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Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices

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INTRODUCTION

Complex and technologically advanced medical devices extend or improve the quality of life of countless Americans. However, if defective in design or manufacture, or if inaccurately labeled, such life-saving devices can turn deadly or cause significant personal pain and injury.

Although medical device manufacturers bear primary responsibility for the safety of their products, federal legislation and regulations obligate the Food and Drug Administration (FDA) to provide reasonable assurance that medical devices are safe and effective for their intended use. Both federal and state courts place considerable faith in the ability of FDA to live up to its enormous responsibilities in this area.[1] The scheme of federal regulation impacts whether common law product liability suits may be brought against device manufacturers. Depending on the circumstances, a common law action involving a Class III device subject to premarket approval (PMA) may be preempted by federal law and thereby subject to early dismissal.

Although the United States Supreme Court has addressed issues of both express and implied preemption of Class III PMA medical devices, some district court rulings reveal an inadequate appreciation of the scope and meaning of the preemption defense and heightened pleading requirements of *Bell Atlantic Corp. v. Twombly*.[2] The rulings reflect at times an overly stringent application of pleading requirements resulting in dismissals of common law actions that are not on their face preempted based on Supreme Court rulings in *Riegel v. Medtronic*,[3] *Buckman v. Plaintiffs' Legal Comm.*,[4] or *Medtronic, Inc. v. Lohr*.[5]

The medical device industry plays a critical role in the delivery of quality healthcare, and their products constitute a significant portion of the costs incurred by the nation's health care system. Manufacturers of implantable devices command premium prices which reflect generous profit margins.[6] Over $76 billion is spent annually in America for implanted medical devices such as defibrillators, spinal implants, artificial hips and knees and pain treatment devices.[7] The industry also benefits from limitations placed on the ability of patients to prosecute personal injury lawsuits involving Class III PMA devices.

As understood by some judges, Class III PMA medical device manufacturers enjoy broad immunity from personal injury lawsuits arising out of malfunctioning or defective devices. This not only results in patients being uncompensated for their

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1 The Supreme Court has recently questioned whether this faith is misplaced in light of FDA's inadequate budget and staff. *See* Wyeth v. Levine, 129 S.Ct. 1187, 1202 n.11 (2009). *See also* Blunt v. Medtronic, Inc., 315 Wis.2d 612, 760 N.W.2d 396 (2009) (concurring opinion noting evidence of serious deficiencies in FDA's process of review and approval of medical devices).

2 550 U.S. 544 (2007).

3 552 U.S. 312 (2008).

4 531 U.S. 341 (2001).

5 518 U.S. 470 (1996).

6 Meir, Barry, *To Their Own Devices*, NY TIMES, (Nov. 5. 2009), at 6.

7 *Id.*

losses, it also forecloses Medicare reimbursement and private insurer subrogation actions against device manufacturers to recover the costs of medical and hospital bills caused by the defective devices and costs accompanying expensive and risky explant and implant replacement procedures. Patients, device manufacturers and the federal government should all have a keen interest in understanding the extent to which preemption is a legitimate defense to common law tort actions.

This article provides a current guide to the proper scope of the preemption defense pertaining to Class III PMA medical devices. Although certain actions are clearly preempted, others can escape preemption if properly investigated and pleaded. The article begins with a review of the principles and presumptions recognized by the Supreme Court in determining preemption, and then moves to an overview of the FDA regulatory scheme for Class III PMA medical devices. This is followed by a discussion of the three pivotal Supreme Court cases addressing medical device preemption, with a focus on the most recent decision. *Riegel* provides the latest insight into the Supreme Court's position on medical device preemption issues but must be understood in the context of *Lohr* and *Buckman*. Finally, preceded by a review of the new *Bell Atlantic Corp. v. Twombly*[8] pleading standard, various district court decisions post-*Riegel* are examined for guidance on whether the usual common law causes of action can escape preemption.

I. THE DOCTRINE OF FEDERAL PREEMPTION

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution, U.S. Const. Art. VI, cl. 2, which invalidates state laws that "'interfere with, or are contrary to,' federal law."[9] The Supreme Court has identified three major situations where there is preemption: 1) "express" preemption, applicable when Congress expressly states its intent to preempt state law; 2) "field" preemption, applicable when "Congress' intent to pre-empt all state law in a particular area may be inferred [because] the scheme of federal regulation is sufficiently comprehensive" or the federal interest is so dominant that enforcement of state laws is precluded; and 3) "conflict" preemption, applicable when "state law is nullified to the extent that it actually conflicts with federal law," even though Congress has not displaced all state law in a given area.[10]

The Supreme Court has recognized that "preemption fundamentally is a question of Congressional purpose."[11] State law is subject to invalidation by federal statutes or regulations. "[S]tate laws can be preempted by federal regulations as well as by the federal statutes."[12] Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes.[13]

A second fundamental touchstone to the Supreme Court's preemption jurisprudence is that "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated … in a field which the States have traditionally occupied,' … we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of

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[8] 550 U.S. 544 (2007).

[9] Hillsborough County v. Automated Med. Labs., 471 U.S. 707, 712 (1985) (quoting Gibbons v. Ogden, 9 Wheat. 1, 211 (1824)).

[10] *Hillsborough County*, 471 U.S. at 713.

[11] *Wyeth*, 129 S.Ct. at 1194. *See also Lohr*, 518 U.S. at 485 (1996) ("'[t]he purpose of Congress is the ultimate touchstone' in every preemption case").

[12] *Hillsborough County*, 471 U.S. at 713.

[13] *Wyeth*, 129 S.Ct. at 1200 (also noting that Congress authorized FDA to determine the scope of medical device preemption under 21 U.S.C. § 360k).

Congress.'"[14] The Court relies on the presumption "because respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'"[15] When the text of an express preemption clause "is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors preemption.'"[16]

II. FDA REGULATION OF MEDICAL DEVICES

FDA regulates medical devices pursuant to the 1976 Medical Device Amendments (MDAs) to the Federal Food, Drug, and Cosmetic Act (FDCA).[17] By enacting the MDAs, Congress "granted FDA new broad powers to regulate medical devices."[18] The MDAs regulate the development, marketing and monitoring of medical devices to assure the safety and efficacy of devices and set forth the approvals to be obtained from FDA before bringing a device to market.

A. *Premarket Approval*

Class III medical devices (e.g., pacemakers) are "for a use in supporting or sustaining human life," or those which pose "a potential unreasonable risk of illness or injury."[19] Unless exempted by regulation, new Class III devices must clear FDA premarket review by either PMA[20] or through the "510(k) process."[21] The PMA process applies to devices introduced after May 28, 1976, the date the MDAs were enacted.[22] Pursuant to PMA procedures, an applicant must submit "all information, published or known … or which should reasonably be known … concerning investigations which have been made to show whether or not such device is safe and effective,"[23] plus a full statement of the components, design and intended uses of the product, manufacturing and processing methods, proposed labeling, and any other information requested by FDA.[24] FDA may refer PMA applications to a panel of qualified experts who prepare a report and recommendation.[25] FDA grants PMA only if it has received "reasonable assurance" that the device is safe and effective under the conditions of use included on the label and has determined that the proposed labeling is not false or misleading.[26]

[14] *Lohr*, 518 U.S. at 485 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); *See id.* Altria Group, Inc. v. Good, 129 S.Ct. 538, 543 (2008).

[15] *See* Bldg. & Constr. Trades Council of Metro. Dist. v. Assoc. Builders & Contractors of Mass./RI. Inc., 507 U.S. 218, 224 (1993) (recognizing a general presumption that Congress does not intend to preempt state causes of action); Lohr, 518 U.S. at 485.

[16] *Altria*, 129 S.Ct. at 543 (*quoting* Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 449 (2005)).

[17] 21 U.S.C. §§ 301 *et seq*.

[18] Michael v. Shiley, Inc., 46 F.3d 1316, 1319 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995).

[19] 21 U.S.C. § 360c(a)(1)(C). Class I devices (e.g., tongue depressors) present little or no risk to human health and safety and are subject only to general manufacturing and labeling controls. Class II devices (e.g., powered wheelchairs) pose a slightly greater risk to human safety and are subject to stricter FDA guidelines, including performance standards and postmarket surveillance measures. *See id.* §§ 360c(a)(1)(A), (a)(1)(B).

[20] *Id.* §§ 360c(a)(1)(C), 306e.

[21] *Id.* § 360c(f)(1); 360e(b)(1).

[22] *Id.* § 360e(b)(1)(A).

[23] *Id.* § 360e(c)(1)(A).

[24] *Id.* § 360e(c)(1)(B)-(G); *see also* 21 C.F.R. § 814.20.

[25] 21 C.F.R. § 814.40.

[26] 21 U.S.C. §§ 360e(d)(1)(A), e(d)(2). Researchers have recently found that various cardiovascular PMA III devices reached market based on studies that were inadequate and open to bias. *See*, *e.g.*, Dhruva, Sanket S., M.D. et al., *Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices,* JAMA, (Dec. 23/30, 2009), Vol. 302, No. 24, pp. 2679-2685. In response, FDA has reportedly acknowledged weaknesses in the clinical trials and has expressed its intent to toughen standards for device approvals. Favole, Jared A. & Mundy, Alicia, *Journals Criticize FDA Trials*, THE WALL ST. J., (Dec. 30, 2009), at p. B-1. This leaves open the question of whether the approval process is as rigorous as previously believed.

In addition to the PMA process, medical devices can receive FDA clearance through the less stringent premarket notification, or "510(k)" process. Pursuant to the 510(k) process, FDA approval to market a device can be secured by submitting a premarket notification application which establishes that the device is "substantially equivalent" to a Class I or II device already on the market or a Class III device on the market prior to May 28, 1976 (predicate devices).[27] This is limited to devices that were on the market prior to May 28, 1976 and for which FDA has not determined whether each device should be re-classified as low-to-moderate risk Class I or II devices, or whether the device must undergo PMA approval.[28] Every 510(k) application must contain information supporting substantial equivalence to a predicate device, proposed labeling, and any additional information requested by FDA.[29] For a device to obtain 510(k) approval, FDA must determine that the new device has the same intended uses as the predicate device, and that it possesses the same technological characteristics or is as safe and effective as the predicate device.[30]

Class III devices are subject to FDA's current good manufacturing practice requirements (CGMP requirements).[31] The CGMP requirements set forth a quality system to control the methods and controls used for the "design, manufacture, packaging, labeling, storage and installation … [of medical devices,] to assure that [they] … will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act …"[32] To comply with the general CGMP requirements, device manufacturers must adopt procedures and controls including: 1) design control; 2) a quality assurance program; 3) "adequate written cleaning procedures and schedules to meet manufacturing process specifications"; 4) written manufacturing specifications and processing procedures; 5) process validation; 6) written procedures for "finished device inspection to assure that device specifications [have been] met"; and 7) corrective and preventive action.[33]

B. *Post-Approval Reporting Requirements*

In addition to the quality system regulation, post-market requirements concerning traceability,[34] and regulations pertaining to tracking[35] and postmarket surveillance,[36] apply to a device either intended for surgical implantation into the body or to sustain life. Device manufacturers are subject to post-approval requirements pertaining to device failure and risk of death or serious injury. Device manufacturers must report to FDA whenever the manufacturer receives or otherwise becomes

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[27] *See* 21 U.S.C. § 360(i)(1)(A); 21 C.F.R. §§ 807.81, 807.87.

[28] On Apr. 9, 2009, FDA required manufacturers of twenty-five Class III predicate devices to submit information bearing on whether the devices should be reclassified or should remain as Class III devices subject to PMA. 74 Fed. Reg. 16214 (Apr. 9, 2009). This recent initiative followed the issuance of a report on Jan. 15, 2009 by the United States Government Accountability Office (GAO), which had criticized FDA for not reexamining and reclassifying the predicate Class III devices. *See Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved Through the Most Stringent Premarket Review Process,* http://www.gao.gov/products/GAO-09-190 (GAO report).

[29] 21 C.F.R. § 807.87.

[30] *See* 21 U.S.C. § 360c(i)(1)(A).

[31] *See Id.* § 360j(f); *see also* 21 C.F.R. §§ 820 *et seq*.

[32] 21 C.F.R. § 820.1.

[33] *Id.* §§ 820.1-.184.

[34] *Id.* § 820.65.

[35] *Id.* Part 821.

[36] *Id.* Part 822.

aware of information that reasonably suggests that one of its marketed devices "1) [m]ay have caused or contributed to a death or serious injury; or 2) [h]as malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."[37] If FDA determines that a device "presents an unreasonable risk of substantial harm to the public health," it may order the manufacturer to notify all affected persons, or require repair or replacement of the device.[38] FDA can also order a labeling change.[39] FDA may order a change in labeling needed to adequately warn of a danger presented by the device:

> [i]f the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or a change in labeling, … the Commissioner will provide written notice to the manufacturer … specifying:
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> 1) The deception or risk of illness or injury or the danger to the health of individuals,
>
> 2) The labeling or change in labeling, … and
>
> 3) The period of time within which the labeling, change in labeling … must be accomplished.[40]

Further, if FDA concludes that a device "presents substantial deception or an unreasonable and substantial risk of illness or injury, … [it] may initiate a proceeding to promulgate a regulation to make such device a banned device."[41]

C. *Labeling Changes*

A Class III device may not be labeled in a manner that is inconsistent with any conditions specified in its PMA,[42] and once a device has received PMA, a manufacturer generally needs FDA approval before making changes to the labeling that would affect safety or effectiveness.[43] "Once a device has received premarket approval, the MDA generally forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness."[44] There is an important exception to the general prohibition on making labeling changes without FDA approval. Under that exception, a manufacturer may temporarily change a

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[37] *Id.* § 803.50(a)(1)-(2); 21 U.S.C. § 360(i)(a)(1). The term "serious injury" means an injury that "A) is life threatening, B) results in permanent impairment of a body function or permanent damage to a body structure, or C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." *Id.* § 360(i)(a)(2).

[38] 21 U.S.C. § 360h.

[39] *Id.* § 360f(a)(2).

[40] 21 C.F.R. § 895.25(a); *see also Reeves v. Acromed Corp.*, 44 F.3d 300, 305 (5th Cir.), *cert. denied*, 515 U.S. 1104 (1995).

[41] 21 U.S.C. § 360f(a).

[42] 21 C.F.R. § 814.80.

[43] 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a); *Riegel*, 128 S.Ct. at 1005.

[44] *Riegel*, 128 S.Ct. at 1005; 21 U.S.C. § 360e(d)(6)(A)(i).

label to enhance safety pending FDA approval of the change.[45] Before approving a change to a label, the FDA evaluates the proposed change under basically the same criteria as the initial application.[46]

III. PREEMPTION UNDER THE FDCA

According to the Supreme Court, preemption of state common law actions involving Class III PMA medical devices may be express or implied.

A. *Express Preemption*

The FDCA includes an express preemption clause that provides, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement- 1) which is different from, or in addition to, any requirement applicable under this 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.[47]

In 1996, the Supreme Court determined, in its first interpretation of the statute, that this language does not preempt common law negligence and strict liability claims alleging injuries caused by a medical device authorized for marketing via the § 510(k) process.[48] The Court noted that the § 510(k) process was not a "requirement" within the meaning of § 360k(a)(1).[49] The Court further held that the common law claims were not preempted by general FDA labeling and manufacturing requirements.[50]

In a decision issued on February 20, 2008, the Supreme Court addressed the meaning of this provision in the context of a Class III medical device that had received PMA.[51] In *Riegel v. Medtronic, Inc.*, the Court first concluded that the PMA process imposes "requirement[s] applicable under this chapter to the device" for the purposes of § 360k(a)(1).[52] As the Court noted, PMA is specific to individual medical devices.[53] A device that has received PMA must "*be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness*."[54] The Court further held that state common-law duties impose "requirements" that, notwithstanding their general nature, are "with respect to" medical devices.[55] As a result, to the extent that a state common-law duty imposes requirements "different

[45] 21 C.F.R. § 814.39(d); *see also* Brooks v. Howmedica, 273 F.3d 785, 796 (8th Cir. 2001), *cert. denied*, 535 U.S. 1056 (2002) (stating that such changes "are valid only after the manufacturer has submitted a Supplemental PMA and only during the pendency of that application").

[46] 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c).

[47] 21 U.S.C. § 360k(a).

[48] *Lohr*, 518 U.S. at 484, 502.

[49] *Id.* at 493-494.

[50] *Id.* at 497-501. Although not addressed in *Lohr*, this conclusion is applicable to other classes of devices. Absent a specific regulation or specific requirement applicable to a specific device, this would also indicate a lack of preemption as to Class I and Class II medical devices. *See* 21 C.F.R § 808.1(d), *Lohr*, 518 U.S. at 496-497, 501.

[51] 128 S.Ct. 999 (2008).

[52] *Id.* at 1007.

[53] *Id.*

[54] *Id.* (emphasis added).

[55] *Id.* at 1007-1010.

from, or in addition to," the requirements imposed by the PMA, those state common-law duties are expressly preempted by § 360k(a).[56] The *Riegel* Court limited its holding to claims that the device "violated state law notwithstanding compliance with the relevant federal requirements."[57] The Supreme Court in *Riegel* held:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the [PMA] requirements imposed by federal law [as distinct from general manufacturing and labeling requirements]. § 360k(a)(1). *Thus, § 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*. [*Medtronic v.*] *Lohr*, 518 U.S., at 495; *see also id.*, at 513 (O'Connor, J., concurring in part, dissenting in part).[58]

The quoted language is referenced to a discussion in the *Lohr* principal opinion which explicitly recognized that common law remedies were not preempted so long as the actions were based on violations of federal regulations:

> The *Lohrs* next suggest that even if "requirements" exist with respect to the manufacturing and labeling of the pacemaker, and even if we can also consider state law to impose a "requirement" under the Act, the state requirement is not preempted unless it is "different from, or in addition to" the federal requirement. § 360k(a)(1). Although the precise contours of their theory of recovery have not yet been defined (the preemption issue was decided on the basis of the pleadings), it is clear that the *Lohrs'* allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, they suggest, can be maintained without being preempted by § 360k, and we agree.
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> *Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the 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 preemption of a state rule insofar as it duplicates the federal rule. *The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.*[59]

The *Riegel* Court also favorably cited Justice O'Connor's observations in *Lohr* (concurring in part, dissenting in part), similarly recognizing that state law claims can be maintained for violations of FDA regulations:

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[56] *Id.* at 1007.

[57] *Id.* at 1011.

[58] *Id.* (bracketed language referenced to 552 U.S. at 1006) (emphasis added). The Court thus seemingly rejected "field" preemption, applicable when Congress intends to preempt all state law in a particular area. *See Hillsborough County*, 471 U.S. at 712. Field preemption is rarely found in areas traditionally regulated by the states. *Id.* at 717.

[59] 518 U.S. at 494-495 (emphasis added).

> I also agree that the *Lohrs'* [negligence and strict liability design] claims [as to § 510(k) device] are not pre-empted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements. *Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law*. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.[60]

Stated otherwise, the *Riegel* Court did not hold common law claims expressly preempted merely because they are related to medical devices approved under the PMA process. The *Riegel* Court recognized that common law actions are preempted only to the extent they are based on requirements that differ from PMA approval; and indicated that common law strict liability and negligence claims are not preempted by general CGMP regulations as they are requirements outside the reach of § 360k.[61]

In order to avoid preemption by § 360k(a), a state-law claim against a PMA Class III device should be premised on a breach of a state-law duty that is the same as a duty imposed under the PMA or one of its implementing regulations.[62] To avoid preemption, conduct that is alleged to give the plaintiff a right to recovery under state law should be conduct prohibited by FDA regulations. Evaluation of whether plaintiff's claims are preempted or not requires identification of the device manufacturer's conduct alleged to give rise to a claim under state law. If that conduct is in compliance with PMA regulations, then plaintiff's claim, if successful, would have the effect of imposing on the device manufacturer a requirement that is different from or in addition to the federal requirement. For that reason, plaintiff's claim would be expressly preempted by § 360k(a).[63]

A representative analysis of what it means to "parallel" a federal requirement within the meaning of *Riegel* and thereby escape preemption was recently set forth by a district court as follows:

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[60] *Id*. at 495 (emphasis added).

[61] As noted in the *Lohr* principal opinion, 518 U.S. at 497, this conclusion is supported by FDA regulations recognizing that preemption applies only to *divergent* state requirements. 21 C.F.R. §§ 808.1(b), (d)(2) ("Section 521(a) [codified at 21 U.S.C. § 360k(a)] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.") There is also a specific regulation acknowledging a lack of preemption concerning adulterated or misbranded devices, 21 C.F.R. § 808.1(d)(6)ii ("Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, *e.g.*, a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.") Another FDA regulation further recognizes that CGMP requirements do not preempt state *remedies*. *Id.* § 808.1(d)(10).

[62] The *Riegel* Court noted, 128 S.Ct. at 1006, that a majority in *Lohr* interpreted § 360k(a)(1) "'substantially informed'" by FDA regulation, 21 C.F.R. § 808.1(d), that says state requirements are preempted only when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device … ." *Lohr*, 518 U.S. at 495. General manufacturing and labeling requirements applicable across the board to all manufacturers were deemed not specific to the § 510(k) device in Lohr. *Id.* at 501. Yet the Court in *Lohr* concluded that state law claims predicated on *violations* of federal law were not preempted. *Id.* at 495. The holding in *Riegel* thus clarified that even specific requirements imposed on a PMA Class III device do not preempt a common law action focused on a violation of those regulations. *Riegel*, 128 S.Ct. at 1011.

[63] Section 360k(a) also requires that the state-law requirement at issue be "related[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a)(2).

> State law claims are preempted to the extent that they impose additional requirements on device manufacturers. Thus, compliance with federal requirements must preclude state law liability. However, a state law claim that requires more than mere noncompliance with federal requirements. For example, that the violation of federal requirements have been reckless or unreasonable is not precluded, notwithstanding the fact that such a claim uses a standard that is literally "different from" the federal requirements. *Lohr*, 518 U.S. at 495. Such a state law claim does not impose conflicting requirements on manufacturers and thereby disrupt the federal regulatory scheme.[64]

If the conduct *is* prohibited by the FDCA, then a state-law claim premised on that conduct is not expressly preempted by § 360k(a). Moreover, *Lohr* and *Riegel*, read in context with FDA's own regulations exempting certain claims from preemption, would seem to even permit some common law claims as to devices in compliance with CGMP requirements of FDA. But that is not the end of the inquiry, for even if a claim is not *expressly* preempted by § 360k(a), it may be *impliedly* preempted as to a state-law fraud-on-FDA claim.

B. *Implied Preemption*

Almost exactly seven years prior to handing down its decision in *Riegel*, the Supreme Court ruled on the viability of a fraud-on-FDA cause of action in *Buckman Co. v. Plaintiffs' Legal Comm.*[65] In *Buckman*, the Supreme Court held that a private right of action for fraud upon FDA was impliedly preempted by the regulatory scheme.[66] "The 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: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'"[67] The *Buckman* Court limited its holding to finding implied preemption as to a cause of action based on fraud-on-FDA.

At the outset of its analysis, the Court in *Buckman* found a fundamental difference between FDA "policing against fraud" and plaintiffs pursuing a traditional common law tort action against device manufacturers.[68] The Court noted that a fraud-on-FDA claim could skew the federal statutory scheme which empowered FDA to punish and deter fraud against FDA.[69] This was contrasted with traditional common law actions which are entitled to a presumption against preemption: "Accordingly-and in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' *Medtronic* [*v. Lohr*,] 518 U.S. at 485, 116 S.Ct. 2240 - no presumption against preemption ob-

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[64] Prudhel v. Endologix, Inc., 2009 WL 2045559, at *8 (E.D. Cal. July 9, 2009). *Contra* McCutcheon v. Zimmer Holdings, 586 F.Supp.2d 917, 922 (N.D. Ill. 2008) (granting defendant summary judgment in light of state tort law not being a mere carbon copy of relevant federal regulations).

[65] 531 U.S. 341 (2001).

[66] *Id.* at 348.

[67] 531 U.S. at 349 n.4 (*quoting* 21 U.S.C. § 337(a)). This provision appears to apply to the prohibited acts specified in § 331 and "such proceedings" as specified in Subchapter III for regulatory enforcement such as injunction (§ 332), penalties (§ 333), and seizure (§ 334). It is silent as to traditional common law tort actions which would not encroach upon the federal regulatory scheme.

[68] 531 U.S. at 347-348.

[69] *Id.* at 348.

tains in this case."[70] The decision hinged on not applying the presumption against preemption. Thus, a private litigant cannot exclusively premise suit against a device manufacturer based on violations of the FDCA in the form of fraudulent representations to FDA made in the course of obtaining approval to market the device.

To avoid being impliedly preempted, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law (where the presumption against preemption does apply),[71] and that would give rise to liability under state law even if the FDCA had never been enacted.[72] If the defendant's conduct is not of this type, then the plaintiff may be regarded as effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman.*[73]

Significantly, *Buckman* was not mentioned by the *Riegel* Court when addressing whether common law tort actions were preempted. The *Riegel* Court firmly acknowledged that parallel common law damages remedies actually furthered the goal of obtaining regulation compliance—it gives the manufacturers another reason to comply with federal law.[74]

Construing *Buckman* as narrowly limited to a cause of action based on fraud-on-FDA reconciles it with the Court's earlier conclusions in *Lohr* and the general presumption against federal preemption of a traditional state common law cause of action for personal injuries. The plurality opinion in *Lohr* stated that "it is apparent that few, if any, common-law duties have been preempted by this statute [§ 360k]."[75] This conclusion was based in part on the Court's understanding of the legislative history of § 360k, which did not disclose a concern about product liability litigation:

> *Indeed, nowhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices.* To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the preemption provision; furthermore, *any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices*.
>
> The legislative history also confirms our understanding that § 360(k) simply was not intended to preempt most, let alone all, general common-law duties enforced by damages actions. There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping preemption of traditional common-law remedies against manufacturers and distributors of defective devices.[76]

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[70] *Id.*

[71] *Lohr*, 518 U.S. at 485.

[72] *Buckman*, 531 U.S. at 353.

[73] *See id.* at 349 n.4.

[74] *Riegel*, 128 S.Ct. at 1011. *See also Buckman*, 531 U.S. at 354 (Stevens, J. & Thomas, J., concurring) ("If the FDA determines both that fraud [on the FDA] has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, *but rather would supplement and facilitate, the federal enforcement scheme.*") (emphasis added).

[75] 518 U.S. at 503.

[76] *Id.* at 490-491 (emphasis added).

So long as fraud-on-FDA is not alleged, the implied preemption holding of *Buckman* should have little or no application to the typical products liability action.

IV. TWOMBLY'S IMPACT ON PREEMPTION MOTIONS

Riegel, *Buckman* and *Lohr* would seem to permit most of the usual product liability common law causes of action, *provided they are properly alleged*. In sum, for a state law claim to survive express and implied preemption, the claim may be premised on conduct subject only to general requirements, such as general CGMP requirements (which, given their general nature, may or may not yield a defectively manufactured device, depending on whether the manufacturer's specific procedures are faithfully followed), or conduct that violates PMA requirements. A plaintiff must further premise the claim on a common law right that exists independently of the FDCA. The overall methodology for framing a non-preempted claim is to first identify conduct which violated the PMA or other specific requirement related to safety or efficacy. If such conduct can also be stated in terms of a breach of a parallel common law duty (e.g., failure to warn under strict liability or negligence, manufacturing defect, breach of warranty or fraud), then it would appear the claim is not preempted. Alternatively, regardless of a specific violation, common law remedies are not preempted by general CGMP requirements.

A. *The New Pleading Standard*

To avoid a Fed. R. Civ. P. (Rule) 12(b)(6) dismissal, a complaint must satisfy the demanding pleading threshold recently set forth by the Supreme Court in *Bell Atlantic Corp. v. Twombly*.[77] Only nine months prior to deciding *Riegel*, the *Twombly* Court abrogated the easily satisfied, long prevailing standard set forth in *Conley v. Gibson* ("a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief")[78] for construing Rule 8. The Court adopted a new standard for resolving Rule 12(b)(6) motions to dismiss based on the factual "plausibility" of a plaintiff's claims.[79] To avoid dismissal, a complaint must include "enough facts to state a claim to relief that is plausible on its face."[80] A plaintiff must plead sufficient facts "to provide the 'grounds' of his 'entitle[ment] to relief,' [which] requires more than labels and conclusions, and [for which] a formulaic recitation of the elements of a cause of action will not do."[81] This new standard effectively eliminates speculative claims that would otherwise lead to expensive discovery and protracted litigation, but if overzealously applied, ignores the requirements of Rule 8 and sweeps legitimate complaints out of court.[82]

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[77] 550 U.S. 544 (2007).

[78] 355 U.S. 41, 45-46 (1957).

[79] 550 U.S. at 560-563.

[80] *Id.* at 570.

[81] *Id.* at 555 (citation omitted).

[82] A recent reasoned application of *Twombly* can be found in Carrigan v. K2M, Inc., 2009 WL 3575680 (C.D. Ill. Oct. 26, 2009). The court denied a Rule 12(b)(6) motion to dismiss filed by the manufacturer of screws implanted during spinal surgery. Essentially, allegations that the screws fractured despite proper placement, accompanied by the usual verbiage setting forth the elements of strict liability and negligence causes of action, were deemed sufficient under Rule 8(a) to give fair notice of the grounds for relief. Another recent case addressed pleading the sufficiency of a defect. Although subject to later disposal by summary judgment for lack of evidence of defect, in a case alleging manufacturing defect, the mere fact of malfunction and ruling out other secondary causes satisfies case-in-chief evidence of defect. *See, e.g.,* Williams v. Cyberonics, Inc., 2009 WL 2914414 (E.D. Pa. Sept. 10, 2009).

As in the past, when reviewing a motion to dismiss, the trial court must still liberally construe the complaint, assuming the facts alleged therein as true and drawing all reasonable inferences from those facts in the plaintiff's favor.[83] A complaint should not be dismissed simply because a court is doubtful that the plaintiff will be able to prove all of the factual allegations contained therein.[84] Accordingly, a well-pleaded complaint will survive a motion to dismiss "even if it appears that a recovery is very remote and unlikely."[85]

Yet the *Twombly* Court explained that "something beyond the mere possibility of [a federal violation] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value."[86] In that vein, the Court stated that "'a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed [to discovery].'"[87]

Twombly obviously counsels that plaintiffs conduct thorough pre-suit investigation to secure available evidence through public and private sources outside the direct control of the device manufacturer.[88] Plaintiff's entitlement to discovery, or lack thereof, will turn on whether he has sufficiently pled an entitlement to relief under Rule 8 generally, and in particular whether his pleading has established a "reasonably founded hope" that discovery "will reveal relevant evidence" to support that claim.[89] Although compliance with Rule 8 requires factual plausibility,

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[83] 550 U.S.at 555-556.

[84] *Id.*

[85] *Id.* 556 (citation omitted).

[86] *Id.* at 557-558 (*citing* Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336, 347 (2005) (internal quotation marks and punctuation omitted)).

[87] *Id.* at 558 (*quoting* Associated Gen. Contractors v. Carpenters, 459 U.S. 519, 528 n. 17 (1983).

[88] Certain categories of information are readily available for the purposes of assessing whether the requisite factual detail exists to plead a plausible claim. Various FDA regulations provide for public access to information bearing on the safety and effectiveness of medical devices, including a summary of the PMA application. *See*, *e.g.,* 21 C.F.R. § 814.9. Under 21 C.F.R. § 803.9, FDA can disclose "any report, including any FDA record of a telephone report" submitted in connection with a manufacturer's reporting requirements as set forth in 21 C.F.R. § 803.1 *et seq*. These medical device reporting regulations (also known as MDR) require manufacturers to: 1) report deaths and serious injuries that a device may have caused or to which it may have contributed, or malfunctions that could lead to death or serious injury, within certain timeframes; 2) maintain files regarding adverse events; 3) submit summary annual reports; and 4) submit specified follow-up reports. Similarly, under § 806.40, reports submitted by manufacturers regarding corrections (the repairing, modifying, adjusting, relabeling, destroying or inspecting a device without removing it from its point of use) or removal of devices (physically removing a device from its point of use to repair, modify, adjust, relabel, destroy or inspect it) are available for public disclosure, although any "confidential" information will be deleted. For the purposes of providing access to publicly available information within FDA's files, the agency's website offers links to various "electronic reading rooms" for each of its divisions, including the Center for Devices and Radiological Health (CDRH). "How to Get Information from CDRH," available at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHFOIAElectronicReadingRoom/ucm135903.htm (last accessed on Oct. 29, 2009). Within CDRH's virtual library are links to various device-specific items of information, such as adverse events databases (which are searchable and cover "device experience reports" on devices that may have malfunctioned or caused serious injury or death), recalls, PMAs, guidance and standards.

[89] Motions to dismiss based on preemption will often be accompanied by motions to stay discovery. Some district courts have concluded that a stay of discovery was not warranted despite a motion to dismiss based on *Riegel* was pending. *See*, *e.g.*, Parker v. Stryker Corp., 2008 WL 4457864 at *2 (D. Colo. Oct. 1, 2008) (in denying defendant's motion to stay the court noted: "Determining whether Plaintiff's claims indeed parallel the regulations by properly alleging violations of the FDA regulations will be a fact-specific inquiry. While Defendants cite cases in which preemption was recognized (and presumably discovery did not proceed), Plaintiff cites cases in which the claims withstood a preemption attack in which presumably discovery did proceed. Therefore, staying this case while Defendants' Motion to Dismiss is pending could substantially delay the ultimate resolution of the matter, with adverse consequences such as a decrease in evidentiary quality and witness availability.") *But see* Ashcroft v. Iqbal,—U.S.—, 129 S.Ct. 1937, 1953-1954 (2009) (*Twombly*, which applies to "all civil actions*,"* dictates that where a plaintiff's "complaint is deficient under Rule 8, he is not entitled to discovery, cabined or otherwise.").

"a procedural rule ought not to be read to insist that a plaintiff plead the level of detail required to prevail at trial."[90] Nevertheless, given the over-eager inclination of some district courts to find *Twombly*-deficient complaints, thought may be given to supporting complaints with summary judgment-like materials such as documents and affidavits of fact and expert witnesses.

1. *The Requirement of Fair Notice*

As a starting point for analysis, it is essential to note that Rule 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief,"[91] in order to "give the defendant fair notice of what the … claim is *and the grounds upon which it rests*."[92] "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle{ment} to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do."[93] The complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."[94] Indeed, the "pleading must contain something more … than … a statement of facts that merely creates a suspicion [of] a legally cognizable right of action."[95]

Notwithstanding that preemption is a fact-based affirmative defense, in order to avoid express preemption in some district courts, plaintiff generally must allege a state-law claim which is premised upon the violation of a federal "requirement." Further, in order to ultimately show an entitlement to relief under any of his common law theories of recovery, he must also show that the violation caused his injury.[96]

Since *Riegel* was decided, manufacturers of Class III PMA devices have successfully raised the preemption defense in Rule 12(b)(6) motions to dismiss. District courts have relied upon *Twombly* in dismissing both thinly pleaded medical device claims and comprehensive and detailed allegations. Dismissals have been premised on a failure to adequately plead a non-preempted common law claim that parallels

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[90] United States v. Grubbs, 565 F.3d 180, 189 (5th Cir. 2009).

[91] Fed.R.Civ.P. 8(a)(2).

[92] *Twombly*, 550 U.S. at 555 (emphasis added) (*quoting* Conley v. Gibson, 355 U.S. 41, 47 (1957)). By the time a lawsuit is filed, the manufacturer may already have notice of the incident and likely grounds for recovery. This is ideally the case, but in reality, manufacturers often receive notice of a lawsuit as the first instance registering a complaint. Yet in instances of multiple failures, the manufacturer is likely to have received a similar complaint even if a specific plaintiff did not provide pre-suit notification. FDA's quality system regulations in 21 U.S.C. Part 820 require manufacturers to maintain complaint files. 21 U.S.C. § 820.198. Procedures must be established to ensure that adverse event complaints are processed, documented, and evaluated. *Id.* § 820.198(a). If the complaint should be reported to FDA under part 803, a detailed investigation must be made, including making a determination if the device met specifications and whether corrective action is necessary. *Id.* § 820.198 (b), (d). Thus, if the incident of serious injury or death is reported to the manufacturer pre-suit, a lawsuit complaint that describes a failed device would be expected to provide fair notice to the device manufacturer, who if in compliance with CGMP, may well already have relevant records of the specific incident or ones similar thereto.

[93] 550 U.S. at 555.

[94] *Id.* (internal citations omitted).

[95] *Id.* (citation omitted).

[96] *See generally* City of Thomasville v. Lease-Afex, Inc., 300 N.C. 651, 656, 268 S.E.2d 190, 194 (1980) ("As in any action for negligence, the essential elements of a suit for products liability sounding in tort must include … evidence of a standard of care owed … breach of the standard of care … injury caused … by the breach, and loss because of the inqury.").

MDA federal requirements, based on violations of federal law.[97] As noted by one district court, plaintiff "cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption."[98]

B. *Preemption is an Affirmative Defense*

In order to plead a legally sufficient complaint, a plaintiff is not required by the Federal Rules of Civil Procedure to rule out the existence of an affirmative defense. That is for the defendant to raise and prove. Federal "preemption is an affirmative defense on which [the] defendant bears the burden of proof."[99] While an affirmative defense can support a Rule 12(c) motion for judgment on the pleadings, it can do so "only where it is 1) definitively ascertainable from the complaint and other sources of information that are reviewable at [the pleadings] stage, and 2) [these] facts establish the affirmative defense with certitude."[100] Accordingly, legal challenges to complaints based on Class III PMA devices would seem to be subject to challenge no earlier than after a defendant has filed an answer raising preemption as an affirmative defense. Nevertheless, defendants often raise preemption as grounds for a Rule 12(b)(6) dismissal, and plaintiffs and some district courts have apparently not appreciated this point of federal procedure.[101]

A defendant may seek to support a Rule 12(b)(6) or 12(c) motion with an affidavit setting forth the status of the device as a PMA Class III device. However, this would effectively convert the motion to dismiss to a Rule 56 motion for summary judgment. A party opposing an early filed motion for summary judgment may file a Rule 56(f) request for leave to conduct discovery bearing on the moving party's assertions.[102]

In assessing whether *Riegel* requires a finding of preemption, the record must be clear that the product in question is a Class III PMA device. Mere reference by the defendant to FDA web pages does not provide a sufficient basis to determine the applicability of *Riegel*, and a district court has discretion to refuse to consider evidence outside the pleadings to determine the motion to dismiss.[103]

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[97] *E.g.*, Covert v. Stryker, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009) (insufficient to merely allege "failure to meet federal requirements" or "violation of CGMPs" without allegation that plaintiff's hip replacement device was manufactured in facility subject to FDA inspection and warning letters, or subject to FDA action or recall; no allegation of any finding by FDA of violation of specific regulation).

[98] *See, e.g., In re Medtronic Sprint Fidelis Leads Products Liability Litigation*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (conclusory allegations of federal violations are insufficient to save claim from preemption).

[99] Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. KG., 510 F.3d 77, 102 1st Cir. (2007), *cert. denied* —U.S.— 129 S. Ct. 58 (2008); *see also Wyeth*, 129 S.Ct. at 1193.

[100] Citibank Global Mkts., Inc. v. Rodriguez Santana, 573 F.3d 17, 23 (1st Cir. 2009).

[101] A recent example of a district court incorrectly assuming that plaintiffs must essentially plead lack of preemption is Williams v. Allergan, 2009 WL 3294873, at *4 (D. Ariz. Oct. 14, 2009) ("Plaintiffs are correct that claims paralleling the MDA are not preempted, such as where state tort claims are based on violations of federal law, but Plaintiffs did not allege any such claims in their Complaint"). *Accord* Covert v. Stryker, 2009 WL 2424559, at *10 ("Plaintiff's complaint does not sufficiently plead any 'parallel' claims.").

[102] *See* Fed. R. Civ. P. 56(f); Walker v. Medtronic, Inc., 2008 WL 4186854 (S.D. W.Va. Sept. 9, 2008) (denying summary judgment based on Rule 56(f) "[w]here key issue of material fact—whether the infusion pump complied with the terms of its premarket approval—has not been fully explored through the discovery process, the court is unable to grant summary judgment"). *See also* Troutman v. Curtis, M.D., 286 Kan. 452, 185 P.3d 930 (2008) (granting summary judgment based on preemption, yet noting plaintiff's failure to ask for additional discovery under state counterpart to Rule 56(f)).

[103] *See* Kavalir v. Medtronic, Inc., 2008 WL 4087950 (N.D. Ill. Aug. 27, 2008).

V. PREEMPTION OVERVIEW POST-*RIEGEL*

Many of the district courts that have decided preemption issues since the Supreme Court's ruling in *Riegel* acknowledge that parallel state common law actions premised on violation of a federal requirement escape preemption, but mistakenly find preemption either by an overly strict application of *Twombly* or by requiring the actions be premised on a CGMP violation, when actually the general CGMP requirements do not preempt common law remedies. The discussion that follows is limited to preemption issues decided in the context of cases involving PMA Class III medical devices. The typical causes of action are addressed in the following order: design defect, failure to warn, delay in taking corrective action, failure to train, manufacturing defect, breach of express warranty, breach of implied warranty, and fraud and negligent misrepresentation.

A. *Design Defect*

A design defect claim which challenges FDA's findings concerning the safety of a device's design[104] imposes requirements that are different from, or in addition to, federal regulations and therefore is preempted.[105]

B. *Failure to Warn*

After obtaining PMA, manufacturers are subject to strict reporting requirements to assure that the device in not adulterated or misbranded and remains safe and effective. A failure to warn claim could be based on a violation of various regulations bearing on labeling requirements and reporting of adverse events.[106] Likely candidates include, but are not limited to, regulations pertaining to a device manufacturer's duty to timely report device malfunctions, that if they were to recur would likely cause or contribute to device-associated death or serious injury:

- §§ 803.1(a) & 803.50(a)—reports of deaths, serious injuries and malfunctions;
- § 803.10(c)(1)-(2)—five days to report if remedial action necessary, otherwise 30 days;
- § 803.53—five day reports;
- § 806.10—reports of correction or removal of a device;
- § 814.84—periodic reports;
- § 820.65—traceability;
- § 822—postmarket surveillance.

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[104] *See* 21 U.S.C. § 360c(a)(2)(c) ("[T]he safety and effectiveness of a device are to be determined … weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.").

[105] *See* Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) ("Plaintiff's defective design claim, which challenges FDA's findings concerning safety of the Trident System's design, necessarily imposes requirements that are different from, or in addition to, federal regulations"); Bausch v. Stryker Corp., 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008).

[106] As noted in Justice Ginsburg's dissent in *Riegel*: "The Court's holding does not reach an important issue outside the bounds of this case: the pre-emptive effect of § 360k(a) where evidence of a medical device's defect comes to light only *after* the device receives premarket approval." 128 S.Ct. at 1013 n.1 (emphasis original).

Post-approval adverse events could occur before a particular plaintiff receives the device or after. If the adverse event occurs after, the warning would be in the nature of a "post-sale duty to warn."

Prior to the Supreme Court's decision in *Riegel*, several Circuit courts held that claims premised on a "post-sale duty to warn" were preempted.[107] Although 21 C.F.R. § 821.1 requires certain device manufacturers to track recipients of devices, and 21 C.F.R. § 814.39 allows manufacturers to enhance earlier approved labels, the failure to issue a warning before FDA approval of the proposed changes was not deemed a regulatory violation.[108] These cases apparently involved situations where the manufacturers timely reported adverse events. In contrast, if part of a scheme to evade or delay a recall, failure to timely report adverse events per the requirement of 21 C.F.R. § 803.1(a) and § 803.53 would seem to lead to a different result, if the holding of *Riegel* is faithfully applied.[109] Although stated in the context of FDA drug regulation, the Supreme Court's recent observations concerning the *complementary* role of common law failure-to-warn actions seems apt, especially as to post-marketing adverse events:

> In keeping with Congress' decision not to pre-empt common-law tort suits, *it appears that the FDA traditionally regarded state law as a complementary form of drug regulation*. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the post-marketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.[110]

Courts finding implied preemption under these circumstances have apparently failed to appreciate that common law claims based on failure to warn do not interfere with FDA regulations.[111]

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[107] Gomez v. St. Jude Medical Div., Inc., 442 F.3d 919, 931 (5th Cir. 2006); McMullen v. Medtronic, Inc., 421 F.3d 482, 488 (7th Cir. 2005); Cupek v. Medtronic, Inc., 405 F.3d 421, 424-425 (6th Cir.), *cert. denied*, 546 U.S. 935 (2005).

[108] *See* McMullen, 421 F.3d at 489-490.

[109] *See* Heisner v. Genzyme Corp., 2008 WL 2940811, at *5 (N.D. Ill. July 25, 2008) (recognizing viability of theory and negligence *per se* claim, yet Rule 12 (b)(6) motion granted with leave for plaintiff to amend complaint). *But see* In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d at 1159-1161 (Rule 12(b)(6) dismissal founded on *implied* preemption as to post-sale duty to warn claims based on Medtronic's apparent violation of 21 C.F.R. § 803.53 by failure to timely report more than 120 adverse event reports which, when finally filed, resulted in FDA issuing a Class I recall); Webster v. Pacesetter, 259 F.Supp.2d 27, 29 (D.D.C. 2003) (failure to warn based on untimely reporting of adverse events deemed preempted by *Buckman*); Lake v. Kardjian, 22 Misc. 3d 960, 874 N.Y.S.2d 751 (2008) (summary judgment in favor of manufacturer; action based on failure to report incidents deemed impliedly preempted).

[110] Wyeth v. Levine, 129 S.Ct. at 1202 (emphasis added).

[111] *See Lohr*, 518 U.S. at 501-502.

1. *Off-Label Promotion*

A failure to warn claim could also be premised on a failure to provide adequate labeling which accords to other uses to which the device is put.[112] This could arise from off-label promotion. Devices are evaluated by FDA with respect to their intended recipients and as to conditions of use and recommendations set forth in the labeling.[113] FDA approval is limited to its assessment of safety and efficacy under such conditions of use set forth in the labeling.[114] Although the FDA evaluation and approval process is limited to intended "on-label" use,[115] FDA recognizes that "off-label" use of medical devices is prevalent. Accordingly, FDA regulations specifically address the issue of "off-label" use of medical devices. One of FDA's labeling provisions states that:

> If a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.[116]

On its face, § 801.4 seems to require a manufacturer to provide adequate labeling for an off-label use if the manufacturer knows or has reason to know of such use, regardless of whether such use was an intended use of the device as set forth in the currently approved label.[117]

FDA issued a guidance document regarding the distribution of information about off-label uses in light of its recognition that "the public health can be served when healthcare professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products."[118] The guidance document largely paraphrases the applicable FDA regulations dealing with dissemination of information on off-label uses. This includes a requirement to disclose all significant risks or safety concerns known to the manufacturer concerning the

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[112] *See* § 21 C.F.R. § 801.4.

[113] 21 U.S.C. § 360c(a)(2).

[114] *Id.* §§ 360(e)(d)(2)(A), (B); 21 C.F.R. § 801.5 ("*Adequate directions for use* means directions under which the layman can use a device safely and for the purposes for which it is intended.").

[115] Relevant intent can be shown by "such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. § 801.4.

[116] *Id.* If the intended use of a device changes, manufacturers must obtain FDA approval for the new use to ensure proper labeling. *Id.* § 807.81(a)(3)(ii).

[117] FDA's jurisdiction extends beyond labeling to include advertising for restricted devices (one which must be prescribed by a physician or used pursuant to a regulation "because of its potentiality for harmful effect or the collateral measures necessary to its use." 21 U.S.C. § 360j(e)). Under Section 352(q), a restricted device is misbranded if its advertising is false or misleading in any particular. Section 352(r) requires manufacturers of restricted devices to include in all advertisements, *inter alia*, "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications." *Id.*

[118] *Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*, (Jan. 2009) at p. 6, *available at* http://www.fda.govloc/op/goodreprint.html (last visited Nov. 16, 2009). There are also regulations requiring, *inter alia*, submission of the information to FDA prior to dissemination, 21 C.F.R. § 99.201(a)(1)-(3), and submission to FDA of a supplemental application for the new use. *Id.* at §§ 99.201(a)(4); 203; 205. Of 1,001 PMA submissions for Class III devices from 2003 to 2007, the vast majority, 784, were supplemental PMA submissions. *See* GAO report, p. 6.

unapproved uses that are not addressed in a journal article provided to physicians as to an off-label use of the device.[119] If a manufacturer follows the guidance recommendations, FDA does not intend to consider the distribution of such information "as establishing intent that the product be used for an unapproved new use."[120]

As recognized in the guidance, there is a distinction between "distribution of information about off-label uses" and off-label *promotion*. Any realistic appraisal of the practice of providing reprints regarding off-label use leads to the conclusion that manufacturers are aware that such publications on off-label uses often lead to increased sales attributed to such unapproved uses. Potentially there is a fine line between dissemination of papers in medical journals and outright promotion. Education is obviously critical to encouraging physicians to find new uses for devices, and thereby create new markets.[121] Some device manufacturers may not be content to stay within the guidelines, however, and when the line is crossed, the activity may be deemed promotional in nature. This could occur, for instance, if the article is drafted by ghostwriters working for the device manufacturer,[122] or a conflict of interest is not disclosed.[123] Off-label *promotion* of medical devices is prohibited. Advertising and other printed materials prepared by the manufacturer or its distributors should not include indications or claims not included in FDA-approved labeling for the device.[124] A medical device that is promoted for an off-label use is considered misbranded and adulterated.[125] The reason a medical device that is distributed for an unapproved new use is considered "misbranded" is that the device fails to include adequate directions and warnings.[126]

Plaintiff might, for example, identify a particular oral or written communication in which the device manufacturer promoted the off-label use of the device. A failure to warn could be based on an illegal promotion unaccompanied by adequate warnings, and directions for safe use concerning the promoted off-label use.[127] Plaintiff must specifically allege that the device manufacturer was aware or should have been aware of the dangers inherent in those off-label uses and yet failed to warn of those dangers or give adequate instructions about those off-label uses. The complaint must also set forth causation—both that use of the device in a particular off-label way caused the injury, and that, had the device manufacturer adequately warned or instructed about this particular off-label use, plaintiff's physician would have either not used it or used the device in a different way.[128]

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[119] 99 C.F.R. §§ 101(a)(3-4); 103(a)(4)(i).

[120] *Id.* Significantly, however, the Guidance does not exempt manufacturers from the requirements of § 801.4, as it recommends that reprints be accompanied by a warning regarding the risks and safety concerns pertaining to the unapproved use. *See* Guidance at p. 6.

[121] "[W]hen a manufacturer has created a market for a product to be used as a device, he or she cannot avoid the reaches of the Act by stating that the product has a different—and non-regulated use." United States v. 789 Cases of Latex Surgeons' Gloves, 799 F.Supp. 1275, 1285 (D. Puerto Rico 1992).

[122] *See* 21 C.F.R. § 99.1(h)(i)(1); Singer Natasha, *Senator Moves to Block Medical Ghostwriting*, http://www.nytimes.com/2009/08/19/health/research/19ethics.html.

[123] *See* 21 C.F.R. § 99.1(j)(1); DeAngelis, Catherine D. & Fontanarosa, Phil B., *Resolving Unreported Conflicts of Interest*, JAMA, (July 8, 2009), Vol. 302, No. 2, pp. 198-199.

[124] *See* 21 C.F.R. § 801.4.

[125] *See* 21 U.S.C. § 352(f); 21 U.S.C. § 351(f); 65 Fed. Reg. 14286-01 (Mar. 16, 2000) ("[A] medical device that is distributed for a 'new use' is 'adulterated,' *see* 21 U.S.C. 351(f), and 'misbranded,' *see* 21 U.S.C. 352(f).").

[126] 21 U.S.C. § 352(f); *cf. Levine*, 129 S.Ct. at 1197 ("the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include 'adequate warnings'" (citation omitted)).

[127] *See* Riley v. Cordis Corp., 625 F. Supp. 2d 769, 783-784 (D. Minn. 2009).

[128] *Id.*; *Heisner*, 2009 WL 1210633 (violation of duty to report incidents post-PMA approval occurred *after* plaintiff's death; Rule 12(b)(6) dismissal granted).

C. *Delay in Corrective Action*

Moreover, failure to comply with the general traceability requirements may provide the basis for a negligence claim. This regulation states:

> Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. *The procedures shall facilitate corrective action … .*[129]

One court has recognized that a failure to report the lot number in adverse event reports could lead to the use of a device that should have been recalled prior to plaintiff's device-related procedure.[130]

D. *Failure to Train*

A state-law action may focus on the manufacturer's alleged failure to train physicians in the correct manner of implantation of a device. Such a theory is distinct from an action founded on inadequate FDA-approved training. A claim that FDA approved inadequate training was found preempted in a Fifth Circuit case decided prior to the Supreme Court's ruling in *Riegel*.[131] As noted by the court in *Gomez v. St. Jude Medical*:

> FDA approved Kendall's warnings and instructions for physicians contained in the Instructions for Use (IFU) through the PMA process. That process required FDA to approve clinical studies and evaluate the results, to specify the labeling requirements, and approve the label that issued. FDA also approved the "Patient Guide" used to provide information and warnings to patients, again through the PMA process. Kendall's training requirements were also subjected to, and approved in, the PMA process. To permit a jury to decide Gomez's claims that the information, warnings, and training material FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on Kendall. The district judge correctly found that Gomez's state-law claims that Kendall's labeling, warning, information, and training were inadequate or incomplete are preempted.[132]

Post-*Riegel*, however, the Supreme Court of Kansas recognized that a complaint alleging *failure to abide by* FDA-approved training guidelines was minimally adequate to state a legally sufficient, non-preempted request for relief.[133]

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[129] 21 C.F.R. § 820.65. (emphasis added).

[130] *See* Rollins v. St. Jude Medical, 583 F. Supp. 790, 804 (W.D. La. 2008).

[131] *Gomez*, 442 F.3d at 931.

[132] *Id.*

[133] *See Troutman*, 286 Kan. 452, 185 P.3d 930 (2008) (granting summary judgment in favor of device manufacturer based on lack of supporting facts). *Accord Rollins*, 583 F.Supp.2d at 801-802 (training requirements for use of Angio-Seal device approved as part of NDA, yet a properly pleaded action potentially existed for failure to train physicians in light of physician advising patient that training was not conducted).

E. *Manufacturing Defect*

The device manufacturer is required to follow CGMP requirements.[134] For example, procedures must be established and maintained to "control product that does not conform to specified procedures."[135] Apparently overlooking the more fundamental point that FDA has explicitly stated that CGMP regulations do not preempt common law remedies,[136] district courts have nevertheless recognized that plaintiffs may avoid preemption by alleging that the device manufacturer failed to comply with these requirements.[137]

1. *Non-preempted Claims*

In the eyes of these courts, to state a non-preempted claim capable of withstanding a Rule 12(b)(6) motion, plaintiff may allege a specific manufacturing failure and a regulatory violation or deviation from the PMA that actually resulted in the manufacture of a defective device.[138] To avoid summary judgment in favor of the device manufacturer, plaintiff must provide some evidence that the device deviated from FDA-approved standards.[139]

In *Purcel v. Advanced Bionics*,[140] the court found that the plaintiffs' strict liability manufacturing defect claims were not preempted. *Purcel* involved a Class III PMA cochlear ear device, known as HiRes90k, which was manufactured by the defendant Advanced Bionics Corporation (Bionics) and implanted in the minor plaintiff's ears in 2005.[141] The lawsuit centered on a feed-through component manufactured by co-defendant Astro Seal, Inc. (Astro).[142] The specific cochlear devices implanted in the minor plaintiff were discovered to have contained moisture levels contrary to the manufacturing specifications approved by FDA.[143] The plaintiffs brought an action alleging that Bionics violated federal regulations by not informing FDA that Astro, a different company from the one Bionics used when its device received

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[134] *See* 21 C.F.R. part 820.

[135] *Id.* § 820.90(a).

[136] *Id.* § 808.1(d)(10).

[137] *See Rollins*, 583 F. Supp. 2d at 799 ("Rollins' claim that Defendants failed to manufacture the Angio-Seal in accordance with FDA specifications is not preempted by the MDA amendments."). *See also Gomez*, 442 F.3d at 933 ("The district judge properly limited Gomez's negligence claims to a claim that the Angio-Seal used in her surgery was defectively manufactured because it did not comply with FDA-approved specifications.").

[138] *See* Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830 (S.D. Ind. 2009) (denying Rule 12(b)(6) motion to dismiss, and finding defective manufacture claims were based on failure to meet FDA requirements); In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d at 1158 (the court recognized that failure to satisfy PMA standards could constitute a permissible parallel claim, yet instant complaint lacked detail to support the allegation); *Prudhel*, 2009 WL 2045559 (parallel claim of strict liability manufacturing defect sufficiently stated by alleging tip of stent delivery device separated as result of failure to comply with requirements of 21 C.F.R. § 820—Quality System Regulation, and prior lots of the stents had been recalled due to tip separation problem); Delaney v. Stryker Orthopaedics, 2009 WL 564243, at *6-7 (D. N.J. Mar. 5, 2009) (manufacturing defect count dismissed due to pleading deficiency of failing to identify a defect or deviation from FDA-reviewed device specifications).

[139] *See* Williams v. Cyberonics, Inc., 654 F.Supp.2d 301, (E.D. Pa. 2009) (granting manufacturer's motion for summary judgment; claim that device was defectively manufactured based on malfunction during normal operation; yet plaintiff produced no evidence that device deviated from PMA).

[140] 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008).

[141] *Id*. at *1.

[142] *Id.*

[143] *Id.*

FDA approval, supplied it with the feed-through component.[144] The new supplier's modifications to the feed-through component allegedly caused the excessive moisture levels and the plaintiff's injury.[145] As evidence that their claims were based on federal violations, the plaintiffs identified device-specific violations: 1) inspection reports and warning letters issued by FDA to Bionics, documenting federal violations between 2001 and 2005 focusing on moisture problems;[146] 2) a voluntary recall issued by Bionics concerning all HiRes90k devices that contained the feed-through component manufactured by Astro;[147] and 3) an FDA enforcement action against Bionics for violations of CGMP and premarket approval requirements as a result of the company's failure to notify FDA of the change in supplier and failing to validate the continued safety and effectiveness of the device.[148] The court thus denied defendants' Rule 12(c) motion to dismiss. Plaintiffs' strict liability claims were deemed not preempted as they were predicated on violations of federal law.

2. *Preempted Claims*

Other manufacturing-defect complaints alleging violations of FDA regulations have been thrown out of court.[149] The decision in *In re Medtronic, Inc. Sprint Fidelis Leads Product Liability Litigation*[150] is an example of a detailed pleading not passing Rule 8 muster in the eyes of the district judge. In granting a Rule 12(b)(6) motion to dismiss, District Judge Richard H. Kyle reasoned as follows:

> Plaintiffs' manufacturing-defect claims are based on a simple assertion: "Medtronic's defective welds caused the Sprint Fidelis leads to fracture." … The welds purportedly were "defective" because "Medtronic used inadequate welding techniques" that did not comply with FDA's Current Good Manufacturing Practices (CGMPs) and Quality System Regulation (QSR) … . Plaintiffs further allege that Medtronic's testing and quality-assurance protocols were inadequate and failed to comply with the CGMPs and QSR … . Hence, Plaintiffs claim that they are seeking only to enforce FDA requirements (the CGMPs/QSR) and, as a result, their manufacturing-defect claims are merely "parallel."[151]

Although these allegations seemingly satisfied *Riegel* and *Twombly* requirements, the court deemed them too generic in nature. Notwithstanding the device at issue being subject to a Class I recall (which plausibly was due to Medtronic's failure to

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[144] *Id.*

[145] *Id.*

[146] *Id.*

[147] *Id.*

[148] *Id.* at *2.

[149] *See Horowitz*, 613 F. Supp. 2d 271 (despite warning letters issued by FDA pertaining to inspections that revealed devices were adulterated and not in conformity with CGMP requirements, and later recall of a batch of devices due to failure to meet manufacturer's specifications, claims dismissed under Rule 12(b)(6) for failure to tie such violations to the specific device at issue in the case); Wolicki Gables v. Arrow Int'l, Inc., 2009 WL 2190069, at *10, 13 (M.D. Fla. July 22, 2009) (granting summary judgment in part because a fact-finder could find liability if a defect rendered the device unreasonably dangerous even if manufacturer followed FDA's manufacturing practices); *Bausch,* 2008 WL 5157940 (Rule 12(b)(6) motion granted; negligence claim found preempted as not "substantially identical" to duties imposed by FDA regulations).

[150] 592 F. Supp. 2d at 1157-1158.

[151] *Id.* at 1157. Significantly, the court did not find the allegations insufficient as to the substantive elements of the various causes of action based on product defect and failure to warn.

comply with manufacturing and quality assurance specifications set forth in the PMA),[152] the lack of additional specificity doomed the complaint:

> Plaintiffs' reliance on the CGMPs and QSR, however, does not save these claims from preemption. It is true that the CGMPs and QSR 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." 21 C.F.R. § 820.1(a)(1). But they are simply too generic, standing alone, to serve as the basis for Plaintiffs' manufacturing-defect claims. The CGMPs and QSR require manufacturers to develop *their own* quality-system controls to ensure that medical devices are safe and effective for their intended use, and they are inherently flexible … . "In most cases, *it is left to the manufacturer to determine the best methods to obtain quality objectives*."
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> * * *
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> The flexibility inherent in the CGMPs and QSR demonstrates why Plaintiffs' manufacturing-defect claims are not "parallel." Plaintiffs allege that Medtronic's welding techniques were "defective," but they have not pleaded how that welding technique violated the CGMPs or QSR. This is likely because the CGMPs and QSR do not provide such a fine level of detail concerning the manufacture of defibrillator leads (or most other medical devices). In the absence of any specific requirement in the CGMPs/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. This is equally true of Plaintiffs' allegation that Medtronic used inadequate testing and quality-assurance methods-Plaintiffs simply have not identified any specific requirements in the CGMPs/QSR that were purportedly violated by Medtronic. Without any such specified requirement, Plaintiffs necessarily seek to impose requirements that differ from the CGMPs/QSR.[153]

Judge Kyle thus assumed that CGMPs were "requirements" within the meaning of § 360k (a), and seemingly failed to see that a failure to establish and maintain

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[152] Given FDA's "rigorous" premarket approval standards and the demonstration of a "reasonable assurance" that the device is both "safe … [and] effective under the conditions of the use prescribed … or suggested in the proposed labeling thereof," 21 U.S.C. § 360e(d)(2)(A)(B), it is reasonable to infer that mass failures over an extended period of time, eventually leading to a Class I recall, reflect deviations from the specifications in the PMA application or failure to comply with manufacturing or quality assurance procedures. If it is unexpectedly failing on a large scale over a significant period of time, it is reasonable to infer that manufacturing and quality assurance standards are being violated, *e.g.*, 21 C.F.R. § 820.90 (control of nonconforming product), and therefore, the as-made product reflects a false and misleading label, in violation of § 352(a) labeling regulations (and adulterated within the meaning of 21 U.S.C. § 351 (e)-(f); (h) as having been manufactured not in conformity with performance standards or in violation of CGMP or premarket approval requirements). In effect, the manufacturer of such a device would be selling a device reflecting changes to the safety and effectiveness of the device, without prior FDA approval in violation of 21 C.F.R. § 814.39(9) and 21 U.S.C. § 360e(d)(6)(A)(i). In contrast, the mere fact of an isolated malfunctioning device and reliance on the doctrine of *res ipsa loquitur* is insufficient to establish negligent manufacture. *See* Clark v. Medtronic, 572 F. Supp. 2d 1090 (D. Minn. 2008) (granting defendant's motion for summary judgment).

[153] *Id.* at 1157-1158 (footnotes omitted). The same result was reached in similar state court proceedings. In re Medtronic Sprint Fidelis Lead Products Liability State Court Litigation, No. 27-CV-07-22446 (Minn. Dist. Ct. Oct. 20, 2009) (opinion *available at* http://op.bna.com/hl.nsf/r?Open=mapi-7xa1556).

procedures to control nonconforming product, for example, stated a legally sufficient violation of both 21 C.F.R. § 820.90 and common law.

a. *Violation of CGMPs Does Not Implicate Implied Preemption*

Underlying the court's related analysis of failure to warn claims (found *impliedly* preempted)[154] seems to be a concern that common law claims would interfere with FDA regulations governing labeling and manufacturing. However, the Court in *Lohr* expressly addressed this issue and found it not a concern:

> [T]he *Lohrs'* common-law claims are not pre-empted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.
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> Similarly, the general state common-law requirements in this suit [defective design and manufacture based on theories of negligence and strict liability, along with failure to warn] were not specifically developed "with respect to" medical devices. *Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements*. The legal duty that is the predicate for the *Lohrs'* negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. As a result, none of the *Lohrs'* claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA.[155]

Justice Breyer concurred.[156] ("I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law

[154] *In re Medtronic Sprint Fidelis*, 592 F. Supp. at 1159-1161.
[155] 518 U.S. at 501-502 (plurality) (emphasis added).
[156] *See id.* at 508.

tort suit, nor, for the reasons discussed, above, can I find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field.")

The Supreme Court in *Riegel* confirmed the continuing viability of its conclusions in *Lohr* concerning lack of preemption as to general manufacturing and labeling requirements:

> Informed by the regulation [21 C.F.R. § 808.1(d)], we concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not preempt the common law claims of negligence and strict liability at issue in *Lohr*. The federal requirements, we said, were not requirements specific to the device in question—they reflected "entirely generic concerns about device regulation generally."[157]

Moreover, as recognized by the FDA, *CGMP regulations do not preempt state remedies*.[158] Judge Kyle's focus on the "generic" nature of alleged CGMP violations seems to have missed the fundamental point that such regulations are not requirements within the meaning of § 360k(a). Moreover, even accepting that general manufacturing and labeling requirements are within the purview of § 360k(a), the court's analysis in *In re Sprint Fidelis* has been criticized as an overly stringent application of *Twombly*.[159]

F. *Breach of Express Warranty*

A breach of express warranty claim can escape preemption based on an allegation that the device failed to meet the promises of the label and package inserts. The focus of such a properly pleaded complaint is on the assertion that the device should fit the description on the label, which was the "basis of the bargain." Stated otherwise, the claim is that the device manufacturer did not meet the promise contained in its label. "[A] state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA," and therefore is not preempted.[160]

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[157] 128 S.Ct. at 1007.

[158] *See* 21 C.F.R. § 808.1(d)(10).

[159] *Hofts*, 597 F. Supp. 2d at 838 ("This court respectfully suggests that this is an unusually stringent application of *Twombly* and Rule 8 of the Federal Rules of Civil Procedure at the motion to dismiss stage. Manufacturing defect claims are not subject, for example, to the 'particularity' pleading requirements of Rule 9.").

[160] Mitchell v. Collagen Corp., 126 F.3d 906, 915 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998); *Hofts*, 597 F. Supp. 2d at 839 ("Howmedica has confused Hofts' express warranty claim with a defective labeling claim, which would be preempted under *Riegel*. Hofts does not allege that the Trident's FDA-approved label was defective. Hofts is perfectly happy with the label. He contends only that the device implanted in his hip should fit the description on that label. He claims that the Trident did not live up to the FDA-approved promises contained in its label and that he was harmed as a result."); Delaney v. Stryker Orthopaedics, 2009 WL 564243 (recognizing that express warranty claims allow plaintiffs to enforce FDA-approved language, yet Rule 12(b)(6) motion granted based on insufficient pleading); Huber v. Howmedica Osteonics Corp., 2008 WL 5451072 (survived motion to dismiss based on allegation that hip replacement device failed and fact-specific allegation that actual published rate of failure greatly exceeded .5 percent defect rate printed on label). *Contra Gomez*, 443 F.3d at 932 (preemption as to breach of express warranty claims based on language approved by the FDA); Bencomo v. Guidant Corp., 2009 WL 1951821 (E.D. La. June 30, 2009) (guide read by plaintiff was approved by FDA); Horowitz, 613 F. Supp. 2d at 285; Parker, 584 F. Supp. 2d at 1303).

G. *Breach of Implied Warranty*

Plaintiffs may claim that devices are unfit for their ordinary purposes because they are adulterated under 21 U.S.C. § 351. FDA's own regulations provide that the MDA's preemption clause does not apply to claims premised on regulation of general applicability, such as the Uniform Commercial Code.[161] The regulation states:

> There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
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> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.* requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.[162]

The *Riegel* Court admitted confusion over the proper interpretation of this regulation, but did not take a clear position on the status of the regulation.[163]

Breach of implied warranty claims have survived Rule 12(b)(6) preemption motions.[164] Rule 12(c) motions have also been denied, as in *Purcel v. Advanced Bionics Corp.* As reasoned by the district court in *Purcel*, dismissal of a properly pleaded implied warranty claim would not serve the policies underlying preemption:

> Although the duties underlying Plaintiffs' implied warranty claims potentially differ from the relevant federal requirements, enforcement of those claims would not interfere with the federal regulatory scheme for medical devices, since Defendants' compliance with the applicable federal requirements would preclude liability under state law, as was the case in *Lohr*. Because dismissal of plaintiffs' claims for breach of the implied warranty of merchantability would not serve the policies underlying preemption, preemption is not warranted here.[165]

H. *Fraudulent and Negligent Misrepresentation*

Under the FDCA, a medical device is deemed misbranded, and its introduction into interstate commerce is prohibited, if its advertising is false or misleading in any particular.[166] To assert a potentially valid misrepresentation claim, plaintiff must allege that the device manufacturer made affirmative misrepresentations to the

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[161] *See* 21 C.F.R. § 808.1(d)(1).

[162] *Id.*

[163] *See* 128 S. Ct. at 1011 ("All in all, we think that § 808.1(d)(1) can add nothing to our analysis but confusion.").

[164] *See Hofts*, 597 F. Supp. 2d at 839-840.

[165] 2008 WL 3874713, at *4. *But see* Miller v. DePuy Spine, Inc., 638 F. Supp. 2d 1226, 1230 (D. Nev. 2009) (plaintiff's contention that a warranty was breached because he did not get natural motion from artificial disc found preempted "because it would impose liability for defendant's use of labeling approved and required by the FDA").

[166] 21 U.S.C. § 352(q)(1); *see also* 21 U.S.C. § 331(a).

plaintiff upon which the plaintiff reasonably relied to his detriment. If the device manufacturer made such representations contrary to the device's PMA, it did so in violation of the FDCA. Imposing liability on the device manufacturer under state law for making such representations would not impose any requirements on the device manufacturer that differ from, or add to, the requirements imposed under the FDCA. False or misleading advertising can give rise to liability under state law even in the absence of the applicable federal law. Therefore, misrepresentation claims may not be preempted insofar as they are based on the device manufacturer's alleged misrepresentations contrary to the PMA. Such claims, however, must be stated with the particularity required by Rule 9(b). This Rule requires parties to allege "with particularity the circumstances constituting fraud or mistake."[167] Under Rule 9(b), a party must allege the who, what, when, where and how.[168] The complaint must describe the contents, as well as the time and place, of the false representations, along with who made the representations, when the representations were made, to whom the representations were made, and how he (or his physician) relied on the representations.

I. *State Court Alternative*

In order to avoid the stringent pleading requirements of *Twombly*, plaintiff may elect to file suit in state court. Depending on the jurisdiction, it may continue to follow the traditional *Conley v. Gibson* approach. If filed in state court, the defendant may seek to remove the case to federal court based on diversity jurisdiction. If complete diversity is lacking, the device manufacturer may attempt to remove the case to federal court based on federal question jurisdiction.[169] Such a removal could well be subject to remand to state court.

1. *Preemption is Not Grounds to Remove to Federal Court*

The content of the plaintiff's "well-pleaded complaint" determines whether an action arises under federal law.[170] Thus, "a case may not be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue."[171] The doctrine of complete preemption is not applicable to FDCA.[172] The jurisdictional doctrine of complete preemption is distinct from "ordinary preemption," which may present a *defense* to an action based on federal law, but is not itself a basis for removal jurisdiction. As the *Joyce* case explained:

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[167] Under common law, any allegation of misrepresentation—whether styled as a claim of intentional misrepresentation or negligent misrepresentation—is considered an allegation of fraud that must be pleaded with particularity.

[168] *See*, *e.g.*, Lum v. Bank of Am., 361 F.3d 217, 224 (3d Cir. 2004).

[169] *See* U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002); 28 U.S.C. §§ 1331, 1441(b).

[170] U.S. Express Lines, 281 F.3d at 389 (*citing* Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 808 (1986)).

[171] Caterpillar Inc. v. Williams, 482 U.S. 386, 393 (1987).

[172] *See* Brown v. Organon USA Inc., 2008 WL 2833294, at *2 (D. N.J. Jul. 21, 2008) ("To the Court's knowledge, the complete preemption doctrine does not apply to the Federal Drug and Cosmetic Act … .").

> Complete preemption occurs when federal law so completely preempts an entire area of law that the state cause of action is entirely displaced by federal law. If this doctrine applies, the district court has removal jurisdiction, even if the well-pleaded complaint rule is not satisfied. … However, if a state claim does not come within this doctrine, the well-pleaded complaint rule still applies, and the district court does not have removal jurisdiction unless a federal cause of action is pled. Even if the complete preemption does not apply, the defendant may nonetheless claim federal preemption as defense [in state court].[173]

Thus, the possibility of a preemption defense does not give rise to federal-question jurisdiction.[174]

VI. CONCLUSION

The *Riegel* holding clearly allows parallel common law actions to escape preemption if premised on noncompliance with a device-specific federal requirement. Moreover, compliance with general CGMP requirements does not clothe manufacturers with immunity from suit, and preemption, when applicable, is an affirmative defense that does not have to be ruled out on the face of the plaintiff's complaint. Implied preemption under *Buckman* appears narrowly limited to actions premised on "fraud-on-FDA." Based upon an understanding of the Supreme Court rulings and relevant FDA regulations, properly researched complaints can be drafted to survive motions to dismiss based on preemption.

[173] Joyce v. RJR Nabisco Holdings Corp., 126 F.3d 166, 171 (3d Cir. 1997) (citation omitted).

[174] *See, e.g.,* Sullivan v. Novartis, 602 F. Supp. 2d 527 (D. N.J. 2009) (granting motion to remand case removed based on claimed "federal question" preemption defense); Sullivan v. Novartis Pharm. Corp., 575 F. Supp. 2d 640, 653 (D. N.J. 2008).