with the FDA’s premarket approval requirements. But the court pointed out that an ICD is a complex device that “can fail for a variety of reasons, including medical complications, body rejection phenomena, allergic reaction, and surgical techniques, all of which occur without someone acting in a negligent manner.”

85. Riegel, 552 U.S. at 330.
88. 572 F. Supp. 2d 1090 (D. Minn. 2008).
89. Id. at 1092.
90. Id. at 1093.
91. Id. at 1095.
92. Id. at 1094–95.
93. Id. at 1094 (quoting Mozes v. Medtronic, Inc., 14 F. Supp. 2d 1124, 1129 (D. Minn. 1998)).
risks, does not guarantee that an approved device is completely safe. The FDA approved warnings about this shock risk when it approved the device and, therefore, the plaintiff’s claim, that the device did not comply with federal requirements simply because it had caused an inappropriate shock, would impose a state-law requirement in addition to the federal requirements.

Such claims also sometimes come in the guise of a claim for breach of the implied warranty of merchantability, but again, if the alleged reason that the product is unmerchantable is because of some aspect of its design or warnings, the claim directly conflicts with prior FDA approval of the adequacy of the device’s design and labeling and is thus preempted. Similarly, if a breach of express warranty claim is based on the device’s label, it, too, is preempted.

In the typical manufacturing defect case, however, the essence of the claim is that the device was not made the way it was supposed to be made according to its design. Therefore, a state-law-based determination of a manufacturing defect does not necessarily conflict with the FDA’s approval of the device’s design for the simple reason that the device was not made according to its design as required by federal law. The state and federal claims may be equivalent. For example, a claim that a device contains a manufacturing defect because it violates FDA requirements for manufacturing quality control may be an un-preempted parallel claim. The state-law requirement of a non-defective product would be the equivalent of the federal-law requirement that a device be manufactured in conformance with federal regulations designed to assure a device’s manufacturing quality.

94. Id.
95. Id. at 1095.
96. Id.
99. As discussed infra in Part IX in greater detail, an important issue in such cases, and one of the great divides among the lower federal courts’ resolution of this issue, is just how detailed the FDA’s regulatory requirements for the device must be in order to be regarded as a “requirement.” Compare Bausch v. Stryker Corp., 630 F.3d 546, 554–556 (7th Cir. 2010) (finding that the FDA’s Quality Control Regulations and CGMP are sufficiently specific to be regarded as a “requirement”), with In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig. (Sprint Fidelis Leads II), 623 F.3d 1200 (8th Cir. 2010) (finding to the contrary).
V. IMPLIED PREEMPTION UNDER THE FDCA—BUCKMAN

Even if a product defect claim against a medical device manufacturer is not expressly preempted because it parallels federal law, it may nonetheless be impliedly preempted. After Lohr, some courts concluded that state common-law fraud-on-the-FDA claims were not preempted when FDA approval of a drug or medical device was secured through the manufacturer’s material misrepresentations or omissions to the FDA during the approval process.\(^{100}\) If the FDA’s approval had been obtained by misrepresentation, then the agency’s safety determination as to the device should not be regarded as a legitimate federal requirement with which state law might conflict. The United States Supreme Court examined this issue, again addressing preemption in the context of the MDA, in Buckman v. Plaintiffs’ Legal Committee.\(^{101}\) In Buckman, plaintiffs injured by orthopedic bone screws brought suit alleging that the defendant, a regulatory consultant, had made fraudulent representations to the FDA in order to obtain approval to market the devices.\(^{102}\) The manufacturer was responsible for the design of the bone screws, but was not a defendant here.\(^{103}\) Instead, the consultant was sued for the manner in which the application for the device’s approval was presented to the FDA.\(^{104}\) As in Lohr, the device had been approved through the less rigorous § 510(k) process.\(^{105}\) But unlike the Lohr Court, the Buckman Court, without any explanation, declined to address whether the express preemption provision of § 360k applied and instead undertook an implied preemption analysis, holding that the plaintiffs’ fraud-on-the-FDA claims were preempted.\(^{106}\) The court explained that the § 510(k) process created a “comprehensive scheme” for

---

100. See, e.g., Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1374–75 (11th Cir. 1999) (holding that state fraud-on-the-FDA claims were not preempted because the FDA’s approval imposed no specific “requirement” on a device that could conflict with state law).
102. Id. at 343.
103. See Thomas O. McGarity, Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts, 41 Washburn L.J. 549, 572 (2002). The manufacturer, AcroMed, was also sued, but AcroMed was dismissed pursuant to a global settlement. Id. Fraud-on-the-FDA was the only claim against the regulatory consultant. Id.
104. Buckman, 531 U.S. at 343.
105. Id. at 346.
106. Id. at 348 n.2 (expressing “no view on whether these claims [were] subject to express pre-emption under 21 U.S.C. § 360k”).
determining whether to approve a device under the “substantially equivalent” standard. That scheme establishes exactly what a manufacturer must submit to the FDA and empowers the FDA to demand further information. Most significantly, the FDA itself is charged with policing fraud in connection with manufacturers’ submissions and has a variety of enforcement options that allow it to make “a measured response to suspected fraud.” The Court said that “[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.” Therefore, permitting the plaintiffs’ state fraud claims would conflict with the FDA’s responsibility to police fraud in accordance with its own judgment and objectives under the FDCA.

For that reason, a unanimous Court concluded that allowing state fraud-on-the-FDA claims would “exert an extraneous pull on the scheme established by Congress.” The Court explained that “[a]s a practical matter, complying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes [would] dramatically increase the burdens facing potential applicants.” Consequently, medical device manufacturers might decline to develop or submit potentially beneficial devices for FDA approval out of fear that they might be exposed to “unpredictable civil liability,” thereby defeating the federal goal of ensuring the availability of efficacious medical devices. The court concluded that state fraud-on-the-FDA claims conflict with the federal medical device regime established by Congress and are therefore preempted.

In so finding, the Supreme Court expressly distinguished fraud-on-the-FDA claims from other state tort claims for inadequate labeling, such as those the Court had previously addressed in Lohr: “[A]lthough [Lohr] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will

107. Id. at 348.
108. See id.
109. Id. at 349.
110. Id. at 349 n.4.
111. Id. at 350–51.
112. Id. at 353.
113. Id. at 350.
114. Id.
115. Id. at 348.
support a state-law claim. The critical distinction between *Lohr* and *Buckman* is the fundamental difference in the source of the cause of action. In *Lohr*, the cause of action was based in traditional state tort law and pre-existed the FDCA. In *Buckman*, on the other hand, the fraud-on-the-FDA claim was premised entirely on the federal regulatory scheme created by the FDA. This distinction may explain why the court opted to forego an express preemption analysis, which focuses on state statutory and common law “requirements,” and to rely instead upon a conflict preemption theory, which is clearly implicated when the objectives and operation of a congressional regulatory scheme are threatened.

VI. **THE “NARROW GAP”**

As indicated at the outset, a state-law-based product liability claim against a Class III medical device manufacturer faces significant hurdles to fit within the “narrow gap” so aptly described in *Riley*. The claim may be expressly preempted because it would effectively impose upon the manufacturer a requirement that is different from or in addition to the requirements imposed upon the manufacturer by the FDA under federal law. According to *Lohr* and *Riegel*, that is especially likely to be the case if the device has undergone a full PMA review in order to obtain FDA approval for marketing. And if it is not expressly preempted, it may, according to *Buckman*, nevertheless be impliedly preempted because recognition of the state-law claim would “exert an extraneous pull on the scheme established by Congress.” In order to survive dismissal, the claims must avoid both express and implied preemption. In determining whether a state-law claim is preempted, several key questions must be answered.

VII. **WHAT IS A “PARALLEL” CLAIM?**

*Riegel* makes clear that state-law-based claims are expressly preempted only if they impose requirements that are “different from, or in addition to” federal requirements, but are not preempted if the state-imposed duties merely “parallel,” rather

---

116.  Id. at 353.
117.  See id. at 347 (“Policing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied’ . . . .”.
119.  531 U.S. at 353.
This brief description of the claims that survive express preemption is sufficiently vague to have resulted in varying interpretations by courts seeking to implement the Riegel ruling. While many cases have raised the issue of whether a state-law claim merely parallels federal requirements applicable to a medical device, they are inconsistent in their outcomes and are not entirely clear about whether there is a core test for parallelism. In particular, there is a split of authority among the federal circuits as to whether the state-law claim must be parallel to a federal requirement specific to the device in question or whether it must be parallel only to a more general, industry-wide requirement.

So what makes a state-law claim “parallel” to a federal-law claim and just how “parallel” must the state and federal requirements be?

VIII. WHAT IS A FEDERAL “REQUIREMENT”?

“In order for a state requirement to be parallel to a federal requirement . . . the plaintiff must show that the requirements are ‘genuinely equivalent.’ State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.”

Thus, a state-law claim must be premised on the breach of a duty that is the same as the duty imposed under the FDCA or one of its implementing regulations.

Genuine equivalency, therefore, first requires that there be a federal requirement applicable to the device. In Walker v. Medtronic, Inc., the plaintiff sued, alleging that an implanted pain medication pump manufactured by the defendant caused the death of her husband when it infused a fatal overdose of...
medication into her husband’s system. The FDA had approved this PMA device designed with a certain flow rate and a delivery accuracy of plus or minus fifteen percent, but had not set a formal performance standard requiring that the pump always remain within that range. Indeed, warnings accompanying the device said that the pump’s flow characteristics could change over time and possibly result in a drug overdose. Walker argued that her complaint stated an un-preempted parallel claim when she alleged that the pump had failed to adhere to the plus or minus fifteen percent specification. However, the Fourth Circuit affirmed the district court’s dismissal of the claim on preemption grounds. The court explained that because the FDA had not established for the device a formal performance standard requiring that the device always remain within fifteen percent of its designed flow rate, there was no binding federal requirement that the device do so. Thus, a failure to remain within those parameters was not a violation of an FDA requirement.

Even where federal law permits a device manufacturer to act in a particular way, that permission does not impose a federal “requirement.” For example, in *McMullen v. Medtronic, Inc.*, the plaintiffs sued the manufacturer of a tremor control device implanted in the brain of a patient with Parkinson’s disease. As part of its approval of this Class III device, the FDA required Medtronic to maintain contact information for patients implanted with the device and also required specific warnings regarding “electrocautery” and “diathermy” that were provided in the manuals for physicians and patients. Electrocautery is the burning or searing of tissue caused by an electrically heated instrument. Diathermy is the localized heating of tissue for therapeutic purposes by means of passing an electric current through the tissue. After McMullen had been implanted with two of these devices in May of 2000, one on each side of his brain, he

126. *Id.* at 576.
127. *Id.* at 574.
128. *Id.* at 574–75.
129. *Id.* at 576.
130. *Id.* at 581.
131. *Id.* at 578.
132. *See id.* at 577–78.
133. 421 F.3d 482 (7th Cir. 2005).
134. *Id.* at 485.
135. *Id.* at 485 n.1.
136. *Id.*
experienced considerable improvement in his Parkinson’s symptoms. However, after a visit in March 2001 to his dentist for a treatment that possibly involved diathermy or electrocautery, he experienced a decline in the control of his Parkinson’s symptoms, which continued despite further surgeries to replace components of the implanted devices. In January 2001, in the wake of an anecdotal report of brain injury to a Parkinson’s patient after a dental treatment that involved the use of diathermy, Medtronic began an investigation that resulted in the sending of warning letters, in May 2001, to patients implanted with the device and their doctors. The letters specifically warned against diathermy treatment, saying that it “can cause tissue damage and can result in severe injury or death.”

McMullen and his wife sued, alleging that Medtronic had breached its postsale duty to warn of the risks associated with diathermy treatment. Their claim was dismissed by the district court on preemption grounds, a result affirmed on appeal by the Seventh Circuit. The key issue was whether Medtronic was required by federal law to provide an additional warning between January 2001, when Medtronic learned of the anecdotal report, and March 2001, when McMullen underwent the dental procedure and was injured.

In order to change the warnings for an approved Class III device, a manufacturer must first obtain the FDA’s approval but is permitted to temporarily amend a warning pending FDA approval of the requested change. The court concluded that because this regulation simply allowed but did not require a warning change prior to FDA approval it did not amount to a federal requirement: “Where a federal requirement permits a course of conduct and the state makes it obligatory, the state’s requirement is in addition to the federal requirement and thus is preempted.”

In Heisner v. Genzyme Corp., the plaintiff’s wife died as a result...
of an allergic reaction to a chemical in a film barrier designed to prevent postsurgical adhesions. The barrier was a Class III medical device approved pursuant to the PMA process and manufactured by the defendant. Her husband sued, claiming that the manufacturer violated a state common-law duty to update the device’s warning label upon acquiring information about the dangerous nature of the synthesized acid in the product that caused the fatal allergic reaction. But the court found that, even though the manufacturer could have temporarily updated its label while awaiting FDA approval of the change, there was no MDA requirement that the manufacturer amend its label to provide a warning of a potential allergic reaction. The court concluded that the claim was preempted because there was no federal duty “‘genuinely equivalent’ to the duty that Plaintiff claims exists under state common law.”

IX. GENERAL OR DEVICE-SPECIFIC REQUIREMENT?

The most important unresolved issue in determining whether there is a federal “requirement” applicable to a medical device is whether the FDA’s regulatory requirements must be specifically applicable to the device in question or may be a more generally applicable requirement applying to entire categories of devices or manufacturer activities.

The FDA typically requires, in the labeling of an approved medical device, specific instructions for use of the device and warnings about potential adverse events that could result from its use. For example, the FDA may require a manual to be given to patients who have had a pacemaker implanted which contains a specific warning to keep “at least 24 inches (60 centimeters) away from the heat source” of an electric induction cooktop. Or FDA requirements may be more generally applicable, such as its CGMP.

148. Id. at *1.
149. Id.
150. Id. at *3.
151. Id.
152. Id.; see also McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005) (“Where a federal requirement permits a course of conduct and the state makes it obligatory, the state’s requirement is in addition to federal requirement and thus is preempted.”).
These regulations represent an “umbrella” approach to regulation applicable to “many different types of devices” and do “not prescribe in detail how a manufacturer must produce a specific device.” 154 They provide “flexibility,” allowing “each manufacturer to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements.” 155

This issue of whether a state-law-based claim must be parallel to a device-specific, or only a more general industry-wide, FDA requirement was discussed by the U.S. Court of Appeals for the Eighth Circuit in the context of a motion to dismiss in In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation (Sprint Fidelis Leads II). 156 Plaintiffs across the country filed actions against Medtronic alleging defects in the leads (small wires) connecting an implantable cardiac defibrillator (ICD) directly to a patient’s heart muscle to carry an electrical impulse. 157 These complaints followed in the wake of a recall by Medtronic of ICDs using a lead termed by the manufacturer as a “Sprint Fidelis” lead. 158 At the time of the recall, approximately 257,000 Sprint Fidelis leads remained implanted in patients. 159 Scores of these claims were consolidated for pretrial proceedings by the Judicial Panel on Multidistrict Litigation. 160 Medtronic filed a motion to dismiss all of the claims in the master complaint, arguing preemption and citing Riegel. 161 The federal district court granted the motion. 162

On appeal, the Eighth Circuit affirmed the dismissal, 163 agreeing that the plaintiffs’ claims were preempted under Riegel and stating that “the crucial question on appeal is whether these claims are parallel claims that avoid preemption because they would not impose state requirements ‘different from or in addition to’ the federal requirements established by PMA approval of the

---

155. Id.
156. Sprint Fidelis Leads II, 623 F.3d 1200 (8th Cir. 2010).
157. Id. at 1203.
158. Id.
160. Id.
161. Id. at 1154–55.
162. Id. at 1165.
163. Sprint Fidelis Leads II, 623 F.3d at 1209.
Sprint Fidelis lead.\textsuperscript{164}

The court first determined that the failure to warn, and related claims, were preempted because “[e]ven if federal law allowed Medtronic to provide additional warnings, as [p]laintiffs alleged, any state law imposing an additional requirement is preempted” because it is a requirement in addition to the federal requirement.\textsuperscript{165} Then the court decided that the design defect claims were also preempted because “they are attacks on the risk/benefit analysis that led the FDA to approve” the device and such claims are expressly preempted.\textsuperscript{166}

The plaintiffs also alleged that the leads had a manufacturing defect because Medtronic’s manufacturing processes were not in compliance with the FDA’s CGMP found in the Quality System Regulations (QSR) applicable to all medical devices.\textsuperscript{167} The district court had concluded that these manufacturing defect claims were preempted because the CGMP provide only general objectives for quality systems applicable to all device manufacturers, and plaintiffs had failed to identify any specific federal manufacturing requirement that was violated.\textsuperscript{168} Consequently, the plaintiffs had not alleged a parallel manufacturing defect claim with the detail required by \textit{Bell Atlantic Corp. v. Twombly}\textsuperscript{169} to avoid preemption under \textit{Riegel}.

On appeal, plaintiffs argued that the district court had held them to an impossible pleading standard because the FDA’s specific manufacturing requirements applicable to this particular product were in the agency’s PMA approval files, which were not accessible without discovery.\textsuperscript{170} However, as the court of appeals explained, the plaintiffs had alleged in their pleading that “state law entitles every person who has an implanted Sprint Fidelis lead[]” to relief because all such leads have an unreasonably high

\footnotesize
\textsuperscript{164} \textit{Id.} at 1205.
\textsuperscript{165} \textit{Id.}
\textsuperscript{166} \textit{Id.} at 1206.
\textsuperscript{167} \textit{Id.} \textit{See generally }21 \textit{C.F.R. Part 820} (2012).
\textsuperscript{168} \textit{Sprint Fidelis Leads I}, 592 F. Supp. 2d 1147, 1157–58 (D. Minn. 2009) (explaining that CGMP are “too generic” and provide only “general objectives” for device manufacturers, and stating that “[i]n the absence of any specific requirement in the [CGMP] . . . holding Medtronic liable for such a [manufacturing] ‘defect’ would impose requirements ‘different from, or in addition to’ those under federal law”).
\textsuperscript{170} \textit{Sprint Fidelis Leads I}, 592 F. Supp. 2d at 1157–59.
\textsuperscript{171} \textit{Sprint Fidelis Leads II}, 625 F.3d at 1206.
risk of failure. This argument amounts to a design defect, not a manufacturing defect, claim. “Thus, as pleaded and argued, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA’s decision to approve” the device.

The court appeared to conclude that any applicable federal requirement must be specific to the device. First, it said nothing to contradict the reasoning underlying the district court’s dismissal of the complaint. That court had said that CGMP “require manufacturers to develop their own quality-system controls . . . and they are inherently flexible,” and therefore concluded that these regulations were “simply too generic” and did “not prescribe in detail how a manufacturer must produce a specific device.” In the absence of any specific requirement in the CGMP/QSR that Medtronic weld the Sprint Fidelis leads in a certain fashion, holding Medtronic liable for such a welding ‘defect’ would impose requirements ‘different from, or in addition to’ those under federal law.” Second, the appellate court said that “courts must exercise [care] in applying Riegel’s parallel claim principle at the pleading stage, particularly to manufacturing defect claims. But here, plaintiffs simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA’s PMA approval of this Class III device.”

Substantially the same result was reached in Horowitz v. Stryker Corp., in which the court found that the plaintiff failed to show that its manufacturing defect claims against the manufacturer of a hip prosthesis were based on a violation of a federal requirement. “[P]laintiff’s ‘reliance on [defendants’ violations of] CGMP[] and QSR . . . does not save these claims from preemption . . . [as such requirements] are simply too generic, standing alone, to serve as the basis for [her] manufacturing-defect claim[].” And, in Ilarraza v. Medtronic, Inc., the plaintiff’s state-law negligence per se claim against the manufacturer of an implantable pain medication pump, based on the manufacturer’s failure to manufacture the

172.  Id. at 1207.
173.  See id.
174.  Id.
175.  Sprint Fidelis Leads I, 592 F. Supp. 2d at 1157 (citation omitted).
176.  Id. at 1158.
177.  Sprint Fidelis Leads II, 625 F.3d at 1207 (emphasis added).
179.  Id. at 284 (alteration in original) (quoting Sprint Fidelis Leads I, 592 F. Supp. 2d at 1157).
pump in accordance with CGMP, was preempted because it was not based on violation of any specific federal requirement. The court concluded that the “intentionally vague and open-ended nature of the regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim.”

The intertwined questions of whether a plaintiff has established a parallel claim and whether the claim is properly pleaded were treated by the Eleventh Circuit in *Wolicki-Gables v. Arrow International, Inc.* in a fashion similar to the Eighth Circuit’s disposition of the claims in the *Sprint Fidelis Leads II* case. Wolicki-Gables alleged that she was injured by a defective pain medication pump system that had been implanted in her back to manage pain resulting from two back injuries. The federal district court dismissed her product liability and other claims after concluding that they were expressly preempted by the MDA. On appeal, the plaintiff argued that her state-law claims survived preemption because they were parallel claims.

The Eleventh Circuit said that plaintiffs must allege in their initial pleading facts that the manufacturer violated a particular federal requirement referring to the allegedly defective device and concluded by saying that “[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.” Because the plaintiff’s complaint did not set forth any specific failure to comply with any FDA regulation that could be linked to the injury, it thus failed to plead an un-preempted parallel claim.

In *Deglemann v. Advanced Medical Optics*, the Court of Appeals

181.  Id. at 588.
183.  Id. at 1297–99.
185.  Wolicki-Gables, 634 F.3d at 1300.
186.  Id. at 1301 (“Parallel claims must be specifically stated in the initial pleadings.”).
187.  Id. (“A plaintiff must allege that ‘[t]he defendant violated a particular federal specification referring to the device at issue.’”) (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).
188.  Id. (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)).
189.  Id. at 1301–02.
190.  659 F.3d 835 (9th Cir. 2011), vacated and dismissed per stipulation, 699 F.3d 1103 (9th Cir. 2012).
for the Ninth Circuit concluded that FDA guidance documents for contact lens solutions created specific federal requirements sufficient to trigger preemption of claims brought by a putative class of consumers, based on California’s Unfair Competition Law and False Advertising Law, that they would not have bought the defendant’s contact lens disinfectant if they had known that it was not as effective as other solutions. 191 The court said that “[t]he first step of our preemption analysis is deciding whether the FDA has promulgated a specific requirement that applies to contact lens solution.” 192 Then, noting that the lens solution was a Class II device that came to market under section 510(k) of the MDA, the court nevertheless concluded that the “special controls” to which the defendant’s lens solution was subject “are federal requirements that apply to the testing, manufacture, and labeling of” such solutions. 193 The FDA’s guidance document with which contact lens solution manufacturers must comply in order to be labeled a disinfecting solution requires such solutions to achieve a prescribed level of efficacy in killing five representative microorganisms. 194 The court concluded that the FDA had thus “promulgated specific requirements” for the defendant’s contact lens solution, and that the plaintiffs’ claims were expressly preempted because they would impose different requirements under the state law. 195

In all of these cases, the courts appear to insist on a federal-law requirement that is aimed quite specifically at the medical device alleged to have been the cause of the plaintiff’s harm. In Deglemann, the FDA guidance document applied in exactly the same way to all contact lens cleaning solutions, but it imposed on all such solutions a specific performance requirement. 196 Other circuits, however, have taken a more liberal view of the pleading requirements for successfully alleging a parallel state claim and avoiding summary dismissal of the complaint on preemption grounds. The Seventh Circuit in Bausch v. Stryker Corp., 197 the Sixth

191. Id. at 842.
192. Id. at 841 (emphasis added).
193. Id. at 841–42.
194. Id. (citing U.S. DEP’T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR CONTACT LENS CARE PRODUCTS 89 (1997)).
195. Id. at 842.
196. Id.
197. 630 F.3d 546 (7th Cir. 2010), cert. denied, 132 S.Ct. 498 (2011).
Circuit in Howard v. Sulzer Orthopedics, and the Fifth Circuit in Hughes v. Boston Scientific Corp. and in Bass v. Stryker Corp., have all found plaintiffs’ pleadings to state parallel claims with sufficient adequacy to avoid dismissal, even where no device-specific federal requirement existed.

In Bausch v. Stryker Corp., the Seventh Circuit was faced with the same issue decided by the Eighth Circuit in the Sprint Fidelis Leads II case. Margaret Bausch alleged that she had been injured by a hip prosthesis manufactured by the defendant that failed because it was “adulterated” and had to be replaced. The FDCA defines an “adulterated” device as one “not in conformity with applicable requirements or conditions.” Bausch alleged that the manufacturer failed to comply with federal standards established by the FDA’s CGMP. The trial court dismissed her complaint, holding that the claims were expressly preempted. On appeal, the court found the key issue to be whether

the plaintiff must allege and prove a violation of a “concrete, device-specific” federal regulation. The issue is important because manufacturers of Class III medical devices are required by federal law to comply with Quality System Regulations established by the FDA. The Quality System Regulations also set forth Current Good Manufacturing Practices.

While the Eighth Circuit held that a plaintiff must plead that a specific federal manufacturing practice applicable to defendant’s device had been violated, the Bausch court noted that the MDA expressly preempts any state-law requirement that is different from or in addition to “any [federal] requirement” applicable to the device and concluded that a plaintiff’s pleading is adequate if it

198. 382 F. App’x 436 (6th Cir. 2010).
199. 631 F.3d 762 (5th Cir. 2011).
200. 669 F.3d 501 (5th Cir. 2012).
201. Sprint Fidelis Leads II, 623 F.3d 1200 (8th Cir. 2010).
202. Bausch, 650 F.3d at 549.
204. Bausch, 650 F.3d at 556.
206. Bausch, 650 F.3d at 554.
207. Sprint Fidelis Leads II, 623 F.3d 1200, 1206 (8th Cir. 2010).
208. 630 F.3d at 555 (emphasis added).
simply alleges violation of the FDA’s CGMP and QSR. 209 “[W]e do not see a sound legal basis for defendants’ proposal to distinguish between general requirements and ‘concrete, device-specific’ requirements.” 210

The Sixth Circuit has also rejected the idea that a federal requirement exists only if there is a device-specific requirement. In Howard v. Sulzer Orthopedics, Inc., the plaintiff alleged that the defendant was negligent per se under Oklahoma law when it manufactured a knee implant that failed due to a manufacturing process that left lubricating oil residue on the implant in violation of the FDA’s CGMP. 211 The court reversed the district court’s grant to the defendant of summary judgment on preemption grounds, concluding that the CGMP are “not so vague as to be incapable of enforcement.” 212

In Hughes v. Boston Scientific Corp., 213 the Fifth Circuit considered a Mississippi state-law-based claim that the manufacturer of a medical device designed to treat excess uterine bleeding had negligently failed to warn about risks associated with the device, because Boston Scientific had failed to report earlier malfunctions of the device resulting in a “serious injury” as required by the FDA’s Medical Device Reporting (MDR) regulations. 214 The pertinent regulations define “serious injury” as “an injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.” 215 Boston Scientific had developed an “algorithm” for reporting that included the reporting of some, but not all, cases in which the device caused some kind of burn injury. 216 The manufacturer later began to report more burn injuries, allegedly in response to a request or direction from the

209. Id.
211. 382 F. App’x 436, 438 (6th Cir. 2010).
212. Id. at 440.
213. 631 F.3d 762 (5th Cir. 2011).
215. 21 C.F.R. § 803.3; see 21 U.S.C. § 360i(a)(2).
216. Under this algorithm, no first-degree and only some second-degree burn injuries were reported. Hughes, 631 F.3d at 766.
FDA. The court concluded that, for purposes of resolving the summary judgment issue, the plaintiff had stated an un-preempted parallel claim when she alleged a state-law failure to warn claim predicated on the manufacturer’s failure to report serious injuries as required by FDA regulations: “A factfinder could infer that a manufacturer’s failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device’s risks.”

And in a more recent Fifth Circuit case, Bass v. Stryker Corp., a plaintiff sued alleging that his hip replacement device, manufactured by the defendant, failed to attach properly to the bone due to manufacturing residuals on the device, requiring a second surgery. After the district court dismissed all of his claims on preemption grounds, Bass appealed, arguing that he had pled parallel state-law claims to the extent that the claims were based on manufacturing defects resulting from violations of FDA regulations. In particular, his pleadings alleged that Stryker initiated a recall of the device following an investigation in which the FDA found manufacturing residuals in excess of those permitted and that the device was therefore “adulterated” within the meaning of the relevant provision of the FDCA. The court noted that the plaintiff’s complaint “specifies with particularity what went wrong in the manufacturing process and cites the relevant FDA manufacturing standards Stryker allegedly violated.” The complaint also alleged that the FDA had determined that the device was “adulterated within the meaning of section 501(h) of the [FDCA].” The court said that

\[\text{[the key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMP]}, \text{but rather the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff’s}\]

217. See id. at 766–67.
218. Id. at 770–71.
219. 669 F.3d 501 (5th Cir. 2012).
220. Id. at 506.
221. Id. at 505–06.
222. 21 U.S.C. § 351(h) (2006); Bass, 669 F.3d at 510.
224. Id. at 511 (citation omitted).
and concluded by holding that “if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMP[] themselves and that this failure caused the injury, the plaintiff will have pleaded a parallel claim.”

A federal district court in the Fifth Circuit has taken an especially liberal view of whether there exists a federal requirement in a case in which a woman brought suit on behalf of her deceased husband who died when a critical part of his implanted heart assist pump system failed, causing the pump to fail and leading to a fatal cardiac arrest. In Bush v. Thoratec Corp., the manufacturer’s device, a Left Ventricular Assist System (LVAS), had been implanted in Mr. Bush in 2008. The LVAS is a mechanical circulatory device used to partially replace the function of a failing heart by providing assistance to that part of the heart that pumps blood into the body’s circulatory system. The device was implanted at McGuire VA Medical Center, while Bush was living in Virginia. He returned to McGuire for inspection and monitoring of his implant for a few months, until he moved to New Orleans, where he then made monthly visits to Tulane Medical Center for the same monitoring. Shortly after Bush had received the implant, the manufacturer issued a press release and sent an Urgent Medical Device Correction letter to the hospitals that installed and monitored this device. That letter indicated that the manufacturer had become aware, over time, that the lead connecting the LVAS to its external controller could fail due to wear and fatigue, warned that the damage may or may not be visible to someone inspecting the lead, identified certain signs of damage, and advised hospitals to request their patients to return for inspection of the lead. Both McGuire and Tulane received
the letter, but neither notified Bush of the risk.\textsuperscript{235} Approximately a year-and-a-half after the warning letter was sent to the hospitals, Bush’s device failed, resulting in his death.\textsuperscript{236}

In her second amended complaint, the plaintiff alleged that the defendant had violated an FDA regulation, which provides guidelines for product recall notices, and that the violation amounted to a failure to warn under state law.\textsuperscript{237}

The defendant-manufacturer argued that the federal regulation was too general to support a parallel state-law claim.\textsuperscript{238} The regulation upon which Bush based her claim characterized the guidelines in the regulation as “[g]eneral.”\textsuperscript{239} Those guidelines say that the “format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall” and describe the purposes of such recall notices “[i]n general terms.”\textsuperscript{240} The court said “[a]dmittedly” the guidelines provided by the regulation were “more general than the MDR reporting requirements allegedly violated in Hughes or the [C]GMP[] allegedly violated in Bass” (both cases in which the Fifth Circuit had rejected arguments that the relevant FDA regulations were too general), but it nevertheless denied the manufacturer’s motion to dismiss on preemption grounds.\textsuperscript{241} The court concluded that the plaintiff’s allegations were “sufficient . . . to survive a motion to dismiss.”\textsuperscript{242}

To call the regulation at issue in Bush “more general” than the one at issue in Hughes is a gross understatement. As the Hughes court explained, the “plain text” of the reporting regulations at issue in that case required the device manufacturer to report “any time” the device “‘may have caused or contributed to death or serious injury,’ or malfunctioned in a manner that ‘would be likely to cause or contribute to a death or serious injury in [sic] the malfunction were to recur.’”\textsuperscript{243} Furthermore, the court pointed out that the term “serious injury” has a definition that is “mandated by

\textsuperscript{235} Id.
\textsuperscript{236} Id.
\textsuperscript{237} Id. at *2.
\textsuperscript{238} Id. at *2.
\textsuperscript{239} 21 C.F.R. § 7.49 (2012).
\textsuperscript{240} Id.
\textsuperscript{242} Id. at *7.
statute.”

A case like *Bush* raises a particular concern about whether there is a “requirement” in any meaningful sense of the term. Before a fact finder can decide whether a federal requirement has been violated, she must understand fairly precisely what conduct is required or prohibited by federal law, and then compare those requirements or prohibitions to the manufacturer’s conduct. The federal regulation at issue in *Bush* is too general, admitting of more than one interpretation of the law’s requirements. The parameters of the federal requirement are questions of law, the answers to which will not become more clear after discovery of more facts. An allegation of a federal requirement of this level of generality should not be “sufficient for [a] Plaintiff to survive a motion to dismiss.” The result may be that a jury will eventually be left to determine the meaning, not just the application, of the law.

This split among the circuits on the critical issue of just how specific the federal requirement allegedly violated must be may ultimately draw the Supreme Court’s attention and lead to review by that Court. Some plaintiffs attempting to avoid dismissal on the pleadings, such as those in *Sprint Fidelis Leads II*, for example, have had trouble showing with sufficient specificity the existence of a federal requirement. There, the Eighth Circuit required the plaintiffs’ pleadings to show that the defendant had “violated a federal requirement specific to the FDA’s PMA approval of this Class III device.” But other courts, such as the Fifth Circuit in *Hughes*, appear to give plaintiffs considerable latitude in pleading the existence of a federal requirement. There the critical issue was whether an FDA reporting regulation that required the reporting of “serious” injuries caused by the device was, indeed, a federal requirement applicable to the defendant’s conduct. That court concluded that a factfinder “could infer” that there was a federal requirement. But the factfinder should not be left to “infer” whether there is a federal requirement applicable to the device in issue; that is, whether federal law *could be* interpreted to apply. That question should be resolved by the court as a matter of law and then leave to the factfinder the task of determining whether

244. Id.
the requirement has or has not been satisfied. It is the difference between deciding whether there is a legal requirement and whether that law has been violated.

X. VIOLATION OF FEDERAL REQUIREMENT?

Assuming that there is a federal requirement applicable to the device, genuine equivalency next requires that the plaintiff allege and prove that the device failed to comply with that federal requirement. Assume, for example, that the manufacturer of a drug-coated stent, which has been approved so as to make it a “restricted device” under the FDCA, represents that the coating on the device does not increase the inflammatory response in coronary arteries into which the stent is implanted. Also assume that this representation was not approved by the FDA nor is it part of the FDA-approved label for the device. That representation would then make the device “misbranded,” and the introduction of the device into interstate commerce would be a violation of the FDCA. Another example, provided by the court in Bass, is to “suppose a manufacturer had represented to the FDA in its pre-approval documentation that each hip implant component would be sterilized for ten minutes at 800 degrees.” Proof that the manufacturer instead sterilized the component at only 200 degrees for five minutes would then demonstrate the manufacturer’s violation of “what it told the FDA.”

On the other hand, an allegation that a device manufacturer was negligent because its implantable pain medication pump should have been labeled with warnings different from what the FDA required does not allege a violation of a federal requirement because the manufacturer cannot change the label without the FDA’s approval.

XI. STATE-LAW DUTY SAME AS DUTY IMPOSED UNDER FEDERAL LAW?

Genuine equivalency also requires the plaintiff to show that the same conduct that violates the FDA requirement gives rise to a state-law cause of action that predates the federal requirement such

249. Id. §§ 331, 352(q)(1).
251. Id. at 513.
252. See Stengel v. Medtronic, Inc., 676 F.3d 1159, 1162 (9th Cir. 2012).
as negligence, strict liability, misrepresentation, or breach of warranty. For example, the same conduct that makes the drug-coated stent misbranded under the FDCA could also give rise to an intentional or negligent misrepresentation claim under state common law or a state statute-based claim for false or misleading advertising.

The part of the *Lohr* court’s opinion discussing parallel state-law claims fell under the heading in the court’s opinion titled “Identity of Requirements Claims.” And, as the *Riley* court subsequently explained, in order for a state-law claim to be parallel and escape express preemption, it “must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA.” The question then becomes: How is it determined whether the requirements of the state and federal-law claims are identical to or the “same as” one another?

In *Bausch v. Stryker Corp.*, the plaintiff alleged that the defendant manufacturers marketed a hip prosthesis that was implanted in her body after the FDA had informed the defendants that a component of the device was “adulterated,” and that the implant failed, requiring surgical replacement of the device leading to a number of injuries. The court first noted that under Illinois law, “violation of a statute or ordinance designed to protect human life or property [i]s prima facie evidence of negligence, though the violation may not always be conclusive on the issue of negligence.” Then, the court found that a manufacturer’s failure to comply with the FDA’s general CGMP regulations would make the device “adulterated” under federal law. Finally, the court concluded that the state-law negligence claim was parallel to the claim of a federal-law violation and thus not expressly preempted, saying that

> [w]hile 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

256. 630 F.3d 546, 548 (7th Cir. 2010).
257. *Id.* at 553.
258. *Id.* at 555.
259. *See id.* at 552 (“[W]here state law is parallel to federal law, section 360k does not preempt the claim.”).
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.260

In Hughes v. Boston Scientific Corp., the court, discussing the plaintiff’s allegation that the defendant violated a state-law duty to warn “by failing to accurately report serious injuries and malfunctions of [its] device as required by the FDA’s . . . regulations,” could prove that allegation because “[a] factfinder could infer that a manufacturer’s failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device’s risks.”261

XII. APPLY “SAME ELEMENTS” TEST?

The Bausch court clearly, and the Hughes court not as clearly, both suggest that the test for determining whether state- and federal-law claims are parallel is analogous to the Blockburger “same elements” test used by the U.S. Supreme Court to determine when two offenses are the “same” for double jeopardy purposes.262 Using this test would require a comparison of the state statute or common law cause of action with the federal statute or regulation. When the elements are compared, if the state-law based-claim requires proof of an element different from those required to prove the federal-law-based claim, then the state-law claim is not parallel. An example of this test in application may be found in City of Baton Rouge v. Ross,263 a case in which a criminal defendant charged with violating a municipal ordinance that prohibited “drug traffic loitering” filed a motion to quash, alleging that the ordinance was expressly preempted by a Louisiana statute providing that no political subdivision of the state “shall enact an ordinance defining as an offense conduct that is defined and punishable as a felony under state law.”264 Importantly for purposes of this discussion of

260. Id. at 557.
261. 631 F.3d 762, 770–71 (5th Cir. 2011) (emphasis added).
262. See, e.g., United States v. Dixon, 509 U.S. 688 (1993); Blockburger v. United States, 284 U.S. 299 (1932). The Fifth Amendment to the U.S. Constitution provides that no person shall “be subject for the same offense to be twice put in jeopardy.” U.S. CONST. amend. V.
263. 654 So. 2d 1311 (La. 1995).
264. LA. REV. STAT. ANN. § 14:143(A) (1995), quoted in Ross, 654 So. 2d at
constitutional preemption principles, the Louisiana Supreme Court first observed that in this case “the State’s interest is one of constitutional import, since the Louisiana Constitution of 1974 expressly accords to the legislature, and not to local governments, the exclusive right to define felonies and to the district attorneys the exclusive right to prosecute them.”

“More particularly, the Louisiana Constitution expressly provides that ‘[n]o local governmental subdivision shall . . . define and provide for the punishment of a felony.’”

When a municipality defines as a misdemeanor an offense that the legislature has designated a felony, and places a defendant in “jeopardy” for committing that offense so that the State cannot later retry the defendant, the municipality effectively prevents the State from inflicting upon the defendant the punishment the Legislature has decided is appropriate for the severity of that defendant’s conduct.

The court then applied the “same elements” test to answer the preemption question, saying that “it provides a straightforward method of determining whether, on its face, a municipal ordinance constitutes the ‘same offense’ as a state felony statute” and concluded that the local ordinance was expressly preempted by the state statute.

But a state-law claim may still be parallel even if it requires proof of additional elements beyond those required to prove a violation of federal law, or if the state-law claim would impose different remedies for the violation than those imposed by federal law. For example, it may be necessary as a matter of state law to prove that violations of the FDCA amount to negligent conduct in order to demonstrate all of the elements of the state-law cause of action. But in Medtronic, Inc. v. Lohr, the court explained that additional elements required to demonstrate a state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a
narrower requirement might be “different from” the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule.  

Furthermore, the state- and federal-law remedies for the defendant’s violation need not be the same. The *Lohr* court concluded that the express preemption provision of the MDA does not deny a state “the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.” Thus, for example, while the remedy for a federal-law violation may be an administrative penalty or some kind of equitable relief, the remedy for the state-law violation for the same conduct may be the imposition of a damages remedy, and the state-law claim will still be considered to be parallel to the federal-law claim. This view of the meaning of a parallel claim was subsequently affirmed in *Riegel* when the court concluded that “§ 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.”

**XIII. THE SCOPE OF EXPRESS PREEMPTION**

In sum, if the state-law-based claim does not parallel a claim for violation of the federal requirements, it is expressly preempted by the MDA. To determine whether a state law claim is preempted because it is different from or in addition to federal law or simply parallels federal law, one must (1) look at the defendant’s conduct that gives rise to the plaintiff’s right to recover under state law, and (2) determine whether that conduct is prohibited by the FDCA. If it is not, the claim is expressly preempted by § 360k(a). The courts differ in their views of the precise scope of express preemption, some holding the view that federal law is broadly preemptive because surviving state-law claims must parallel narrow device-
specific federal requirements, while others maintain that state-law claims need only parallel broader generally-applicable federal requirements to remain un-preempted. This scope-of-express-preemption question will ultimately have to be resolved by the Supreme Court.

However, even if not expressly preempted, the state-law claim may be impliedly preempted under *Buckman*. It is to that question that we now turn.

**XIV. WHICH PARALLEL CLAIMS ARE IMPLIEDLY PREEMPTED?**

As noted earlier, the *Buckman* court drew a distinction between the claim for fraud against the federal agency and the state-law causes of action raised in *Lohr*, including the claim for failure to warn of pacemaker lead failures despite knowledge of earlier failures, noting that *Lohr* “can be read to allow certain state-law causes of action that parallel federal safety requirements.”

In *Lohr*, the plaintiffs’ claims were based upon traditional state-law tort theories of negligence and strict liability. But in *Buckman*, by way of contrast, the plaintiffs were bringing a claim based upon, and that existed solely because of, the FDCA. That distinction was important to the outcome in which the court rejected the plaintiffs’ argument that “any violation of the FDCA will support a state-law claim.” It is thus clear that some state-law claims based on an FDCA violation are impliedly preempted but also clear that some FDCA violations will support an un-preempted parallel state-law claim. The court did not consider whether parallel state-law claims not based on fraud, but based on negligence or strict liability, or some other theory of liability, might also be impliedly preempted. Therefore the scope of *Buckman* is far from clear, and the court has not subsequently made clear which state-law claims involving federal-law violations interfere with the FDA’s regulatory and enforcement authority, and are therefore impliedly preempted, and which are not.

After *Buckman*, some commentators suggested that the Supreme Court’s implied preemption analysis could be extended beyond fraud-on-the-FDA claims to preclude other common law

---

claims. Several courts have indeed read *Buckman* broadly to mean that any private action that incorporates a violation of an FDA regulation is impliedly preempted.

An early example of an expansive interpretation of *Buckman* is *Flynn v. American Home Products Corp.*, a case in which the Minnesota Court of Appeals applied *Buckman* to hold that a plaintiff’s common-law-fraud and consumer-fraud claims, based on fraud-on-the-FDA, were “preempted by federal law and are not actionable in Minnesota.” The plaintiff, who had taken a generic version of the prescription diet drug combination known as “fen-phen,” sued the manufacturer of a brand-name version of one of the drug’s components, fenfluramine. Although the plaintiff had never consumed the defendant’s product, she alleged that the defendant violated FDA requirements by failing to report information regarding known adverse health events associated with the drug and instead misrepresented to the FDA that the drug was safe. As a result, she claimed, physicians began prescribing the drug as part of the fen-phen combination, and her doctor, without knowing the risks, prescribed her the generic fen-phen version.

The court dismissed her common-law and consumer-fraud claims on preemption grounds, noting that, as in *Buckman*, the FDA had the authority to police the regulatory violations that formed the bases of the plaintiff’s claims. Not only would the existence of state-law-misrepresentation and consumer-fraud claims conflict with the FDA’s authority to consistently police such violations within its regulatory powers, but also, “50 state-law causes of action for violation of the FDA’s detailed regulations would increase the burdens placed on applicants for FDA approval.”

---

277. See, e.g., Rebecca Porter, *Supreme Court Rules that Suit for Fraud on Federal Agency Is Preempted*, TRIAL, Apr. 2001, at 17, 82 (“[Buckman] ‘could leave consumers out in the cold without any remedy.’”) (quoting Jeffrey White, Associate General Counsel for the Association of Trial Lawyers of America); Raymond M. Williams & Anita Jain, *Preemption of State “Fraud-on-the-FDA” Claims*, FOR DEF., June 2001, at 23–25, 50 (“[The] FDA’s regulatory scheme is arguably just as endangered when liability is imposed due to a state law failure to warn or design defect claim as it is when liability is imposed for a fraud-on-the-FDA claim.”).


279. Id. at 345.

280. Id.

281. Id.

282. Id. at 349.

283. Id. (citing Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 350 (2001)).
More recently, in *Lewkut v. Stryker Corp.*, the plaintiff alleged that his hip implant was defective and sued the manufacturer claiming relief under Texas law for negligence, strict liability, and that state’s Deceptive Trade Practices Act. According to the complaint, manufacturing residues coating part of the implant prevented it from being securely held into the hip socket. To the extent that these state-law claims paralleled federal requirements prohibiting “adulterated devices,” the federal district court ruled that they were implicitly preempted because such federal violations “are to be enforced through the United States government only.”

Similarly, in *Wheeler v. DePuy Spine, Inc.*, the court concluded that a plaintiff’s claim that it was negligent under Florida law for the manufacturer of an artificial spinal disc to not accurately disclose to the FDA the number of complications associated with the implant’s use of which the manufacturer was aware, appeared to be an impliedly preempted claim for noncompliance with MDA provisions: “The FDCA ‘leaves no doubt’ that it is the Federal Government and not private litigants who are authorized to sue for noncompliance with the medical device provisions.” And in *Riley v. Cordis*, the plaintiff was implanted with a stent manufactured by the defendant. After he later suffered a heart attack, due to a blood clot that had formed at the site of his stent, he brought numerous claims against the stent manufacturer including a claim that Cordis was promoting the off-label use of the stent in a manner not authorized by the FDCA. The court ruled that such a claim was impliedly preempted. It is not private parties but “the FDA [that] is charged with the difficult task of regulating the marketing . . . of medical devices.”

Plaintiffs suing device manufacturers for injuries allegedly caused by a device commonly assert a negligence per se count in their pleadings, arguing that a violation of federal regulations demonstrates negligence under state common law. They argue that the negligence per se claim thus does not impose any

---

285.  *Id.* at 651.
286.  *Id.* at 659.
287.  *Id.*
289.  *Id.* at 1269 n.4.
291.  *Id.* at 783.
292.  *Id.* at 778.
requirement on a device manufacturer that is different from or in addition to federal requirements. Nevertheless, some courts have found these claims to be impliedly preempted.\textsuperscript{293} For example, in \textit{McClelland v. Medtronic, Inc.}, a decedent’s estate sued for the decedent’s death, arguing that it was caused by a defective pulse generator, a critical part of a pacemaker manufactured by the defendant.\textsuperscript{294} The plaintiff sued in Florida state court, alleging negligence per se as part of its complaint.\textsuperscript{295} Medtronic removed the case to federal court and argued that the negligence per se claim should be dismissed because Florida law does not recognize a cause of action for violations of the FDCA or its implementing regulations.\textsuperscript{296} The court agreed, saying that “under Florida law, the violation of a statute can only give rise to civil liability if the statute indicates an intention to create a private cause of action.”\textsuperscript{297} Noting that “[t]he FDCA expressly provides that all actions to enforce the Act ‘shall be by and in the name of the United States,’” the court concluded that “[t]his language evidences legislative intent to prohibit a private right of action for a violation of the FDCA. Therefore, Plaintiff cannot assert a negligence per se claim based on violations of the FDCA or the FDA’s implementing regulations.”\textsuperscript{298} In other words, the court concluded that the negligence per se count of the plaintiff’s complaint should be dismissed for failure to state a claim under state law, and the reason that it failed to state a claim was that the FDCA does not indicate an intention to create a private cause of action. Indeed, to the contrary, that statute indicates Congress’s intent that enforcement of those FDA regulations is the exclusive province of the FDA.

But while some courts have found the scope of \textit{Buckman} preemption to be quite broad, others have limited its holding solely

\begin{thebibliography}{99}
\bibitem{293} But several courts have ruled that such claims are not preempted. \textit{See infra}, text accompanying notes 317–335.
\bibitem{295} \textit{Id.}
\bibitem{296} \textit{Id.} at *2, *4.
\bibitem{297} \textit{Id.} at *5 (citing Murthy v. N. Sinha Corp., 644 So. 2d 983, 985–86 (Fla. 1994)).
\bibitem{298} \textit{Id.} But many states have held that a state-law negligence per se claim can be based on violation of FDA regulations. \textit{See, e.g.}, Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919, 932–33 (5th Cir. 2006); Stanton v. Astra Pharm. Prods., Inc., 718 F.2d 553, 563–64 (3d Cir. 1983); Ezagui v. Dow Chem. Corp., 598 F.2d 727, 735 (2d Cir. 1979); Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455, 461 (4th Cir. 1960); Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 876 (E.D. Wis. 1999).
\end{thebibliography}
to fraud-on-the-FDA claims.

In *Stengel v. Medtronic, Inc.*, a panel of the Ninth Circuit ruled that certain parallel state-law claims of negligence were impliedly preempted. The plaintiff in this case alleged that he was rendered paraplegic as a result of an inflammation that had developed in his spine at the site of a catheter that was part of an implanted pain medication pump manufactured by Medtronic. In a proposed amended complaint, Stengel alleged that under federal law and regulation Medtronic “was under a continuing duty to monitor the product after premarket approval and to discover and report to the FDA any complaints about the product’s performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.” The court noted that, to whatever extent the alleged violations of FDA regulations are actionable under state law, they “parallel the federal requirements, and thus are not expressly preempted.” But, the court explained, the Stengels’ theory that survived express preemption was that if Medtronic had acted with reasonable care in complying with the regulations that required it to provide information to the FDA, the agency would have required the manufacturer to warn physicians about the risk, and Stengel could have avoided the injury caused by the pump. In effect, the plaintiffs were alleging that “the defendant . . . misinformed the FDA tacitly by failing to report information that it had a duty to report.” Relying on *Buckman*, the court ruled that this claim was impliedly preempted. “There is no meaningful distinction between the Stengels’ failure-to-warn claims and the fraud-on-the-FDA claims held to be preempted in *Buckman*. This conclusion is consistent with that of the Eighth Circuit in *Sprint Fidelis Leads II*, in which the court described plaintiff’s allegations that “Medtronic failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations”
as “simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in Buckman.”

However, after granting a rehearing en banc, the full court reversed the panel decision and concluded that this “continuing duty to monitor . . . and report to the FDA” claim was not impliedly preempted. Describing the plaintiffs’ proposed new state-law claim in their amended complaint as “specifically . . . a failure to warn the FDA,” the court concluded that “[i]t is a state-law claim that is independent of the FDA’s pre-market approval process that was at issue in Buckman.” and thus not impliedly preempted.

In reaching its conclusion that the state-law claim is “independent of” federal requirements for the device, the court reviewed Buckman and said that the plaintiffs’ claims there were “wholly federal”; that they “alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA.” But this is obviously not literally correct. The Buckman plaintiffs did allege state-law claims, alleging that the defendant had committed fraud when it made certain statements to the FDA in the course of obtaining approval for the device at issue in that case. If no state-law claims had been alleged in Buckman, the preemption issue upon which the outcome in the case turned would not have arisen. In describing the preempted state-law claims in Buckman as “wholly federal,” perhaps the Stengel court meant that the alleged wrongdoing in that case arose entirely out of the defendant’s dealings with the FDA. Similarly, the Stengels’ failure-to-warn claim arose entirely out of Medtronic’s dealings with, or failure to deal with by reporting to, the FDA. The court’s explanation thus fails to distinguish the Stengels’ claims from the preempted claims in Buckman. However, even if the court’s reasoning in Stengel is obscure, the result clearly stands for the proposition that state-law claims are not impliedly preempted unless they are specifically a

308.  Sprint Fidelis Leads II, 623 F.3d 1200, 1205–06 (8th Cir. 2010).
309.  Stengel v. Medtronic Inc., 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc).
310.  Id. at 1233.
311.  Id.
312.  Id. at 1230.
313.  Id. at 1230.
315.  See 531 U.S. 341 at 347–48 (“Here, petitioner’s dealings with the FDA were prompted by the MDA, and the very subject matter of petitioner’s statements were dictated by that statute’s provisions.”).
fraud-on-the-FDA claim, a result and reasoning very much in line with that of the Fifth Circuit in *Hughes v. Boston Scientific Corp.*\(^{316}\)

In *Globetti v. Sandoz Pharmaceutical Corp.*, a prescription drug case, a federal district court rejected the defendant’s argument that the plaintiff’s claims all involved communications with the FDA and, therefore, were preempted under *Buckman*.\(^{317}\) The court concluded that *Buckman* was limited to fraud-on-the-FDA claims alleging “that the federal agency was itself the victim of the fraud” and did not preclude common law claims for misrepresentation and failure to warn.\(^{318}\) As the court explained, “[a]lthough *Buckman* precludes a plaintiff from seeking damages because the defendant lied to the FDA, it is something completely different to contend that plaintiff is precluded from seeking damages for injuries due to lies to her.”\(^{319}\) Those alleged injuries arose from duties owed to the plaintiff, not the FDA, which existed separate and apart from the requirements of the MDA.\(^{320}\) Thus, the court concluded, the plaintiff could not recover simply because the defendant may have made misrepresentations to the FDA, but she could recover for misrepresentations directed to her or her physician.\(^{321}\)

Just as in the Ninth Circuit’s opinion in *Stengel*,\(^{322}\) the Seventh Circuit in *Bausch* and the Fifth Circuit in *Hughes* have interpreted the preemptive effect of *Buckman* to be limited strictly to fraud-on-the-FDA claims, and have found plaintiffs’ state-law claims to be traditional tort claims that are “not analogous”\(^{323}\) to a claim of fraud on the agency such as those in *Buckman* and, thus, not impliedly preempted.

In *Bausch*, the plaintiff alleged that the injury-causing device was “adulterated” under federal law and that this violation of federal law was prima facie evidence of negligence.\(^{324}\) “Illinois
treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence, though the violation may not always be conclusive on the issue of negligence. But the court rejected the defendant’s assertion that such a claim was impliedly preempted because it was effectively an effort to enforce federal law, saying that

[w]hile 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 [state-law] 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.

In Hughes v. Boston Scientific Corp., the plaintiff sued the manufacturer of a medical device intended for the treatment of excess uterine bleeding, alleging, inter alia, that the manufacturer was negligent per se for violating the FDA safety reporting regulations applicable to the device. Explaining that “[n]egligence per se is a legal theory that assists a party to prove that his adversary was negligent,” the court concluded that the plaintiff was “not foreclosed by § 360k from arguing . . . that the doctrine of negligence per se is available to assist her in proving her claim.” The court rejected the notion that the plaintiff’s claim was an attempt to exercise the enforcement authority granted exclusively to the FDA and was therefore impliedly preempted.

The court said that the negligence claim was “not analogous” to Buckman’s fraud-on-the-FDA theory.

The plaintiffs in Buckman were attempting to assert a freestanding federal cause of action based on violation of the FDA’s regulations; the plaintiffs did not assert violation of a state tort duty. In contrast, Hughes is

325. Id. at 553.
326. Id. at 557.
327. 631 F.3d 762 (5th Cir. 2011). The court relied in part on its pre-Riegel decision, Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919, 933 (5th Cir. 2006), in which it held that negligent manufacturing claims based on violations of FDA requirements were not impliedly preempted.
328. Id. at 765.
329. Id. at 771.
330. Id. at 775–76.
331. Id. at 775.
asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of [a] product, a claim that can be proven by showing a violation of the federal regulations.\textsuperscript{332}

Some courts thus find the scope of implied preemption to be limited to situations strongly analogous to that which gave rise to \textit{Buckman} itself, that is, claims that are “wholly federal”\textsuperscript{333} or “a freestanding federal cause of action.”\textsuperscript{334} But as long as some “traditional state tort law”\textsuperscript{335} claim is alleged, even if the conduct that would allow the plaintiff to prevail under that state-law claim amounts to fraud-on-the-FDA, that is sufficient to avoid dismissal of the claim. However, other courts have interpreted the \textit{Buckman} holding more expansively to include preemption of state-law claims that, at bottom, “would not exist if the FDCA did not exist”\textsuperscript{336} such as a negligence per se claim in which the allegedly negligent conduct is conduct that violates a requirement established by federal law.

\textbf{XV. THE SCOPE OF IMPLIED PREEMPTION}

To the extent that parallel state-law claims incorporate the same elements as must be shown to demonstrate a violation of federal law, they either are effectively negligence per se claims or strongly analogous to a negligence per se claim. Negligence per se is a doctrine that allows for the incorporation of a statutory or regulatory requirement as the standard of conduct for non-negligent behavior.\textsuperscript{337} But use of this doctrine does not convert a state-law cause of action for negligence into a private federal-law cause of action.\textsuperscript{338} On the other hand, a federal statute may

\textsuperscript{332} \textit{Id.}
\textsuperscript{333} \textit{See supra} note 315 and accompanying text.
\textsuperscript{334} \textit{See supra} note 332 and accompanying text.
\textsuperscript{335} Bausch v. Stryker, 630 F.3d 546, 557 (7th Cir. 2010).
\textsuperscript{336} Riley v. Cordis, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).
\textsuperscript{337} \textit{See} David G. Owen, \textit{Proving Negligence in Modern Products Liability Litigation}, 36 \textit{Ariz. St. L.J.} 1003, 1005–06 (2004) (“In such situations, a court borrows the specific standard of conduct set forth in the statute, deferring to the legislative determination of proper behavior, in substitution for the general definition of due care.”).
\textsuperscript{338} \textit{See} Lowe v. Gen. Motors Corp., 624 F.2d 1373, 1379 (5th Cir. 1980) (“The mere fact that the law which evidences negligence is Federal while the negligence action itself is brought under State common law does not mean that the state law claim metamorphoses into a private right of action under Federal regulatory
expressly or impliedly provide a private right of action—that is, a right enforceable by private parties that is created by federal law. Whether a federal-law cause of action exists by implication is determined by looking at congressional intent. Negligence per se and implied cause of action are, therefore, different doctrines, and this difference suggests a useful analytical basis for distinguishing between those parallel state-law claims that are impliedly preempted and those that are not.

One can certainly argue, from the exclusive-federal-enforcement language of the FDCA itself and from the Supreme Court’s analysis in Buckman, that the only state-law claims impliedly preempted are those that amount to a claim of an implied federal cause of action to enforce a federal requirement arising from the FDCA. However, Buckman is far from clear and some of the policy arguments favoring preemption of the plaintiffs’ claims in that case are equally applicable to some state-law claims that preexisted the FDCA but have some of the same effects on the FDA’s enforcement discretion and resources. For example, a plaintiff might allege that it is negligence per se under state law to fail to report to the FDA certain information about the safety of a medical device after it has been approved for use. The success of the plaintiff’s state-law claim relies on demonstrating that the defendant has violated FDA reporting requirements and may result in the imposition of money damages if the negligence per se claim succeeds. Yet the FDA may simultaneously choose not to pursue the device manufacturer for those same reporting violations based on a judgment that the violations resulted from the manufacturer’s mistaken-in-good-faith interpretations of the requirements, or that it would be inconsistent with past agency applications or enforcement of the regulations, or that it would be inappropriate to impose civil

339. See, for example, 42 U.S.C. § 7604 (2006), the citizen suit provision of the Clean Air Act, providing that “any person may commence a civil action in his own behalf” against any person, including governmental entities, for violations of the act.


341. 21 U.S.C. § 337(a) (2006); see Merrell Dow Pharm., Inc., v. Thompson, 478 U.S. 804, 817 (1986) (“Congress has determined that there should be no private, federal cause of action for the violation [of the FDCA].”).

342. See, for example, Hughes v. Boston Scientific Corp., 631 F.3d 762, 764 (5th Cir. 2011), in which the court found such a claim not to be impliedly preempted.
penalties or other sanctions for the violation. Allowing the state-law claim to proceed could skew the FDA’s efforts “to achieve a somewhat delicate balance of statutory objectives” and interfere with the flexibility granted by federal law to the agency that “is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives”—two of the concerns that led the Buckman court to conclude that the claims brought by plaintiffs in that case sufficiently conflicted with federal objectives so that they were impliedly preempted.\(^{343}\)

The Supreme Court will ultimately have to attempt to more clearly resolve the scope of Buckman implied preemption.

**XVI. Plaintiffs’ Pleading Problems**

Plaintiffs’ success in these suits has depended in large part on two factors. The first is whether they have been able to gain access to documents or other information regarding the premarket approval process and subsequent data before a dismissal on preemption grounds cuts off any further discovery. And the second is whether their pleading of a parallel state claim is made with sufficient specificity to satisfy the enhanced pleading requirements engendered by *Bell Atlantic Corp. v. Twombly*\(^{344}\) and *Ashcroft v. Iqbal*.\(^{345}\) The adequacy-of-pleading issue arises typically when the defendant files a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6)\(^{346}\) for failure to state a claim. In federal courts, this rule must be interpreted in conjunction with Federal Rule of Civil Procedure 8(a)(2) which sets out the requirements for pleading a claim for relief and calls for “a short and plain statement of the claim showing that the pleader is entitled to relief.”\(^{347}\) To avoid dismissal, the plaintiff must plead specific facts, not mere conclusory allegations, that are sufficient to “‘nudge[] [his] claims’ . . . ‘across the line from conceivable to plausible.’”\(^{348}\) This means pleading “enough facts to state a claim to relief that is plausible on its face” and “raise a right to relief above the

---

346. Or an equivalent state rule of procedure.
347. FED. R. CIV. P. 8(a)(2).
It appears that these pleading requirements may have had some, though not a dramatic, impact on the outcomes of medical device litigation. These factors are related, of course, because the level of specificity possible at the pleading stage turns in no small part on the amount of discovery that has been available up to the time that the court rules on the defendant’s motion to dismiss on preemption grounds.

One problem in these cases for plaintiffs is trying to plead their claims in a way that avoids preemption and dismissal on the pleadings for that reason. The cases show that it is very typical for the plaintiff to already have amended their original complaint by the time the court addresses the preemption issue raised by the defense. Amendment or further amendment is not always allowed, especially if the court thinks that even the amended pleadings would still allege preempted claims so that amendment would be futile. Even when plaintiffs have had the opportunity to

349. *Twombly*, 550 U.S. at 555 (citations omitted). In *Ashcroft v. Iqbal*, the Supreme Court rejected an argument that its earlier decision in *Twombly* should be limited to pleadings made in the context of an antitrust dispute, such as that which gave rise to *Twombly*: “This argument is not supported by *Twombly* and is incompatible with the Federal Rules of Civil Procedure. Though *Twombly* determined the sufficiency of a complaint sounding in antitrust, the decision was based on our interpretation and application of Rule 8. That Rule in turn governs the pleading standard ‘in all civil actions and proceedings in the United States district courts.’” *Iqbal*, 556 U.S. at 684 (citations omitted).


351. If the claim pleaded is preempted, it would ordinarily be dismissed because it fails to state a claim upon which relief can be granted. See, e.g., Fed. R. Civ. P. 12(b)(6).


353. See, e.g., Gross v. Stryker Corp., 858 F. Supp. 2d 466, 505 (W.D. Pa. 2012) (“In this Court’s estimation, leave to amend is not required because any amendment of Plaintiff’s Complaint would be futile. Plaintiff’s strict liability claims against [Defendant] are not viable under Pennsylvania law. He has not set forth any facts supporting a breach of express warranty claim. Finally, his
amend their pleadings, that is sometimes not enough to save the case from dismissal.\footnote{354}

Another problem for plaintiffs arises when their allegations are challenged as lacking the specificity necessary to avoid dismissal under the enhanced pleading requirements of \textit{Twombly} and \textit{Iqbal}. A plaintiff may try to avoid dismissal by arguing that he does not have enough information to be any more specific and needs discovery to develop that information.\footnote{355} The courts vary in their

remaining claims are expressly preempted, do not meet the narrow exception of parallel claims, or are conceded. For these reasons, the Court declines to grant Plaintiff the opportunity to amend.

\begin{quote}
Reeves v. Pharmajet, Inc., 846 F. Supp. 2d 791, 798–99 (N.D. Ohio 2012) (“Moreover, the Court finds that granting a motion to amend the Complaint would be futile in this instance because the essence of Plaintiff’s current claim is an alleged violation of the FDCA for which there is no private cause of action. Moreover, the new potential claims suggested by Plaintiff involving negligent misrepresentation or fraud would fail for the same reason and there is also the problem that Plaintiff did not and cannot allege that [Defendant] made any misrepresentations to the Plaintiff, thus preventing the establishment of either potential new claim.”). \textit{But see} Leonard v. Medtronic, Inc., No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *12 (N.D. Ga. Aug. 19, 2011) (“Plaintiffs make several new factual allegations in their response related to Leonard’s injuries and death which are not in the original complaint. These allegations relate to plaintiffs’ ability to state a valid claim for relief and to the timeliness issue. Further, the complaint was filed several months before the Eleventh Circuit’s decision in Wolicki-Gahles, which set the parameters for a valid parallel claim under \textit{Riegell}. In the interests of justice, the Court will grant plaintiffs leave to amend their complaint.”).\footnote{355}

\end{quote}

\footnote{354}{See, e.g., Funk, 631 F.3d at 779 (plaintiff amended complaint once, sought leave to file second amended complaint but motion denied by trial court; dismissal based on first amended complaint affirmed on appeal); Loreto v. Procter & Gamble Co., 737 F. Supp. 2d 909, 924 (S.D. Ohio 2010) (“Because Plaintiffs had the opportunity to amend their Complaints after having notice of [defendant’s] position, and because such amendment failed to cure any pleading deficiencies, another amendment is not warranted.”). \textit{But see} Bass v. Stryker Corp., 669 F.3d 501, 510 (5th Cir. 2012) (“Bass has sufficiently pleaded parallel claims in his first amended complaint, to the extent that the claims are based upon manufacturing defects resulting from violations of federal regulations.”).}

\footnote{355}{See, e.g., Sprint Fidelis Leads II, 625 F.3d 1200, 1206–07 (8th Cir. 2010) (“On appeal, Plaintiffs primarily argue that the district court’s application of \textit{Twombly} in this case held them to an impossible pleading standard because the FDA’s specific federal manufacturing requirements are set forth in the agency’s PMA approval files that are accessible, without discovery, only to Medtronic and to the FDA. This argument—which focuses on the timing of the preemption ruling—would have considerable force in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit. \textit{Compare} Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 598 (8th Cir. 2009) (while plaintiffs ‘must offer sufficient factual allegations to show that he or she is not merely engaged in a fishing expedition or strike suit, we must also take account of their limited access to crucial information.’)” (footnote omitted)).}
Some deny the plaintiff’s motion to allow more discovery, concluding that it would not alter the eventual outcome. Others allow the plaintiff to conduct discovery—in practice, that alone increases the plaintiff’s settlement leverage—so that they may obtain (assuming it is there to discover) the further information needed for a detailed statement of the specific bases for the claim.

If discovery is unlikely to provide the information necessary to make a plaintiff’s allegations more specific, then there is not an adequate reason to allow the plaintiff to proceed any further. But courts should deny a motion to dismiss on the pleadings and allow for at least some discovery if the information necessary to craft pleadings with sufficient specificity is otherwise beyond the reach of the plaintiff and likely to be discovered. The preemption issue can then be decided in the context of a motion for summary judgment.

XVII. CONCLUSION

The precise contours of the narrow gap through which a plaintiff bringing a product defect claim against a medical device manufacturer must sail in order to avoid having her claims preempted are not yet clear. The plaintiff’s state-law claims must not impose on the manufacturer requirements that are different from, or in addition to, those imposed by the FDCA and its

356. See, e.g., Gross, 858 F. Supp. 2d at 503 (“No discovery is necessary here because, even after discovery, Plaintiff would still not be able to allege any viable claims against Stryker. In fact, numerous district courts across the country have dismissed very similar actions in their entirety at the motion to dismiss stage.”); Stengel v. Medtronic, Inc., No. CV 10–318–TUC–RCC, 2010 WL 4483970, at *3 (D. Ariz. Nov. 9, 2010), aff’d, 676 F.3d 1159 (9th Cir. 2012) (“[A]dditional discovery is futile because Plaintiff’s claims are preempted and additional discovery will not remedy that.”).

357. See, e.g., Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010) (District court’s refusal to allow amendment of pleadings reversed as abuse of discretion: “In applying that standard to claims for defective manufacture of a medical device in violation of federal law, moreover, district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.”); Warren v. Howmedica Osteonics Corp., No. 4:10 CV 1346 DDN, 2010 WL 5093097, at *7 (E.D. Mo. Dec. 8, 2010) (“[P]laintiffs are entitled to proceed with their suit and obtain information through discovery.”); Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009) (“With discovery, [plaintiff] may or may not be able to prove [his] claims . . . .”).
implementing regulations, or the claim is expressly preempted by the MDA. Instead, the requirements that state law imposes on the manufacturer must simply parallel the requirements imposed by federal law. There are two key issues to be resolved in the express preemption cases. The first is just how specific the applicable federal law must be in order to be regarded as a requirement of federal law. The second is how to determine whether the state-law claim merely parallels a federal law requirement.

As to the first question, the courts should determine whether there is a federal requirement found either in the FDCA or its implementing regulations that clearly applies to the medical device at issue. The requirement need not be device-specific but must clearly apply either to all devices of that category or to all medical devices. This is a question of law that should be resolved by the court, not a question that should be left to the factfinder. The factfinder’s role is to then determine whether the defendant has or has not complied with that requirement. But if the applicability of the alleged federal “requirement” is not clear, then a jury should not be left to decide whether federal law could be interpreted to apply. The court should first determine whether there is a legal requirement and leave to the factfinder only the question of whether that law has been violated. And as to deciding the second question, courts should look carefully at the elements of both the federal and state law claims to see whether the elements necessary to prove a violation of federal law are the same as the elements necessary, but not necessarily sufficient, to prove the state-law claim. If so, the state-law claim merely parallels the federal-law claim and is not expressly preempted by the MDA.

Then, to determine whether a parallel state law claim is impliedly preempted, the courts must confront and resolve the question of Buckman’s scope. Is it limited only to claims of a violation of the FDCA with no underlying preexisting state-law cause of action? Or are even traditional state-law claims, such as negligence per se claims, preempted because they would not exist in the absence of a requirement established by federal law, the enforcement of which should be the exclusive province of the FDA?

If the Supreme Court’s primary rationale for finding preemption in Buckman is that the FDCA does not create a private federal cause of action for enforcement of the act, then lower federal courts should distinguish between plaintiffs’ claims that
amount simply to a claim of an implied federal cause of action to enforce a federal requirement arising from the FDCA and state-law causes of action, such as negligence per se, in which a standard of conduct established by federal law is simply incorporated into the state-law claim, and not find preemption only in the latter kind of cases.